Nederlandse norm

NEN-EN-ISO 14644-1
(en)

Stof- en kiemarme ruimten en omgevingen - Deel 1: Classificatie van luchtreinheid op basis van deeltjesconcentraties (ISO 14644-1:2015,IDT)

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

Vervangt NEN-EN-ISO 14644-1:1999;
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NEN

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EUROPEAN STANDARD

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English Version

Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)

Salles propres et environnements maîtrisés apparentés - Partie 1: Classification de la propreté particulaire de l'air (ISO 14644-1:2015)

Reinräume und zugehörige Reinraumbereiche - Teil 1: Klassifizierung der Luftreinheit anhand der Partikelkonzentration (ISO 14644-1:2015)

This European Standard was approved by CEN on 27 November 2015.

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Contents

Page

European foreword

This document (EN ISO 14644-1:2015) has been prepared by Technical Committee ISO/TC 209 "Cleanrooms and associated controlled environments" in collaboration with Technical Committee CEN/TC 243 “Cleanroom technology” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2016, and conflicting national standards shall be withdrawn at the latest by June 2016.

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

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Endorsement notice

The text of ISO 14644-1:2015 has been approved by CEN as EN ISO 14644-1:2015 without any modification.

INTERNATIONAL STANDARD

ISO 14644-1

Second edition
2015-12-15

Cleanrooms and associated controlled environments —

Part 1: Classification of air cleanliness by particle concentration

Salles propres et environnements maîtrisés apparentés —

Partie 1: Classification de la propreté particulaire de l'air

Reference number
ISO 14644-1:2015(E)

Contents

Page

Foreword

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

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

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

The committee responsible for this document is ISO/TC 209, *Cleanrooms and associated controlled environments*.

This second edition cancels and replaces the first edition (ISO 14644-1:1999), which has been technically revised throughout.

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

— *Part 1: Classification of air cleanliness by particle concentration*

— *Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration*

— *Part 3: Test methods*

— *Part 4: Design, construction and start-up*

— *Part 5: Operations*

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

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

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

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

Attention is also drawn to ISO 14698, *Cleanrooms and associated controlled environments — Biocontamination control:*

— *Part 1: General principles and methods*

— *Part 2: Evaluation and interpretation of biocontamination data*

Introduction

Cleanrooms and associated controlled environments provide for the control of contamination of air and, if appropriate, surfaces, to levels appropriate for accomplishing contamination-sensitive activities. Contamination control can be beneficial for protection of product or process integrity in applications in industries such as aerospace, microelectronics, pharmaceuticals, medical devices, healthcare and food.

This part of ISO 14644 specifies classes of air cleanliness in terms of the number of particles expressed as a concentration in air volume. It also specifies the standard method of testing to determine cleanliness class, including selection of sampling locations.

This edition is the result of a response to an ISO Systematic Review and includes changes in response to user and expert feedback validated by international enquiry. The title has been revised to "Classification of air cleanliness by particle concentration" to be consistent with other parts of ISO 14644. The nine ISO cleanliness classes are retained with minor revisions. Table 1 defines the particle concentration at various particle sizes for the nine integer classes. Table E.1 defines the maximum particle concentration at various particle sizes for intermediate classes. The use of these tables ensures better definition of the appropriate particle-size ranges for the different classes. This part of ISO 14644 retains the macroparticle descriptor concept; however, consideration of nano-scale particles (formerly defined as ultrafine particles) will be addressed in a separate standard.

The most significant change is the adoption of a more consistent statistical approach to the selection and the number of sampling locations; and the evaluation of the data collected. The statistical model is based on adaptation of the hypergeometric sampling model technique, where samples are drawn randomly without replacement from a finite population. The new approach allows each location to be treated independently with at least a 95 % level of confidence that at least 90 % of the cleanroom or clean zone areas will comply with the maximum particle concentration limit for the target class of air cleanliness. No assumptions are made regarding the distribution of the actual particle counts over the area of the cleanroom or clean zone; while in ISO 14644-1:1999 an underlying assumption was that the particle counts follow the same normal distribution across the room, this assumption has now been discarded to allow the sampling to be used in rooms where the particle counts vary in a more complex manner. In the process of revision it has been recognized that the 95 % UCL was neither appropriate nor was applied consistently in ISO 14644-1:1999. The minimum number of sampling locations required has been changed, compared with ISO 14644-1:1999. A reference table, Table A.1, is provided to define the minimum number of sampling locations required based on a practical adaptation of the sampling model technique. An assumption is made that the area immediately surrounding each sampling location has a homogeneous particle concentration. The cleanroom or clean zone area is divided up into a grid of sections of near equal area, whose number is equal to the number of sampling locations derived from Table A.1. A sampling location is placed within each grid section, so as to be representative of that grid section.

It is assumed for practical purposes that the locations are chosen representatively; a "representative" location (see A.4.2) means that features such as cleanroom or clean zone layout, equipment disposition and airflow systems should be considered when selecting sampling locations. Additional sampling locations may be added to the minimum number of sampling locations.

Finally, the annexes have been reordered to improve the logic of this part of ISO 14644 and portions of the content of certain annexes concerning testing and test instruments have been included from ISO 14644-3:2005.

The revised version of this part of ISO 14644 addresses the ≥ 5 µm particle limits for ISO Class 5 in the sterile products annexes of the EU, PIC/S and WHO GMPs by way of an adaptation of the macroparticle concept.

The revised version of this part of ISO 14644 now includes all matters related to classification of air cleanliness by particle concentration. The revised version of ISO 14644-2:2015 now deals exclusively with the monitoring of air cleanliness by particle concentration.

Cleanrooms may also be characterized by attributes in addition to the classification of air cleanliness by particle concentration. Other attributes, such as air cleanliness in terms of chemical concentration, may be monitored and the attribute’s grade or level may be designated along with the classification of the ISO Class of cleanliness. These additional attributes do not suffice alone to classify a cleanroom or clean zone.

Cleanrooms and associated controlled environments —

Part 1: Classification of air cleanliness by particle concentration

1 Scope

This part of ISO 14644 specifies the classification of air cleanliness in terms of concentration of airborne particles in cleanrooms and clean zones; and separative devices as defined in ISO 14644-7.

Only particle populations having cumulative distributions based on threshold (lower limit) particle sizes ranging from 0,1 µm to 5 µm are considered for classification purposes.

The use of light scattering (discrete) airborne particle counters (LSAPC) is the basis for determination of the concentration of airborne particles, equal to and greater than the specified sizes, at designated sampling locations.

This part of ISO 14644 does not provide for classification of particle populations that are outside the specified lower threshold particle-size range, 0,1 µm to 5 µm. Concentrations of ultrafine particles (particles smaller than 0,1 µm) will be addressed in a separate standard to specify air cleanliness by nano-scale particles. An M descriptor (see Annex C) may be used to quantify populations of macroparticles (particles larger than 5 µm).

This part of ISO 14644 cannot be used to characterize the physical, chemical, radiological, viable or other nature of airborne particles.

2 Normative references

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

ISO 14644-2:2015, *Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration*

ISO 14644-7, *Cleanrooms and associated controlled environments — Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)*

3 Terms and definitions

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

3.1 General

3.1.1
cleanroom
room within which the number concentration of airborne particles is controlled and classified, and which is designed, constructed and operated in a manner to control the introduction, generation and retention of particles inside the room

Note 1 to entry: The class of airborne particle concentration is specified.

Note 2 to entry: Levels of other cleanliness attributes such as chemical, viable or nanoscale concentrations in the air, and also surface cleanliness in terms of particle, nanoscale, chemical and viable concentrations might also be specified and controlled.

Note 3 to entry: Other relevant physical parameters might also be controlled as required, e.g. temperature, humidity, pressure, vibration and electrostatic.

3.1.2
clean zone
defined space within which the number concentration of airborne particles is controlled and classified, and which is constructed and operated in a manner to control the introduction, generation and retention of contaminants inside the space

Note 1 to entry: The class of airborne particle concentration is specified.

Note 2 to entry: Levels of other cleanliness attributes such as chemical, viable or nanoscale concentrations in the air, and also surface cleanliness in terms of particle, nanoscale, chemical and viable concentrations might also be specified and controlled.

Note 3 to entry: A clean zone(s) can be a defined space within a cleanroom or might be achieved by a separative device. Such a device can be located inside or outside a cleanroom.

Note 4 to entry: Other relevant physical parameters might also be controlled as required, e.g. temperature, humidity, pressure, vibration and electrostatic.

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

3.1.4
classification
method of assessing level of cleanliness against a specification for a cleanroom or clean zone

Note 1 to entry: Levels should be expressed in terms of an ISO Class, which represents maximum allowable concentrations of particles in a unit volume of air.

3.2 Airborne particles

3.2.1
particle
minute piece of matter with defined physical boundaries

3.2.2
particle size
diameter of a sphere that produces a response, by a given particle-sizing instrument, that is equivalent to the response produced by the particle being measured

Note 1 to entry: For discrete-particle light-scattering instruments, the equivalent optical diameter is used.

3.2.3
particle concentration
number of individual particles per unit volume of air

3.2.4
particle size distribution
cumulative distribution of particle concentration as a function of particle size

3.2.5
macroparticle
particle with an equivalent diameter greater than 5 µm

3.2.6
M descriptor
designation for 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 1 to entry: The M descriptor can be regarded as an upper limit for the averages at sampling locations. M descriptors cannot be used to define ISO Classes, but the M descriptor may be quoted independently or in conjunction with ISO Classes.

