Draft for Public Comment

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Part 1: Classification of air cleanliness by particle concentration

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This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

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The British Standards which implement International or European publications referred to in this draft may be found via the British Standards Online Service on the BSI web site **http://www.bsigroup.com.**

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Introduction
This draft standard is based on European discussions in which the UK has taken an active part. Your comments on this draft are welcome and will assist in the preparation of the consequent British Standard. Comment is particularly welcome on national, legislative or similar deviations that may be necessary.

Even if this draft standard is not approved by the UK, if it receives the necessary support in Europe, the UK will be obliged to publish the official English Language text unchanged as a British Standard and to withdraw any conflicting standard.

UK Vote
Please indicate whether you consider the UK should submit a negative (with reasons) or positive vote on this draft.

Submission of Comments

- The guidance given below is intended to ensure that all comments receive efficient and appropriate attention by the responsible BSI committee. **Annotated drafts are not acceptable and will be rejected.**

- All comments must be submitted, preferably electronically, to the Responsible Committee Secretary at the address given on the front cover. Comments should be compatible with version 6.0 or version 97 of Microsoft Word for Windows, if possible; otherwise comments in ASCII text format are acceptable. **Any comments not submitted electronically should still adhere to these format requirements.**

- All comments submitted should be presented as given in the example below. Further information on submitting comments and how to obtain a blank electronic version of a comment form are available from the BSI website at: **http://www.bsigroup.com/en/Standards-and-Publications/Current-work/DPCs/**

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: **ISO/DIS xxxx**

1	2	(3)	4	5	(6)	(7)
MB	**Clause No./ Subclause No./Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/Note**	**Type of comment**	**Commend (justification for change) by the MB**	**Proposed change by the MB**	**Secretariat observations on each comment submitted**
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN ISO 14644-1

December 2010

ICS 13.040.35

Will supersede EN ISO 14644-1:1999

English Version

Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO/DIS 14644-1:2010)

Salles propres et environnements maîtrisés apparentés - Partie 1: Classification de la propreté particulaire de l'air (ISO/DIS 14644-1:2010)

Reinräume und zugehörige Reinraumbereiche - Teil 1: Klassifizierung der Luftreinheit anhand der Partikelkonzentration (ISO/DIS 14644-1:2010)

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 243.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

This draft European Standard was established by CEN in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. prEN ISO 14644-1:2010: E

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Foreword

This document (prEN ISO 14644-1:2010) 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 document is currently submitted to the parallel Enquiry.

This document will supersede EN ISO 14644-1:1999.

Endorsement notice

The text of ISO/DIS 14644-1:2010 has been approved by CEN as a prEN ISO 14644-1:2010 without any modification.

DRAFT INTERNATIONAL STANDARD ISO/DIS 14644-1

ISO/TC **209** Secretariat: **ANSI**

Voting begins on
2010-12-02

Voting terminates on
2011-05-02

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

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

[Revision of first edition (ISO 14644-1:1999)]

ICS 13.040.35

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

Contents

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Foreword

This edition is the result of a 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 the standard. The nine ISO cleanliness classes are retained unchanged, but Table 1 defines the particle concentration at various particle sizes for the nine integer classes. The use of Table 1 ensures better definition of the appropriate particle-size ranges for the different classes. A formula is retained to allow definition of intermediate decimal classes. The standard retains the concept of ultrafine and macroparticle descriptors for particle sizes outside the range appropriate for measurement using airborne particle counters.

The most significant change is the adoption of a more consistent statistical approach to the selection of number of sample locations and the evaluation of the data collected. The number of sample locations compared with the 1999 version of the standard have been changed. The approach allows each location to be treated independently with a 95 % level of confidence that at least 90 % of the cleanroom or clean zone will comply with the maximum particle concentration limit for the target class of air cleanliness. A reference table is provided to define the number of sample locations required. Because a degree of randomness is required, the cleanroom or clean zone is then divided into equal sectors and the sample location placed randomly within each sector.

Finally, the annexes have been reordered to improve the logic of the standard.

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 14644-1 was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*.

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

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: Specifications for monitoring and periodic testing to prove continued compliance with ISO 14644-1:XXXX*

— *Part 3: Test methods*

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

— *Part 5: Operations*

— *Part 6: Vocabulary*

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

— *Part 8: Classification of airborne molecular contamination*

— *Part 9: Classification of surface cleanliness by particle 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 or surfaces to levels appropriate for accomplishing contamination-sensitive activities. Contamination control can be beneficial for protection of product or process integrity in applications such as aerospace, microelectronics, pharmaceuticals, medical devices and healthcare.

This part of ISO 14644 specifies ISO classes of air cleanliness in terms of particle concentration in air volume. It also specifies the standard method of testing to determine classification, including selection of sampling locations, and evaluation of class from the data collected.

Cleanrooms and associated controlled environments —

Part 1:
Classification of air cleanliness by particle concentration

1 Scope

This part of ISO 14644 covers the classification of air cleanliness in cleanrooms and associated controlled environments exclusively in terms of concentration of airborne particles. 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 discrete-particle airborne counting and sizing instruments 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 of the specified particle-size range, 0,1 µm to 5 µm. Concentrations of ultrafine particles (particles smaller than 0,1 µm) and macroparticles (particles larger than 5 µm) may be used to quantify these populations in terms of U descriptors and M descriptors (see 3.3.1 and 3.3.2), respectively.

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

NOTE The actual distribution of particle concentrations within incremental size ranges is normally not predictable and is typically variable over time.

2 Normative reference

The following normative document contains provisions, which, through reference in this text, constitute provisions of this part of ISO 14644. Subsequent amendments to or revisions of this publication do not apply. However, parties to agreements based on this part of ISO 14644 are encouraged to investigate the possibility of applying the most recent editions of the normative document indicated below.

