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Cleanrooms and associated controlled environments—

Part 1:

Classification of airborne particulates

Salles propres et environnements contrôlés apparentés —

Partie 1: Classification des particules en suspension dans l'air

ICS 13.040.30

Descriptors: clean rooms, air pollution, particulate air pollutant, classification.

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ISO/CEN PARALLEL ENQUIRY

The CEN Secretary-General has advised the ISO Secretary-General that this ISO/DIS covers a subject of interest to European standardization. **In accordance with subclause 5.1 of the Vienna Agreement, consultation on this ISO/DIS has the same effect for CEN members as would a CEN enquiry on a draft European Standard.** Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month FDIS vote in ISO and formal vote in CEN.

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

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Foreword

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

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*.

Annexes B, C, and F form an integral part of this International Standards. Annexes A, D, and E 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 and healthcare.

This International Standard 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 International Standard is limited to a designated range of considered particle sizes for determination of particle concentration limits. This International Standard 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 International Standard is one of a series of standards concerned with cleanrooms and associated subjects. 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 International Standards prepared by ISO/TC 209.

1 Scope

This part of International Standard ISO 14644 covers the classification of air cleanliness in cleanrooms and associated controlled environments. Classification in accordance with this standard is specified and accomplished exclusively in terms of concentration of airborne particles. Furthermore, the only particle populations considered for classification purposes are those having cumulative distributions based on threshold (lower limit) sizes ranging from 0,1 μm to 5 μm . Classification of air cleanliness in cleanrooms and clean zones may be accomplished in any of three occupancy states.

Particle populations outside these size limitations, that is, those in the ultrafine particle size range (smaller than 0,1 μm) as well as those in the macroparticle size range (larger than 5 μm), cannot be classified in accordance with this standard. Concentrations of particles in these outlying size ranges may, however, be specified in terms of U descriptors or M descriptors, as described in Annex E.

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

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

2 Definitions

2.1 General

2.1.1 Cleanroom:

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

2.1.2 Clean zone:

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

2.1.3 Installation:

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

2.1.4 Classification:

The level (or the process of specifying or determining the level) of airborne particulate cleanliness applicable to a cleanroom or clean zone. The cleanliness level is expressed in terms of an ISO Class N, which represents maximum allowable concentrations (in particles/ m^3 of air) for considered sizes of particles. The concentrations are determined by using the formula given in 3.2.

2.2 Airborne particles

2.2.1 Particle:

A 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:

The 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. (For discrete-particle, light-scattering instruments, the equivalent optical diameter is used).

2.2.3 Particle concentration:

The number of individual particles per unit volume of air.

2.2.4 Particle size distribution:

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

2.2.5 Ultrafine particle:

A particle with an equivalent diameter less than 0,1 μm .

2.2.6 Macroparticle:

A particle with an equivalent diameter greater than 5 μm .

2.2.7 Fibre:

A particle having an aspect ratio of 10 or greater.

2.3 Descriptors

2.3.1 U descriptor:

The measured or specified concentration in particle/ m^3 of air, including the ultrafine particles.

The U descriptor may be regarded as an upper limit (or as the upper confidence limit) for sampling location averages, 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 an airborne particulate cleanliness class.

2.3.2 M descriptor:

The measured or specified concentration of macroparticles/m³ of air, expressed in terms of the equivalent diameter that is characteristic of the measurement method used.

The M descriptor may be regarded as an upper limit (or as the upper confidence limit) for sampling location averages, 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 an airborne particulate cleanliness class.

2.4 Occupancy states

2.4.1 As-built:

The 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:

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

2.4.3 Operational:

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

2.5 Roles

2.5.1 Customer:

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

2.5.2 Supplier:

The 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 “operational” state(s).

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 formula:

$$C_n = 10^N \times \left(\frac{0.1}{D}\right)^{2,08}$$

where:

C _n	represents the maximum permitted concentration (in particles/m ³ 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 µm.
0,1	is a constant with a dimension of µm.

Table 1 presents selected airborne particulate cleanliness classes and the corresponding particle concentrations for particles equal to and larger than the considered sizes shown. Table 1 is expressed in graphical form as Figure A.1 in Annex A. In case of dispute, the concentration of C_n as derived from the formula shall serve as the standard value.

