INTERNATIONAL STANDARD

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Cleanrooms and associated controlled environments —

Part 1:
Classification of air cleanliness

Salles propres et environnements maîtrisés apparentés —

Partie 1: Classification de la propreté de l'air

Contents

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 nongovernmental, 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.

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.

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

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

— *Part 1: Classification of air cleanliness*

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

— *Part 3: Metrology and test methods*

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

— *Part 5: Operations*

— *Part 6: Terms and definitions*

— *Part 7: Enhanced clean devices*

Users should note that the titles listed for parts 2 to 7 are working titles at the time of the release of part 1. In the event that one or more of these parts are deleted from the work programme, the remaining parts may be renumbered.

Annexes B and C form an integral part of this part of ISO 14644. Annexes A, D, E, and F are for information only.

Introduction

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

This part of ISO 14644 assigns ISO classification levels to be used for the specification of air cleanliness in cleanrooms and associated controlled environments. It also prescribes the standard method of testing as well as the procedure for determining the concentration of airborne particles.

For classification purposes, this part of ISO 14644 is limited to a designated range of considered particle sizes for determination of particle concentration limits. This part of ISO 14644 also provides standard protocols for the determination and designation of cleanliness levels that are based on airborne concentrations of particles smaller or larger than the size range designated for classification.

This part of ISO 14644 is one of a series of standards concerned with cleanrooms and contamination control. Many factors besides airborne particulate cleanliness must be considered in the design, specification, operation, and control of cleanrooms and other controlled environments. These are covered in some detail in other parts of the International Standards prepared by ISO/TC 209.

In some circumstances, relevant regulatory agencies may impose supplementary policies or restrictions. In such situations, appropriate adaptations of the standard testing procedures may be required.

Cleanrooms and associated controlled environments —

Part 1:
Classification of air cleanliness

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) sizes ranging from 0,1 µm to 5 µm are considered for classification purposes.

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, respectively.

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

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

2 Definitions

For the purposes of this part of ISO 14644, the following definitions apply.

2.1 General

2.1.1

cleanroom
room in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimize the introduction, generation, and retention of parti-

cles inside the room, and in which other relevant parameters, e.g. temperature, humidity, and pressure, are controlled as necessary

2.1.2

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

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

2.1.3

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

2.1.4

classification
level (or the process of specifying or determining the level) of airborne particulate cleanliness applicable to a cleanroom or clean zone, expressed in terms of an ISO Class N, which represents maximum allowable concentrations (in particles per cubic metre of air) for considered sizes of particles

NOTE 1   The concentrations are determined by using equation (1) in 3.2.

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 (lower threshold values) applicable for classification in accordance with this International

Standard are limited to the range from 0,1 μm through 5 μm. Air cleanliness may be described and specified (but not classified) in terms of U descriptors or M descriptors (see 2.3.1 or 2.3.2) for considered threshold particle sizes that are outside of the range covered by classification.

NOTE 4   Intermediate ISO classification numbers may be specified, with 0,1 the smallest permitted increment; i.e., the range of intermediate ISO classes extends from ISO Class 1,1 through ISO Class 8,9.

NOTE 5   Classification may be specified or accomplished in any of three occupancy states (see 2.4).

2.2 Airborne particles

2.2.1

particle
solid or liquid object which, for purposes of classification of air cleanliness, falls within a cumulative distribution that is based upon a threshold (lower limit) size in the range from 0,1 μm to 5 μm

2.2.2

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-counting, light-scattering instruments, the equivalent optical diameter is used.

2.2.3

particle concentration
number of individual particles per unit volume of air

2.2.4

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

2.2.5

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

2.2.6

macroparticle
particle with an equivalent diameter greater than 5 μm

2.2.7

fibre
particle having an aspect (length-to-width) ratio of 10 or more

2.3 Descriptors

2.3.1

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

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

2.3.2

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 characterize the cleanroom or clean zone). M descriptors cannot be used to define airborne particulate cleanliness classes, but they may be quoted independently or in conjunction with airborne particulate cleanliness classes.

2.4 Occupancy states

2.4.1

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

2.4.2

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

2.4.3

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

Table 1 — Selected airborne particulate cleanliness classes for cleanrooms and clean zones

ISO classification number (N)	Maximum concentration limits (particles/m³ of air) for particles equal to and larger than the considered sizes shown below (concentration limits are calculated in accordance with equation (1) in 3.2)					
	0,1 µm	0,2 µm	0,3 µm	0,5 µm	1 µm	5 µm
ISO Class 1	10	2				
ISO Class 2	100	24	10	4		
ISO Class 3	1 000	237	102	35	8	
ISO Class 4	10 000	2 370	1 020	352	83	
ISO Class 5	100 000	23 700	10 200	3 520	832	29
ISO Class 6	1 000 000	237 000	102 000	35 200	8 320	293
ISO Class 7				352 000	83 200	2 930
ISO Class 8				3 520 000	832 000	29 300
ISO Class 9				35 200 000	8 320 000	293 000
NOTE Uncertainties related to the measurement process require that concentration data with no more than three significant figures be used in determining the classification level						

2.5 Roles

2.5.1

customer

organization, or the agent thereof, responsible for specifying the requirements of a cleanroom or clean zone

2.5.2

supplier

organization engaged to satisfy the specified requirements of a cleanroom or clean zone

3 Classification

3.1 Occupancy state(s)

The particulate cleanliness 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 2.4).