3.2.7
unidirectional airflow
controlled airflow through the entire cross-section of a cleanroom or a clean zone with a steady velocity and airstreams that are considered to be parallel

3.2.8
non-undirectional airflow
air distribution where the supply air entering the cleanroom or clean zone mixes with the internal air by means of induction

3.3 Occupancy states

3.3.1
as-built
condition where the cleanroom or clean zone is complete with all services connected and functioning but with no equipment, furniture, materials or personnel present

3.3.2
at-rest
condition where the cleanroom or clean zone is complete with equipment installed and operating in a manner agreed upon, but with no personnel present

3.3.3
operational
agreed condition where the cleanroom or clean zone is functioning in the specified manner, with equipment operating and with the specified number of personnel present

3.4 Testing instrumentation (see Annex F)

3.4.1
resolution
smallest change in a quantity being measured that causes a perceptible change in the corresponding indication

Note 1 to entry: Resolution can depend on, for example, noise (internal or external) or friction. It may also depend on the value of a quantity being measured.

[SOURCE: ISO/IEC Guide 99:2007, 4.14]

3.4.2
maximum permissible measurement error
extreme value of measurement error, with respect to a known reference quantity value, permitted by specifications or regulations for a given measurement, measuring instrument, or measuring system

Note 1 to entry: Usually, the term “maximum permissible errors” or “limits of error” is used where there are two extreme values.

Note 2 to entry: The term “tolerance” should not be used to designate “maximum permissible error”.

[SOURCE: ISO/IEC Guide 99:2007, 4.26]

3.5 Instrument specifications

3.5.1
LSAPC
light scattering airborne particle counter
light scattering discrete airborne particle counter
instrument capable of counting and sizing single airborne particles and reporting size data in terms of equivalent optical diameter

Note 1 to entry: The specifications for the LSAPC are given in ISO 21501-4:2007.

3.5.2
discrete-macroparticle counter
instrument capable of counting and sizing single airborne macroparticles

Note 1 to entry: See Table F.1 for specifications.

3.5.3
time-of-flight particle sizing apparatus
discrete-particle counting and sizing apparatus that defines the aerodynamic diameter of particles by measuring the time for a particle to accommodate to a change in air velocity

Note 1 to entry: This is usually done by measuring the particle transit time optically after a fluid stream velocity change.

Note 2 to entry: See Table F.2 for specifications.

4 Classification

4.1 Occupancy state(s)

The air cleanliness class by particle concentration of air in a cleanroom or clean zone shall be defined in one or more of three occupancy states, viz. "as-built," "at-rest" or "operational" (see 3.3).

4.2 Particle size(s)

One, or more than one, threshold (lower limit) particle sizes situated within the range from ≥0,1 µm to ≥5 µm are to be used to determine air cleanliness particle concentration for classification.

4.3 ISO Class number

Air cleanliness class by particle concentration shall be designated by an ISO Class number, *N*. The maximum permitted concentration of particles for each considered particle size is determined from Table 1.

Particle number concentrations for different threshold sizes in Table 1 do not reflect actual particle size and number distribution in the air and serve as criteria for classification only. Examples of classification calculations are included in Annex B.

Table 1 — ISO Classes of air cleanliness by particle concentration

ISO Class number (N)	Maximum allowable concentrations (particles/m^3) for particles equal to and greater than the considered sizes, shown below[a]					
	0,1 µm	0,2 µm	0,3 µm	0,5 µm	1 µm	5 µm
1	*10*[b]	[d]	[d]	[d]	[d]	[e]
2	100	*24*[b]	*10*[b]	[d]	[d]	[e]
3	1 000	237	102	*35*[b]	[d]	[e]
4	10 000	2 370	1 020	352	*83*[b]	[e]
5	100 000	23 700	10 200	3 520	832	[d, e, f]
6	1 000 000	237 000	102 000	35 200	8 320	293
7	[c]	[c]	[c]	352 000	83 200	2 930
8	[c]	[c]	[c]	3 520 000	832 000	29 300
9[g]	[c]	[c]	[c]	35 200 000	8 320 000	293 000

[a] All concentrations in the table are cumulative, e.g. for ISO Class 5, the 10 200 particles shown at 0,3 µm include all particles equal to and greater than this size.

[b] These concentrations will lead to large air sample volumes for classification. Sequential sampling procedure may be applied; see Annex D.

[c] Concentration limits are not applicable in this region of the table due to very high particle concentration.

[d] Sampling and statistical limitations for particles in low concentrations make classification inappropriate.

[e] Sample collection limitations for both particles in low concentrations and sizes greater than 1 µm make classification at this particle size inappropriate, due to potential particle losses in the sampling system.

[f] In order to specify this particle size in association with ISO Class 5, the macroparticle descriptor M may be adapted and used in conjunction with at least one other particle size. (See C.7.)

[g] This class is only applicable for the in-operation state.

4.4 Designation

The designation of airborne particle concentration for cleanrooms and clean zones shall include

a) the ISO Class number, expressed as "ISO Class N",

b) the occupancy state to which the classification applies, and

c) the considered particle size(s).

If measurements are to be made at more than one considered particle size, each larger particle diameter (e.g. $D2$) shall be at least 1,5 times the next smaller particle diameter (e.g. $D1$), i.e. $D2 \geq 1{,}5 \times D1$.

EXAMPLE ISO Class number; occupancy state; considered particle size(s)

ISO Class 4; at rest; 0,2 µm, 0,5 µm

4.5 Intermediate decimal cleanliness classes and particle size thresholds

Where intermediate classes, or intermediate particle size thresholds for integer and intermediate classes are required, refer to informative Annex E.

5 Demonstration of compliance

5.1 Principle

Compliance with air cleanliness (ISO Class) requirements specified by the customer is verified by performing specified testing procedures and by providing documentation of the results and conditions of testing.

At-rest or operational classification may be performed periodically based upon risk assessment of the application, typically on an annual basis.

For monitoring cleanrooms, clean zones and separative devices, ISO 14644-2:2015 shall be used.

NOTE Where the installation is equipped with instrumentation for continuous or frequent monitoring of air cleanliness by particle concentration and other parameters of performance as applicable, the time intervals between classification may be extended provided that the results of the monitoring remain within the specified limits.

5.2 Testing

The reference test method for demonstrating compliance is given in Annex A (normative). Alternative methods or instrumentation (or both), having at least comparable performance, may be specified. If no alternative is specified or agreed upon, the reference method shall be used.

Tests performed to demonstrate compliance shall be conducted using instruments which are in compliance with calibration requirements at the time of testing.

5.3 Airborne particle concentration evaluation

Upon completion of testing in accordance with Annex A, the concentration of particles (expressed as number of particles per cubic metre) in a single sample volume at each sampling location shall not exceed the concentration limit(s) given in Table 1 or Table E.1 for intermediate decimal classes for the considered size(s). If multiple single sample volumes are taken at a sampling location, the concentrations shall be averaged and the average concentration must not exceed the concentration limits given in Table 1 or Table E 1. Intermediate particle sizes shall be derived from Formula (E.1).

Particle concentrations used for determination of compliance with ISO Classes shall be measured by the same method for all considered particle sizes.

5.4 Test report

The results from testing each cleanroom or clean zone shall be recorded and submitted as a comprehensive report, along with a statement of compliance or non-compliance with the specified designation of air cleanliness class by particle concentration.

The test report shall include

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

b) the number and year of publication of this part of ISO 14644, i.e. ISO 14644-1:2015,

c) a 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 (a diagrammatic representation can be helpful),

d) the specified designation criteria for the cleanroom or clean zone, including the ISO Class number, 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, and

f) the test results, including particle concentration data for all sampling locations.

If concentrations of macroparticles are quantified, as described in Annex C, the relevant information should be included with the test report.

Annex A
(normative)

Reference method for classification of air cleanliness by particle concentration

A.1 Principle

A discrete-particle-counting instrument is used to determine the concentration of airborne particles, equal to and greater than the specified sizes, at designated sampling locations.

A.2 Apparatus requirements

A.2.1 Particle-counting instrument

The instrument shall have a means of displaying or recording the count and size of discrete particles in air with a size discrimination capability to detect the total particle concentration in the appropriate particle size ranges for the class under consideration.

NOTE Light scattering (discrete) airborne particle counters (LSAPC) are commonly used for undertaking air cleanliness classification.

A.2.2 Instrument calibration

The particle counter shall have a valid calibration certificate: the frequency and method of calibration should be based upon current accepted practice as specified in ISO 21501-4.[1]

NOTE Some particle counters cannot be calibrated to all of the required tests in ISO 21501-4. If this is the case, record the decision to use the counter in the test report.

A.3 Preparation for particle count testing

Prior to testing, verify that all relevant aspects of the cleanroom or clean zone that contribute to its integrity are complete and functioning in accordance with its performance specification.

Care should be taken when determining the sequence for performing supporting tests for cleanroom performance. ISO 14644-3, Annex A provides a checklist.

A.4 Establishment of sampling locations

A.4.1 Deriving the number of sampling locations

Derive the minimum number of sampling locations, N_L, from Table A.1. Table A.1 provides the number of sampling locations related to the area of each cleanroom or clean zone to be classified and provides at least 95 % confidence that at least 90 % of the cleanroom or clean zone area does not exceed the class limits.

Table A.1 — Sampling locations related to cleanroom area

Area of cleanroom (m^2) less than or equal to	Minimum number of sampling locations to be tested (N_L)
2	1
4	2
6	3
8	4
10	5
24	6
28	7
32	8
36	9
52	10
56	11
64	12
68	13
72	14
76	15
104	16
108	17
116	18
148	19
156	20
192	21
232	22
276	23
352	24
436	25
636	26
1 000	27
> 1 000	See Formula (A.1)

NOTE 1 If the considered area falls between two values in the table, the greater of the two should be selected.

NOTE 2 In the case of unidirectional airflow, the area may be considered as the cross section of the moving air perpendicular to the direction of the airflow. In all other cases the area may be considered as the horizontal plan area of the cleanroom or clean zone.

A.4.2 Positioning the sampling locations

In order to position the sampling locations

a) use the minimum number of sampling locations N_L derived from Table A.1,

b) then divide the whole cleanroom or clean zone into N_L sections of equal area,

c) select within each section a sampling location considered to be representative of the characteristics of the section, and

d) at each location, position the particle counter probe in the plane of the work activity or another specified point.

