
Cleanrooms and associated controlled environments —

**Part 3:
Test methods**

Salles propres et environnements maîtrisés apparentés —

Partie 3: Méthodes d'essai



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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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

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

- *Part 1: Classification of air cleanliness*
- *Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1*
- *Part 3: Test methods*
- *Part 4: Design, construction and start-up*
- *Part 5: Operations*
- *Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)*
- *Part 8: Classification of airborne molecular contamination*

The following part is under preparation:

- *Part 6: Vocabulary*

Introduction

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

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

NOTE Not all cleanroom parameter test procedures are shown in this part of ISO 14644. The procedures and apparatus to characterize other parameters, of concern in cleanrooms and clean zones used for specific products or processes, are discussed elsewhere in other documents prepared by ISO/TC 209 [for example, procedures for control and measurement of viable materials (ISO 14698), testing cleanroom functionality (ISO 14644-4), and testing of separative devices (ISO 14644-7)]. In addition, other standards can be considered to be applicable.

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

Cleanrooms and associated controlled environments —

Part 3: Test methods

WARNING — The use of this part of ISO 14644 may involve hazardous materials, operations and equipment. This part of ISO 14644 does not purport to address all of the safety problems associated with its use. It is the responsibility of the user of this part of ISO 14644 to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.

1 Scope

This part of ISO 14644 specifies test methods for designated classification of airborne particulate cleanliness and for characterizing the performance of cleanrooms and clean zones. Performance tests are specified for two types of cleanrooms and clean zones: those with unidirectional flow and those with non-unidirectional flow, in three possible occupancy states: as-built, at-rest and operational. The test methods recommend test apparatus and test procedures for determining performance parameters. Where the test method is affected by the type of cleanroom or clean zone, alternative procedures are suggested. For some of the tests, several different methods and apparatus are recommended to accommodate different end-use considerations. Alternative methods not included in this part of ISO 14644 may be used if based on agreement between customer and supplier. Alternative methods do not necessarily provide equivalent measurements.

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

2 Normative references

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

ISO 7726:1998, *Ergonomics of the thermal environment — Instruments for measuring physical quantities*

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

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

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

3 Terms and definitions

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

3.1 General

3.1.1

cleanroom

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

[ISO 14644-1:1999, 2.1.1]

3.1.2

clean zone

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

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

[ISO 14644-1:1999, 2.1.2]

3.1.3

installation

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

[ISO 14644-1:1999, 2.1.3]

3.1.4

separative device

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

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

3.2 Airborne particle measurement

3.2.1

aerosol generator

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

3.2.2

airborne particle

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

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

3.2.3

count median particle diameter

CMD

median particle diameter based on the number of particles

NOTE For the count median, one half of the particle number is contributed by the particles with a size smaller than the count median size, and one half by particles larger than the count median size.

3.2.4**macroparticle**

particle with an equivalent diameter greater than 5 µm

[ISO 14644-1:1999, 2.2.6]

3.2.5**M descriptor**

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

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

[ISO 14644-1:1999, 2.3.2]

3.2.6**mass median particle diameter****MMD**

median particle diameter based on the particle mass

NOTE For the mass median, one half of mass of all particles is contributed by particles with a size smaller than the mass median size, and one half by particles larger than the mass median size.

3.2.7**particle concentration**

number of individual particles per unit volume of air

[ISO 14644-1:1999, 2.2.3]

3.2.8**particle size**

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

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

[ISO 14644-1:1999, 2.2.2]

3.2.9**particle size distribution**

cumulative distribution of particle concentration as a function of particle size

[ISO 14644-1:1999, 2.2.4]

3.2.10**test aerosol**

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

3.2.11**U descriptor**

measured or specified concentration in particles per cubic metre of air, including the ultrafine particles

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

[ISO 14644-1:1999, 2.3.1]

3.2.12

ultrafine particle

particle with an equivalent diameter less than 0,1 µm

[ISO 14644-1:1999, 2.2.5]

3.3 Air filters and systems

3.3.1

aerosol challenge

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

3.3.2

designated leak

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

3.3.3

dilution system

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

3.3.4

filter system

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

3.3.5

final filter

filters in a final position before the air enters the cleanroom

3.3.6

installed filter system

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

3.3.7

installed filter system leakage test

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

3.3.8

leak

⟨of air filter system⟩ penetration of contaminants that exceed an expected value of downstream concentration through lack of integrity or defects

3.3.9

scanning

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

3.3.10

standard leak penetration

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

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

3.4 Airflow and other physical states

3.4.1

air exchange rate

rate of air exchange expressed as number of air changes per unit of time and calculated by dividing the volume of air delivered in the unit of time by the volume of the space

3.4.2

average airflow rate

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

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

3.4.3

measuring plane

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

3.4.4

non-unidirectional airflow

air distribution where the supply air entering the clean zone mixes with the internal air by means of induction

[ISO 14644-4:2001, 3.6]

3.4.5

supply airflow rate

air volume supplied into an installation from final filters or air ducts in unit of time

3.4.6

total airflow rate

air volume that passes through a section of an installation in unit of time

3.4.7

unidirectional airflow

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

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

[ISO 14644-4:2001, 3.11]

3.4.8

uniformity of airflow

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

3.5 Electrostatic measurement

3.5.1

discharge time

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

3.5.2

offset voltage

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

3.5.3

static-dissipative property

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

3.5.4

surface voltage level

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

3.6 Measuring apparatus and measuring conditions

3.6.1

aerosol photometer

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

3.6.2

anisokinetic sampling

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

3.6.3

cascade impactor

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

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

3.6.4

condensation nucleus counter

CNC

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

3.6.5

counting efficiency

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

3.6.6

differential mobility analyzer

DMA

instrument for measuring the particle size distribution, based on the electrical mobility of particles

3.6.7

diffusion battery element

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

3.6.8

discrete-particle counter

DPC

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

3.6.9**false count****background noise count****zero count**

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

3.6.10**flowhood with flowmeter**

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

3.6.11**iso-axial sampling**

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

3.6.12**isokinetic sampling**

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

3.6.13**particle size cutoff device**

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

3.6.14**threshold size**

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

3.6.15**time-of-flight particle size measurement**

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

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

3.6.16**virtual impactor**

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

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

3.6.17**witness plate**

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

3.7 Occupancy states**3.7.1****as-built**

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

[ISO 14644-1:1999, 2.4.1]

3.7.2

at-rest

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

[ISO 14644-1:1999, 2.4.2]

3.7.3

operational

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

[ISO 14644-1:1999, 2.4.3]

4 Test procedures

4.1 Cleanroom tests

4.1.1 Required test

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

Table 1 — Required test for installation

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

4.1.2 Optional tests

Table 2 lists other tests appropriate for testing of an installation. These tests can be applied in each of the three designated occupancy states. These tests may not be all-inclusive, nor may all of the tests be required for any given certification project. Tests and test methods should be selected in a manner agreed between the customer and supplier. Selected tests can also be repeated on a regular basis as part of a routine facility monitoring program (see ISO 14644-2). Guidelines for the selection of tests and a checklist of tests are given in Annex A. Test methods are outlined in Annex B.

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

Table 2 — Optional tests for installation

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

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

4.2 Principle

4.2.1 Airborne particle count

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

- a) classification test (see B.1);
- b) ultrafine particle test (optional) (see B.2);
- c) macroparticle test (optional) (see B.3).

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

4.2.2 Airflow test

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

4.2.3 Air pressure difference test

The purpose of the air pressure difference test is to verify the capability of the cleanroom system to maintain the specified pressure differential between the installation and its surroundings. The air pressure difference test should be performed after the installation has met the acceptance criteria for airflow velocity or volume, airflow uniformity and other applicable tests. Details of the air pressure difference test are given in B.5.

4.2.4 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 installation, and that the filters are free of defects (small holes and other damages in the filter medium and frame seal) and leaks (bypass leaks in the filter frame and gasket seal, leaks in the filter bank framework). These tests do not check the efficiency of the system. 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. Two different leak detection techniques are given in B.6.

4.2.5 Airflow direction test and visualization

The purpose of this test is to confirm either the airflow direction or airflow pattern or both in regard to the design and performance specifications. If required, spatial characteristics of airflow in the installation may also be confirmed. Procedures for this test are given in B.7.

4.2.6 Temperature and humidity uniformity tests

The purpose of these tests is to demonstrate the capability of the cleanroom air-handling system to maintain air temperature and moisture (expressed as relative humidity or dew point) levels 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.8 and B.9.

4.2.7 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 installations. 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.10.

4.2.8 Particle deposition test

The purpose of this test is to measure the quantity (number or mass) or the effects (light scatter or area coverage) of particles deposited upon surfaces at any orientation. Some procedures for this test are given in B.11.

4.2.9 Recovery test

The recovery test is performed to determine whether the installation 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 installations. The procedure for this test is given in B.12.

When an artificial aerosol is used, residue contamination of the installation should be avoided.

4.2.10 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.13.

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) name and address of the testing organization, and the date on which the test was performed;
- b) number and year of publication of this part of ISO 14644, i.e. ISO 14644-3: date of current issue;
- 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) 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) 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 instrument and its current calibration certificate;
- f) 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 recommended tests of an installation and the sequence in which to carry them out

A.1 General

The test procedures described in this part of ISO 14644 may be used for demonstrating compliance with the performance criteria of a user-specified installation and for performing periodic testing.

The choice of tests may be based in part on factors such as the design of the installation, operational states and the required level of certification.

The sequence of tests should be determined beforehand between customer and supplier, and should be such as to minimize wasted effort in the event of non-compliance.

A.2 Test checklist

Table A.1 provides a checklist of tests and apparatus. Details of the test sequence should be decided upon by agreement between customer and supplier.