NOTE It should be recognized that the "as-built" state is applicable to newly completed or newly modified cleanrooms or clean zones. Once testing in the "as-built" state is completed, further testing for compliance will be performed in the "at-rest" or the "operational" state, or both.

3.2 Classification number

Airborne particulate cleanliness 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 the equation:

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

(1)

where

C_n is the maximum permitted concentration (in particles per cubic metre of air) of airborne particles that are equal to or larger 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. Intermediate ISO classification numbers may be specified, with 0,1 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 1 presents selected airborne particulate cleanliness classes and the corresponding particle concentrations for particles equal to and larger than the considered sizes shown. Figure A.1 (see annex A) provides a representation of the

selected classes in graphical form. In case of dispute, the concentration C_n as derived from equation (1) shall serve as the standard value.

3.3 Designation

The designation of airborne particulate cleanliness for clean-rooms 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 concentration(s), as determined by the classification equation (1) where each considered threshold particle size is in the range from 0,1 µm through 5 µm.

Example designation:

ISO Class 4; operational state; considered sizes:

0,2 µm (2 370 particles/m^3), 1 µm (83 particles/m^3)

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., D_2) shall be at least 1,5 times the next smaller particle diameter (e.g., D_1).

e.g.: $D_2 \geq 1,5 \times D_1$

4 Demonstration of compliance

4.1 Principle

Compliance with air cleanliness (ISO class) requirements specified by the customer is verified by performing specified testing procedures and by providing specified documentation of the results and conditions of testing, as agreed upon by the customer and the supplier.

4.2 Testing

The reference test method for demonstrating compliance is given in annex B. An alternative method having comparable accuracy may be specified, although if no method is specified or agreed upon, the reference method shall be used.

Tests performed to demonstrate compliance shall be conducted using calibrated instruments.

4.3 Airborne particle concentration limits

Upon completion of testing in accordance with 4.2, average particle concentrations and the 95% upper confidence limit

(when applicable) shall be calculated using equations shown in annex C.

Average particle concentration(s), calculated in accordance with equation (C.1), shall not exceed the concentration limit(s) determined by use of equation (1) in 3.2, as specified [3.3 c)] for the considered size(s).

In addition, for situations in which the number of sampling locations involved is at least two but not more than nine, the calculation of 95% upper confidence limits in accordance with C.3 shall not exceed the concentration limits established above.

NOTE   Worked examples of classification calculations are provided in annex D.

Particle concentrations used for determination of conformance to classification limits shall be measured by the same method for all considered particle sizes.

4.4 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 noncompliance with the specified designation of airborne particulate cleanliness classification.

The test report shall include the following:

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: 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 location coordinates.

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

Annex A
(informative)

Graphical illustration of the classes of Table 1

Figure A.1 depicts the air cleanliness classes of Table 1 in graphical form, for illustration purposes only. The ISO classes of Table 1 are shown as lines representing the class concentration limits for the considered threshold particle sizes. They are based on calculations using equation (1) of 3.2 As the lines only approximate the class limits, they are not to be used to define the limits. Such determinations are made in accordance with equation (1).

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.