3.3 Designation

The designation of airborne particulate cleanliness for cleanrooms and clean zones shall include:

- The classification number, expressed as “ISO Class N.”
- The occupancy state to which the classification applies.
- The considered particle size(s), and the related concentration(s), as determined by the classification formula (3.2) where each considered particle size is between 0,1 µm and 5 µm, inclusive.

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).

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

Table 1 Selected airborne particulate cleanliness classes for cleanrooms and clean zones						
ISO classification number (N)	Maximum concentration limits (particles/m ³ of air) for particles equal to and larger than the considered sizes shown below (concentration limits are calculated in accordance with 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	325	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	29 300
ISO Class 8				3 520 000	832 000	293 000
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.

4 Demonstration of compliance

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.

4.1 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.

4.2 Airborne particle concentration limits

Upon completion of testing in accordance with 4.1, the average particle concentration(s) (see C.2) shall not exceed the concentration limit(s) determined by use of the formula in 3.2, as specified (3.3c) 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.

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

4.3 Documentation

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:

- The name and address of the testing organization, and the date on which the test was performed.
- The number and date of this part of this International Standard, i.e. ISO 14644-1: 199X.
- 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.
- 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.

Annex A (informative)

Graphical illustration of the classes of table 1

Figure A.1 depicts the data from table 1 in graphical form, for illustrative purposes only. Since the classification lines shown in figure A.1 only approximate the class limits, they cannot be used for precisely defining class limits; for such determinations, equation (1) given in 3.2 may be used.

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.

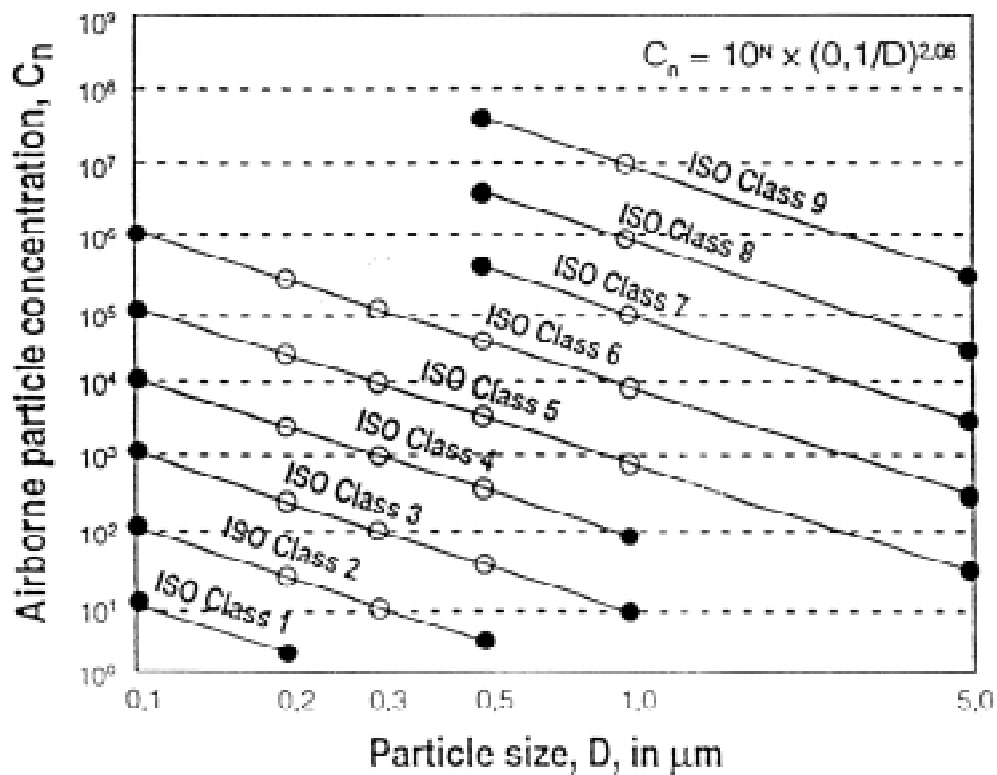


Figure A.1 — Graphical representation of the airborne particulate cleanliness classes for ISO shown in table. 1.