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

3 Definitions

For the purposes of this part of ISO 14644, the following 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 minimise 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

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 minimise 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.

3.1.3
classification
level of air cleanliness by particle concentration applicable to a cleanroom or clean zone, expressed in terms of an ISO Class *N*, which represents maximum allowable concentrations expressed as particles per cubic metre, for particles equal to and greater than the considered sizes

NOTE 1 The maximum allowable concentrations are defined in Table 1 in 4.2 or determined by Equation (1) in 4.2 if specifying an intermediate decimal class.

NOTE 2 Classification in accordance with this International Standard is limited to the range extending from ISO Class 1 through ISO Class 9.

NOTE 3 The considered particle sizes applicable for classification in accordance with this International Standard are limited to the range from ≥ 0,1 µm to ≤ 5 µm.

NOTE 4 Air cleanliness may be described and specified (but not classified) in terms of U descriptors or M descriptors (see 3.3.1 or 3.3.2) for considered threshold particle sizes that are outside of the range covered by classification.

NOTE 5 intermediate decimal ISO classification numbers may be specified, with 0,1 being the smallest permitted increment; i.e. the range of intermediate decimal ISO classes extends from ISO Class 1,1 through ISO Class 8,9.

NOTE 6 Classification may be specified or accomplished in any of three occupancy states (see 3.4).

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

3.2.6
macroparticle
particle with an equivalent diameter greater than 5 µm

3.2.7
unidirectional airflow
controlled airflow through the entire cross-section of a clean zone with a steady velocity and approximately parallel airstreams

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

3.3 Descriptors

3.3.1
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 characterise the cleanroom or clean zone). U descriptors cannot be used to define air cleanliness classes by particle concentration, but they may be quoted independently or in conjunction with air cleanliness classes by particle concentration.

3.3.2
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 characterise the cleanroom or clean zone). M descriptors cannot be used to define air cleanliness classes by particle concentration, but they may be quoted independently or in conjunction with air cleanliness classes by particle concentration.

3.4 Occupancy states

3.4.1
as-built
condition where the cleanroom or clean zone is complete with all services connected and functioning but with no production equipment, materials or personnel present

3.4.2
at-rest
condition where the cleanroom or clean zone is complete with equipment installed and operating in a manner agreed upon by the customer and supplier, but with no personnel present

3.4.3
operational
condition where the cleanroom or clean zone is functioning in the specified manner, with the specified number of personnel present and working in the manner agreed upon

3.5 Roles

3.5.1
customer
organisation, or the agent thereof, responsible for specifying the requirements of a cleanroom or clean zone

3.5.2
supplier
organisation engaged to satisfy the specified requirements of a cleanroom or clean zone

4 Classification

4.1 Occupancy state(s)

The air cleaniness 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 3.4).

4.2 Classification number

Air cleanliness class by particle concentration shall be designated by a classification number, N. The maximum permitted concentration of particles, C_n, for each considered particle size, D, is determined from Table 1.

Table 1 — Air cleanliness classification table by particle concentration

ISO classification number (N)	Maximum allowable concentrations (particles/m³) 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
ISO Class 1	*10* [b]	[d]	[d]	[d]	[d]	[e]
ISO Class 2	100	*24* [b]	*10* [b]	[d]	[d]	[e]
ISO Class 3	1 000	237	102	*35* [b]	[d]	[e]
ISO Class 4	10 000	2 370	1 020	352	*83* [b]	[e]
ISO Class 5	100 000	23 700	10 200	3 520	832	[e]
ISO Class 6	1 000 000	237 000	102 000	35 200	8 320	293
ISO Class 7	[c]	[c]	[c]	352 000	83 200	2 930
ISO Class 8	[c]	[c]	[c]	3 520 000	832 000	29 300
ISO Class 9	[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 inappropriate, due to potential particle losses in the sampling system.

A representation of the selected classes in graphical form is provided in Figure E.1 (see Annex E).

Equation (1), below, shall be used to determine the maximum particle concentration for intermediate decimal classes at the considered particle size:

$$C_n = 10^N \times \left(\frac{0{,}1}{D}\right)^{2{,}08} \tag{1}$$

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 classification number, which shall not exceed a value of 9 or be less than 1. Intermediate decimal ISO classification numbers may be specified, with 0,1 being the smallest permitted increment of *N*.

D is the considered particle size, in micrometres.

0,1 is a constant, with a dimension of micrometres.

Table E.1 (see Annex E) provides examples of intermediate decimal classes. The associated notes to Table E.1 identify restrictions due to sampling and collection limitations.

4.3 Designation

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

a) the classification number, expressed as “ISO Class *N*”;

b) the occupancy state to which the classification applies;

c) the considered particle size(s), and the related class limit(s), as determined by the classification table (Table 1) or Equation (1) where each considered lower threshold particle size is in the range from 0,1 μm through 5 μm.

The considered particle size(s) for which the concentration(s) will be measured shall be agreed upon by the customer and the supplier.

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 designations:

ISO Class 4; at rest; 0,2 μm 0,5 μm

ISO Class 7,5; in operation; 0.5 μm

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, as agreed upon by the customer and the supplier.

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 calibrated instruments.

5.3 Airborne particle concentration evaluation

Upon completion of testing in accordance with 5.2, the concentration of particles (expressed as number of particles per cubic metre) in the single sample volume at each sample location shall not exceed the concentration limit(s) given in Table 1 or derived from Equation (1) for intermediate decimal classes for the considered size(s). If multiple single sample volumes are taken at a sample location, the concentration shall be averaged and the average concentration must not exceed the concentration limits given in Table 1 or derived from Equation (1) for intermediate decimal classes.

Particle concentrations used for determination of conformance to classification limits 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 organisation, 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:date of current issue;

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;

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

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

NOTE If concentrations of ultrafine particles or macroparticles are quantified, as described in Annex C, the pertinent information should be included with the test report.