The classification lines do not represent actual particle size distributions found in cleanrooms and clean zones.
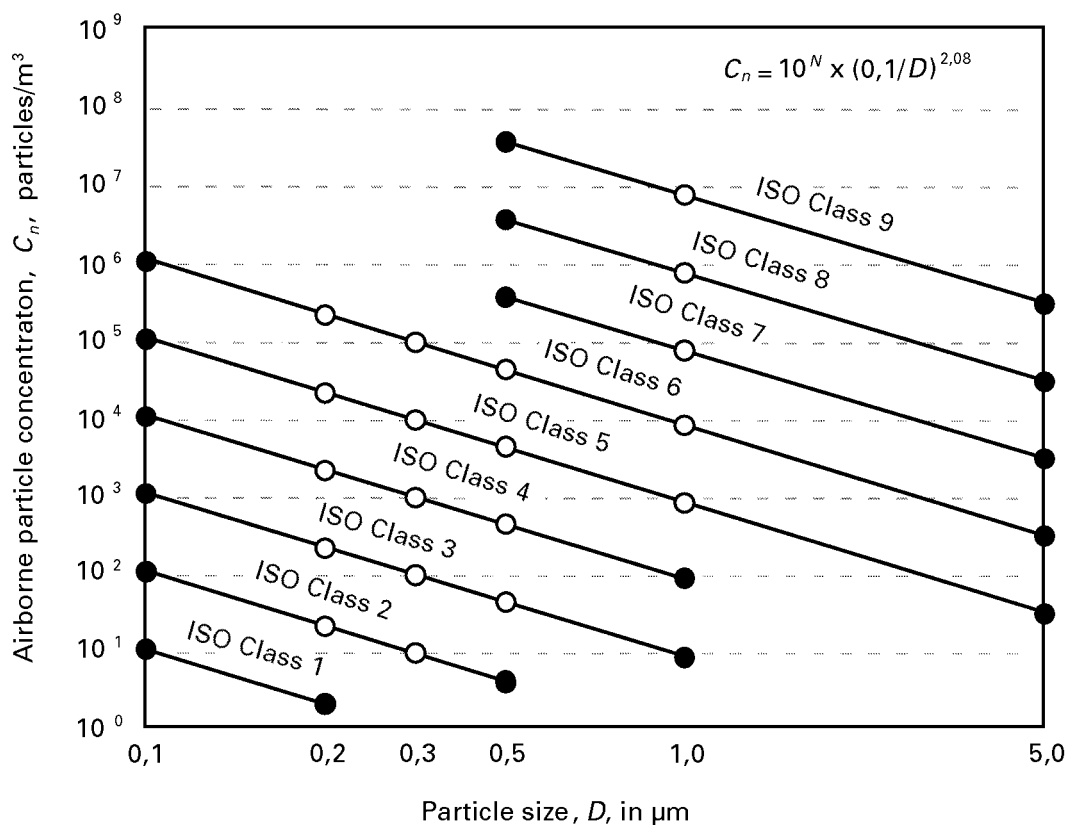

Figure A.1 — Graphical representation of ISO-class concentration limits for selected ISO classes

NOTE 1 C_n represents the maximum permitted concentration (in particles per cubic metre of air) of airborne particles equal to and larger than the considered particle size.

NOTE 2 N represents the specified ISO class number.

Annex B
(normative)

Determination of particulate cleanliness classification using a discrete-particle-counting, light-scattering instrument

B.1 Principle

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

B.2 Apparatus requirements

B.2.1 Particle-counting instrument

Discrete-particle counter (DPC), a light-scattering device having 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, and a suitable sampling system.

B.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.

B.3 Pretest conditions

B.3.1 Preparation for testing

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

Such pretesting may include, for example:

a) airflow volume or velocity tests;

b) air pressure difference test;

c) containment leakage test;

d) installed filter leakage test.

B.3.2 Pretest equipment setup

Perform equipment setup and pretest calibration of the instrument in accordance with the manufacturer's instructions.

B.4 Sampling

B.4.1 Establishment of sampling locations

B.4.1.1

Derive the minimum number of sampling point locations from equation (B.1):

$$N_L = \sqrt{A} \qquad \text{(B.1)}$$

where

N_L is the minimum number of sampling locations (rounded up to a whole number).

A is the area of the cleanroom or clean zone in square metres.

NOTE   In the case of unidirectional horizontal airflow, the area A may be considered as the cross section of the moving air perpendicular to the direction of the airflow.

B.4.1.2

Ensure that the sampling locations are evenly distributed throughout the area of the cleanroom or clean zone and positioned at the height of the work activity.

If the customer specifies additional sampling locations, their number and positions shall also be specified.

NOTE   Such additional locations may be those considered critical, based on a risk analysis.

B.4.2 Establishment of single sample volume per location

B.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 considered particle size were at the class limit for the designated ISO class.

The single sample volume V_s per location is determined by using equation (B.2):

$$V_s = \frac{20}{C_{n,m}} \times 1\ 000 \qquad \text{(B.2)}$$

where

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

NOTE   When V_s is very large, the time required for sampling can be substantial. By using the sequential sampling procedure (see annex F), both the required sample volume and the time required to obtain samples may be reduced.

B.4.2.2
The volume sampled at each location shall be at least 2 litres, with a minimum sampling time at each location of 1 min.

B.4.3   Sampling procedure

B.4.3.1
Set up the particle counter (B.2.1) in accordance with the manufacturer's instructions and in compliance with the instrument calibration certificate.

B.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., nonunidirectional airflow), the inlet of the sampling probe shall be directed vertically upward.

B.4.3.3
Sample the volume of air determined in B.4.2, as a minimum, at each sampling location.

B.4.3.4
Where only one sampling location is required (B.4.1), take a minimum of three single sample volumes (B.4.2) at that location.