Table A.1 — Checklist of recommended tests and their sequence for a clean installation

Selection of test procedure and sequence ^a	Test procedure	Test procedure reference	Selection of test apparatus ^b	Test apparatus	Apparatus reference	Comments
	Airborne particle count for classification and test measurement	B.1		Discrete-particle counter (DPC)	C.1	
	Airborne particle count for ultrafine particles	B.2		Condensation nucleus counter (CNC)	C.2.1	
				Discrete-particle counter (DPC)	C.2.2	
				Particle size cutoff device	C.2.3	
	Airborne particle count for macroparticles	B.3			C.3	
	Airborne particle count for macroparticles with particle collection	B.3.3.2		Microscopic measurement on collected filter paper	C.3.1	
				Cascade impactor	C.3.2	

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
	Airborne particle count for macroparticles without particle collection	B.3.3.3		Discrete-particle counter (DPC)	C.3.3	
				Time-of-flight particle apparatus	C.3.4	
	Airflow	B.4			C.4	
	Airflow velocity measurement in unidirectional airflow installation	B.4.2.2 and B.4.2.3		Thermal anemometer	C.4.1.1	
				Ultrasonic anemometer, 3-dimensional or equivalent	C.4.1.2	
				Vane-type anemometer	C.4.1.3	
				Pitot-static tubes and manometer	C.4.1.4	
	Supply airflow velocity measurement in non-unidirectional airflow installation	B.4.3.3		Thermal anemometer	C.4.1.1	
				Ultrasonic anemometer, 3-dimensional or equivalent	C.4.1.2	
				Vane-type anemometer	C.4.1.3	
				Pitot-static tubes and manometer	C.4.1.4	
	Total airflow rate measurement downstream of installed filters	B.4.3.2		Integrating volume hood meter	C.4.2.1	
				Orifice meter	C.4.2.2	
				Venturi meter	C.4.2.3	
	Airflow rate measurement in supply air duct	B.4.2.5		Integrating volume hood meter	C.4.2.1	
				Orifice meter	C.4.2.2	
				Venturi meter	C.4.2.3	
				Pitot-static tubes and manometer	C.4.1.4	
	Air pressure difference measurement	B.5		Electronic micro-manometer	C.5.1	
				Inclined manometer	C.5.2	
				Mechanical differential pressure gauge	C.5.3	
	Installed filter leakage	B.6			C.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
	Installed filter system leakage scan	B.6.2 and B.6.3		Linear aerosol photometer	C.6.1.1	
				Logarithmic aerosol photometer	C.6.1.2	
				Discrete- particle counter (DPC)	C.6.2	
				Aerosol generator	C.6.3	
				Aerosol source substances	C.6.4	
				Dilution system	C.6.5	
				Condensation nucleus counter	C.2.1	
	Test for filters mounted in ducts or air-handling units	B.6.4		Linear aerosol photometer	C.6.1.1	
				Logarithmic aerosol photometer	C.6.1.2	
				Discrete- particle counter (DPC)	C.6.2	
				Aerosol generator	C.6.3	
				Aerosol source substances	C.6.4	
				Dilution system	C.6.5	
				Condensation nucleus counter	C.2.1	
	Airflow direction and visualization	B.7		Tracers	C.7.1	
				Thermal anemometer	C.7.2	
				Ultrasonic anemometer 3-dimensional	C.7.3	
				Aerosol generator	C.7.4	
				Fog generator	C.7.4	
	Temperature	B.8			C.8	
	General Temperature	B.8.2.1		Glass thermometer	C.8.1	
				Thermometer	C.8.2	
				Resistance temperature device	C.8.3	
				Thermistor	C.8.4	

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
	Comprehensive temperature	B.8.2.2		Glass thermometer	C.8.1	
				Thermometer	C.8.2	
				Resistance temperature device	C.8.3	
				Thermistor	C.8.4	
	Humidity	B.9		Humidity monitor, capacitive	C.9.1	
				Humidity monitor, hair	C.9.2	
				Dew point sensor	C.9.3	
				Psychrometer	C.9.4	
	Electrostatic and ion generator	B.10			C.10	
	Electrostatic	B.10.2.1		Electrostatic voltmeter	C.10.1	
				High resistance ohm-meter	C.10.2	
				Charged plate monitor	C.10.3	
	Ion generator	B.10.2.2		Electrostatic voltmeter	C.10.1	
				High resistance ohm-meter	C.10.2	
				Charged plate monitor	C.10.3	
	Particle deposition	B.11		Witness plate		
				Binocular compound microscope		
				Particle fallout photometer	C.11.1	
				Surface particle counter	C.11.2	
				Particle generator	C.11.3	
	Recovery	B.12		Discrete-particle counter (DPC)	C.12.1	
				Aerosol generator	C.12.2	
				Dilution system	C.12.3	
	Containment leak	B.13			C.13	
	DPC method	B.13.2.1		Discrete-particle counter (DPC)	C.13.1	
				Aerosol generator	C.13.2	
				Dilution system	C.13.3	
	Photometer method	B.13.2.2		Photometer	C.13.4	
				Aerosol generator	C.13.2	

^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.

Annex B (informative)

Test methods

B.1 Airborne particle count for classification and test measurement

B.1.1 Principle

This test method specifies the measurement of airborne particle concentrations with size distributions having a threshold size between 0,1 μm and 5 μm . Measurements can be made in any of three defined occupancy states; as-built, at-rest and operational. The measurements are made to certify or verify the cleanliness classification of the installation in accordance with ISO 14644-1 or to make periodic measurements in accordance with ISO 14644-2. The procedure given in B.1 has been adapted from IEST-G-CC1001:1999^[11].

B.1.2 Test procedure

B.1.2.1 General

The number of sample points, location selection, clean zone classification determination, and the quantity of data required should be in accordance with ISO 14644-1. B.1 provides reference methods for air sampling at each sample point location. Other appropriate methods of equivalent accuracy and which provide equivalent data may be used by agreement between customer and supplier. If no other method has been agreed upon, or in case of dispute, the reference method in this annex should be used.

NOTE Where detailed information on cleanroom testing using a discrete-particle counter (DPC) is required or further information on DPC standards is required, the standard methods ^{[2] [3] [4] [11] [23] [24]} may be used.

B.1.2.2 Procedure for airborne particle count

Install the DPC intake at the specified sampling location, and set up the DPC flow rate and select the particle size threshold(s) in accordance with ISO 14644-1. A sampling probe should be selected to permit close to isokinetic sampling in areas with unidirectional flow^[1]. The sample probe velocity should not differ from sampled air velocity by more than 20 %. If this is not possible, set the sampling probe inlet facing into the predominant direction of the airflow; in locations where sampled airflow being sampled is not controlled or predictable (e.g. non-unidirectional airflow), the inlet of the sampling probe shall be directed vertically upward. The transit tube from the sample probe inlet to the DPC sensor should be as short as possible. For sampling of particles larger than and equal to 1 μm , the transit tube length should not exceed the manufacturer's recommended length and diameter.

Sampling errors due to small particle loss by diffusion and large particle loss by sedimentation and impaction should be no greater than 5 %.

B.1.3 Apparatus for airborne particle count

A DPC, as described in C.1, should be capable of counting and sizing particles in air with size discrimination commensurate with the class of the installation under consideration. The DPC should be capable of displaying or recording the particle count in those size ranges, and should have a valid calibration certificate, as described in C.1.

B.1.4 Test reports

By agreement between customer and supplier, the following information and data and the test report in Clause 5 should be recorded for classification or testing of the installation:

- a) background noise count rate for the DPC;
- b) type of measurement: classification or monitoring test;
- c) cleanliness classification of the installation;
- d) particle size range(s) and counts;
- e) DPC inlet sampled flow rate and flow rate through the sensing chamber volume;
- f) sample location(s);
- g) sampling protocol for classification or sampling plan for monitoring;
- h) occupancy state(s);
- i) other data relevant for measurement.

B.2 Airborne particle count for ultrafine particles

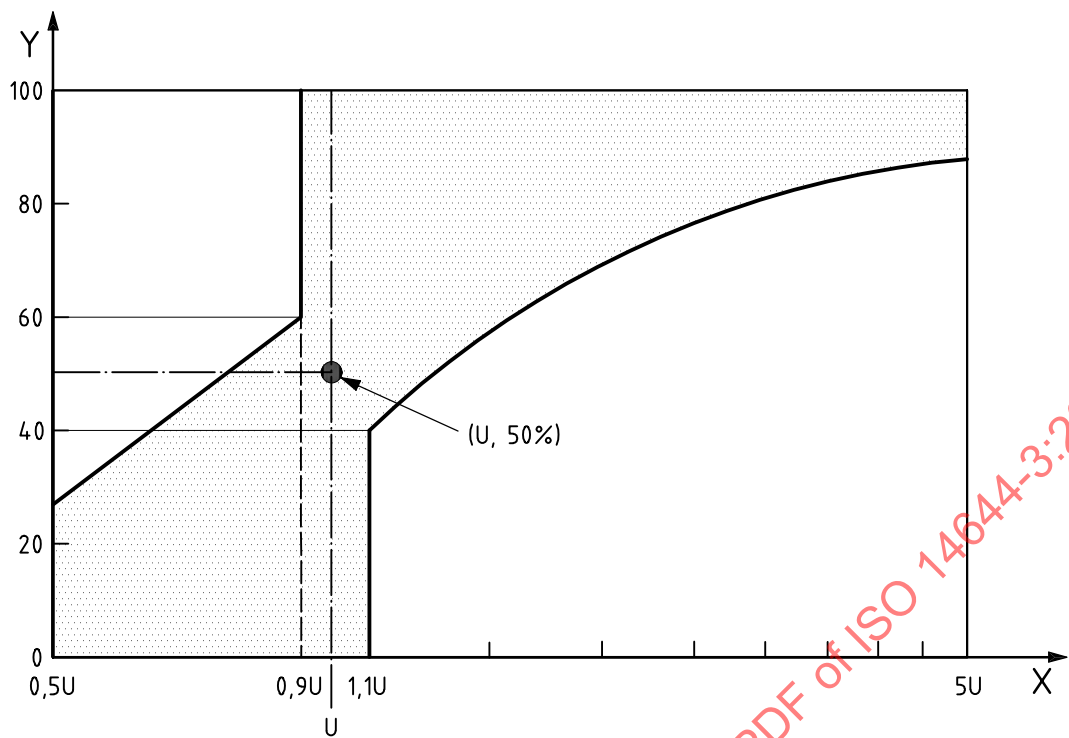
B.2.1 Principle

B.2.1.1 General

This test method specifies the measurement of airborne particle concentrations with size distributions having threshold sizes smaller than $0,1 \mu\text{m}$; that concentration is referred to as the U descriptor. The procedure given in B.2 has been adapted from IEST-G-CC1002:1999^[12]. Measurements can be made in a cleanroom or clean zone installation in any of the three designated occupancy states. The measurements are made to define the concentration of ultrafine particles in the installation in accordance with ISO 14644-1:1999, Annex E, or to make periodic measurements in accordance with ISO 14644-2:2000.