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Annex A
(normative)

Reference method for determination of air cleanliness classification 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 (LSAP) are commonly used for determination of particle concentration classification.

A.2.2 Instrument calibration

The instrument shall have a valid calibration certificate; the frequency and method of calibration should be based on current accepted practice.

NOTE: See normative reference to ISO 21501-4.

A.3 Pretest conditions

A.3.1 Preparation for testing

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

Such pre-testing may include, for example:

a) airflow tests (e.g. air volume, air velocity, or uniformity of unidirectional airflow);

b) air pressure difference test;

c) containment leak test;

d) installed filter system leakage test.

A.3.2 Pretest equipment setup

Perform equipment setup in accordance with the manufacturer's instructions.

A.4 Sampling

A.4.1 Establishment of sampling locations

A.4.1.1

Derive the minimum number of sampling locations, N_L, from Table A.1. Table A.1 provides the number of sample 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 all locations do not exceed the class limits.

Table A.1 — Sample locations related to cleanroom area

Area of cleanroom (m^2) less than or equal to	Minimum number of sample locations to be tested (N_L)
1	1
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
500	26
NOTE 1 The number of sample locations in Table A.1 are based on area units of 1, 2, and 4 m^2, to achieve 95 % confidence that at least 90 % of the total area does not exceed the class limit.	

Table A.1 *(continued)*

NOTE 2 If the zone area falls between two values in the table, the greater of the two should be selected.
NOTE 3 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.
NOTE 4 For practical purposes, it is assumed that each sample location is representative of its associated area unit.
NOTE 5 Cleanrooms in excess of 500 m^2 in area shall be considered as a series of smaller zones.

A.4.1.2

In order to position the sample locations, identify the minimum number of sample locations from Table A.1, use this number to divide the clean zone into equal sectors, and within each sector randomly select a sample location positioned at the height of the work activity.

If the customer specifies additional sampling locations, their number and positions shall also be specified. Such additional locations may be those considered critical, based on risk analysis.

A.4.2 Establishment of single sample volume and sampling time per location

A.4.2.1

At each sampling location, sample a sufficient volume of air that a minimum of 20 particles would be detected 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 Equation (A.1):

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

where

V_s is the minimum single sample volume per location, expressed in litres (except see D.4.2.2).

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

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

Each single sample volume at each location shall be the same — unless the optional sequential sampling procedure (see Annex D) is used — and shall be expressed in litres. When V_s is very large, the time required for sampling can be substantial. By using the optional sequential sampling procedure, both the required sample volume and the time required to obtain samples may be reduced.

A.4.2.2

The volume sampled at each location shall be at least 2 litres, with a minimum sampling time of 1 minute for each sample at each location.

A.4.3 Sampling procedure

A.4.3.1

Set up the particle counter (see A.2) in accordance with the manufacturer's instructions and in compliance with the instrument calibration certificate.

A.4.3.2

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.4.3.3

If necessary, allow stable conditions to be established before sampling.

Sample the volume of air determined in A.4.2.1, as a minimum, for each sample at each sampling location.

A.4.3.4

If during testing at multiple locations in any one of the three occupancy states, an unusually high result is found at a particular location in the single sample volume, further testing may be undertaken at the location to investigate the problem and determine if the location meets the classification.

A.5 Recording of results

A.5.1 Average concentration of particles at each sampling location

A.5.1.1

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 classification of air cleanliness.

A.5.1.2

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 (A.5.1.1), according to Equation (A.2).

$$\overline{x}_i = \frac{[x_{i.1} + x_{i.2} + \ldots x_{i.n}]}{n} \tag{A.2}$$

where

$\overline{x}_i$ 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.5.1.3

Calculate the concentration per cubic metre.

$$C_i = \frac{\overline{x}_i \times 1\,000}{V_t} \tag{A.3}$$

where

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

V_t is the adopted single sample volume in litres.

A.6 Interpretation of results

A.6.1 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 in accordance with Table 1 or intermediate decimal class Equation (1).

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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 for an air cleanliness by particle concentration of ISO Class 5 in operation. The classification is to be performed using a discrete-particle counter having a flow rate of 28,3 litres per minute. Two particle sizes are considered: $D \geq 0{,}3$ µm and $D \geq 0{,}5$ µm.

The number of sample 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 Equation (A.1) as follows:

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

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

$$V_s = (0{,}00568) \times 1\,000$$

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

The single sample volume has been calculated to be 5,68 litres. As the discrete-particle counter being used for this test had a flow rate of 28,3 litres per minute, a 1-minute single sample count would be required (see A.4.2.2) and therefore 28,3 litres would be sampled for each single sample volume.

NOTE In A.4.2.2, 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 minute. The sampling at each position must occur for at least 1 minute; if the minimum sample volume as calculated is satisfied within the 1-minute period, then the sample process can be stopped at the end of 1 minute. If the calculated minimum volume cannot be obtained within the 1-minute 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 sample time needed to satisfy both the 1-minute 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, x_i, 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

Sample location	Sample 1 x_i ≥ 0,3 µm	Location average (counts per 28,3 litres)	Location average (counts per cubic metre = location average × 35,3)	Limit for 0,3 µm counts at ISO Class 5	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

Sample location	Sample 1 x_i ≥ 0,5 µm	Location average (counts per 28,3 litres)	Location average (counts per cubic metre = location average × 35,3)	Limit for 0,5 µm counts at ISO Class 5	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 ≥ 0,3 µm is less than the limit of 10 200 particles/m^3 and D ≥ 0,5 µm is less than the limit of 3 520 particles/m^3 as established in B.1.2; therefore, the air cleanliness by particle concentration of the cleanroom meets the required classification.