B.5 Recording of results

B.5.1   Average concentration of particles at each sampling location

B.5.1.1
Record the result of each sample measurement as the concentration of each of the considered particle size(s) (3.3) appropriate to the relevant classification of air cleanliness.

NOTE   Consideration should be given to the requirements of B.6.1 before proceeding with the calculation of the 95% upper confidence limit.

B.5.1.2
When only one sampling location is used, calculate and record the average value of the sample data (B.4.3.4) for each considered particle size.

B.5.1.3
When two or more single sample volumes are taken at a location, compute the average particle concentration for each considered particle size from the individual sample particle concentrations (B.5.1.1), according to the procedure given in C.2, and record the results.

B.5.2   Requirement for computing the 95% upper confidence limit (UCL)

B.5.2.1
When the number of locations sampled is more than one and less than ten, compute the overall mean of the averages, standard deviation, and 95% upper confidence limit from the average particle concentrations for all locations (B.5.1) following the procedure described in C.3.

B.5.2.2
When only a single location is sampled, or when more than nine are sampled, computing the 95% upper confidence limit is not applicable.

B.6 Interpretation of results

B.6.1   Classification requirements
The cleanroom or clean zone is deemed to have met the specified air cleanliness classification if the averages of the particle concentrations measured at each of the locations and, when applicable, the 95% upper confidence limit calculated according to B.5.2, do not exceed the concentration limits determined in accordance with equation (1) of 3.2.

If the results of testing fail to meet the specified air cleanliness classification, testing may be performed at additional, evenly distributed sampling locations. The results of recalculation, including data from the added locations, shall be definitive.

B.6.2   Treatment of outliers
The result of the 95% UCL calculation may fail to meet the specified ISO class designation. If the noncompliance is caused by a single, nonrandom "outlier" value resulting from an erroneous measurement (due to procedural error or equipment malfunction) or from an unusually low particle concentration (due to exceptionally clean air), the outlier may be excluded from the calculation, provided that:

a) the calculation is repeated, including all remaining sampling locations;

b) at least three measurement values remain in the calculation;

c) no more than one measurement value is excluded from the calculation;

d) the suspected cause of the erroneous measurement or low particle concentration is documented and accepted by both the customer and supplier.

NOTE   Widely divergent values for particle concentrations among the locations sampled may be reasonable and even intentional, depending on the nature of the application of the clean installation under test.

Annex C
(normative)

Statistical treatment of particle concentration data

C.1 Rationale

This statistical analysis considers only random errors (lack of precision), not errors of a nonrandom nature (e.g. bias associated with erroneous calibration).

C.2 Algorithm for computation of average particle concentration at a location ($\bar{x}_i$)

When multiple samples are taken at a location, equation (C.1) shall be used to determine the average particle concentration at the location. Calculation of the average particle concentration shall be performed for each sampling location at which two or more samples have been taken.

$$\bar{x}_i = \frac{x_{i,1} + x_{i,2} + \dots + x_{i,n}}{n} \qquad \text{(C.1)}$$

where

  $\bar{x}_i$ is the average particle concentration at location i, representing any location.

  $x_{i,1}$ to $x_{i,n}$ are the particle concentrations of the individual samples.

  n is the number of samples taken at location i.

C.3 Algorithms for computation of 95% upper confidence limit

C.3.1   Principle

This procedure is applicable only if the number of sampling locations is more than one and less than ten. In such circumstances, this procedure shall be used in addition to the algorithm of equation (C.1).

C.3.2   Overall mean of the averages ($\bar{\bar{x}}$)

Using equation (C.2), determine the overall (grand) mean of the averages.

$$\bar{\bar{x}} = \frac{\left(\bar{x}_{i,1} + \bar{x}_{i,2} + \dots + \bar{x}_{i,m} \right)}{m} \qquad \text{(C.2)}$$

where

  $\bar{\bar{x}}$ is the overall mean of the location averages.

  $\bar{x}_{i,1}$ to $\bar{x}_{i,m}$ are individual location averages, determined by using equation (C.1).

  m is the number of individual location averages.

All individual location averages are equally weighted, regardless of the number of samples taken at any given location.

C.3.3   Standard deviation of the location averages (s)

Using equation (C.3), determine the standard deviation of the location averages.

$$s = \sqrt{\frac{\left(\bar{x}_{i,1} - \bar{\bar{x}} \right)^2 + \left(\bar{x}_{i,2} - \bar{\bar{x}} \right)^2 + \dots + \left(\bar{x}_{i,m} - \bar{\bar{x}} \right)^2}{(m-1)}} \qquad \text{(C.3)}$$

where

  s is the standard deviation of the location averages.