B.2.1.2 Counting efficiency

The counting efficiency of the system used to measure a U descriptor should fall within the shaded envelope region shown in Figure B.1^[12]. This region of acceptable performance centres on a counting efficiency of 50 % at the defined ultrafine particle size, shown as size "U". It includes a tolerance band of ± 10 % of the ultrafine particle size, shown as sizes "1,1U" and "0,9U" in Figure B.1. The acceptable minimum and maximum counting efficiencies for particles above and below the ± 10 % size tolerance band are based on the calculated penetration of a diffusion element having at least 40 % penetration efficiency for particles 10 % larger than the defined ultrafine particle size and at least 60 % penetration efficiency for particles 10 % smaller than the defined ultrafine particle size.



Key

X particle diameter, μm
Y counting efficiency, %

	0,5U	0,9U	U	1,1U	5U
Example U = 0,02	0,010	0,018	0,02	0,022	0,10
Example U = 0,03	0,015	0,027	0,03	0,033	0,15
Example U = 0,05	0,025	0,045	0,05	0,055	0,25

Figure B.1 — Acceptability envelope for the counting efficiency of selected apparatus

If the DPC or condensation nucleus counter (CNC) has a counting efficiency curve that falls to the right of the shaded envelope of Figure B.1, the DPC or CNC should not be used to measure or verify the U descriptor. If the curve falls to the left of the shaded envelope, the counting efficiency can be decreased by modifying it with a particle size cutoff device as described in B.2.1.3. In this case, the counting efficiency of the modified DPC or CNC becomes the product of the counting efficiency of the unmodified DPC or CNC and the fractional penetration of the particle size cutoff device.

B.2.1.3 Particle size cutoff device

To achieve the desired counting efficiency characteristic required to measure or verify a U descriptor, a particle size cutoff device can be attached to the sample inlet of the DPC or CNC whose counting efficiency curve falls to the left of the shaded envelope of Figure B.1. The counting efficiency curve of the combined DPC or CNC, sample inlet, and particle size cutoff device will be modified to fall within the required shaded envelope of Figure B.1.

Particle size cutoff devices remove particles smaller than a defined size, reducing penetration in a well-defined and reproducible manner. A wide variety of sizes and configurations of particle size cutoff devices are available and acceptable, provided that they produce the required penetration characteristics. As suitable particle size cutoff devices, diffusion battery elements and virtual impactors can be used. Penetration is a function of particle physical properties, device configuration and volumetric flow rate. Care is required with all particle size cutoff devices to ensure that they be used only at the flow rates for which they were designed and

that they are installed so as to avoid accumulation of electrostatic charge. Charge accumulation can be minimized by ensuring that the particle size cutoff device is suitably electrically grounded.

B.2.2 Procedure for ultrafine particle count

Set up the sample inlet probe of the DPC or CNC (with the particle size cutoff device, if required). Sample the required air volume at each sample point and make replicate measurements as required in accordance with ISO 14644-1, Annex B or ISO 14644-2. The sampling of ultrafine particles with a small sampling flow rate and long sampling tube can cause a significant diffusion loss. The sampling error due to ultrafine particles loss by diffusion should be no greater than 5 %. Calculate the U descriptor concentrations in the defined ultrafine particle size ranges, as agreed upon between customer and supplier, and report the data. Where information on stability of ultrafine particle concentration is required, make three or more measurements at selected locations at time intervals, as agreed upon between customer and supplier.

B.2.3 Apparatus for ultrafine particle count

DPC as described in C.3 or CNC as described in C.2 is used. If a DPC is used, it should have a counting efficiency of 50 % for ultrafine particles as defined in ISO 14644-1 Annex B, and a capability for accurate particle size definition up to at least 1 μm . The threshold size counting efficiency for the DPC or CNC should be defined in accordance with Figure B.1. If a DPC or CNC is used that is capable of detecting particles smaller than the desired size, a particle size cutoff device, with known particle size penetration performance, as described in B.2.1.3, should be used.

B.2.4 Test reports

By agreement between customer and supplier, the following information and data should be recorded as described in Clause 5 for measuring the U descriptor of the clean zone installation:

- a) identification of the DPC or CNC and particle size cutoff device, if used, and the calibration status;
- b) ultrafine particle size threshold defined for the U descriptor data;
- c) background noise count rate for the DPC, when used;
- d) particle size cutoff device performance data, as required;
- e) type of measurement: U descriptor measurement or monitoring;
- f) cleanliness classification of the installation;
- g) ultrafine particle measurement system inlet and sensing volume flow rates;
- h) sample point location(s);
- i) sampling plan for determination or sampling plan for testing, as specified;
- j) occupancy state(s);
- k) other data relevant for measurement.

B.3 Airborne particle count for macroparticles

B.3.1 Principle

This test method describes the measurement of airborne particles with a threshold size larger than 5 μm in diameter (macroparticles). The procedure given in B.3 has been adapted from IEST-G-CC1003:1999^[13]. Measurements can be made in a cleanroom or clean zone installation in any of the three designated occupancy states. The measurements are made to define the concentration of macroparticles in clean areas in accordance with ISO 14644-1:1999, Annex E, or to make periodic measurements in accordance with

ISO 14644-2. The need for proper sample acquisition and handling to minimize losses of macroparticles in the sample handling operations is emphasized.

B.3.2 Sample handling considerations

Careful sample collection and handling is required when working with macroparticles. A complete discussion of the requirements for systems, which can be used for isokinetic or anisokinetic sampling and particle transport to the point of measurement, is provided elsewhere^{[1] [13]}.

B.3.3 Measurement methods for macroparticles

B.3.3.1 General

There are two general categories of macroparticle measurement methods. Comparable results may not be produced if different measurement methods are used. Correlation between different methods may not be possible for this reason. The particle size information produced by the various methods is summarized here:

- a) collection by filtration or inertial effects, followed by microscopic measurement of the number and size, or measurement of the mass of collected particles:
 - 1) filter collection and microscopic measurement (B.3.3.2.1) will report macroparticles using particle size based upon the agreed diameter;
 - 2) cascade impactor collection and microscopic measurement [B.3.3.2.2 a)] will report macroparticles using particle size based upon the microscopist's choice of reported particle diameter;
 - 3) cascade impactor collection and weight measurement [B.3.3.2.2 b)] will report macroparticles using particle size based upon an aerodynamic diameter;
- b) in situ measurement of the concentration and size of macroparticles with a time-of-flight particle counter or a DPC:
 - 1) DPC measurement (B.3.3.3.2) will report macroparticles using particle size based upon an equivalent optical diameter;
 - 2) time-of-flight particle size measurement (B.3.3.3.3) will report macroparticles using particle size based upon an aerodynamic diameter.

B.3.3.2 Macroparticle measurement with particle collection

B.3.3.2.1 Filter collection and microscopic measurement

Select a membrane filter and a holder or a pre-assembled aerosol monitor; a membrane with pore size of 2 µm or less should be used. Label the filter holder to identify the filter holder location and installation. Connect the outlet to a vacuum source that will draw air at the required flow rate. If the sample location in which macroparticle concentration is to be determined is a unidirectional flow area, the flow rate should be established to permit isokinetic sampling into the filter holder or aerosol monitor inlet and the inlet should face into the unidirectional flow.

The filter holder or aerosol monitor inlet should be located to face vertically upward. For installations operating at ISO Class 6 (see ISO 14644-1) and cleaner, the sampled air volume should be no less than 0,28 m³. For installations operating less clean than ISO Class 6, the sampled air volume should be no less than 0,028 m³.

Remove the cover from the membrane filter holder or aerosol monitor and store in a clean location. Sample the air at the sample point locations as determined by agreement between the customer and supplier. If a portable vacuum pump is used to draw air through the membrane filter, the exhaust from that pump should be vented outside the clean installation or through a suitable filter. After the sample collection has been completed, replace the cover on the filter holder or aerosol monitor. The sample holder should be transported

in such a manner that the filter membrane is maintained in a horizontal position at all times and is not subjected to vibration or shock between the time the sample is captured and when it is analyzed. Count the particles on the filter surface^[4].

B.3.3.2.2 Cascade impactor collection and measurement

In the case of cascade impactors, the sampled airflow passes through a series of jets of decreasing orifice size. The larger particles are deposited directly below the largest orifices and smaller particles are deposited at each successive stage of the impactor. Two types of cascade impactors can be used for collection of macroparticles. In one, the particles are deposited upon the surfaces of removable plates that are removed for subsequent weighing or microscopic examination. Sampling flow rates of 0,000 47 m³/s or more are typically used for this type of cascade impactor. In the other type, the particles are deposited upon piezo-electric quartz microbalance mass sensors, which weigh the particles collected by each impactor stage. This cascade impactor type usually uses significantly smaller flow rates.

- a) For the first type of cascade impactor, the initial tare weight of each collection stage is recorded or a tare number of particles per unit area of each stage are counted before any measurements are made. The impactor is operated for a period of 10 min or more. At the end of that time, it is sealed and moved to the balance or microscope for evaluation. The collection stages are removed and the weight or number of particles accumulated upon each stage capable of collecting macroparticles is recorded. The macroparticle concentration is then defined as the total weight or number on the pertinent impactor stages divided by the total airflow, which was passed through the impactor.
- b) For the second type of cascade impactor, the particle mass data are collected at the time of sampling. Since the microbalance sensors for each stage can be set to indicate the change in mass, it is not usually necessary to determine initial tare weights before sample collection begins. As with the other cascade impactor, stages can be removed and measurements made for individual particles with a light microscope or for particle composition using an electron microscope. The sample flow rate is adjusted to 0,000 39 m³/s and sample duration set to time periods from 10 min to several hours, depending upon the class of clean zone. The impactor is placed at the pre-selected sample point location and turned on. At the end of the sample period, the impactor can be moved to other locations and additional sample measurements can be made. The macroparticle concentration is then defined as the total weight or number on the pertinent impactor stages divided by the total airflow, which was passed through the impactor.

B.3.3.3 Macroparticle measurement without particle collection

B.3.3.3.1 General

Macroparticles can be measured without collecting particles from the air. The process involves optical measurement of the particles suspended in the air. An air sample is moved at a specific flow rate through a DPC, which reports either the equivalent optical diameter or the aerodynamic diameter of the particles.

B.3.3.3.2 Discrete-particle counter (DPC) measurement

Procedures for macroparticle measurement using a DPC are the same as those in B.1 for airborne particle count with one exception. The exception is that the DPC in this case does not require sensitivity for detection of particles less than 1 µm since data are required only for macroparticle counting. Care is required to ensure that the DPC samples directly from the air at the sample location. Sample transit tubes longer than 1 m to the DPC should not be used. The DPC should be capable of sample flow of 0,000 47 m³/s and should be fitted with an inlet sized for isokinetic sampling in unidirectional flow zones. In areas where non-unidirectional flow exists, the DPC should be located with the sample inlet facing vertically upward. The sample inlet diameter should be no less than 30 mm.