B.2 Example 2

B.2.1

A cleanroom has a floor area of 9 m^2 and is specified for an air cleanliness by particle concentration of ISO Class 3 in operation. The classification is to be performed using a discrete-particle counter having a flow rate of 50,0 litres per minute. Only one particle size (D ≥ 0,1 µm) is considered.

The number of sample 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/m^3

B.2.3

The required single sample volume can be calculated from Equation (A.1) 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 litres. As the discrete-particle counter being used for this test had a flow rate of 50,0 litres per minute, a 1-minute single sample count would be required (see A.4.2.2) and therefore 50,0 litres 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

Sample location	Sample 1 x_i ≥ 0,1 μm	Location average (counts per 50,0 litres)	Location average (counts per cubic metre = location average × 20)	Limit for ≥ 0,1 μm counts at ISO Class 3	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 classification.

B.3 Example 3

B.3.1

A cleanroom has a floor area of 64 m^2 and is specified for an air cleanliness by particle concentration of ISO Class 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 sample locations, N_L, is determined to be twelve, 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 Equation (A.1) as follows:

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

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

$$V_s = (0{,}00568) \times 1\,000$$

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

The single sample volume has been calculated to be 5,68 litres. As the discrete-particle counter used for this test had a flow rate of 28,3 litres per minute, a 1-minute single sample count would be required (see A.4.2.2) and therefore 28,3 litres 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

Sample location	Sample 1 $x_i \geq 0{,}5$ µm	Location average concentration (counts per 28,3 litres)	Location average concentration (counts per cubic metre = location average × 35,3)	Limit for 0,5 µm counts at ISO Class 5	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

Table B.4 *(continued)*

Sample location	Sample 1 $x_i \geq 0{,}5\ \mu m$	Location average concentration (counts per 28,3 litres)	Location average concentration (counts per cubic metre = location average × 35,3)	Limit for 0,5 µm counts at ISO Class 5	Pass/fail
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/m^3 established in Table 1; therefore, the air cleanliness by particle concentration of the cleanroom meets the required classification.

B.4 Example 4

B.4.1

A cleanroom has a floor area of 25 m^2 and is specified for an air cleanliness by particle concentration of ISO Class 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 sample locations is determined to be seven, based on Table A.1.

B.4.2

The particle concentration limit for ISO Class 5 at ≥ 0,5 µm is calculated using Table 1 as follows:

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

B.4.3

The required single sample volume can be calculated from Equation (A.1) as follows:

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

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

$$V_s = (0{,}00568) \times 1\ 000$$

V_s = 5,68 litres

The single sample volume has been calculated to be 5,68 litres. As the discrete-particle counter being used for this test had a flow rate of 28,3 litres per minute, a 1-minute single sample count would be required (see A.4.2.2) and therefore 28,3 litres would be sampled for each single sample volume.

B.4.4

At each sampling location the number of single sample volumes varies from one to three. The number of particles per cubic metre, x_i, is calculated for each location and recorded in Table B.5:

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

Sample location	Sample 1 x_i ≥ 0,5 μm	Sample 2 x_i ≥ 0,5 μm	Sample 3 x_i ≥ 0,5 μm	Location average (counts per 28,3 litres)	Location average (counts per cubic metre = location average × 35,3)	Limit for ≥ 0,5 μm counts at ISO Class 5	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	54	159	78	97	3 424	3 520	Pass
5	1	0		0,5	18	3 520	Pass
6	19	22	17	19	682	3 520	Pass
7	5	15	3	7	271	3 520	Pass
8	38	21		30	1 041	3 520	Pass
9	148	74	132	118	4 165	3 520	Fail
10	48	62	53	54	1 918	3 520	Pass

B.4.5

At sample location 9, 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 4, one of the individual particle count concentrations does not meet the limit established in Table 1; however, neither the average particle concentration for location 3 nor the average particle concentration for location 4 meets the limit established in Table 1. Because location 9 does not meet the air cleanliness by particle concentration, the cleanroom does not meet the required classification.

B.5 Example 5

B.5.1

A cleanroom has a floor area of 10,7 m^2 and is specified for an air cleanliness by particle concentration of ISO Class 7,3 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 ≥ 0,5 μm) is considered.

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

B.5.2

The particle concentration limit for ISO Class 7,3 at ≥ 0,5 μm is calculated using Equation (1) as follows:

$$C_n\ (\geq 0{,}5\ \mu m) = 10^N \times \left(\frac{0{,}1}{D}\right)^{2{,}08} \text{ where } N = 7{,}3 \text{ and } D = 0{,}5\ \mu m$$

$$C_n\ (\geq 0{,}5\ \mu m) = 10^{7{,}3} \times \left(\frac{0{,}1}{0{,}5}\right)^{2{,}08}$$

$$C_n\ (\geq 0{,}5\ \mu m) = 19\ 952\ 623 \times 0{,}035167572$$

$$C_n\ (\geq 0{,}5\ \mu m) = 701\ 685 \text{ rounded to three significant digits} = 702\ 000 \text{ particles/m}^3$$

B.5.3

The required single sample volume can be calculated from Equation (A.1) as follows:

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

$$V_s = \left(\frac{20}{702\ 000}\right) \times 1\ 000$$

$$V_s = (0{,}00002849) \times 1\ 000$$

$$V_s = 0{,}0285 \text{ litres}$$

The single sample volume has been calculated to be 0,0285 litres. As the discrete-particle counter being used for this test had a flow rate of 28,3 litres per minute, a 1-minute single sample count would be required (see A.4.2.2) and therefore 28,3 litres would be sampled for each single sample volume.