C.3.4 95% upper confidence limit (UCL) for the overall mean

Using equation (C.4), determine the 95% upper confidence limit for the overall mean.

$$95\% \text{ UCL} = \bar{\bar{x}} + t_{0,95} \left(\frac{s}{\sqrt{m}} \right) \qquad \text{(C.4)}$$

where

  $t_{0,95}$ represents the 95th percentile (quantile) of the t distribution, with m–1 degrees of freedom.

Values of the Student's t distribution ($t_{0,95}$) for the 95% UCL are given in Table C.1. Alternatively, Student's t distributions provided in statistical computer programmes are also acceptable.

Table C.1 — Student's t distribution for the 95% upper confidence limit

Number of individual averages (m)	2	3	4	5	6	7-9
t	6,3	2,9	2,4	2,1	2,0	1,9

Annex D
(informative)
Worked examples of classification calculations

D.1 Example 1

D.1.1

The cleanroom under consideration has an area (A) of 80 m². Conformance with the specified airborne particulate cleanliness classification is to be determined in the operational state.

The specified air cleanliness classification of the cleanroom is ISO Class 5.

D.1.2

Two considered particle sizes are specified: 0,3 μm (D_1) and 0,5 μm (D_2).

a) Both particle sizes are within the size limitations for ISO Class 5 [see 3.3 c) and Table 1]: 0,1 μm ≤ 0,3 μm, 0,5 μm ≤ 5 μm.

b) Application of the particle size ratio requirement, $D_2 \geq 1,5$ x D_1 [see 3.3 c)], shows compliance: 0,5 μm ≥ (1,5 x 0,3 μm = 0,45 μm).

D.1.3

The maximum permitted airborne particle concentrations are calculated in accordance with equation (1) (see 3.2).

For particles ≥ 0,3 μm (D_1):

$$C_n = \left(\frac{0,1}{0,3}\right)^{2,08} \times 10^5 = 10\ 176 \tag{D.1}$$

rounded to 10 200 particles/m³

For particles ≥ 0,5 μm (D_2):

$$C_n = \left(\frac{0,1}{0,5}\right)^{2,08} \times 10^5 = 3\ 517 \tag{D.2}$$

rounded to 3 520 particles/m³

D.1.4

The number of sampling point locations are derived in accordance with equation (B.1) (see B.4.1.1):

$$N_L = \sqrt{A} = \sqrt{80} = 8,94 \text{ (rounded to 9)} \tag{D.3}$$

Therefore the minimum number of sampling locations is nine and, as the number of sampling locations is less than ten, the calculation of the 95 % UCL according to annex C is applicable.

D.1.5

The single sample volume, V_s, is calculated in litres in accordance with equation (B.2) (see B.4.2.1):

$$V_s = \frac{20}{C_{n,m}} \times 1\ 000$$
$$= \frac{20}{3\ 517} \times 1\ 000 \tag{D.4}$$
$$= 5,69 \text{ litres}$$

The result is greater than 2 litres, and the sample volume selected was 28 litres over a period of 1 min (a flow rate commonly available in discrete-particle-counting light-scattering instruments).

This selection was based on:

a) V_s >2 litres (see B.4.2.2)

b) $C_{n,m}$ >20 particles/m³ (see B.4.2.1)

c) Sampling time ≥ 1 min (see B.4.2.2)

D.1.6

At each sampling location, only one single sample volume (28 litres) is taken (B.4.2.1). The counts obtained from the measurements are recorded (B.5.1.1) below.

Sampling location	Number of particles (≥0,3 μm)	Number of particles (≥0,5 μm)
1	245	21
2	185	24
3	59	0
4	106	7
5	164	22
6	196	25
7	226	23
8	224	37
9	195	19

D.1.7

From the raw data (D.1.6), the number of particles per cubic metre, x_i, is calculated:

Sampling location	$x_i \geq 0,3$ µm	$x_i \geq 0,5$ µm
1	8 750	750
2	6 607	857
3	2 107	0
4	3 786	250
5	5 857	786
6	7 000	893
7	8 071	821
8	8 000	1 321
9	6 964	679

Each calculated concentration value for 0,3 µm and 0,5 µm is less than the limits established in D.1.3. This satisfies the first part of classification (B.6.1) and therefore calculation of the 95% UCL according to annex C can proceed.

D.1.8

Computation of average concentration in accordance with equation (C.1) (see C.2) is not applicable, as the sample volumes taken were single volumes which represent an average particle concentration at each location. The overall means of the averages are calculated in accordance with equation (C.2) (see C.3.2).