The DPC size range settings are established so that only macroparticles are detected. The data from one size below 5 µm (see ISO 14644-1, Table 1) should be recorded to ensure that the concentration of detected particles below the macroparticle size is not sufficiently high to cause coincidence error in the DPC measurement. The particle concentration in that lower size range, when added to the macroparticle

concentration, should not exceed 50 % of the maximum recommended particle concentration specified for the DPC being used.

B.3.3.3.3 Time-of-flight particle size measurement

Macroparticle dimensions can be measured with time-of-flight apparatus. An air sample is drawn into the apparatus and accelerated by expansion through a nozzle into a partial vacuum, where the measurement region is located. Any particles in that air sample will accelerate to match the air velocity in the measurement region. The particles' acceleration rate will vary inversely with mass of particle. The relationship between the air velocity and the particle velocity at the point of measurement can be used to determine the aerodynamic diameter of the particle. With knowledge of the pressure difference between the ambient air and the pressure at the measurement region, the air velocity can be calculated directly. The particle velocity is measured by the time of flight between two laser beams. The time-of-flight apparatus should measure aerodynamic diameters of particles up to 20 µm, with sizing resolution better than 10 %. Sample acquisition procedures are the same as those required when using a DPC to measure macroparticles. In addition, the same procedures as for the DPC are used with this apparatus in order to establish the particle size ranges to be reported.

B.3.4 Procedure for macroparticle count

Set up the sample inlet probe of the selected apparatus. Sample the required air volume to collect at least 20 macroparticles at each sample point and make measurements as specified in ISO 14644-1 or ISO 14644-2. Calculate the M descriptor concentration in the selected particle size range(s), as agreed between customer and supplier, and report the data. Where information on the stability of macroparticle concentration is required, make three or more measurements at selected locations at time intervals agreed between customer and supplier.

B.3.5 Test reports

By agreement between customer and supplier, the following information and data should be recorded as described in Clause 5, for classification or testing of the installation:

- a) definition of the particle parameter to which the apparatus responds;
- b) type of measurement: classification or test M descriptor determination or monitoring;
- c) type designations of each measurement instrument and apparatus used and its calibration status;
- d) cleanliness classification of the installation;
- e) macroparticle size range(s) and the counts for each size range reported;
- f) apparatus inlet sample flow rate and flow rate through sensing volume;
- g) sample point location(s);
- h) sampling schedule plan for classification or sampling protocol plan for testing;
- i) occupancy state(s);
- j) stability of macroparticle concentration, if required;
- k) other data relevant for measurement.

B.4 Airflow test

B.4.1 Principle

The purpose of these tests is to measure airflow velocity and uniformity, and supply airflow rate in cleanrooms and clean zones. Measurement of velocity distribution is necessary in unidirectional airflow cleanrooms and clean zones, and supply airflow rate in non-unidirectional cleanrooms. Measurement of supply airflow rate is

carried out to ascertain the air volume supplied to the clean installation per unit of time, and this value can also be used to determine the air changes per unit of time. The supply airflow 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 airflow rate being the product of velocity and area. The choice of procedure should be agreed between customer and supplier. These tests are applicable in all three of the designated occupancy states.

B.4.2 Procedure for unidirectional airflow installation test

B.4.2.1 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 grid cells of equal area^[15].

B.4.2.2 Supply airflow velocity

The airflow velocity should be measured at approximately 150 mm to 300 mm from the filter face. The number of measuring points should be sufficient to determine the supply airflow rate in cleanrooms and clean zones, and should be the square root of 10 times of area in square metres but no less than 4. At least one point should be measured for each filter outlet or fan-filter unit. A curtain may be used to exclude disturbances to the unidirectional airflow.

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

B.4.2.3 Uniformity of velocity within the cleanroom

The uniformity of velocity should be measured at approximately 150 mm to 300 mm from the filter face and the subdivision into grid cells should be defined as agreed between customer and supplier.

When production apparatus and workbenches are installed, it is important to confirm occurrence of significant airflow variations. Therefore, the measurement of the uniformity of velocity should not be done at positions close to these obstructions.

The measured data may not indicate the characteristics of the cleanroom or clean zone installation itself. The data to be used to determine the uniformity of velocity, i.e. the velocity distribution should be agreed between customer and supplier.

The measuring time at each position should be sufficient to ensure a repeatable reading.

B.4.2.4 Supply airflow rate measured by filter face velocity

The results of the airflow velocity test carried out in accordance with B.4.2.2 can be used to calculate the total supply airflow rate as follows:

$$Q = \sum (U_c \times A_c) \quad (\text{B.1})$$

where

Q is the total airflow rate;

U_c is the airflow velocity at each cell centre;

A_c is the cell area which is defined as the installation area divided by the number of measuring points;

Σ is the summation for all cells.

B.4.2.5 Supply airflow rate in air ducts

Supply airflow rate in ducts may be measured by volumetric flowmeters such as orifice meters, Venturi meters and anemometers, referenced in ISO 5167-1 through ISO 5167-4^[19] [20] [21] [22].

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 grid cells of equal areas, and then the airflow velocity should be measured at the centre of each cell. The number of grid cells is agreed between customer and supplier, e.g. 9 or 16. The airflow volume rate should be evaluated in the same way as defined in B.4.2.4. For a circular duct, the airflow volume rate by Pitot static tubes may be determined by the procedure as typically described in EN 12599^[10].

B.4.3 Procedure for non-unidirectional airflow installation test

B.4.3.1 General

Air volume supply rate and air-change rate are the most important parameters. In some cases, measurement of supply airflow velocity from individual outlets is necessary to determine the airflow volume from each outlet^[15].

B.4.3.2 Supply airflow rate measured at the inlet

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

B.4.3.3 Supply airflow rate calculated from filter face velocity

Evaluation of the supply airflow rate without a flowhood may be done with an anemometer downstream of each final filter. The supply airflow rate is determined from the airflow velocity multiplied by the area of exit. A curtain may be used to exclude disturbances to the unidirectional airflow.

For the number of measuring points and the calculation of supply airflow rate, refer to B.4.2.3 and B.4.2.4, respectively.

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

B.4.3.4 Supply airflow rate in air ducts

Supply airflow rate in air ducts should be determined in the same way as defined in B.4.2.5.

B.4.4 Apparatus for airflow tests

Descriptions and measurement specifications of apparatus are provided in C.4. For airflow velocity measurements, ultrasonic anemometers, thermal anemometers, vane-type anemometers, or their equivalent, can be used.

For supply airflow rate measurements, orifice meters, Venturi meters, Pitot static tubes, averaging Pitot static tubes and manometers, or their equivalent, can be used.

Airflow velocity measurements should be made with apparatus that will not be 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 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.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 of tests and measurements, and measuring conditions;
- b) type designations of each measurement instrument and apparatus used and its calibration status;
- c) measurement locations and the nominal distance from the filter face;
- d) occupancy state(s);
- e) other data relevant for measurement.

B.5 Air pressure difference test

B.5.1 Principle

The purpose of this test is to verify the capability of the complete installation to maintain the specified pressure difference between the installation and its surroundings, and between separate spaces within the installation^[15]. 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.

B.5.2 Procedure for air pressure difference test

It is advisable to confirm that the supply air volume and installation balancing are within specifications before commencing the measurement of differential pressure between rooms or between rooms and outside areas.

With all doors closed, the pressure difference between the cleanroom and any surrounding environment should be measured and recorded.

If the installation is subdivided into more than one cleanroom, the pressure differences between the innermost room and the next adjacent room should be measured. The measurement should be continued until the pressure difference between the last enclosure and surrounding ancillary environment and against the external environment is measured.

The pressures being measured are very small and incorrect measurement techniques can easily give erroneous readings. The following should be considered:

- a) installation of permanent measuring points is recommended;
- b) take measurements near to the middle of the cleanroom and away from any supply air inlets or return air outlet devices which may influence the local pressure at the measuring point.

B.5.3 Apparatus for air pressure difference test

Apparatus descriptions and measurement specifications are provided in C.5. An electronic micromanometer, inclined manometer, or mechanical differential pressure gauge can be used.

The apparatus should have a valid calibration certificate.

B.5.4 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 measurement instrument and apparatus used and its calibration status;
- c) cleanliness classes of the rooms considered;
- d) measurement point locations;
- e) occupancy state(s).

B.6 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 part of ISO 14644 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 part of ISO 14644.

B.6.1 Principle

B.6.1.1 General

This test is performed to confirm that the filter system is properly installed and that leaks have not developed during use. Portions of the test methods given in B.6 have been adapted from IEST-RP-CC034.2^[18]. The test verifies the absence of leakage, relevant to the cleanliness performance of the installation. The test is performed by introducing an aerosol challenge upstream of the filters and scanning immediately downstream of the filters and support frame or by sampling in a downstream duct. The test is a leak test of the complete filter installation comprising the filter media, frame, gasket and grid system. The installed filter system leak test should not be confused with the efficiency test of individual filters at the place of manufacture. The test will be applied to cleanrooms in "as-built" or in "at-rest" occupational states, and be undertaken when commissioning new cleanrooms, or when existing installations require re-testing, or after the final filters have been replaced.

Two procedures for filter systems with ceiling, wall or apparatus mounted filters are described in B.6.2 and B.6.3. A procedure for duct mounted filters is described in B.6.4. The tests outlined below may be performed with either an aerosol photometer (method B.6.2) or a DPC (method B.6.3). The test results obtained with these two methods are not directly comparable.

B.6.1.2 Using an aerosol photometer

The aerosol photometer method (B.6.2) may be used for testing:

- a) cleanrooms in which local aerosol injection points are provided in the duct distribution system that allow the specified high aerosol challenge concentrations to be achieved;
- b) systems incorporating filters with integral MPPS (Most Penetrating Particle Size) penetrations equal to and greater than 0,003 %;
- c) 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.

NOTE The aerosol photometer method is known to create 100 to 1 000 times the aerosol concentration on a filter of the same grade, when compared to the DPC method.

B.6.1.3 Using a discrete-particle counter (DPC)

The DPC method (B.6.3) is more sensitive, and the filter system becomes less contaminated than by using the aerosol photometer method. It may be used for testing:

- a) cleanrooms with all types of air-handling systems;
- b) systems incorporating filters with MPPS (Most Penetrating Particle Size) penetrations down to 0,000 005 %;
- c) 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.