Additional sampling locations may be selected for locations considered critical. Their number and positions shall also be agreed and specified.

Additional sections and associated sampling locations may be included to facilitate subdivision into equal sections.

For non-unidirectional airflow cleanrooms or clean zones, locations may not be representative if they are located directly beneath non-diffused supply air sources.

A.4.3 Sampling locations for large cleanrooms or clean zones

When the area of the cleanroom or clean zone is greater than 1 000 m^2, apply Formula (A.1) to determine the minimum number of sampling locations required.

$$N_{\mathrm{L}} = 27 \times \left(\frac{A}{1\,000} \right) \tag{A.1}$$

where

N_{L} is the minimum number of sampling locations to be evaluated, rounded up to the next whole number;

A is the area of the cleanroom in m^2.

A.4.4 Establishment of single sample volume and sampling time per location

At each sampling location, sample a volume of air sufficient to detect a minimum of 20 particles if the particle concentration for the largest selected particle size were at the class limit for the designated ISO Class.

The single sample volume, V_{S}, per sampling location is determined by using Formula (A.2):

$$V_{\mathrm{s}} = \left(\frac{20}{C_{n,m}} \right) \times 1\,000 \tag{A.2}$$

where

Vs is the minimum single sample volume per location, expressed in litres (except see Annex D);

$C_{n,m}$ is the class limit (number of particles per cubic metre) for the largest considered particle size specified for the relevant class;

20 is the number of particles that could be counted if the particle concentration were at the class limit.

The volume sampled at each location shall be at least 2 l, with a minimum sampling time of 1 min for each sample at each location. Each single sample volume at each sampling location shall be the same.

When V_{S} is very large, the time required for sampling can be substantial. By using the optional sequential sampling procedure (see Annex D), both the required sample volume and the time required to obtain samples may be reduced.

A.5 Sampling procedure

A.5.1 Set up the particle counter (see A.2) in accordance with the manufacturer's instructions including performing a zero count check.

A.5.2 The sampling probe shall be positioned pointing into the airflow. If the direction of the airflow being sampled is not controlled or predictable (e.g. non-unidirectional airflow), the inlet of the sampling probe shall be directed vertically upward.

A.5.3 Ensure normal conditions for the selected occupancy state are established before sampling.

A.5.4 Sample the volume of air determined in A.4.4, as a minimum, for each sample at each sampling location.

A.5.5 If an out-of-specification count is found at a location due to an identified abnormal occurrence, then that count can be discarded and noted as such on the test report and a new sample taken.

A.5.6 If an out-of-specification count found at a location is attributed to a technical failure of the cleanroom or equipment, then the cause should be identified, remedial action taken and retesting performed of the failed sampling location, the immediate surrounding locations and any other locations affected. The choice shall be clearly documented and justified.

A.6 Processing of results

A.6.1 Recording of results

Record the result of each sample measurement as the number of particles in each single sample volume at each of the considered particle size(s) appropriate to the relevant ISO Class of air cleanliness.

NOTE For particle counters with a concentration calculation mode, the manual evaluation may not be necessary.

A.6.1.1 Average concentration of particles at each sampling location

When two or more single sample volumes are taken at a location, calculate and record the average number of particles per location at each considered particle size from the individual sample particle concentrations, according to Formula (A.3).

$$\bar{x}_i = \left(\frac{x_{i.1} + x_{i.2} + \ldots x_{i.n}}{n} \right) \tag{A.3}$$

where

$\bar{x}_i$ is the average number of particles at location i, representing any location;

$x_{i.1}$ to $x_{i.n}$ are the number of particles in individual samples;

n is the number of samples taken at location i.

A.6.1.2 Calculate the concentration per cubic metre

$$C_i = \frac{\bar{x}_i \times 1000}{V_t} \tag{A.4}$$

where

C_i is the concentration of particles per cubic metre;

$\bar{x}_i$ is the average number of particles at location i, representing each location;

V_t is the selected single sample volume in litres.

A.6.2 Interpretation of results

A.6.2.1 Classification requirements

The cleanroom or clean zone is deemed to have met the specified air cleanliness classification requirements if the average of the particle concentrations (expressed as number of particles per cubic metre) measured at each of the sampling locations does not exceed the concentration limits determined from Table 1.

If intermediate classes or particle sizes are used, as defined in Annex E, appropriate limits derived from Table E.1 or Formula (E.1) should be used.

A.6.2.2 Out-of-specification result

In the event of an out-of-specification count, an investigation shall be undertaken. The result of the investigation and remedial action shall be noted in the test report (see 5.4).

Annex B
(informative)

Examples of classification calculations

B.1 Example 1

B.1.1 A cleanroom has a floor area of 18 m^2 and is specified to be ISO Class 5 in operation. The classification is to be performed using a discrete-particle counter having a flow rate of 28,3 l per minute. Two particle sizes are considered: $D \geq 0{,}3$ µm and $D \geq 0{,}5$ µm.

The number of sampling locations, N_L, is determined to be six, based on Table A.1.

B.1.2 The particle concentration limits for ISO Class 5 are taken from Table 1:

C_n (≥ 0,3 µm) = 10 200 particles/m^3

C_n (≥ 0,5 µm) = 3 520 particles/m^3

B.1.3 The required single sample volume can be calculated from Formula (A.2) as follows:

$$V_s = \left(\frac{20}{C_{n,m}}\right) \times 1\,000$$

$$V_s = \left(\frac{20}{3\,520}\right) \times 1\,000$$

$$V_s = (0{,}005\,68) \times 1\,000$$

$$V_s = 5{,}68 \text{ litres}$$

The single sample volume has been calculated to be 5,68 l. As the LSAPC being used for this test had a flow rate of 28,3 litres per minute, a 1-min single sample count would be required (see A.4.4) and therefore 28,3 l would be sampled for each single sample volume.

NOTE In A.4.4, the minimum sample volume for the procedure is set by calculating the minimum sample volume as shown above and then determining the sample volume obtained for the operation of the particle counter in the time period of 1 min. The sampling at each position must occur for at least 1 min; if the minimum sample volume as calculated is satisfied within the 1-min period, then the sampling process can be stopped at the end of 1 min. If the calculated minimum volume cannot be obtained within the 1-min period with the flow rate of the instrument to be used, then the sampling must continue for a longer time period until at least the minimum sample volume has been obtained. Because there are several possible flow rates for particle counters, users are cautioned to verify the flow rate of the specific instrument(s) to be used when determining the sampling time needed to satisfy both the 1-min requirement and the calculated minimum sample volume.

B.1.4 At each sampling location only one sample volume is taken. The number of particles per cubic metre, xi, is calculated for each location and each particle size as shown in Tables B.1 and B.2.

Table B.1 — Sampling data for particles ≥ 0,3 µm

Sampling location	Sample 1 $x_i \geq 0{,}3$ µm (counts per 28,3 l)	Location sample average (counts per 28,3 l)	Location concentration average (counts per m³ = location average × 35,3)	ISO Class 5 limit for 0,3 µm particle size	Pass/fail
1	245	245	8 649	10 200	Pass
2	185	185	6 531	10 200	Pass
3	59	59	2 083	10 200	Pass
4	106	106	3 742	10 200	Pass
5	164	164	5 789	10 200	Pass
6	196	196	6 919	10 200	Pass

Table B.2 — Sampling data for particles ≥ 0,5 µm

Sampling location	Sample 1 $x_i \geq 0{,}5$ µm (counts per 28,3 l)	Location sample average (counts per 28,3 l)	Location concentration average (counts per m³ = location average × 35,3)	ISO Class 5 limit for 0,5 µm particle size	Pass/fail
1	21	21	741	3 520	Pass
2	24	24	847	3 520	Pass
3	0	0	0	3 520	Pass
4	7	7	247	3 520	Pass
5	22	22	777	3 520	Pass
6	25	25	883	3 520	Pass

B.1.5 Each value of the concentration for $D \geq 0{,}3$ µm is less than the limit of 10 200 particles/m³ and $D \geq 0{,}5$ µm is less than the limit of 3 520 particles/m³ as established in B.1.2; therefore, the air cleanliness by particle concentration of the cleanroom meets the required ISO Class.

B.2 Example 2

B.2.1 A cleanroom has a floor area of 9 m² and is specified to be ISO Class 3 in operation. The classification is to be performed using a discrete-particle counter having a flow rate of 50,0 l per minute. Only one particle size ($D \geq 0{,}1$ µm) is considered.

The number of sampling locations, N_L, is determined to be five, based on Table A.1.

B.2.2 The particle concentration limit for ISO Class 3 at ≥ 0,1 µm is taken from Table 1:

C_n (≥ 0,1 µm) = 1 000 particles/m³

B.2.3 The required single sample volume can be calculated from Formula (A.2) as follows:

$$V_s = \left(\frac{20}{C_{n,m}}\right) \times 1\,000$$

$$V_s = \left(\frac{20}{1\,000}\right) \times 1\,000$$

$$V_s = (0{,}02) \times 1\,000$$

$$V_s = 20{,}0 \text{ litres}$$

The single sample volume has been calculated to be 20,0 l. As the discrete-particle counter being used for this test had a flow rate of 50,0 l per minute, a 1-min single sample count would be required (see A.4.4) and therefore 50,0 l would be sampled for each single sample volume.

B.2.4 At each sampling location only one sample volume is taken. The number of particles per cubic metre, x_i, is calculated for each location and recorded in Table B.3.

Table B.3 — Sampling data for particles ≥ 0,1 μm

Sampling location	Sample 1 x_i ≥ 0,1 μm (counts per 50,0 l)	Location sample average (counts per 50,0 l)	Location concentration average (counts per m³ = location average × 20)	ISO Class 3 limit for ≥ 0,1 μm particle size	Pass/fail
1	46	46	920	1 000	Pass
2	47	47	940	1 000	Pass
3	46	46	920	1 000	Pass
4	44	44	880	1 000	Pass
5	9	9	180	1 000	Pass

B.2.5 Each value of the concentration for D ≥ 0,1 μm is less than the limit of 1 000 particles/m^3 established in Table 1; therefore, the air cleanliness by particle concentration of the cleanroom meets the required ISO Class.