For particles $\geq 0,3$ µm:

$$\bar{\bar{x}} = \frac{1}{9}\begin{pmatrix} 8\ 750 + 6\ 607 + 2\ 107 + 3\ 786 \\ +5\ 857 + 7\ 000 + 8\ 071 + 8\ 000 \\ +6\ 964 \end{pmatrix} \tag{D.5}$$

$$= \frac{1}{9} \times 57\ 142$$

$$= 6\ 349,1 \text{ rounded to } 6\ 349 \text{ particles/m}^3$$

For particles $\geq 0,5$ µm:

$$\bar{\bar{x}} = \frac{1}{9}\begin{pmatrix} 750 + 857 + 0 + 250 + 786 \\ +893 + 821 + 1\ 321 + 679 \end{pmatrix} \tag{D.6}$$

$$= \frac{1}{9} \times 6\ 357$$

$$= 706,3 \text{ rounded to } 706 \text{ particles/m}^3$$

D.1.9

The standard deviations of the location averages are calculated in accordance with equation (C.3) (see C.3.3).

For particles $\geq 0,3$ µm:

$$s^2 = \frac{1}{8}\begin{bmatrix} (8\ 750 - 6\ 349)^2 + (6\ 607 - 6\ 349)^2 \\ +(2\ 107 - 6\ 349)^2 + (3\ 786 - 6\ 349)^2 \\ +(5\ 857 - 6\ 349)^2 + (7\ 000 - 6\ 349)^2 \\ +(8\ 071 - 6\ 349)^2 + (8\ 000 - 6\ 349)^2 \\ +(6\ 964 - 6\ 349)^2 \end{bmatrix} \tag{D.7}$$

$$= \frac{1}{8} \times 37\ 130\ 073$$

$$= 4\ 641\ 259,1 \text{ rounded to } 4\ 641\ 259$$

$$s = \sqrt{4\ 641\ 259} \tag{D.8}$$

$$= 2\ 154,4 \text{ rounded to } 2\ 154 \text{ particles/m}^3$$

For particles $\geq 0,5$ µm:

$$s^2 = \frac{1}{8}\begin{bmatrix} (750 - 706)^2 + (857 - 706)^2 \\ +(0 - 706)^2 + (250 - 706)^2 \\ +(786 - 706)^2 + (893 - 706)^2 \\ +(821 - 706)^2 + (1\ 321 - 706)^2 \\ +(679 - 706)^2 \end{bmatrix} \tag{D.9}$$

$$= \frac{1}{8} \times 1\ 164\ 657$$

$$= 145\ 582,1 \text{ rounded to } 145\ 582$$

$$s = \sqrt{145\ 582} \tag{D.10}$$

$$= 381,6 \text{ rounded to } 382 \text{ particles/m}^3$$

D.1.10

The 95% upper confidence limits (UCL) are calculated in accordance with equation (C.4) (see C.3.4). As the number of individual averages is $m = 9$, the t distribution taken from Table C.1 is $t = 1,9$.

$$95\% \text{ UCL } (\geq 0,3 \text{ µm}) = 6\ 349 + 1,9\left(\frac{2\ 154}{\sqrt{9}}\right)$$

$$= 7\ 713,2 \tag{D.11}$$

$$\text{rounded to } 7\ 713 \text{ particles/m}^3$$

$$95\% \text{ UCL } (\geq 0,5\,\mu\text{m}) = 706 + 1,9\left(\frac{382}{\sqrt{9}}\right)$$
$$= 947,9 \tag{D.12}$$

rounded to 948 particles/m^3

D.1.11

The interpretation of results is carried out according to B.6.1. In D.1.7, it was shown that the particle concentration of each single sample volume is less than the specified class limits. In D.1.10, it was shown that the calculated values of the 95% UCL are also less than the class limits established in D.1.3.

Therefore the airborne particulate cleanliness of the cleanroom meets the required classification.

D.2 Example 2

D.2.1

This example is constructed to show the influence of the 95% UCL calculations on the results.

A cleanroom is specified for a particulate cleanliness of ISO Class 3 in operation. The number of sampling locations has been determined to be five. As the number of sampling locations is more than one and less than ten, the calculation of the 95% UCL according to annex C is applicable.

Only one particle size ($D \geq 0,1\ \mu$m) is considered.

D.2.2

The particle concentration limit for ISO Class 3 at $\geq 0,1\ \mu$m is taken from Table 1:

$$C_n \ \ (\geq 0,1\ \mu\text{m}) \ = \ 1\ 000 \text{ particles/m}^3$$

D.2.3

At each sampling location, only one single sample volume is taken (B.5.1.1). The number of particles per cubic metre, x_i, is calculated for each location and recorded below:

Sampling location	$x_i \geq 0,1\ \mu$m
1	926
2	958
3	937
4	963
5	214

Each value of the concentration for $D = 0,1\ \mu$m is less than the limit established in D.2.2. This result satisfies the first part of classification (B.6.1) and therefore calculation of the 95% UCL according to annex C can proceed.