B.6.2 Procedures for installed filter system leakage scan test with an aerosol photometer

B.6.2.1 General

Preparatory steps are contained in B.6.2.2 to B.6.2.5, the test procedure itself in B.6.2.6, acceptance criteria and repair actions are to be found in B.6.2.7 and B.6.6^[14] ^[15] ^[18].

B.6.2.2 Choice of upstream aerosol challenge

An artificially generated polydisperse or atmospheric aerosol should be introduced into the upstream airflow to achieve the natural upstream aerosol to reach the required homogeneous challenge concentration. The mass median particle diameter (MMD) for this production method will typically be between 0,5 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.6.4.

B.6.2.3 Concentration of upstream aerosol challenge and its verification

The concentration of the aerosol challenge upstream of the filter should be between 10 mg/m³ and 100 mg/m³. Concentrations lower than 20 mg/m³ can reduce the sensitivity for leak detection. Concentrations greater than 80 mg/m³ can give rise to excessive filter fouling over an extended test period^[18].

Appropriate measures 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 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 upon between customer and supplier. ASME N510-1989^[1] and IEST-RP-CC034.2:1999^[18] may also be of value.

B.6.2.4 Determination of probe size

The sample probe inlet size should be calculated from consideration of the sample flow rate of the measuring instrument and the filter exit airflow velocity so that the probe inlet air velocity approximates to the filter exit airflow velocity. The sampling probe should be of square or rectangular configuration. The inlet velocity distribution should be carefully considered^[18].

$$D_p = \frac{q_{va}}{U \times W_p} \quad (\text{B.2})$$

where

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

q_{va} is the actual sample flow rate of the measuring instrument, expressed in cubic centimetres per second;

U is the filter exit airflow velocity, expressed in centimetres per second;

W_p is the probe dimension perpendicular to the scan direction, expressed in centimetres.

NOTE The air velocity should be:

$$(U + 20\%) \geq U_s \geq (U - 20\%)$$

also expressed as

$$1,2 U \geq U_s \geq 0,8 U$$

where

U is the airflow velocity at the filter exit;

$U_s = \frac{q_{va}}{D_p \times W_p}$ is the air velocity at the probe inlet.

B.6.2.5 Determination of scan rate

The probe traverse scan rate S_r should be approximately $15/W_p$ cm/s^[18]. For example, when using a 3 cm × 3 cm square probe, S_r is 5 cm/s.

B.6.2.6 Procedure for installed 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 photometers probe as follows:

- the airflow velocity test (B.4) for initial qualification should be done prior performing this test;
- measurements of the aerosol upstream of the filters according to section B.6.2.3 should be taken first to verify the aerosol concentration and also its distribution homogeneity;
- the probe should then be traversed at a scan rate not exceeding the value for S_r stated in section B.6.2.5, 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;
- 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;
- 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.6.2.3).

B.6.2.7 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 photometer.

Designated leaks are deemed to have occurred where a reading greater than 10^{-4} (0,01 %) of the upstream challenge aerosol concentration. Alternative acceptance criteria may be agreed between the customer and the supplier.

For actions to be taken to eliminate detected leaks, see section B.6.6.

NOTE Different penetrations of filters and/or response times of photometers may require consideration of different designated leak criteria, refer to IEST-RP-CC034.2 ^[18].

B.6.3 Procedure for installed filter system leakage scan test with a DPC

B.6.3.1 General

The two-stage approach of this in situ filter leak test method provides accuracy and speed:

- 1) The clean side of the filter should be scanned for a potential leak. During scanning with a DPC, detection of more than the observed acceptable counts C_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 determinations of C_a and T_s are described in B.6.3.6.
- 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 DPC, detection of more than the observed acceptable counts (C_a) in sustained residence time T_r indicates the presence of a leak. The determinations of C_a and T_r are described in B.6.3.6.

B.6.3.2 Conditions for aerosol

An artificially generated polydisperse or atmospheric aerosol should be introduced to the upstream airflow to reach the necessary challenge concentration.

NOTE A guide to aerosol source substances is given in C.6.4.

The following conditions should be met:

- a) count median particle diameter (CMD) should be between 0,1 μm and 0,5 μm ;
- b) threshold size of the DPC should be equal to or lower than this mean aerosol particle size;
- c) if the DPC has more than one channel available between the threshold size and 0,5 μm , the one with the highest downstream particles reading should be chosen;
- d) average equivalent mean particle size should be adjusted close to the mid point size of the most suitable DPC channel used.

B.6.3.3 Concentration and verification of upstream aerosol

The concentration of the aerosol challenge upstream of the filter should be sufficiently high to achieve acceptable practical scan rates according to section B.6.3.5. 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 suitable dilution system may be required to avoid exceeding the concentration tolerance of the DPC (coincidence error). The performance of the dilution system used should be verified at the beginning and the end of each period of use^[16].

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. Concentrations lower than the average will reduce the sensitivity to small leaks, while higher concentrations increase the sensitivity to small leaks. Therefore, it is better to monitor upstream concentration. Further details on how to conduct the air-aerosol mixing test, including the frequency and number of locations for taking upstream samples^[4] should be agreed upon between the customer and the supplier^[18].

B.6.3.4 Determination of probe size

Refer to B.6.2.4.

B.6.3.5 Procedure for installed filter system leakage scan test

Refer to B.6.2.6, provided that B.6.2.3 and B.6.2.5 have been substituted with B.6.3.3 and B.6.3.6.4, respectively.

B.6.3.6 Preparatory calculations and evaluation

B.6.3.6.1 Symbols and flow diagram of preparatory calculations and evaluation

The symbols in this section are shown as follows:

- C_c is the challenge aerosol concentration upstream of the filter (particles/cm³);
- P_s is the maximum allowable integral MPPS (Most Penetrating Particle Size) penetration of the filter to be tested;
- P_L is the standard leak penetration of the filter to be tested;
- K is the factor expressing how much P_L may be larger than P_s ;
- q_{Vs} is the standard value of sample flow rate, $q_{Vs} = 472 \text{ cm}^3/\text{s}$ (= 28,3 l/min);
- q_{Va} is the actual sample flow rate of the discrete-particle counter (cm³/s);
- S_r is the probe scan rate (cm/s);
- D_p is the probe dimension parallel to the scan direction (cm);
- N_p is the expected number of particle counts which characterize the designated leak [particles];
- N_{pa} is the actual number of particle counts which characterize the designated leak [particles];
- C_a is the observed acceptable count [particles];
- T_s is the sample acquisition time (s);
- T_r is the sustained residence time (s).

The flow diagram of preparatory calculations and evaluation is presented in Figure B.2.

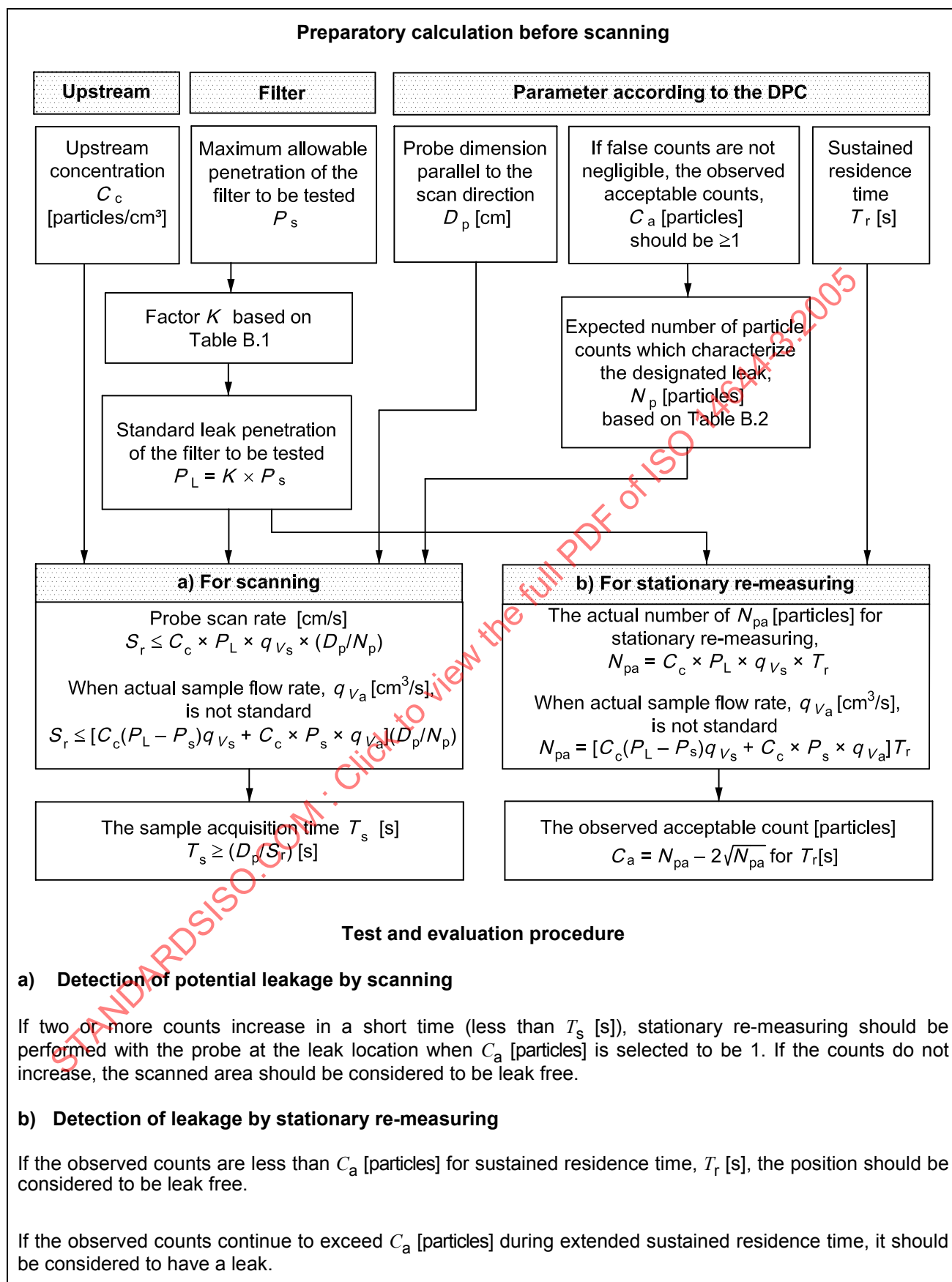


Figure B.2 — Flow diagram of preparatory calculations and evaluation

B.6.3.6.2 Standard leak penetration of the filter to be tested, P_L

Standard leak penetration, P_L , is defined as penetration detected by a DPC with a standard sample flow rate when the sampling probe is stationary over the leak. The standard sample flow rate, q_{VS} , is defined as 472 cm³/s (28,3 l/min).