B.3 Example 3

B.3.1 A cleanroom has a floor area of 64 m^2 and is specified ISO Class 5 in operation. The classification is to be performed using a discrete-particle counter having a flow rate of 28,3 l per minute. Only one particle size (D ≥ 0,5 μm) is considered.

The number of sampling locations, N_L, is determined to be 12, based on Table A.1.

B.3.2 The particle concentration limit for ISO Class 5 at ≥ 0,5 μm is taken from Table 1:

C_n (≥ 0,5 μm) = 3 520 particles/m^3

B.3.3 The required single sample volume can be calculated from Formula (A.2) as follows:

$$V_s = \left(\frac{20}{C_{n,m}}\right) \times 1\,000$$

$$V_s = \left(\frac{20}{3\,520}\right) \times 1\,000$$

$$V_s = (0{,}005\,68) \times 1\,000$$

$$V_s = 5{,}68 \text{ litres}$$

The single sample volume has been calculated to be 5,68 l. As the discrete-particle counter used for this test had a flow rate of 28,3 l per minute, a 1-min single sample count would be required (see A.4.4) and therefore 28,3 l would be sampled for each single sample volume.

B.3.4 At each sampling location only one sample volume is taken. The number of particles per cubic metre, x_i, is calculated for each location and recorded in Table B.4.

Table B.4 — Sampling data for particles ≥ 0,5 µm

Sampling location	Sample 1 $x_i \geq 0{,}5$ µm	Location sample average concentration (counts per 28,3 l)	Location concentration average (counts per m³ = location average × 35,3)	ISO Class 5 limit for 0,5 µm particle size	Pass/fail
1	35	35	1 236	3 520	Pass
2	22	22	777	3 520	Pass
3	89	89	3 142	3 520	Pass
4	49	49	1 730	3 520	Pass
5	10	10	353	3 520	Pass
6	60	60	2 118	3 520	Pass
7	18	18	635	3 520	Pass
8	44	44	1 553	3 520	Pass
9	59	59	2 083	3 520	Pass
10	51	51	1 800	3 520	Pass
11	6	6	212	3 520	Pass
12	31	31	1 094	3 520	Pass

B.3.5 Each value of the concentration for D = 0,5 µm is less than the limit of 3 520 particles/m³ established in Table 1; therefore, the air cleanliness by particle concentration of the cleanroom meets the required ISO Class.

B.4 Example 4

B.4.1 A cleanroom has a floor area of 25 m² and is specified to be ISO Class 5 in operation. The classification is to be performed using a discrete-particle counter having a flow rate of 28,3 l per minute. Only one particle size ($D \geq 0{,}5$ µm) is considered.

The minimum number of sampling locations from Table A.1 is 7.

B.4.2 The particle concentration limit for ISO Class 5 at ≥ 0,5 µm is obtained from Table 1 as follows:

$$C_n (\geq 0{,}5\ \mu\text{m}) = 3\ 520 \text{ particles/m}^3$$

B.4.3 The required single sample volume can be calculated from Formula (A.2) as follows:

$$V_s = \left(\frac{20}{C_{n,m}}\right) \times 1000$$

$$V_s = \left(\frac{20}{3520}\right) \times 1000$$

$$V_s = (0,00568) \times 1000$$

$$V_s = 5,68 \text{ litres}$$

The single sample volume has been calculated to be 5,68 l. As the discrete-particle counter being used for this test had a flow rate of 28,3 l per minute, a 1-min single sample count would be required (see A.4.4) and therefore 28,3 l would be sampled for each single sample volume.

B.4.4 The number of sampling locations required from Table A.1 is 7, however, this example shows that the customer and supplier have agreed to add an additional 3 locations, making 10 in total. At each sampling location the number of single sample volumes varies from 1 to 3.

B.4.5 For recording purposes, the number of particles (concentration) per cubic metre, x_i, is calculated from the average count per unit volume (28,3 l) at each location (28,3 × 35,3) as in Table B.5.

Table B.5 — Sampling data for particles ≥ 0.5 µm

Sampling location	Sample 1 $x_i \geq 0,5$ µm (counts per 28,3 l)	Sample 2 $x_i \geq 0,5$ µm (counts per 28,3 l)	Sample 3 $x_i \geq 0,5$ µm (counts per 28,3 l)	Location sample average (counts per 28,3 l)	Location concentration average (counts per m^3 = location average × 35,3)	ISO Class 5 limit for ≥ 0,5 µm particle size	Pass/fail
1	47	57		52	1 836	3 520	Pass
2	12			12	424	3 520	Pass
3	162	78	32	91	3 201	3 520	Pass
4	148	74	132	118	4 165	3 520	Fail
5	1	0		0,5	18	3 520	Pass
6	19	22	17	19	682	3 520	Pass
7	5	15	3	8	271	3 520	Pass
8	38	21		30	1 041	3 520	Pass
9	54	159	78	97	3 424	3 520	Pass
10	48	62	53	54	1 918	3 520	Pass

B.4.6 At sampling location 4, the average sample volume concentration of 4 165 does not meet ISO Class 5 maximum particle count criteria of 3 520. At location 3 and location 9, one of the individual particle count concentrations does not meet the limit established in Table 1; however, the average particle concentration for location 3 and the average particle concentration for location 9 do meet the limit established in Table 1. Because location 4 does not meet the air cleanliness by particle concentration, the cleanroom does not meet the required ISO Class.

B.5 Example 5

B.5.1 A cleanroom has a floor area of 10,7 m^2 and is specified to be ISO Class 7,5 in operation. The classification is to be performed using a discrete-particle counter having a flow rate of 28,3 litres per minute. Only one particle size ($D \geq 0,5$ µm) is considered.

The number of sampling locations is determined to be 6, based on Table A.1.

B.5.2 The particle concentration limit for ISO Class 7,5 at ≥ 0,5 µm is obtained from Table E.1.

$$C_n(\geq 0{,}5\,\mu\text{m}) = 10^N \times \left(\frac{0{,}1}{D}\right)^{2{,}08} \quad \text{where } N = 7{,}5 \text{ and } D = 0{,}5\,\mu\text{m}$$

$$C_n(\geq 0{,}5\,\mu\text{m}) = 10^{7{,}5} \times \left(\frac{0{,}1}{0{,}5}\right)^{2{,}08}$$

$$C_n(\geq 0{,}5\,\mu\text{m}) = 31\,622\,777 \times 0{,}035\,167\,57$$

$$C_n(\geq 0{,}5\,\mu\text{m}) = 1\,112\,096 \text{ rounded to three significant digits} = 1\,110\,000 \text{ particles/m}^3$$

B.5.3 The required single sample volume can be calculated from Formula (A.2) as follows:

$$V_s = \left(\frac{20}{C_{n,m}}\right) \times 1\,000$$

$$V_s = \left(\frac{20}{1\,112\,000}\right) \times 1\,000 = 0{,}017\,99 \text{ litres}$$

The single sample volume has been calculated to be 0,01799 l. As the discrete-particle counter being used for this test had a flow rate of 28,3 l per minute, a 1-min single sample count would be required (see A.4.4) and therefore 28,3 l would be sampled for each single sample volume.

B.5.4 At each sampling location the number of single sample volumes varies from 1 to 3. The number of particles per cubic metre, x_i, is calculated for each location and recorded in Table B.6.

Table B.6 — Sampling data for particles ≥ 0,5 µm

Sampling location	Sample 1 x_i ≥ 0,5 µm (counts per 28,3 l)	Sample 2 x_i ≥ 0,5 µm (counts per 28,3 l)	Sample 3 x_i ≥ 0,5 µm (counts per 28,3 l)	Location sample average (counts per 28,3 l)	Location concentration average (counts per m^3 = location average × 35,3)	ISO Class 7,5 limit for 0,5 µm particle size	Pass/ fail
1	11 679			11 679	412 269	1 110 000	Pass
2	9 045			9 045	319 289	1 110 000	Pass
3	12 699			12 699	448 275	1 110 000	Pass
4	26 232	27 555	34 632	29 473	1 040 397	1 110 000	Pass
5	7 839			7 839	276 717	1 110 000	Pass
6	13 669			13 669	482 516	1 110 000	Pass

B.5.5 At sampling location 4, the third sample volume concentration of 1 222 507 (34 632 × 35,3) did not meet the ISO Class 7,5 maximum particle count criteria of 1 110 000. The concentration of each single sample volume does not meet the limit established by using Table E.1; however, the average particle concentration for each of the sampling locations does meet the limit established by application of Table E.1. Therefore, the air cleanliness by particle concentration of the cleanroom meets the required ISO Class.

B.6 Example 6

B.6.1 A cleanroom has a floor area of 2 100 m^2 and is specified to be ISO Class 7 in operation. The classification is to be performed using a discrete-particle counter having a flow rate of 28,3 litres per minute. Only one particle size ($D \geq 0{,}5$ µm) is considered.

The number of sampling locations, N_L, given by Table A.1 is limited to cleanrooms of 1 000 m^2 area.

For a cleanroom of 2 100 m^2, the number of sampling locations, N_L, is derived from Formula (A.1):

$$2\,100 \times \left(\frac{27}{1\,000} \right) = 56{,}7 \text{ rounded to } 57$$

B.6.2 The particle concentration limit for ISO Class 7 at ≥ 0,5 µm is taken from Table 1:

C_n (≥ 0,5 µm) = 352 000 particles/m^3

B.6.3 The required single sample volume can be calculated from Formula (A.2) as follows:

$$V_s = \left(\frac{20}{C_{n,m}} \right) \times 1\,000$$

$$V_s = \left(\frac{20}{352\,000} \right) \times 1\,000$$

$$V_s = \left(0{,}000\,056\,8 \right) \times 1\,000$$

$$V_s = 0{,}056\,8 \text{ litres}$$

The single sample volume has been calculated to be 0,0568 l. As the discrete-particle counter being used for this test had a flow rate of 28,3 l per minute, a 1-min single sample count would be required (see A.4.4) and therefore 28,3 l would be sampled for each single sample volume.