D.2.4

The overall mean of the averages is calculated in accordance with equation (C.2) (see C.3.2):

$$\overline{\overline{x}} = \frac{1}{5}\ (926 + 958 + 937 + 963 + 214)$$
$$= \frac{1}{5} \times 3\ 998 \tag{D.13}$$
$$= 799,6 \text{ rounded to } 800 \text{ particles}\,/\,\text{m}^3$$

D.2.5

The standard deviation of the location averages is calculated in accordance with equation (C.3) (see C.3.3):

$$s^2 = \frac{1}{4}\left[\begin{array}{l}(926 - 800)^2 + (958 - 800)^2 \\ + (937 - 800)^2 + (963 - 800)^2 \\ + (214 - 800)^2\end{array}\right]$$
$$= \frac{1}{4} \times 429\ 574 \tag{D.14}$$
$$= 107\ 393,5 \text{ rounded to } 107\ 394$$

$$s = \sqrt{107\ 394} = 327,7 \tag{D.15}$$

rounded to 328 particles/m^3

D.2.6

The 95% UCL is calculated in accordance with equation (C.4) (see C.3.4):

As the number of individual averages is $m = 5$, the t distribution taken from Table C.1 is $t = 2,1$.

$$95\% \text{ UCL } = 800 + 2,1\ \left(\frac{328}{\sqrt{5}}\right) \tag{D.16}$$
$$= 1\ 108 \text{ particles/m}^3$$

D.2.7

The particle concentrations of all of the single sample volumes are less than the specified classification limit (D.2.2).

Calculation of the 95% upper confidence limit shows, however, that the airborne particulate cleanliness of the cleanroom does *not* meet the specified classification.

This constructed example demonstrates the effect of a single outlying low particle concentration (i.e. location 5) on the result of the 95% UCL test.

Because nonconformance of the air cleanliness classification results from application of the 95% UCL, and is caused by a single, low particle concentration, the procedure described in B.6.2 may be followed to determine whether the nonconformance can be waived.

Annex E
(informative)

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

E.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 E.2 (for U descriptors) and E.3 (for M descriptors).

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

E.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 B.4.1 and the minimum sample volume V_s should be 2 litres (B.4.2.2).

E.2.2 U descriptor format

The ultrafine particle concentration of the U descriptor may be used alone or as a supplement to the airborne particulate cleanliness class. 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 $\geq$ 0,01 μm, the designation would be: "U (140 000; 0,01 μm)".

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 particulate cleanliness 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.

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

E.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 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.

E.3.2 M descriptor format

The M descriptor may be specified independently or as a supplement to the ISO classes of airborne particulate cleanliness. 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 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 particulate cleanliness class, the macroparticle concentration (*a*) should be not greater than the particle concentration limit (particles per cubic metre) applicable to the considered size of 5 µm for the specified ISO class.

Annex F
(informative)

Sequential sampling procedure

F.1 Background and limitations

F.1.1 Background

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 be realized when the concentration is near the specified limit. Sequential sampling is most appropriate when air cleanliness is expected to quality as ISO Class 4 or cleaner.

NOTE   For further information on sequential sampling, see *IEST-G-CC1004* [3].

F.1.2 Limitations

The principal limitations of sequential sampling are:

a) The procedure is only applicable to sampling aimed at a total of 20 particles per measurement, for particles of the considered size at the specified class or concentration limit.

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

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

F.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:

Upper limit: $C = 3{,}96 + 1{,}03\,E$ (F.1)

Lower limit: $C = -3{,}96 + 1{,}03\,E$ (F.2)

where

C is the observed count;

E is the expected count.

To facilitate comparisons, helpful references have been provided in the form of a graph, Figure F.1, and in tabular form as Table F.1. Either format may be used.

As air is being sampled at each designated location, the running total particle count is continuously compared to reference count limits which are a function of the proportion of the prescribed total volume that has been sampled. If the running total count is less than the lower reference count limit corresponding to the volume that has been sampled, the air being
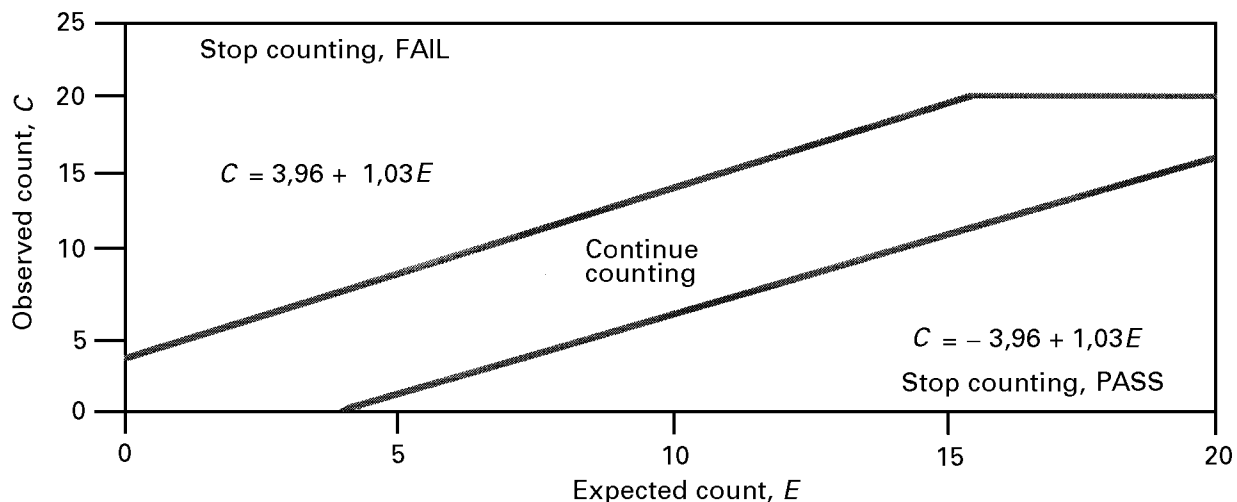