P_L is chosen by agreement between customer and supplier, or is based on Table B.1 and Equation (B.3), in function of K and P_s .

$$P_L = K \times P_s \quad (\text{B.3})$$

Table B.1 — K in function of P_s

Maximum allowable penetration, P_s	$\leq 5 \times 10^{-4}$	$\leq 5 \times 10^{-5}$	$\leq 5 \times 10^{-6}$	$\leq 5 \times 10^{-7}$	$\leq 5 \times 10^{-8}$
Factor, K	10	10	30	100	300

P_s should be defined as the maximum allowable integral MPPS (Most Penetrating Particle Size) penetration of the filter to be tested as specified by the manufacturer. Nominal specific penetration at the specific particle size may be used in the absence of MPPS penetration.

NOTE P_L includes penetration of normal filter media and leakage.

In certain areas, local penetration may be greater than overall integral penetration.

For the manual scanning procedure, C_a may be replaced by N_p . It is recommended that N_p be greater than or equal to 2, and consideration of B.6.3.6.3 is not required.

For correlation with the acceptance criterion of the photometer method (see B.6.2), the maximum allowable penetration could be adapted to 0,01 % for filters with an integral penetration of 0,05 % and 0,005 %. In this case, the mean particle size of aerosol should be approximately 0,8 ($\pm 0,2$) μm .

B.6.3.6.3 Expected number of particle counts, N_p , and acceptance criteria, C_a

One observed count, C_a , gives upper confidence limit, N_p , by statistical calculation. Some pairs of C_a and N_p are given in Table B.2. A smaller value of N_p will allow faster scanning or allow lower upstream concentration.

- If false counts are negligible, the pair, $C_a = 0$, $N_p = 3,7$ should be selected.
- If false counts are not negligible, a value for $C_a \geq 1$ should be selected.

Table B.2 —Upper limit of the 95 % confidence interval of a Poisson distribution^[8] [17]

Observed C_a	Upper limit N_p	Observed C_a	Upper limit N_p	When N_p is larger than 19,7, $C_a = N_p - 2\sqrt{N_p}$ (B.4)
0	3,7	6	13,1	
1	5,6	7	14,4	
2	7,2	8	15,8	
3	8,8	9	17,1	
4	10,2	10	18,4	
5	11,7	11	19,7	

B.6.3.6.4 The scan rate, S_r

The probe traverse scan rate, S_r , should be determined from the following formula:

$$S_r \leq C_c \times P_L \times q_{VS} \times \frac{D_p}{N_p} = C_c \times P_L \times 472 \times \frac{D_p}{N_p} \quad (\text{B.5}) \quad [18]$$

S_r should not be higher than 8 (cm/s).

S_r and C_a should be selected first and the challenge aerosol concentration C_c should then be calculated from Equation (B.5).

B.6.3.6.5 Sustained residence time, T_r , and N_{pa} and C_a for T_r

- a) Selection of sustained residence time, T_r (s)

Any observed counts greater than C_a , should be cause for stationary re-measuring in sustained residence time T_r . In the case of using commercial DPC, T_r should be set at one or a few times the fixed interval of DPC.

- b) Calculation of the actual number of, N_{pa} (particles), for T_r (s) and C_a (particles)

The actual number of particle counts which characterize a designated leak, N_{pa} for T_r can be obtained from Equation (B.6). When the number of N_{pa} is large, C_a can be calculated from Equation (B.7).

$$N_{pa} = C_c \times P_L \times q_{VS} \times T_r \quad (\text{B.6})$$

$$C_a = N_{pa} - 2\sqrt{N_{pa}} \quad (\text{B.7})$$

B.6.3.6.6 Detection of potential leakage by scanning

- a) In the case of observed counts smaller than C_a (particles)

The observed counts equal to or smaller than C_a in equal or longer time than sample acquisition time T_s confirm the absence of leaks. Sample acquisition time, T_s , is equal to or greater than the time spent for the probe crossing a leak, as given in Equation (B.8)^[18]:

$$T_s \geq \frac{D_p}{S_r} \quad (\text{B.8})$$

- b) In the case of observed counts larger than C_a (particles)

Any observed counts, greater than C_a (particles), should be cause for sustained residence time investigating with the probe at the leak location.

When scanning manually, the detection of a potential leak is possible by observing the visual and/or acoustic output of the DPC. To be able to distinguish between acceptable and non-acceptable counts, the aerosol concentration in front of a filter should be adapted so that the tolerable particle count is not higher than 10 particles.

Sampling interval of the DPC should be long enough to avoid the affect of reset time between intervals.

B.6.3.6.7 Detection of leakage by stationary re-measuring

- a) Observed counts smaller than C_a (particles)

The observed counts for T_r , equal to or smaller than C_a confirm an absence of leaks.

- b) Observed counts larger than C_a [particles]

If observed count exceeds C_a , stationary re-measuring may be considered. If observed count still exceeds C_a , the filter should be considered to have a leak.

B.6.3.7 Revision for non-standard flow rate

Standard leak penetration leak, P_L , is defined with a standard sample flow-rate, $q_{VS} = 472 \text{ cm}^3/\text{s}$ (28,3 l/min). Particles counts from leak are independent of actual sample flow-rate, q_{Va} [cm^3/s], in contrast with particles from normal filter media. When using non-standard sample flow rate, equations could be revised as follows:

$$S_r \leq [C_c(P_L - P_s) q_{VS} + C_c \times P_s \times q_{Va}] \frac{D_p}{N_p} \quad (\text{B.9})$$

$$N_{pa} = [C_c(P_L - P_s) q_{VS} + C_c \times P_s \times q_{Va}] T_r \quad (\text{B.10})$$

B.6.3.8 Example of an application with evaluation

An example of the evaluation procedure is shown in Figure B.3.

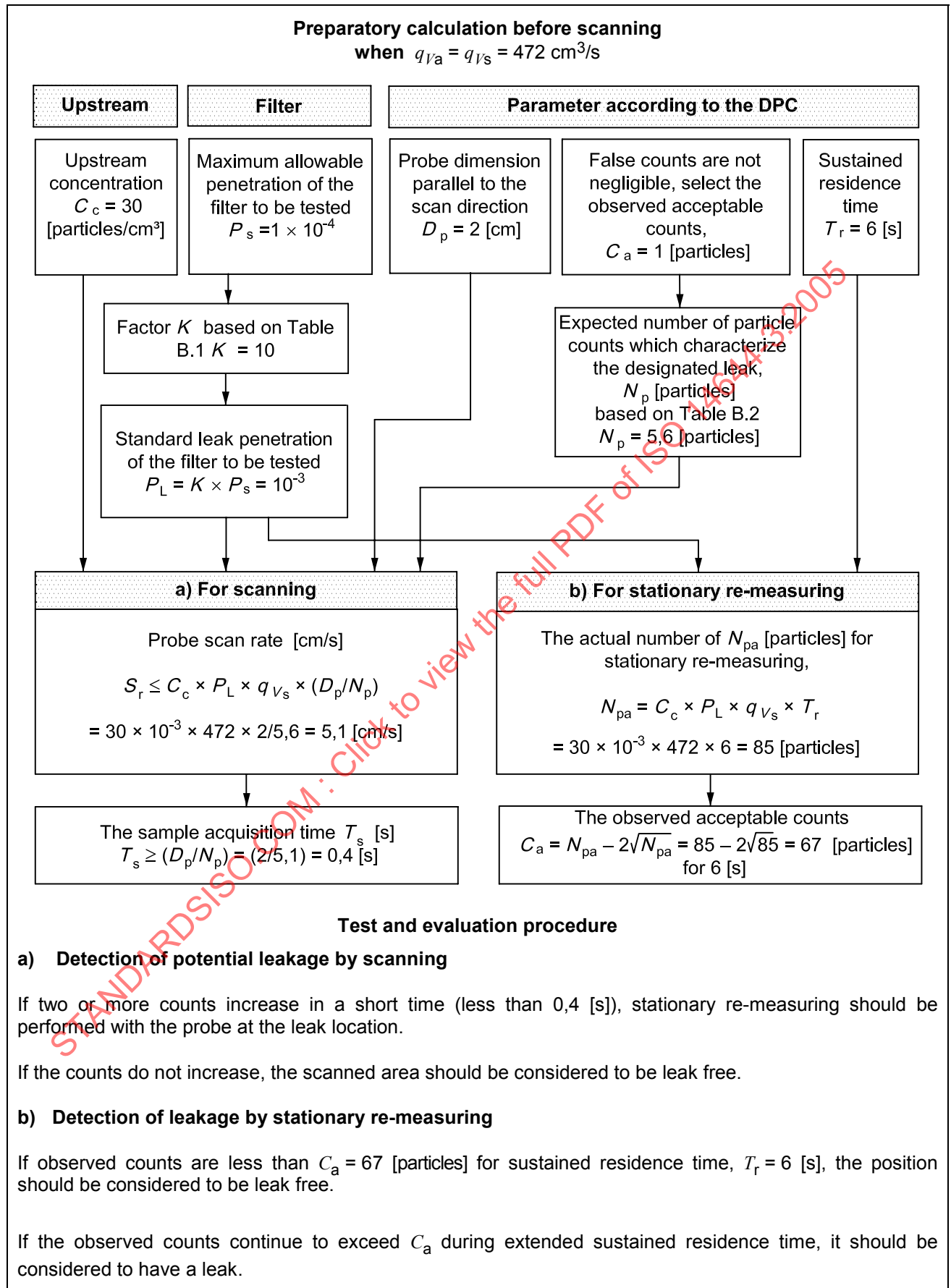


Figure B.3 — Flow diagram of evaluation procedure

B.6.4 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 installations with duct-mounted filters. This procedure may also be used to determine overall leakage of multistage filter installations without individual stage tests. These tests may also be used for terminally mounted filters as long as they are positioned in installations with a non-unidirectional flow regime. This method is much less sensitive for finding leaks than the methods described in B.6.2 and B.6.3^[1] [6] [9].

The test is performed by introducing the challenge aerosol upstream of the filters installed remotely to the cleanroom. The particle concentration of the filtered air is then measured in the duct or air-handling unit, and compared to the upstream concentration to determine the total efficiency or penetration of the filter installation^[18].