B.6.4 At each sampling location only one sample volume is taken. The number of particles per cubic metre, x_i, is calculated for each location and recorded in Table B.7.

Table B.7 — Sampling data for particles ≥ 0,5 µm

Sampling location	Sample 1 x_i ≥ 0,5 µm (counts per 28,3 l)	Location sample average (counts per 28,3 l)	Location concentration average (counts per m^3 = location average × 35,3)	ISO Class 7 limit for 0,5 µm particle size	Pass/fail
1	5 678	5 678	200 434	352 000	Pass
2	7 654	7 654	270 187	352 000	Pass
3	2 398	2 398	84 650	352 000	Pass
4	4 578	4 578	161 604	352 000	Pass
5	8 765	8 765	309 405	352 000	Pass
6	4 877	4 877	172 159	352 000	Pass
7	8 723	8 723	307 922	352 000	Pass
8	7 632	7 632	269 410	352 000	Pass
9	7 643	7 643	269 798	352 000	Pass
10	6 756	6 756	238 487	352 000	Pass
11	5 678	5 678	200 434	352 000	Pass
12	5 476	5 476	193 303	352 000	Pass
13	8 576	8 576	302 733	352 000	Pass
14	7 765	7 765	274 105	352 000	Pass
15	3 456	3 456	121 997	352 000	Pass
16	5 888	5 888	207 847	352 000	Pass
17	3 459	3 459	122 103	352 000	Pass
18	7 666	7 666	270 610	352 000	Pass
19	8 567	8 567	302 416	352 000	Pass
20	8 345	8 345	294 579	352 000	Pass
21	7 998	7 998	282 330	352 000	Pass
22	7 665	7 665	270 575	352 000	Pass
23	7 789	7 789	274 952	352 000	Pass
24	8 446	8 446	298 144	352 000	Pass
25	8 335	8 335	294 226	352 000	Pass
26	7 988	7 988	281 977	352 000	Pass
27	7 823	7 823	276 152	352 000	Pass
28	7 911	7 911	279 259	352 000	Pass
29	7 683	7 683	271 210	352 000	Pass
30	7 935	7 935	280 106	352 000	Pass
31	6 534	6 534	230 651	352 000	Pass
32	4 667	4 667	164 746	352 000	Pass
33	6 565	6 565	231 745	352 000	Pass
34	8 771	8 771	309 617	352 000	Pass
35	5 076	5 076	179 183	352 000	Pass
36	6 678	6 678	235 734	352 000	Pass
37	7 100	7 100	250 630	352 000	Pass
38	8 603	8 603	303 686	352 000	Pass

Table B.7 *(continued)*

Sampling location	Sample 1 $x_i \geq 0,5$ µm (counts per 28,3 l)	Location sample average (counts per 28,3 l)	Location concentration average (counts per m³ = location average × 35,3)	ISO Class 7 limit for 0,5 µm particle size	Pass/fail
39	7 609	7 609	268 598	352 000	Pass
40	7 956	7 956	280 847	352 000	Pass
41	7 477	7 477	263 939	352 000	Pass
42	7 145	7 145	252 219	352 000	Pass
43	6 998	6 998	247 030	352 000	Pass
44	7 653	7 653	270 151	352 000	Pass
45	6 538	6 538	230 792	352 000	Pass
46	3 679	3 679	129 869	352 000	Pass
47	4 887	4 887	172 512	352 000	Pass
48	7 648	7 648	269 975	352 000	Pass
49	8 748	8 748	308 805	352 000	Pass
50	7 689	7 689	271 422	352 000	Pass
51	7 345	7 345	259 279	352 000	Pass
52	7 888	7 888	278 447	352 000	Pass
53	7 765	7 765	274 105	352 000	Pass
54	6 997	6 997	246 995	352 000	Pass
55	6 913	6 913	244 029	352 000	Pass
56	7 474	7 474	263 833	352 000	Pass
57	8 776	8 776	309 793	352 000	Pass

B.6.5 Each value of the concentration for $D \geq 0,5$ µm is less than the limit of 352 000 particles/m^3 established in Table 1; therefore, the air cleanliness by particle concentration of the cleanroom meets the required ISO Class.

Annex C
(informative)

Counting and sizing of airborne macroparticles

C.1 Principle

In some situations, typically those related to specific process requirements, alternative levels of air cleanliness may be specified on the basis of particle populations that are not within the size range applicable to classification. The maximum permitted concentration of such particles and the choice of test method to verify compliance are matters for agreement between the customer and the supplier. Considerations for test methods and prescribed formats for specification are given in C.2.

C.2 Consideration of particles larger than 5 µm (macroparticles) — M descriptor

C.2.1 Application

If contamination risks caused by particles larger than 5 µm are to be assessed, sampling devices and measurement procedures appropriate to the specific characteristics of such particles should be employed.

The measurement of airborne particle concentrations with size distributions having a threshold size between 5 µm and 20 µm can be made in any of three defined occupancy states: as-built, at-rest and operational.

As particle liberation within the process environment normally dominates the macroparticle fraction of the airborne particle population, the identification of an appropriate sampling device and measurement procedure should be addressed on an application-specific basis. Factors such as density, shape, volume and aerodynamic behaviour of the particles need to be taken into account. Also, it may be necessary to put special emphasis on specific components of the total airborne population, such as fibres.

C.2.2 M descriptor format

The M descriptor may be specified as a complement to the air cleanliness class by particle concentration. The M descriptor is expressed in the format

"ISO M (a; b); c"

where

- a is the maximum permitted concentration of macroparticles (expressed as macroparticles per cubic metre of air);
- b is the equivalent diameter (or diameters) associated with the specified method for measuring macroparticles (expressed in micrometres);
- c is the specified measurement method.

EXAMPLE 1 To express an airborne concentration of 29 particles/m^3 in the particle size range ≥ 5 µm based on the use of an LSAPC, the designation would be: "ISO M (29; ≥ 5 µm); LSAPC".

EXAMPLE 2 To express an airborne particle concentration of 2 500 particles/m^3 in the particle size range of > 10 µm based on the use of a time-of-flight aerosol particle counter to determine the aerodynamic diameter of the particles, the designation would be: "ISO M (2 500; ≥ 10 µm); time-of-flight aerosol particle counter".

EXAMPLE 3 To express an airborne particle concentration of 1 000 particles/m^3 in the particle size range of 10 to 20 µm, based on the use of a cascade impactor followed by microscopic sizing and counting, the designation would be: "ISO *M* (1 000; 10 to 20 µm); cascade impactor followed by microscopic sizing and counting".

NOTE 1 If the population of airborne particles being sampled contains fibres, they can be accounted for by supplementing the M descriptor with a separate descriptor for fibres, which has the format "M_{fibre} (a; b); c".

NOTE 2 Suitable methods of test for concentrations of airborne particles larger than 5 µm are given in IEST-G-CC1003.[2]

C.3 Airborne particle count for macroparticles

C.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 C.3 has been adapted from IEST-G-CC1003:1999.[2] Measurements can be made in a cleanroom or clean zone installation in any of the three designated occupancy states: as-built, at-rest or operational. The measurements are made to define the concentration of macroparticles, and the principles in 5.1, 5.2 and 5.4 may be applied. The need for proper sample acquisition and handling to minimize losses of macroparticles in the sample handling operations is emphasized.

C.3.2 General

The number of sampling locations, location selection and quantity of data required should be in accordance with A.4. The customer and supplier should agree upon the maximum permitted concentration of macro-particles, the equivalent diameter of the particles and the specified measurement method. 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 Annex C should be used.

C.3.3 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 in IEST-G-CC1003:1999.[2]

C.3.4 Measurement methods for macroparticles

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 methods and particle size information produced by the various methods is summarized in C.3.4.1 and C.3.4.2.

C.3.4.1 *In situ* measurement

Using *in situ* measurement of the concentration and size of macroparticles with a time-of-flight particle counter or an LSAPC:

a) LSAPC measurement (C.4.1.2) will report macroparticles using particle size based upon an equivalent optical diameter;

b) time-of-flight particle size measurement (C.4.1.3) will report macroparticles using particle size based upon an aerodynamic diameter.

C.3.4.2 Collection

Collection by filtration or inertial effects, followed by microscopic measurement of the number and size of collected particles:

a) filter collection and microscopic measurement (C.4.2.2) will report macroparticles using particle size based upon the agreed diameter;

b) cascade impactor collection and microscopic measurement (C.4.2.3) will report macroparticles using particle size based upon the choice of reported particle diameter.

C.4 Methods for macroparticle measurement

C.4.1 Macroparticle measurement without particle collection

C.4.1.1 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 LSAPC, which reports either the equivalent optical diameter or the aerodynamic diameter of the particles.

C.4.1.2 Light-scattering particle counter (LSAPC) measurement

Procedures for macroparticle measurement using an LSAPC are the same as those in Annex A for airborne particle count with one exception. The exception is that the LSAPC 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 LSAPC samples directly from the air at the sampling location. The LSAPC should have a sample flow rate of at least 28,3 l/min and should be fitted with an inlet probe sized for isokinetic sampling in unidirectional flow zones. In areas where non-unidirectional flow exists, the LSAPC should be located with the sample inlet facing vertically upward.

A sampling probe should be selected to permit close to isokinetic sampling in areas with unidirectional flow. If this is not possible, set the sampling probe inlet facing into the predominant direction of the airflow; in locations where the 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 sampling probe inlet to the LSAPC 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, and will typically be no longer than 1 m in length.

Sampling errors due to large particle loss in sampling systems should be minimised.

The LSAPC size range settings are established so that only macroparticles are detected. The data from one size below 5 µm 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 LSAPC 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 LSAPC being used.