B.5.4

At each sampling location the number of single sample volumes varies from one to three. 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

Sample location	Sample 1 $x_i \geq$ 0,5 µm	Sample 2 $x_i \geq$ 0,5 µm	Sample 3 $x_i \geq$ 0,5 µm	Location average (counts per 28,3 litres)	Location average (counts per cubic metre = location average × 35,3)	Limit for 0,5 µm counts at ISO Class 7,3	Pass/fail
1	11 679			11 679	412 269	702 000	Pass
2	9 045			9 045	319 289	702 000	Pass
3	12 699			12 699	448 275	702 000	Pass
4	21 926	17 555	14 632	18 038	636 730	702 000	Pass
5	7 839			7 839	276 717	702 000	Pass
6	13 669			13 669	482 516	702 000	Pass

B.5.5

At sample location 4, the first sample volume concentration of 773 988 (21 926 × 35,3) did not meet the ISO Class 7,3 maximum particle count criteria of 702 000. Each single sample volume of the concentration does not meet the limit established by using Equation (1) (and illustrated in informative Annex E, Table E.1); however, the average particle concentration for each of the sample locations does meet the limit established by application of Equation (1). Therefore, the air cleanliness by particle concentration of the cleanroom meets the required classification.

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Annex C
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Considerations for counting and sizing of particles outside the size range applicable for classification

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 (for U descriptors) and C.3 (for M descriptors).

C.2 Consideration of particles smaller than 0,1 µm (ultrafine particles) — U descriptor

C.2.1 Application

If contamination risks caused by particles smaller than 0,1 µm are to be assessed, sampling devices and measurement procedures appropriate to the specific characteristics of such particles should be employed.

The number of sampling locations should be established in accordance with Table A.1 and the minimum sample volume, V_s, should be 2 litres (see A.4.2.2).

C.2.2 U descriptor format

The ultrafine particle concentration of the U descriptor may be used alone or as a supplement to the air cleanliness class by particle concentration. The U descriptor is expressed in the format

"*U* (*x*; *y*)," where

x is the maximum permitted concentration of ultrafine particles (expressed as ultrafine particles per cubic metre of air);

y is the size in micrometres at which the applicable discrete-particle counter counts such particles with 50 % counting efficiency.

EXAMPLE To express a maximum permitted ultrafine particle concentration of 140 000 particles/m^3 in the particle size range ≥ 0,01 µm, the designation would be: "U (140 000; 0,01)."

NOTE 1 Suitable methods of test for concentrations of airborne particles smaller than 0,1 µm are given in IEST-G-CC1002.[1]

NOTE 2 If the U descriptor designation is used as a supplement to an airborne particle concentration class, the ultrafine particle concentration (*x*) should be not less than the particle concentration limit (particles per cubic metre) applicable to the considered size of 0,1 µm for the specified ISO class.

C.3 Consideration of particles larger than 5 µm (macroparticles) — M descriptor

C.3.1 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.

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 the density, shape, volume and aerodynamic behavior 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.3.2 M descriptor format

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

"*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.

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

EXAMPLE 1 To express an airborne particle concentration of 10 000 particles/m^3 in the particle size range of > 5 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:

"M (10 000; > 5 µm); time-of-flight aerosol particle counter."

EXAMPLE 2 To express an airborne particle concentration of 1 000 particles/m^3 in the particle size range of 10 µm to 20 µm, based on the use of a cascade impactor followed by microscopic sizing and counting, the designation would be:

"M (1 000; 10 µm to 20 µm); cascade impactor followed by microscopic sizing and counting."

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

NOTE 3 If the M descriptor designation is used as a supplement to an airborne particle concentration class, the macroparticle concentration (*a*) should be no greater than the particle concentration limit (particles per cubic metre) applicable to the considered size of 5 µm for the specified ISO class.

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Annex D
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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 sample acquisition time. The sequential sampling technique measures the rate of counting and predicts the likelihood of passing or failing classification. 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.

The technique reviews the rate of count in order to predict likely pass or fail. Some savings may also to be realised when the concentration is near the specified limit. Sequential sampling is most appropriate for air cleanliness of ISO Class 4 or cleaner. It can also be used for other classes when the selected particle size gives rise to low counts at the class limit.

NOTE For further information on sequential sampling, see IEST-G-CC1004[3] or JIS B 9920:2002.[4]

D.1.2 Limitations

The principal limitations of sequential sampling are:

a) The procedure is only applicable when the sample size is determined by the requirement to take a sufficient sample such that you would see a count of 20 at the class limit for the largest considered particle size (see A.4.2.1)

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

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 equations for upper- and lower-limit boundaries:

$$\text{Upper limit: } C_{fail} = 3{,}96 + 1{,}03\,E \tag{D.1}$$

$$\text{Lower limit: } C_{pass} = -3{,}96 + 1{,}03\,E \tag{D.2}$$

where

C is the observed count (actual count acquired in sampling time t)

C_{fail} is the upper limit of the observed count

C_{pass} is the lower limit of the observed count

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

According to Equation (A.1), single sampling volume, V_s, is calculated as follows:

$$V_s = \frac{20}{C_{n,d}} \times 1\,000 \tag{D.3}$$

where:

V_s is the minimum single sample volume per location, expressed in litres (except see D.4.2.2).

$C_{n,d}$ is the class limit (number of particles per cubic metre) for the considered particle size, d, 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 sampling time is calculated as follows:

$$t = \frac{V}{Q} \tag{D.4}$$

where:

V is the accumulative sample volume (m^3)

Q is the sampling flow rate of the particle counter (m^3/s)

The expected count is defined as follows:

$$E = Q \times t \times C_{n,d} \tag{D.5}$$

where

t is sampling time (in seconds)

$C_{n,d}$ is airborne particle concentration (particles/m^3) at the selected particle size for classification.