The airflow velocity test (B.4) for initial qualification should be done prior performing this test.

Measurements of the upstream aerosol concentration according to section B.6.2.3 (photometer method) or B.6.3.4 (DPC method) should be taken first to verify the aerosol concentration and homogeneity.

Measurement of downstream aerosol concentration should be carried out at least at one point per filter cell after uniform mixing downstream of the filter. If uniform mixing does not occur, an alternative test should be applied. Measurement should be taken at several equally spaced locations in a plane, between 30 cm and 100 cm downstream of the filter, within the duct and at a distance of approximately 3 cm from the duct wall.

Measurements of the particle concentrations upstream of the filters should be repeated at reasonable time intervals to confirm stability of the challenge aerosol source (see B.6.2.3).

From the measured concentrations, the total penetrations should be calculated for each downstream location and for the particle size for which the measuring apparatus should be adjusted.

None of the penetrations should be higher than five times the specified nominal MPPS (Most Penetrating Particle Size) penetration of the filter. However, for photometers this penetration should not be greater than 10^{-4} (0,01 %). Any other acceptance criteria for the efficiency test for filters may be established by agreement between the customer and the supplier.

Repairs or rectification of leaks may be made according to B.6.6 or by procedures agreed between the customer and the supplier.

NOTE For applications, where ducted filters are required to be leak tested by scanning, the methods described in B.6.2 and B.6.3 should be used.

B.6.5 Apparatus and materials for installed filter system leakage tests

Apparatus specified in B.6.5.1 to B.6.5.4 should have a valid calibration certificate.

B.6.5.1 Aerosol photometer with logarithmic or linear function (see C.6.1).

B.6.5.2 Discrete-particle counter (DPC) (see C.6.2), having a sufficiently high sample flow rate and the capability to detect the particle size relevant to the leak test being undertaken. DPC and aerosol photometers are limited to use in instances where the background counts or concentrations are less than 10 % of that which characterizes a designated leak.

B.6.5.3 Suitable pneumatic or thermal aerosol generator(s) to provide appropriate challenge aerosol concentration in the appropriate size range (see C.6.3).

B.6.5.4 Suitable aerosol dilution system.

B.6.5.5 Suitable aerosol source substances (see C.6.4).

B.6.6 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.6.7 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: photometer or discrete-particle counter (DPC);
- b) type designations of each measurement instrument and apparatus used and its calibration status;
- c) any special condition or departures or both from this test method and any special procedures agreed on between the customer and the supplier;
- d) measured upstream aerosol concentrations with their sample point locations and the corresponding time of measurement;
- e) sample flow rate; and for DPC measurements, the particle size range;
- f) calculated average upstream aerosol concentration and its distribution;
- g) calculated acceptance criteria applied for the downstream measurements;
- h) result of the downstream measurement for each clearly identified filter, area section or measuring location;
- i) final result of the test for each defined location;
- j) 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.7 Airflow direction test and visualization

B.7.1 Principle

The purpose of airflow direction test and visualization is to confirm that the airflow direction and its uniformity conform to the design and performance specifications and, if required, spatial and temporal characteristics of airflow in the installation.

NOTE Computational Fluid Dynamics (CFD) used as a predictive or analytical tool is not considered in this part of ISO 14644.

B.7.2 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 installation is actually visualized by the use of fibre tracer thread, or tracer particulate matter. Storage devices such as a video camera, chemical films, disks or tapes record the profiles. The fibre tracer thread or tracer particulate 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 installation. The technique is based on tracer particle image processing techniques using computers.

Care should be taken to ensure that the operator(s) do not interfere with the airflow patterns being investigated.

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

B.7.3 Procedures for airflow direction test and visualization

B.7.3.1 Tracer thread method

The test is carried out by observation of tufts, e.g. silk threads, single nylon fibres, flags 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 on the indicated airflow. The airflow deflection is measured between two points (example 2 m to 0,5 m) to calculate the deviation angle.

B.7.3.2 Tracer injection method

The test is carried out by observation or imaging of the behaviour of tracer particles illuminated by high-intensity light sources, and provides information about the direction and uniformity of airflow in installations. 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 will result in their motion diverging from that of the airflow being observed.

B.7.3.3 Airflow visualization method by image processing techniques

Processing particle image data derived from the method described in B.7.3.2 on video frames or films provide 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.7.3.4 Airflow visualization method by the 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 installation under investigation. Processing of the measured data provides the information about the airflow distribution.

B.7.4 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.7.

B.7.5 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 measurement instrument and apparatus used and its calibration status;
- c) visualization point locations;
- d) images stored on photographs or video cassettes, 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.8 Temperature test

B.8.1 Principle

The purpose of this test is to demonstrate the capability of the installation's air-handling system 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. Portions of the test methods given in B.8 have been adapted from IEST-RP-CC006.3^[15]. Two levels of test methods are presented. The first is a general test, described in B.8.2.1, which defines procedures suitable for a primary test of an installation in the as-built state. The second is a comprehensive test described in B.8.2.2, which is applicable in at-rest or operational states. This second test is applicable to areas having more exacting temperature performance requirements.

B.8.2 Procedure for temperature test

B.8.2.1 General temperature test

This test is performed following completion of the airflow uniformity tests and adjustment of the air-conditioning system controls. This test should be performed after the air-conditioning system has been operated and the conditions have been stabilized.

The temperature should be measured at a minimum of one location for each temperature-controlled zone.

Each sensor should be placed at the designated location at work-level height.

After sufficient time is allowed for the sensor to stabilize, the temperature reading at each location should be recorded.

Measurements should be performed as appropriate for the purpose of application and the measurement time should be at least 5 min with one value recorded at least every minute.

B.8.2.2 Comprehensive temperature test

This test is recommended for areas having strict environmental control specifications.

This test should be performed at least 1 h after the air-conditioning system has been operated and the conditions have been stabilized.

The work zone should be divided into a grid of equal areas. Individual testing areas should be selected by agreement between the customer and supplier.

The number of measuring locations should be at least two.

The temperature probe should be positioned at work-level height and at a distance of no less than 300 mm from the ceiling, walls, or floor of the installation.

The probe position should be selected with due consideration of the presence of heat sources.

Measurements should be performed as appropriate for the purpose of application and the measurement time should be at least 5 min with one value recorded at least every minute.

B.8.3 Apparatus for temperature test

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

- a) thermometers;
- b) resistance temperature devices;
- c) thermistors.

The minimum measurement resolution requirement for the apparatus is 1/5 of the allowable temperature range for the difference between the set point temperature and the permissible range of variation allowed from that set point.

The apparatus should have a valid calibration certificate.

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 of tests and measurements, and measuring conditions;
- b) type designations of each measurement instrument and apparatus used and its calibration status;
- c) measurement point locations;
- d) occupancy state(s).

B.9 Humidity test

B.9.1 Principle

The purpose of this test is to demonstrate the capability of the installation's air-handling system 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. Portions of the test method given in B.9 have been adapted from IEST-RP-CC006.3^[15].

B.9.2 Procedure for humidity test

The test is performed following completion of the airflow uniformity tests and the adjustment of air-conditioning system controls.

This test should be performed with the air-conditioning system fully operational and when stable conditions have been achieved.

The humidity sensor should be located at least at one location for each humidity control zone, and sufficient time should be allowed for the sensor to stabilize.

Measurements should be performed as appropriate for the purpose of application after the sensor has stabilized, and the measurement time should be at least 5 min.

The measurement points, frequency, intervals and period for data recording should be agreed between the customer and the supplier.

The humidity test should be performed in conjunction with the temperature test.

B.9.3 Apparatus for humidity test

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

Typical sensors are:

- a) dielectric thin film capacitor humidity sensor;
- b) dew point sensor;
- c) psychrometer.

The minimum measurement resolution for the apparatus should be 1/5 of the allowable humidity range for the difference between the set point humidity and the permissible range of variation allowed from that set point. 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 measurement instrument and apparatus used and its calibration status;
- c) temperature;
- d) measured point locations;
- e) occupancy state(s).

B.10 Electrostatic and ion generator tests

B.10.1 Principle

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 installation 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.10.2 Procedures for electrostatic and ion generator tests

B.10.2.1 Procedure for electrostatic test

B.10.2.1.1 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.10.2.1.2 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.10.2.2 Procedure for ion generator test

B.10.2.2.1 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.10.2.2.2 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.10.2.2.3 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.10.3 Apparatus for electrostatic and ion generator tests

- a) Electrostatic voltmeter or electrostatic field meter for measurement of the surface electrostatic voltage level for the electrostatic test;
- b) high resistance ohm meter for measurement of the static-dissipative property for the electrostatic test;
- c) 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.11. The apparatus should have a valid calibration certificate.

B.10.4 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 measurement instrument and apparatus used and its calibration status;
- c) temperature, humidity and other environmental data if relevant;

- d) measuring point locations;
- e) occupancy state(s);
- f) other data relevant for measurement.

B.11 Particle deposition test

B.11.1 Principle

This test describes procedures and apparatus for sizing and counting particles that are or can be deposited from the air onto product or work surfaces in the installation. Deposited particles are collected on witness plates with appropriate surface characteristics similar to those of the at-risk surface under consideration, and are sized and counted using optical microscopes, electron microscopes, or surface scanning apparatus. A particle fallout photometer may be used to obtain particle deposition rate data. Data for deposited particles should be reported in terms of mass or number of particles per unit surface area per unit of time.

B.11.2 Procedure for particle deposition test

B.11.2.1 Collection of particles on witness plates

The witness plate should be placed in the same plane as the at-risk surface. The witness plate should be at the same electrical potential as the test surface. The following procedures and methods should be followed when manipulating witness plates.

- a) Verify that all cleanroom systems are functioning correctly, in accordance with operational requirements.
- b) Identify each witness plate uniquely and clean it as required in order to reduce the surface particle concentration to the lowest possible level. Determine the background concentration of particles on each witness plate.
- c) Maintain 10 % of the witness plates as controls. These should be handled in exactly the same manner as the test witness plates without exposure.
- d) Transport all witness plates to the test locations in such manner as to prevent airborne particles from contaminating their surfaces.
- e) Expose the test witness plates for time intervals ranging up to 48 h, depending upon the cleanroom type, its mode of operation, and the particle counting apparatus that will be used. The exposure time should be adjusted, if necessary, to obtain sufficient particle deposition upon the witness plate surface to provide statistically valid data that satisfies user requirements.
- f) Cover and collect the exposed witness plates and store them in their closed containers so that they are protected from further contamination.