C.4.1.3 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 particle 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. Sample acquisition procedures are the same as those required when using a LSAPC to measure macroparticles. In addition, the same procedures as for the LSAPC are used with this apparatus in order to establish the particle size ranges to be reported.

C.4.2 Macroparticle measurement with particle collection

C.4.2.1 General

Macroparticles can be measured by collecting particles from the air. An air sample is transported at a specific flow rate through a collection device. Microscopic analysis is used to count the collected particles.

NOTE The mass of the collected particles can also be determined but since the air cleanliness is determined by number concentration this is not addressed in this part of ISO 14644.

C.4.2.2 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 fewer 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 sampling 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.

Determine the sample volume required by using Formula (C.1).

Remove the cover from the membrane filter holder or aerosol monitor and store in a clean location. Sample the air at the sampling 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 analysed. Count the particles on the filter surface (see ASTM F312-08).[3]

C.4.2.3 Cascade impactor collection and measurement

In a cascade impactor particle separation is carried out by inertial impaction of particles. 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. The aerodynamic diameter correlates directly with the regional collection of particles in the impactor flow path.

For the measurement of the air cleanliness by particle concentration a type of cascade impactor meant for collection and counting of macroparticles can be used. In this one the particles are deposited upon the surfaces of removable plates that are removed for subsequent microscopic examination. Sampling flow rates of 0, 47 litres/sec or more are typically used for this type of cascade impactor.

C.5 Procedure for macroparticle count

Determine the "ISO *M* (*a*; *b*); *c*" descriptor concentration in the selected particle size range(s), as agreed between customer and supplier, and report the data.

At each sampling location, sample a volume of air sufficient to detect a minimum of 20 particles for the selected particle size at the determined concentration limit.

The single sample volume, V_S, per sampling location is determined by using Formula (C.1):

$$V_s = \left(\frac{20}{C_{n,m}}\right) \times 1\,000 \tag{C.1}$$

where

V_S is the minimum single sample volume per location, expressed in litres (except see D.4.2);

$C_{n,m}$ is the class limit (number of particles per cubic metre) for the largest considered particle size specified for the relevant class;

20 is the number of particles that could be counted if the particle concentration were at the class limit.

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.

Set up the sample inlet probe of the selected apparatus and undertake the test.

C.6 Test reports for macroparticle sampling

The following test information and data should be recorded:

a) definition of the particle sizes to which the apparatus responds;

b) measurement method;

c) method of measurement of M descriptor level or limit as an adjunct to the ISO Class;

d) type designations of each measurement instrument and apparatus used and its calibration status;

e) ISO Class of the installation;

f) macroparticle size range(s) and the counts for each size range reported;

g) apparatus inlet sample flow rate and flow rate through sensing volume;

h) sampling location(s);

i) sampling schedule plan for classification or sampling protocol plan for testing;

j) occupancy state(s);

k) other relevant data for measurement such as stability of macroparticle concentration.

C.7 Adaptation of the macroparticle descriptor to accommodate consideration of ≥ 5 µm particle size for ISO Class 5 cleanrooms

In order to express an airborne concentration of 29 particles/m^3 in the particle size range ≥ 5 µm based on the use of an LSAPC, the designation would be “ISO *M* (29; ≥ 5 µm); LSAPC” and for 20 particle/m^3 the designation would be “ISO *M* (20; ≥ 5 µm); LSAPC” (see Table 1, Note f).

Annex D
(informative)

Sequential sampling procedure

D.1 Background and limitations

D.1.1 Background

In some circumstances where it is necessary or required to classify a clean controlled environment with a very low particle concentration at the class limit, sequential sampling is a useful technique that allows reduction of the sample volume and sampling time. The sequential sampling technique measures the rate of counting and predicts the likelihood of passing or failing to meet the requirements of the ISO Class. If the air being sampled is significantly more or significantly less contaminated than the specified class concentration limit for the considered particle size, use of the sequential sampling procedure can reduce sample volumes and sampling times, often dramatically.

Some savings may also to be realized when the concentration is near the specified limit. Sequential sampling is most appropriate for air cleanliness of ISO Class 4 or cleaner. It may also be used for other classes when the limit for the chosen particle size is low. In that case, the required sample volume may be too high for detecting 20 expected counts.

NOTE For further information on sequential sampling, see IEST-G-CC1004[4] or JIS B 9920:2002.[5]

D.1.2 Limitations

The principal limitations of sequential sampling are

a) the procedure is only applicable when expected counts from a single sample are < 20 for the largest particle size (see A.4.4),

b) each sample measurement requires supplementary monitoring and data analysis, which can be facilitated through computerised automation, and

c) particle concentrations are not determined as precisely as with conventional sampling procedures due to the reduced sample volume.

D.2 Basis for the procedure

The procedure is based on comparison of real-time cumulative particle counts to reference count values. Reference values are derived from formulae for upper- and lower-limit boundaries:

$$\text{upper limit: } C_{fail} = 3{,}96 + 1{,}03\ E \qquad \text{(D.1)}$$

$$\text{lower limit: } C_{pass} = -3{,}96 + 1{,}03\ E \qquad \text{(D.2)}$$

where

C_{fail} is the upper limit for the observed count;

C_{pass} is the lower limit for the observed count;

E is the expected count (shown by Formula (D.5), the class limit).

According to Formula (A.2), the single sample volume, V_s, is calculated as follows:

$$V_s = \left(\frac{20}{C_{n,m}} \right) \times 1\,000 \tag{D.3}$$

where

V_s is the minimum single sample volume per location, expressed in litres;

$C_{n,m}$ is the class limit (number of particles per cubic metre) for the considered particle size specified for the relevant class;

20 is the defined number of particles that could be counted if the particle concentration were at the class limit.

The total sampling time t_t is calculated as follows:

$$t_t = \frac{V_s}{Q} \tag{D.4}$$

where

V_s is the accumulative sample volume (litres);

Q is the sampling flow rate of the particle counter (litres/s).

The expected count is defined as follows:

$$E = \frac{Q \times t \times C_{n,m}}{1\,000} \tag{D.5}$$

where

t is sampling time (in seconds).

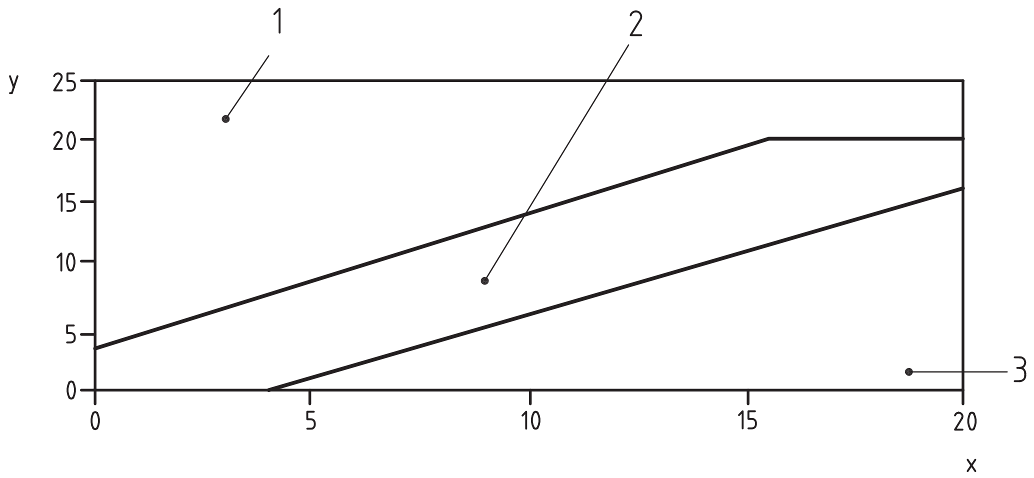
To aid in understanding, a graphical illustration of the sequential sampling procedure is provided in Figure D.1. As air is being sampled at each designated sampling location, the running total particle count is continuously compared to the expected count for the proportion of the prescribed total volume that has been sampled. If the running total count is less than the lower limit C_{pass} corresponding to the expected count, the air being sampled is found to meet the specified class or concentration limit, and sampling is halted.

If the running count exceeds the upper limit C_{fail} corresponding to the expected count, the air being sampled fails to meet the specified class or concentration limit, and sampling is halted. As long as the running count remains between the upper and lower limits, sampling continues until the observed count becomes 20 or the cumulative sample volume, V, becomes equal to the minimum single sample volume, V_s, where the expected count becomes 20.

In Figure D.1, the number of observed counts, C, is plotted versus the expected count, E, until either the sampling is halted or the count reaches 20.

D.3 Procedure for sampling

Figure D.1 illustrates the boundaries established in Formulae (D.1) and (D.2), as truncated by the limitations of E = 20, representing the time required to collect a full sample, and C = 20, the maximum observed count allowed.



Key

x expected count, E

y observed count, C

1 stop counting, FAIL ($C \geq 3{,}96 + 1{,}03E$)

2 continuous counting

3 stop counting, PASS ($C \leq -3{,}96 + 1{,}03E$)

Figure D.1 — Boundaries for pass or fail by the sequential sampling procedure

The observed count is plotted versus the expected count for air having a particle concentration precisely at the specified class level. The passage of time corresponds to increasing numbers of expected counts, with E = 20 representing the time required to accumulate a full sample volume if the particle concentration were at the class limit.

The procedure for sequential sampling using Figure D.1 is as follows:

1) record the total number of particles counted as a function of time;

2) calculate the expected count following the procedure described in D.2, Formula (D.5);

3) plot the total count versus the expected count as in Figure D.1;

4) compare the count with the upper and lower limit lines of Figure D.1;

5) if the cumulative observed count crosses the upper line, sampling at the location is stopped and the air is reported to have failed compliance with the specified class limit;

6) if the cumulative observed count crosses the lower line, sampling is stopped and the air passes compliance with the specified class limit;

7) if the cumulative observed count remains between the upper and lower lines, sampling will continue.

If the total count is 20 or fewer at the end of the prescribed sampling period and has not crossed the upper line, the air is judged to have complied with the class limit.