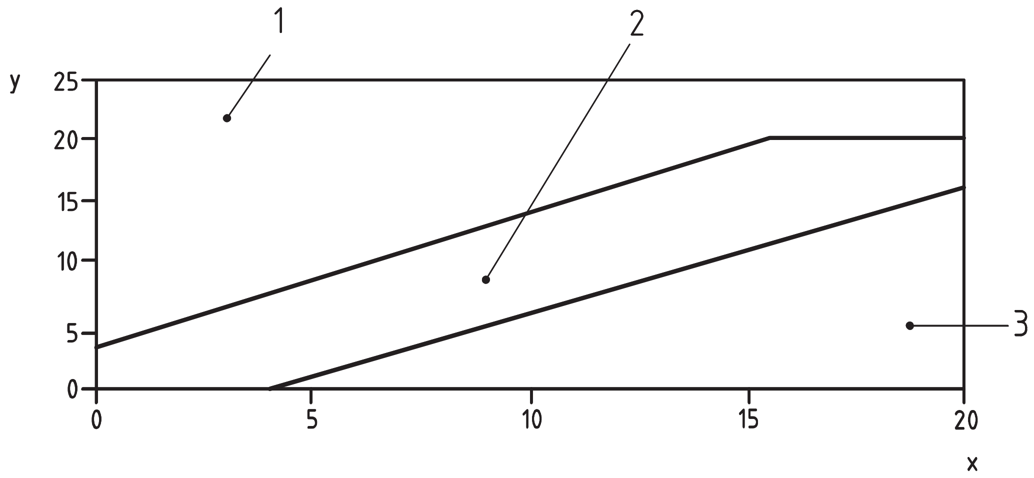
To aid in understanding, a graphical illustration of the sequential sampling procedure is provided in Figure D.1. As air is being sampled at each designated sampling location, the running total particle count is continuously compared to the expected count for the proportion of the prescribed total volume that has been sampled. If the running total count is less than the lower limit 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 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 sampling volume, V, becomes equal to the minimum single sampling 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 Equations (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 = 3,96 + 1,03E)
2 Continuous counting
3 Stop counting, PASS (C = -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.3.

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 less 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) To evaluate 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 Sampling flow rate of particle counter is 0,0283 m^3/min (28,3 litres/min) (0,47 litres/s).

b) Preparation before measurement — method for calculation of reference count

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 Equations D.1 and D.2, or Figure D.1.

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

Measurement periods	Sampling time (s)	Expected count	Upper reference count	Lower reference count
	t	$E = Q \times t \times C_n$ E is the expected count Q is the sampling flow rate t is the sampling time C_n is the maximum permitted concentration of airborne particles that are equal to or larger than the considered particle size	C_H = 3,96 + 1,03 E	C_L = -3,96 + 1,03 E
1st	5	2,4	7 (6,4)	0 (-1,5)
2nd	10	4,7	9 (8,8)	0 (0,9)
3rd	15	7,1	12 (11,2)	3 (3,3)
4th	20	9,4	14 (13,7)	5 (5,8)
5th	25	11,8	17 (16,1)	8 (8,2)
6th	30	14,1	19 (18,5)	10 (10,6)

NOTE: The numeric value in parentheses shows the result of calculation of the upper reference count and the lower reference 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 reference count is rounded up to the first decimal place of calculated value.

—The lower reference count is rounded down to the first decimal place of calculated value.

c) Evaluation using sequential sampling procedure

The expected count provided in the first measurement is 2,4; it is judged to “PASS” when the observed count is 0, and it is judged to “FAIL” when the observed count is 7. However, when the observed count is between 1 and 6, the result cannot be judged. In this case, sampling is continued. When sampling is continued, the cumulative observed count may increase. This is easy to judge because both the expected count and the reference count increase. Sampling is continued until the end of the evaluation. If the cumulative observed count is 20 or less at the end of prescribed sampling period and has not crossed the upper line, the air cleanliness classification is judged to “PASS.”

D.4.2 Example 2: to be revised to ISO Class 3 at ≥ 0.5 µm

D.4.2.1 Evaluation of a cleanroom with a target air cleanliness of ISO Class 5 (5 µm, 29 particles/m^3) by the sequential sampling procedure

NOTE This is a special example of a class limit outside the boundaries of this part of ISO 14644 classification and is used to illustrate the sequential sampling technique for low concentrations of large particles.

D.4.2.2 Calculate the single sample volume, *L*, according to Equation (D.3)

$$V_s = \frac{20}{C_{n,m} \times 1\,000} = \frac{20}{29 \times 1\,000} = 689\,655\ L \text{ (or } 0{,}689655\ \text{m}^3\text{)} \tag{D.6}$$

D.4.2.3 Calculate the sampling total time, t_t, in seconds according to Equation (D.3)

The sampling flow rate (*V*) of particle counter (*Q*) is 0,00283 m^3/min.

$$t_t = \frac{V}{Q} = 24{,}37 \text{ min (or } 1462{,}2 \text{ s)} \tag{D.7}$$

D.4.2.4 Calculate the result table

a) Calculate the expected count, *E*, according to Equation (D.8)

$$E = Q \times t \times C_n \tag{D.8}$$

b) Calculate the upper and lower reference count according to Equations (D.1) and (D.2).

c) The calculation result is shown in Table D.2 and Figure D.2.