NOTES:

- 1 C_n represents the maximum permitted concentration (in particles/m³ of air) of airborne particles equal to and larger than the considered particle size.
- 2 N represents the specified ISO class number.

Annex B (normative)

Method of test for the 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 Instrument

B.2.1

A discrete-particle counter, 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

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

B.3 Pretest conditions

B.3.1

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

Such pretesting will normally include:

- a) Airflow volume or velocity tests.
- b) Air pressure difference test.
- c) Containment leakage test.
- d) Installed filter leakage test.

B.3.2

Perform a 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 the formula:

$$N_L = \sqrt{A}$$

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 air controlled space in m^2 .

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

NOTE: If the customer specified additional sampling locations, their number and positions must also be specified. Such additional locations may be those considered as critical based on a risk analysis.

B.4.2

Establishment of single sample volume per location.

B.4.2.1

Sample a sufficient volume of air at each location that a minimum of 20 particles would be detected if the particle concentration for the relevant class were at the class limit for the largest considered particle size.

The single sample volume V_s per location is determined by using the formula:

$$V_s = \frac{20}{C_{n,m}} \times 1000$$

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/ m^3) 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 minute.

B.4.3 Procedure for sampling**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**

Concentration of particles per sample location.

B.5.1.1

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

NOTE: Consideration should be given at this point 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 sample location is used, calculate the average value of the sample data (B.4.3.4).

B.5.1.3

When more than one single sample volume is taken at a location, compute the average particle concentration from the individual sample particle concentrations (B.5.1.1) according to the procedure given in C.2.

B.5.2 Computing the 95% upper confidence limit**B.5.2.1**

When the number of locations sampled is more than one and less than ten, compute the mean of the averages, standard deviation, standard error, 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 there is only one, or more than nine, locations sampled, computing of the 95% upper confidence limit will not be applicable.

B.6 Interpretation of results**B.6.1**

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 3.2.

NOTE: 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

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 General

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 (P)

NOTE: This procedure is applicable to any number of sampling locations.

$$P = \frac{(T_1 + T_2 + \dots + T_x)}{X}$$

where:

P is the average particle concentration at one location.

T_1 to T_x are the particle concentrations of the individual samples.

X is the number of samples taken at the location.

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

NOTE: This procedure is applicable only to situations where the number of sampling locations is at least two but not more than nine. In such circumstances, this procedure shall be used in addition to the algorithm of C.2.

C.3.1 Mean of the averages (M)

$$M = \frac{(P_1 + P_2 + \dots + P_Y)}{Y}$$

where:

M is the mean of the averages

P_1 to P_Y are individual location averages.

Y 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.3.2 Standard deviation of the mean (SD)

$$SD = \sqrt{\frac{(P_1 - M)^2 + (P_2 - M)^2 + \dots + (P_Y - M)^2}{(Y - 1)}}$$

where:

SD is the standard deviation of the mean

C.3.3 Standard error of the mean (SE)

$$SE = \frac{SD}{\sqrt{Y}}$$

where:

SE is the standard error of the mean.

C.3.4 95% upper confidence limit (UCL)

$$UCL = M + (t \times SE)$$

where:

t is Student's t factor, which is dependent on the number of individual averages (Y), and guarantees with 95% confidence that all individual averages are within the computed UCL (see basic statistics texts).

The values of the t factor for 95% UCL are given in Table C.1.

No. of individual averages (Y)	2	3	4	5-6	7-9
1	6.3	2.9	2.4	2.1	1.9

Table C.1: Student's t factor for 95% upper confidence limit.

Annex D (informative)

Worked examples of classification calculations

D.1 Example 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.

D.1.1

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

D.1.2

Two considered particle sizes are specified: 0,5 µm (D₂) and 0,3 µm (D₁).