D.4 Examples of sequential sampling

D.4.1 Example 1

a) Evaluation of a cleanroom with a target air cleanliness of ISO Class 3 (0,1 µm, 1 000 particles/m^3) by the sequential sampling procedure. This procedure looks at the rate of count and seeks to predict likely pass or fail.

NOTE The sampling flow rate of particle counter is 0,0283 m^3/min (28,3 l/min or 0,47 l/s).

b) Preparation before measurement — method for calculation of limit values.

Table D.1 shows the calculation result. First, the expected count is calculated based on sampling time. Next, the upper reference count and the lower reference count are calculated by using Formulae (D.1) and (D.2), or Figure D.1.

Table D.1 — Calculation tabulation of the upper and lower reference count

Measurement period	Sampling time (s)	Total sampled air volume	Expected count	Upper limit for the observed count	Lower limit for the observed count
	t	*litre*	*According to Formula (D.5)*	C_{fail} = 3,96 + 1,03 E	C_{pass} = −3,96 + 1,03 E
1st	5	2,4	2,4	7 (6,4)	N.A. (−1,5)
2nd	10	4,7	4,7	9 (8,8)	0 (0,9)
3rd	15	7,1	7,1	12 (11,2)	3 (3,3)
4th	20	9,4	9,4	14 (13,7)	5 (5,8)
5th	25	11,8	11,8	17 (16,1)	8 (8,2)
6th	30	14,2	14,1	19 (18,5)	10 (10,6)
7th	35	16,5	16,5	20 (21,0)	13 (13,0)
8th	40	18,9	18,9	20 (23,4)	15 (15,5)
9th	45	21,2	21,2	21	20

NOTE The numeric value in parentheses shows the result of calculation of the upper and lower limits for the observed count to one decimal place. However, as the actual data are integer values, each calculated value is handled at the time of evaluation as the integer value shown.

The upper limit for the observed count is rounded up to the first decimal place of calculated value.

The lower limit for the observed count is rounded down to the first decimal place of calculated value.

When C_{pass} calculated according to Formula (D.2) is negative, it is denoted by ‘N.A.’ (not applicable). In this case, we cannot conclude that the air cleanliness satisfies the target ISO Class, even if the observed count is zero.

c) Evaluation using sequential sampling procedure.

The expected count provided in the first measurement is 2,4; it is judged to “FAIL” when the observed count is greater or equal to 7. However, when the observed count during this sampling period is between 0 and 6, the result cannot be judged. In this case, sampling is continued. When sampling is continued, the cumulative observed count may increase. Sampling is continued until either the prescribed single sample volume is achieved or the observed count has crossed one of the lines for C_{pass} or C_{fail}, respectively. If the cumulative observed count is 20 or fewer at the end of the prescribed sampling period and has not crossed the upper line, the air cleanliness classification is judged to “PASS”. If the cumulative observed count is less than or equal to the rounded down values for C_{pass} before achieving the full sampling period, the sampling is stopped and the classification is judged to “PASS”.

D.4.2 Example 2

Evaluation of a cleanroom with a target air cleanliness of ISO Class 3 (0,5 µm, 35 particles/m^3) by the sequential sampling procedure. The sampling flow rate of the particle counter (Q) is 0,0283 m^3/min = 0,47 l/s.

Calculate the single sample volume, V_S, according to Formula (D.3).

$$V_s = \left(\frac{20}{C_{n,m}}\right) \times 1\,000 = \frac{20}{35} \times 1\,000 = 571,429 \text{ litres} \tag{D.6}$$

Calculate the total sampling time, t_t, according to Formula (D.4). This is the longest time necessary to evaluate the sampling location. The sequential sampling procedure should shorten this time.

$$t_t = \frac{V_s}{Q} = 1211,5\text{s} = 20,19 \text{ min} \tag{D.7}$$

Calculate the result table:

1) calculate the expected count, E, according to Formula (D.5);

$$E = \frac{Q \times t \times C_{n,m}}{1\,000} \tag{D.8}$$

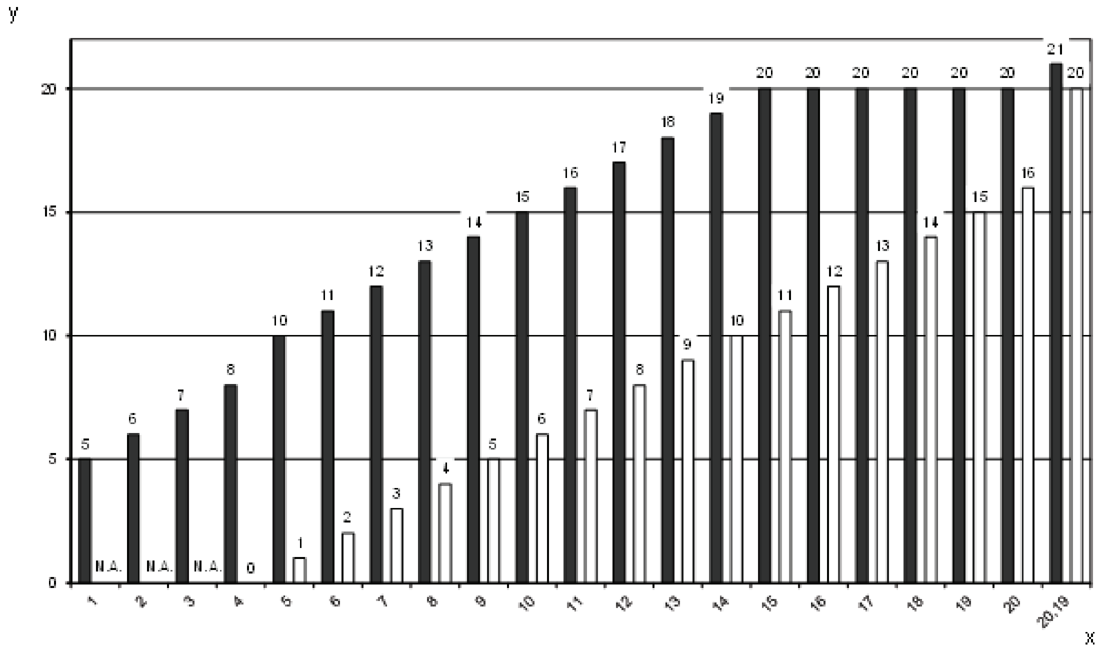
2) calculate the upper and lower limit for the observed count according to Formulae (D.1) and (D.2);

3) the calculation result is shown in Table D.2 and Figure D.2.

Table D.2 — Calculation result of the total sample air volume, expected count, upper limit and lower limit

t (min)	*t* (s)	Total sampled air volume, $Q \times t$	Expected count, E	Limits	
				Upper, C_{fail}	Lower, C_{pass}
1	60	28,3	1,0	5 (5,0)	N.A. (−2,9)
2	120	56,6	2,0	7 (6,0)	N.A. (−1,9)
3	180	84,9	3,0	8 (7,0)	N.A. (−0,9)
4	240	113,2	4,0	9 (8,0)	0 (0,1)
5	300	141,5	5,0	10 (9,1)	1 (1,1)
6	360	169,8	5,9	11 (10,1)	2 (2,2)
7	420	198,1	6,9	12 (11,1)	3 (3,2)
8	480	226,4	7,9	13 (12,1)	4 (4,2)
9	540	254,7	8,9	14 (13,1)	5 (5,2)
10	600	283,0	9,9	15 (14,2)	6 (6,2)
11	660	311,3	10,9	16 (15,2)	7 (7,3)
12	720	339,6	11,9	17 (16,2)	8 (8,3)
13	780	367,9	12,9	18 (17,2)	9 (9,3)
14	840	396,2	13,9	19 (18,2)	10 (10,3)
15	900	424,5	14,9	20 (19,3)	11 (11,3)
16	960	452,8	15,8	20 (20,3)	12 (12,4)
17	1 020	481,1	16,8	20 (21,3)	13 (13,4)
18	1 080	509,4	17,8	20 (22,3)	14 (14,4)
19	1 140	537,7	18,8	20 (23,3)	15 (15,4)
20	1 200	566,0	19,8	20 (24,4)	16 (16,4)
$20,19 = t_t$	1 211,5	$571,429 = V_s$	20	21	20

In Figure D.2, the upper and lower limits for the observed count are plotted versus the count acquisition time. Each vertical bar shows the limits (upper and lower) at 1-min intervals.



Key

x count time (min)

y count limits (particles)

upper limit for the observed count

lower limit for the observed count

Figure D.2 — Graphical representation of the pass or fail boundaries for sequential sampling

Compare the cumulative observed count and the upper and lower limits and apply the procedure described in D.3.

a) Fail situation, see Table D.3.

Table D.3 — Example sequential sampling particle counts

t (min)	*t* (s)	Expected count, *E*	Limit for the cumulative observed count		Observed count during interval	Cumulative observed count, *C*	Result
			Upper, C_{fail}	Lower, C_{pass}			
1	60	1,0	5	N.A.	2	2	Continue
2	120	2,0	7	N.A.	3	5	Continue
3	180	3,0	8	N.A.	1	6	Continue
4	240	4,0	9	0	0	6	Continue
5	300	5,0	10	1	5	11	FAIL

The expected count provided in the first measurement is 1,0; the cumulative observed count is judged to “FAIL” when it is greater than or equal to 5. However, when the cumulative observed count is between 0 and 5, it cannot be judged. In the present example, the sampling has to be continued. When the sampling is continued, the cumulative observed count increases. However, it is easy to judge because both the expected count and the reference count increase. In the 5th measurement (t = 300 s), the cumulative observed count is 11 and exceeds the upper limit (10). Then it is judged to “FAIL.”

b) Pass situation see Table D.4.