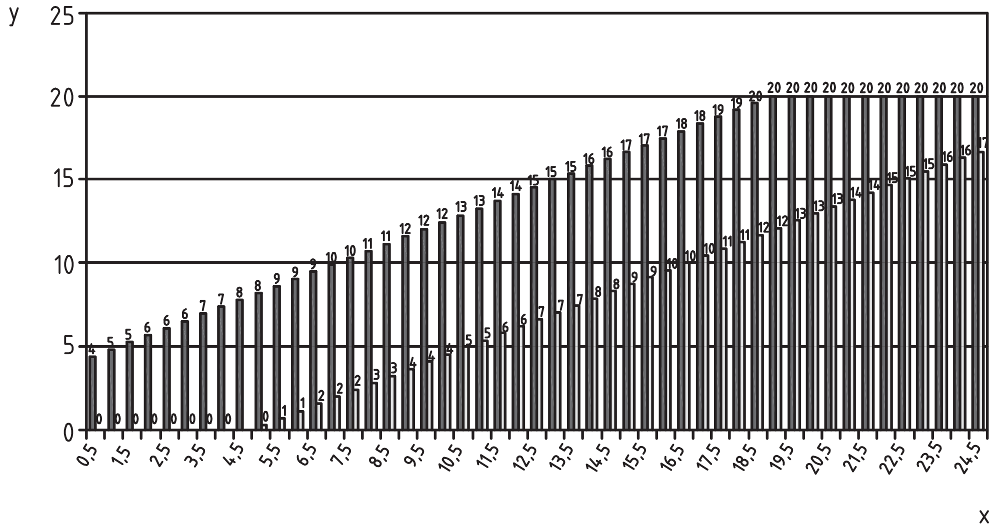
Table D.2 — Calculation result of the total sample air volume, expected count, upper limit and lower limit

t (min)	*t* (s)	Total sampled air volume, *L*	Expected count, *E*	Observed count, *C*	
				Upper limit, C_H	Lower limit, C_L
0,5	30	14,15	0,4	4	0
1	60	28,3	0,8	5	0
1,5	90	42,45	1,2	5	0
2	120	56,6	1,6	6	0
2,5	150	70,75	2,1	6	0
3	180	84,9	2,5	6	0
3,5	210	99,05	2,9	7	0
4	240	113,2	3,3	7	0
4,5	270	127,35	3,7	8	0
5	300	141,5	4,1	8	0
5,5	330	155,65	4,5	9	1
6	360	169,8	4,9	9	1
6,5	390	183,95	5,3	9	2
7	420	198,1	5,7	10	2

Table D.2 *(continued)*

t (min)	*t* (s)	Total sampled air volume, *L*	Expected count, *E*	Observed count, *C*	
				Upper limit, C_H	Lower limit, C_L
7,5	450	212,25	6,2	10	2
8	480	226,4	6,6	11	3
8,5	510	240,55	7,0	11	3
9	540	254,7	7,4	12	4
9,5	570	268,85	7,8	12	4
10	600	283	8,2	12	4
10,5	630	297,15	8,6	13	5
11	660	311,3	9,0	13	5
11,5	690	325,45	9,4	14	6
12	720	339,6	9,8	14	6
12,5	750	353,75	10,3	15	7
13	780	367,9	10,7	15	7
13,5	810	382,05	11,1	15	7
14	840	396,2	11,5	16	8
14,5	870	410,35	11,9	16	8
15	900	424,5	12,3	17	9
15,5	930	438,65	12,7	17	9
16	960	452,8	13,1	17	10
16,5	990	466,95	13,5	18	10
17	1 020	481,1	14,0	18	10
17,5	1 050	495,25	14,4	19	11
18	1 080	509,4	14,8	19	11
18,5	1 110	523,55	15,2	20	12
19	1 140	537,7	15,6	20	12
19,5	1 170	551,85	16,0	20	13
20	1 200	566	16,4	20	13
20,5	1 230	580,15	16,8	20	13
21	1 260	594,3	17,2	20	14
21,5	1 290	608,45	17,6	20	14
22	1 320	622,6	18,1	20	15
22,5	1 350	636,75	18,5	20	15
23	1 380	650,9	18,9	20	15
23,5	1 410	665,05	19,3	20	16
24	1 440	679,2	19,7	20	16
24,37 = t_t	1 462,2	689,671 = V_s	20	20	17

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



Key

x Count time (min)
y Observed count (particles/m^3)

Upper observed count

Lower observed count

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

D.4.2.5 Compare the cumulative observed count and the upper and lower limits and apply the procedure described in D.3

a) Fail situation

Table D.3 — Example sequential sampling particle counts

t (min)	*t* (s)	Measurement count	Cumulative observed count, *C*	Expected count, *E*	Observed count, *C* Upper limit, C_H	Observed count, *C* Lower limit, C_L	Result
0,5	30	1	1	0 (0,4)	4	0	Continue
1	60	1	2	0 (0,8)	5	0	Continue
1,5	90	2	4	1,2	5	0	Continue
2	120	1	5	1,6	6	0	Continue
2,5	150	1	6	2,1	6	0	Continue
3	180	0	6	2,5	6	0	Continue
3,5	210	0	6	2,9	7	0	Continue
4	240	0	6	3,3	7	0	Continue
4,5	270	1	7	3,7	8	0	Continue
5	300	4	11	4,1	8	0	FAIL

The expected count provided in the first measurement is 0,4; it is judged to "PASS" when the observed count is 0, and it is judged to "FAIL" when the observed count is 4. However, when the observed count is between 0 and 4, it cannot be judged. In this case, the sampling is 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 10th measurement (t = 300 seconds), the cumulative observed count is 11 and exceeds the upper limit (8). Then it is judged to "FAIL."

b) Pass situation

Table D.4 — Example sequential sampling particle counts

t (min)	t (s)	Measurement count	Cumulative observed count, C	Expected count, E	Observed count, C		Result
					Upper limit, C_H	Lower limit, C_L	
0,5	30	0	0	0 (0,4)	4	0	Continue
1	60	0	0	0 (0,8)	5	0	Continue
1,5	90	0	0	1,2	5	0	Continue
2	120	0	0	1,6	6	0	Continue
2,5	150	0	0	2,1	6	0	Continue
3	180	0	0	2,5	6	0	Continue
3,5	210	0	0	2,9	7	0	Continue
4	240	0	0	3,3	7	0	Continue
4,5	270	0	0	3,7	8	0	Continue
5	300	0	0	4,1	8	0	Continue
6	**360**	**0**	**0**	**4,9**	**9**	**1**	**PASS**

The expected count provided in the first measurement is 0,4, and it is judged with "PASS" when the observed count is 0, and it is judged to "FAIL" when the observed count is 4. However, when the observed count is between 0 and 4, it cannot be judged. In this case, the sampling is continued, but the cumulative observed count does not increase. In the 11th measurement (t = 360 seconds), the cumulative observed count is 0 and is equal to the lower limit (0). Then it is judged to "PASS."