Figure F.1 — Boundaries for pass or fail by the sequential sampling procedure

Table F.1 — Upper and lower limits for time at which C observed counts should arrive

FAILS IF COUNT, C, COMES EARLIER THAN EXPECTED		PASSES IF COUNT, C, COMES LATER THAN EXPECTED	
Fractional time, t	Observed Count	Fractional time, t	Observed Count
0,001 9	4	0,192 2	0
0,050 5	5	0,240 7	1
0,099 2	6	0,289 3	2
0,147 6	7	0,337 8	3
0,196 1	8	0,386 4	4
0,244 7	9	0,434 9	5
0,293 2	10	0,483 4	6
0,341 7	11	0,532 0	7
0,390 2	12	0,580 5	8
0,438 8	13	0,629 1	9
0,487 3	14	0,667 6	10
0,535 9	15	0,726 2	11
0,584 4	16	0,774 7	12
0,633 0	17	0,823 3	13
0,681 5	18	0,871 8	14
0,730 0	19	0,920 3	15
0,778 6	20	0,968 9	16
1,000 0	21	1,000 0	17

NOTE   Fractional times are given as the fraction of total times (t = 1,000 0 at the class limit).

sampled is found to meet the specified class or concentration limit, and sampling is halted.

If the running count exceeds the upper reference count limit corresponding to the volume sampled, 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 full sample has been accumulated.

In the graph, Figure F.1, the number of observed counts, C, is plotted versus E, the expected number of counts for air being sampled at a rate (volume versus time) that would produce 20 counts in the time it would take to measure a full single sample of air if the concentration were at the specified limit for the considered particle size.

Table F.1 provides an equivalent method, in which the time of the observed count, C, is compared with incremental fractions of the time that would be required to measure a full single sample, as shown in the table. If the count occurs earlier than would be expected from the table, the air being sampled fails to meet the specified limit. If the count occurs later than

expected, the air being sampled meets the prescribed limit. At most, 21 comparisons of particle arrival times with the limiting times on the table would be required.

F.3 Procedure for sampling

F.3.1   Sequential sampling references

Two optional comparison techniques are provided for judging the result as data collection proceeds. Progressive computerized analysis of the data is beneficial and recommended.

F.3.2   Graphical sampling comparison

Figure F.1 illustrates the boundaries established in equations (F.1) and (F.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.

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 F.1 is as follows:

As sampling proceeds, record the number of particles counted as a function of time, and compare the count with the upper and lower limit lines of Figure F.1. 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. If the cumulative observed count crosses the lower line, sampling is stopped and the air passes the specified class limit. 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.

F.3.3   Tabular sampling comparison

Table F.1 provides an equivalent method for use with sequential sampling, also based on equations (F.1) and (F.2). The time, t, on the table is assigned a value of "1,000 0" to represent the duration of a complete single sample. The volume of this sample is the volume necessary to provide 20 particles, if the air contains precisely the class limit equivalent concentration of particles of the considered size. The time values listed in the table are the fractional portions of the total time required for accumulation of the entire single sample.

The procedure for sequential sampling using Table F.1 is as follows:

As sampling proceeds, record the number of particles counted as a function of time, and compare the time at which each count is observed with the times shown in the two columns of the table. If a given cumulative observed count occurs earlier than expected, as indicated by comparison with the left-hand column, sampling is stopped and the air is reported to have failed compliance with the specified class limit. If the cumulative observed count occurs later than expected, as indicated by comparison with the right-hand column, sampling is stopped and the air is reported to be in compliance with the specified limit. If the cumulative observed count continuously arrives between the times shown in the two columns, sampling will continue. If counting continues through 21 comparisons with the left-hand column and no count arrives earlier than its expected time, the air passes the specified limit for a full single sample.

Bibliography

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

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

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