Table D.4 — Example sequential sampling particle counts

t (min)	*t* (s)	Expected count, *E*	Limits for the cumulative observed count		Observed count during interval	Cumulative observed count, *C*	Result
			Upper, C_{fail}	Lower, C_{pass}			
1	60	1.0	5	N.A.	0	0	Continue
2	120	2.0	7	N.A.	0	0	Continue
3	180	3.0	8	N.A.	0	0	Continue
4	240	4.0	9	0	0	0	PASS

The expected count provided in the first measurement is 1,0, the cumulative observed count is judged to “FAIL” when it is greater than or equal to 5. However, when the observed count is between 0 and 5, it cannot be judged. In the present example, the sampling is continued, but the cumulative observed count does not increase. In the 4th measurement (t = 240 s), the cumulative observed count is 0 and is equal to the lower limit (0). Then it is judged to “PASS.”

Annex E
(informative)

Specification of intermediate decimal cleanliness classes and particle size thresholds

E.1 Intermediate decimal cleanliness classes

If intermediate decimal cleanliness classes are required, Table E.1 should be used.

Table E.1 provides the permitted intermediate decimal air cleanliness classes. Uncertainties associated with particle measurement make increments of less than 0,5 inappropriate, and the notes beneath the table identify restrictions due to sampling and particle collection limitations.

Table E.1 — Intermediate decimal air cleanliness classes by particle concentration

	Concentration of particles (particles/m^3)[a]					
ISO Class number (N)	0,1	0,2	0,3	0,5	1,0	5,0
ISO Class 1,5	[32][b]	[d]	[d]	[d]	[d]	[e]
ISO Class 2,5	316	[75][b]	[32][b]	[d]	[d]	[e]
ISO Class 3,5	3 160	748	322	111	[d]	[e]
ISO Class 4,5	31 600	7 480	3 220	1 110	263	[e]
ISO Class 5,5	316 000	74 800	32 200	11 100	2 630	[e]
ISO Class 6,5	3 160 000	748 000	322 000	111 000	26 300	925
ISO Class 7,5	[c]	[c]	[c]	1 110 000	263 000	9 250
ISO Class 8,5[f]	[c]	[c]	[c]	11 100 000	2 630 000	92 500

[a] All concentrations in the table are cumulative, e.g. for ISO Class 5,5, the 11 100 particles shown at 0,5 µm include all particles equal to and greater than this size.

[b] These concentrations will lead to large air sample volumes for classification. See Annex D, Sequential sampling procedure.

[c] Concentration limits are not applicable in this region of the table due to very high particle concentration.

[d] Sampling and statistical limitations for particles in low concentrations make classification inappropriate.

[e] Sample collection limitations for both particles in low concentrations and sizes greater than 1 µm make classification inappropriate, due to potential particle losses in the sampling system.

[f] This class is only applicable for the in-operation state.

E.2 Intermediate particle sizes

If intermediate particle sizes are required for any integer or decimal class, Formula (E.1) may be used to determine the maximum particle concentration at the considered particle size:

$$C_n = 10^N \times \left(\frac{\mathrm{K}}{D}\right)^{2,08} \tag{E.1}$$

where

C_n is the maximum permitted concentration (particles per cubic metre) of airborne particles that are equal to and greater than the considered particle size. C_n is rounded to the nearest whole number, using no more than three significant figures;

N is the ISO Class number, which shall not exceed a value of 9 or be less than 1;

D is the considered particle size, in micrometres, that is not listed in Table 1;

K is a constant, 0,1, expressed in micrometres.

Annex F
(informative)

Test instruments

F.1 Introduction

This annex describes the measuring apparatus that should be used for the recommended tests given in Annexes A, C and D.

In this annex, data given in Tables F.1 and F.2 indicate the minimum necessary requirements for each item of apparatus. 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.

F.2 Instrument specifications

The following instruments should be used for the recommended tests given in Annexes A, C and D:

a) light scattering (discrete) airborne particle counter (LSAPC);

NOTE The specifications for the LSAPC are given in ISO 21501-4:2007.[1]

b) discrete-macroparticle counter;

c) time-of-flight particle sizing apparatus;

d) microscopic measurement of particles collected on filter paper. See ASTM F312-8.[3]

The terms and definitions for these instruments are given in Clause 3.

Table F.1 — Specifications for discrete-macroparticle counter

Item	Specification
Measuring limits	The minimum detectable size should be in the range 5 to 80 µm and be appropriate for the particle size under consideration and the instrument capability. The maximum particle number concentration of the LSAPC should be equal to or higher than maximum expected concentration for the particles under consideration
Resolution	20 % for calibration particles of a size specified by the manufacturer
Maximum permissible error	20 % for particle count at a specified size setting

Table F.2 — Specifications for time-of-flight particle sizing apparatus

Item	Specification
Measuring limits	Particle size 0,5 to 20 µm; Particle concentration $1,0 \times 10^3/m^3$ to $1,0 \times 10^8/m^3$
Resolution	aerodynamic diameter: 0,02 µm at 1,0 µm; 0,03 µm at 10 µm
Maximum permissible error	10 % of full reading

Bibliography

[1] ISO 21501-4:2007, *Determination of particle size distribution — Single particle light interaction methods — Part 4: Light scattering airborne particle counter for clean spaces*

[2] ASTM F312-08, *Standard Test Methods for Microscopical Sizing and Counting Particles from Aerospace Fluids on Membrane Filters. ASTM International*

[3] IEST-G-CC1003. Measurement of Airborne Macroparticles. Institute of Environmental Sciences and Technology, Arlington Heights, Illinois, 1999

[4] IEST-G-CC1004. Sequential-Sampling Plan for Use in Classification of the Particulate Cleanliness of Air in Cleanrooms and Clean Zones. Institute of Environmental Sciences and Technology, Arlington Heights, Illinois, 1999

[5] JIS B 9920:2002, *Classification of air cleanliness for cleanrooms. Japanese Standards Association*

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Waarom betaalt u voor een norm?
Normen zijn afspraken voor en door de markt, zo ook deze norm. NEN begeleidt het gehele normalisatieproces. Van het bijeenbrengen van partijen, het maken en vastleggen van de afspraken en het bieden van hulp bij de toepassing van de normen. Om deze diensten te kunnen bekostigen betalen alle belanghebbende partijen die aan tafel zitten voor het normalisatieproces, en u als gebruiker voor normen en trainingen. NEN is een stichting en heeft geen winstoogmerk.

Wat is nu precies de toegevoegde waarde van normen?
Stelt u zich eens voor … u wilt in het buitenland geld pinnen, maar uw bankpas past niet. Of uw nieuwe telefoon herkent uw simkaart niet. De samenstelling van de benzine over de grens is anders waardoor u niet kunt tanken. Het dagelijks leven zou zonder goede afspraken over producten, processen en diensten een stuk complexer zijn.

Het maken en vastleggen van afspraken door belanghebbende partijen noemen we het normalisatieproces. Normalisatie had vanouds betrekking op techniek en producten. Nu worden steeds vaker normen voor diensten ontwikkeld. Zo zijn er afspraken op het gebied van gezondheidszorg, schuldhulpverlening, kennisintensieve dienstverlening, externe veiligheid en MVO.

Normen zorgen voor verbetering van producten, diensten en processen; qua veiligheid, gezondheid, efficiëntie, kwaliteit en duurzaamheid. Dit ziet u op de werkvloer, in de omgang met elkaar en in de samenleving als geheel. Organisaties die normalisatie onderdeel van hun strategie maken, vergroten hun professionaliteit, betrouwbaarheid en concurrentiekracht.

Wat doet NEN?
NEN ondersteunt in Nederland het normalisatieproces. Als een partij zich tot NEN richt met de vraag om een afspraak tot stand te brengen, gaan wij aan de slag. We onderzoeken in hoeverre normalisatie mogelijk is en er interesse voor bestaat. Wij nodigen vervolgens alle belanghebbende partijen uit om deel te nemen. Een breed draagvlak is een randvoorwaarde. De afspraken komen op basis van consensus tot stand en worden vastgelegd in een document. Dit is meestal een norm. Afspraken die in een NEN-norm zijn vastgelegd mogen niet conflicteren met andere geldige NEN-normen. NEN-normen vormen samen een coherent geheel. Een belanghebbende partij kan een producent, ondernemer, dienstverlener, gebruiker, maar ook de overheid of een consumenten- of onderzoeksorganisatie zijn. De vraag is niet altijd om een norm te ontwikkelen. Vanuit de overheid komt regelmatig het verzoek om te onderzoeken of er binnen een bepaalde sector of op een bepaald terrein normalisatie mogelijk is. NEN doet dan onderzoek en start afhankelijk van de uitkomsten een project. Deelname staat open voor alle belanghebbende partijen. NEN beheert ruim 30.000 normen. Dit zijn de in Nederland aanvaarde internationale (ISO, IEC), Europese (EN) en nationale normen (NEN). In totaal zijn er ruim 800 normcommissies actief met in totaal bijna 5.000 normcommissieleden. Een goed beheer van de omvangrijke normencollectie en de afstemming tussen nationale, Europese en internationale normcommissies vereisen dan ook een zeer goede infrastructuur.

Betalen kleine organisaties net zoveel als grote organisaties?
Het uitgangspunt is dat alle partijen die deelnemen aan het normalisatieproces een evenredig deel betalen. De normcommissieleden kunnen onderling andere afspraken maken. Zo worden er wel eens afspraken gemaakt dat de grote partijen een groter deel betalen dan de kleinere bedrijven. De prijzen voor normen zijn voor iedereen gelijk. De kosten voor licenties zijn afhankelijk van de omvang van een organisatie en het aantal gebruikers.

Voordelen van normalisatie en normen
Gegarandeerde kwaliteit | Veiligheid geborgd | Bevordert duurzaamheid | Opschalen en vermarkten van nieuwe innovatieve producten | Meer (internationale) handelsmogelijkheden | Verhoogde effectiviteit en efficiëntie | Onderscheidend in de markt.

Voordelen van deelname
Invloed op de (internationale en Europese) afspraken | Als eerste op de hoogte van veranderingen | Netwerk; ook op Europees en internationaal niveau | Kennisvergroting.