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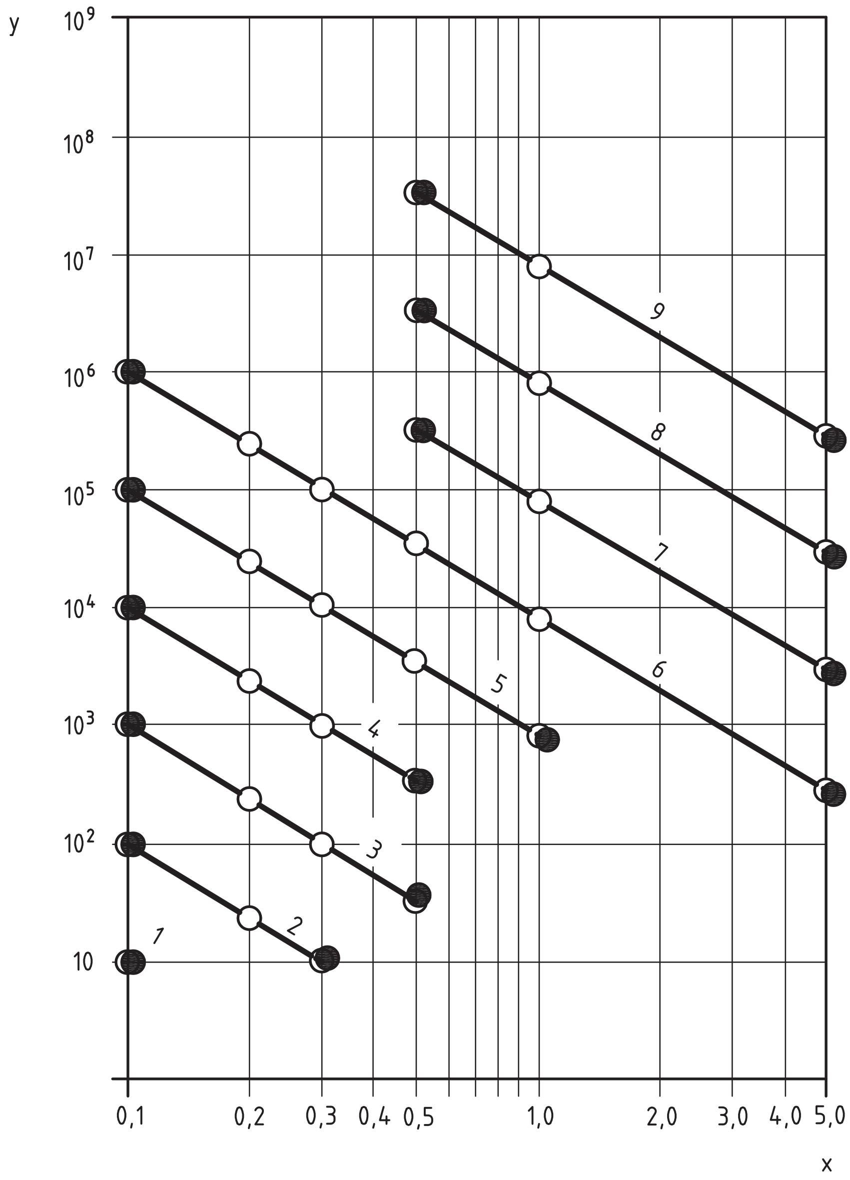
Annex E
(informative)

Illustration of the ISO cleanliness classes

Figure E.1 depicts the air cleanliness classes of Table 1 in graphical form, for illustration purposes only.



Key

x Particle size, *D* (µm)
y Airborne particle concentration, C_n (particles/m^3)

1	ISO Class 1	4	ISO Class 4	7	ISO Class 7
2	ISO Class 2	5	ISO Class 5	8	ISO Class 8
3	ISO Class 3	6	ISO Class 6	9	ISO Class 9

Figure E.1 — Graphical representation of the integer ISO air cleanliness classes by particle concentration

The ISO classes of Table 1 are shown on Figure E.1 as lines representing the class concentration limits for the considered threshold particle sizes. As the lines only approximate the class limits, they are not to be used to define the limits.

The classification lines shown on the graph may not be extrapolated beyond the solid circle symbols, which indicate the minimum and maximum particle-size limits acceptable for each of the ISO classes shown.

Table E.1 provides examples of intermediate decimal air cleanliness classes. The notes identify restrictions due to sampling and collection limitations.

Table E.1 — Examples of intermediate decimal air cleanliness classes by particle concentration, derived from Equation (1)

	Concentration of particles (particles/m^3) [a]					
ISO classification 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	924
ISO Class 7,5	c	c	c	1 110 000	263 000	9 240
ISO Class 8,5	c	c	c	11 100 000	2 630 000	92 400

[a] All concentrations in the table are cumulative, e.g. for ISO Class 5,5, the 11 100 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. 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.

Bibliography

[1] *IEST-G-CC1002, Determination of the Concentration of Airborne Ultrafine Particles.* Arlington Heights, Illinois: Institute of Environmental Sciences and Technology (1999)

[2] *IEST-G-CC1003, Measurement of Airborne Macroparticles.* Arlington Heights, Illinois: Institute of Environmental Sciences and Technology (1999)

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

[4] *JIS B 9920:2002, Classification of air cleanliness for cleanrooms.* Tokyo, Japan: Japanese Standards Association (2002)