B.11.2.2 Counting and sizing collected particles

Counting and sizing of particles collected on witness plates is carried out to obtain reproducible data that can be used to categorize the cleanliness of the area being tested.

When using an optical light microscope, calibrated linear or circular graticules may be used for the particle sizing measurements. With an electron microscope, calibrated gratings with known line spacing may be used to relate the image dimensions to actual size. When using a surface scanner, size calibration information supplied by the manufacturer may be used. Data from counts over a partial area of the witness plate may be extrapolated to the entire plate surface area (statistical counting). Extrapolation may be made as described in Reference [4]:

- a) Count and size the particles on all witness plates, including the control plates. Enumerate the particles on the total area of all witness plates and categorize them in appropriate particle size ranges, based on the particle diameters.
- b) Determine the surface concentration of deposited particles for each witness plate:

$$D = \frac{N_t - N_b}{A_w} \quad (\text{B.11})$$

where

D is the deposited surface concentration of particles;

N_t is the total surface concentration of particles;

N_b is the number of particles larger or equal to the defined minimum size on the witness plate surface after cleaning, but before exposure to the cleanroom environment;

A_w is the witness plate area, in square centimetres.

- c) Average the values of D for the control witness plates.
- d) Determine the net increase in surface concentration for each witness plate by subtracting the average control witness plate concentration from the average test witness plate concentration. Divide the net concentration by the test witness plate exposure time. This calculation yields a particle deposition rate (PDR) in terms of particles deposited per square centimetre per unit of time.
- e) Record the mean PDR value and its standard deviation.

B.11.3 Apparatus for particle deposition test

B.11.3.1 Witness plate material

Depending upon particle size to be detected and means of measurement the following may be used:

- a) micro-porous membrane filters;
- b) double-sided adhesive tape;
- c) Petri dishes;
- d) Petri dishes containing a contrasting colour (black) polymer, such as polyester resin;
- e) photographic film (sheet);
- f) microscope slides (plain or with evaporated metal film coating);
- g) glass or metal mirror plates;
- h) semiconductor wafer blanks;
- i) glass photo mask substrates.

The surface smoothness of the witness plate should be appropriate to the size of the particles that will be counted to ensure that the particles are easily visible. The means of measurement employed should be capable of resolving and measuring the smallest particle size to be enumerated.

B.11.3.2 Additional apparatus

Various apparatus may be used for counting and sizing particles that have settled onto the witness plate surface. These fall into four general categories, depending upon the size of the particles of concern^[25] ^[28]:

- a) light microscopes (particles larger than or equal to 2 μm);
- b) electron microscopes (particles larger than or equal to 0,02 μm);
- c) surface analysis scanners (particles larger than or equal to 0,1 μm);
- d) particle fallout photometer (up to 1 % covered of surface area).

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

B.11.4 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 measurement instrument and apparatus used and its calibration status;
- c) measured point locations;
- d) occupancy state(s).

B.12 Recovery test

B.12.1 Principle

This test is performed to determine the ability of the installation to eliminate airborne particles. Cleanliness recovery performance after a particle generation event is one of the most important abilities of the installation. This test is only important and recommended for non-unidirectional airflow systems because the recovery performance is a function of air re-circulation ratio, inlet-outlet airflow geometry, thermal conditions and the air distribution characteristics within the controlled zone, whereas in uni-directional airflow system, the contamination is displaced by the controlled airflow and the recovery time is a function of locality and distance. This test should be carried out upon an installation in the as-built or at-rest state.

This test is not recommended for ISO Classes 8 and 9.

When an artificial aerosol is used, residue contamination of the installation should be avoided.

B.12.2 Cleanliness recovery performance

Recovery performance is evaluated by using the 100:1 recovery time or the cleanliness recovery rate. The 100:1 recovery time is defined as the time required for decreasing the initial concentration by a factor of 0,01 times and the cleanliness recovery rate is defined as the rate of change of particle concentration by time. It is possible to estimate both of them from the same particles concentration decay curve.

The measurements should be made inside the time range where the decay 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 the coincident loss should occur or so low that the counting uncertainty should occur.

NOTE The experimental evaluation of the 100:1 recovery time is the preferred measurement procedure.

B.12.3 Procedure for recovery test

B.12.3.1 Evaluation by 100:1 recovery time

Direct measurement of the 100:1 recovery time can be performed when it is possible to set up the initial particle concentration at 100 or more times the target cleanliness level.

Care should be taken to avoid coincidence error and potential contamination of the DPC optics. Before testing, calculate the concentration required to carry out the 100:1 recovery time test. If the concentration exceeds the maximum capability of the DPC such that coincidence occurs either use the dilution system, reduce the concentration to avoid coincidence or replace the 100:1 recovery time test with the recovery rate test (B.12.3.2).

- a) Set up the particle counter in accordance with the manufacturer's instructions and the apparatus calibration certificate.
- b) Place the DPC probe at the testing point, the measuring points and the number of measurements should be determined by agreement between the customer and supplier. The DPC probe should not be placed directly under the air outlet.
- c) Adjust the single sample volume to the same value used for determining the cleanliness class. The delay-time of the counter from starting each count to the output recording should be adjusted to no more than 10 s.
- d) The particle size used in this test should be less than 1 μm . It is recommended that the size channel used by the DPC corresponds to that of the maximum number concentration of the aerosol.
- e) The cleanroom area to be examined should be contaminated with an aerosol while the air-handling units are in operation.
- f) Raise the initial particle concentration to 100 or more times the target cleanliness level.
- g) Commence measurements at 1 min intervals. Note the time when the particle concentration reaches the $100 \times$ target concentration threshold (t_{100n}).
- h) Note the time when the particle concentration reaches the target cleanliness level, (t_n).
- i) The 100:1 recovery time is represented by $t_{0,01} = (t_n - t_{100n})$.

B.12.3.2 Evaluation by recovery rate

Recovery performance can be determined from the slope of particle concentration decay curve at the required cleanliness class (see ISO 14644-1), as follows:

- a) plot the data of decreasing particle concentration on a square coordinate graph with the time values on the abscissa and the concentration values on the ordinate by a logarithmic scale;
- b) cleanliness recovery rate is obtained from the slope value of the line.

The cleanliness recovery rate between two successive measurements is calculated from the following equation:

$$n = -2,3 \times \frac{1}{t_1} \log_{10} \left(\frac{C_1}{C_0} \right) \quad (\text{B.12})$$

where

n is the cleanliness recovery rate;

t_1 is the time elapsed between the first and second measurement ;

C_0 is the initial concentration;

C_1 is the concentration after time t_1

$$= C_0 \exp(-n t_1)$$

Average five to ten of recovery rate values obtained in a measurement.

The recovery rate and 100:1 recovery time can be related as follows:

$$n = -2,3 \times \frac{1}{t_{0,01}} \log_{10} \left(\frac{1}{100} \right) = -2,3 \times \frac{1}{t_{0,01}} (-2) = 4,6 \times \frac{1}{t_{0,01}} \quad (\text{B.13})$$

B.12.4 Apparatus and measurement points for recovery test

The apparatus listed below should have a valid calibration certificate.

The number of measuring points may be decided by the agreements between customer and supplier.

B.12.4.1 Aerosol generator and artificially generated aerosol, which have the same characteristics as those described in B.6.

B.12.4.2 Discrete-particle counter (DPC), which has the efficiency described in C.1 and C.6.

B.12.4.3 Dilution system, if necessary, as described by C.12.3.

B.12.5 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 measurement instrument and apparatus used and its calibration status;
- b) number and location of measured points;
- c) occupancy state(s).

B.13 Containment leak test

B.13.1 Principle

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

B.13.2 Procedures for containment leak test

B.13.2.1 Discrete-particle counter (DPC) 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/m³ 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 determined based on agreement between customer and supplier.

B.13.2.2 Photometer method

Produce an aerosol outside the cleanroom or device in accordance with B.6.2.2 in concentration high enough to cause the photometer to exceed full scale on the 0,1 % setting.

A reading on the photometer 0,1 % setting 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 0,01 % of the photometer scale.

B.13.3 Apparatus for containment leak test

The following apparatus should have a valid calibration certificate.

B.13.3.1 Artificially generated aerosol source, as described in B.6.5;

B.13.3.2 Discrete-particle counter (DPC), as specified in C.1, or **photometer**, as specified in C.6.1, and which should have a lower particle size discrimination capability of 0,5 µm or smaller;

B.13.4 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 measurement instrument and apparatus used and its calibration status;
- b) data collection technique;
- c) measurement point locations;
- d) occupancy state(s).

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Annex C (informative)

Test apparatus

This annex describes the measuring apparatus that should be used for the recommended tests given in this part of ISO 14644.

In this annex, data given in Tables C.1 to C.29 indicate the minimum necessary requirements for each item of apparatus. Items are listed and numbered to correspond with Annex B, e.g. the apparatus numbered C.1 is used in the test procedure given in B.1. Those responsible for planning tests may refer to Annex C for the selection of test apparatus and to Annex A for a checklist of recommended tests of an installation and the sequence in which to carry them out. Measuring apparatus should be chosen subject to agreement between the customer and supplier.

This annex is informative, and should not prevent the use of improved apparatus as it becomes available. Alternative test apparatus may be appropriate and may be used subject to agreement between customer and supplier.

C.1 Airborne particle count

C.1.1 Light-scattering discrete-particle counter DPC, instrument capable of counting and sizing single airborne particles and reporting size data in terms of equivalent optical diameter.

The specifications for the light-scattering discrete-particle counter are given in Table C.1.

Table C.1 — Specifications for the light-scattering discrete-particle counter

Item	Specification
Sensitivity/resolution ^a	Chosen between 0,1 µm to 5 µm with ≤ 10 % size resolution
Uncertainty of measurement	± 20 % of concentration error at the size setting
Calibration interval	12 months maximum or specified performance verification
Counting efficiency	(50 ± 20) % at minimum size threshold and (100 ± 10) % for particles greater than or equal to 1,5 times the minimum threshold size
Lower concentration range	False count rate is insignificant in comparison to actually expected minimum counting rate. The low count rate should be zero particles for a certain time (e.g. no counts for 5 min)
Upper concentration range	Two times greater than upper limit of the installation cleanliness class concentration at point of use, and no more than 75 % of the manufacturer's maximum recommended concentration
^a Apparatus with particle sizing resolution greater than 10 % can produce particle count results that can vary up to one order of magnitude.	