- a) Both particle sizes are within the size limitations for ISO Class 5 (see 3.3c and Table 1): 0,1 µm ≤ 0,3 µm, 0,5 µm ≤ 5 µm.
- b) Application of the particle size ratio requirement, D₂ ≥ 1,5 x D₁ (see 3.3c), 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 (3.2):

$$C_n(D_1) = \left(\frac{0,1}{0,3}\right)^{2,08} \times 10^5 = 10\,176.$$

rounded to 10 200 particles/m³

$$C_n(D_2) = \left(\frac{0,1}{0,5}\right)^{2,08} \times 10^5 = 3\,517.$$

rounded to 3 520 particles/m³

D.1.4

The number of sampling point locations are derived (B.4.1.1):

$$NL = \sqrt{A} = \sqrt{80} = 8,94 \text{ (rounded to 9)}$$

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 is calculated (B.4.2.1):

$$V_s = \frac{20}{C_n(D_2)} \times 1000$$

$$= \frac{20}{3517} \times 1000$$

$$= 5.69 \text{ litres (>2 litres)}$$

The result is greater than 2 litres, and the sample volume selected was 28 litres over a period of one minute.

This selection was based on:

- a) V_s > 2 litres (see B.4.2.2)
- b) C_n(D₂) > 20 (see B.4.2.1)
- c) Sample time ≥ 1 minute (see B.4.2.2)
- d) The sample volume taken was calibrated at exactly 28 litres.

D.1.6

At each sampling location, only one single sample volume is taken (B.4.2.1). The results of the measurements are recorded (B.5.1.1) in the table below.

Sampling location	Number of particle in 28 litres (20,3 µm)	Number of particles in 28 litres (20,5 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	105	10

D.1.7

From the raw data (D.1.6), the number of particles/m³, P, is calculated:

Sampling location	P(D ₁ ≥ 0,3 μm)	P(D ₂ ≥ 0,5 μm)
1	8750	750
2	6607	857
3	2107	0
4	3786	250
5	5857	786
6	7000	893
7	8071	821
8	8000	1321
9	6964	679

Each calculated concentration value for D₁ and D₂ 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 (C.2) is not applicable, as the sample volumes taken were single volumes which represent an overall average particle concentration. The means of the averages are calculated from C.3.1:

$$\begin{aligned}
 M(D_1) &= \frac{1}{9} \left(\begin{array}{l} 8750 + 6607 + 2107 + 3786 \\ + 5857 + 7000 + 8071 + 8000 \\ + 6964 \end{array} \right) \\
 &= \frac{1}{9} \times 57\,142 \\
 &= 6349.1 \text{ rounded to } 6349 \text{ particles/m}^3
 \end{aligned}$$

$$\begin{aligned}
 M(D_2) &= \frac{1}{9} \left(\begin{array}{l} 750 + 857 + 0 + 250 + 786 \\ + 893 + 821 + 132 + 679 \end{array} \right) \\
 &= \frac{1}{9} \times 6357 \\
 &= 706,3 \text{ rounded to } 706 \text{ particles/m}^3
 \end{aligned}$$

D.1.9

The standard deviations of the means are calculated (C.3.2):

$$SD^2(D_1) = \frac{1}{8} \left[\begin{array}{l} + (8750 - 6349)^2 + (6607 - 6349)^2 \\ + (2107 - 6349)^2 + (3786 - 6349)^2 \\ + (5857 - 6349)^2 + (7000 - 6349)^2 \\ + (8071 - 6349)^2 + (8000 - 6349)^2 \\ + (6964 - 6349)^2 \end{array} \right]$$

$$\begin{aligned}
 &= \frac{1}{8} \times 37\,130\,073 \\
 &= 4\,641\,259,1 \text{ rounded to } 4\,641\,259
 \end{aligned}$$

$$\begin{aligned}
 SD(D_1) &= \sqrt{4\,641\,259} \\
 &= 2\,154,4 \text{ rounded to } 2154 \text{ particles/m}^3
 \end{aligned}$$

$$SD^2(D_2) = \frac{1}{8} \left[\begin{array}{l} + (750 - 706)^2 + (857 - 706)^2 \\ + (0 - 706)^2 + (250 - 706)^2 \\ + (786 - 706)^2 + (893 - 706)^2 \\ + (821 - 706)^2 + (1321 - 706)^2 \\ + (679 - 706)^2 \end{array} \right]$$

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

$$= 145\,582,13 \text{ rounded to } 145\,582$$

$$\begin{aligned}
 SD(D_2) &= \sqrt{145\,582} \\
 &= 381,6 \text{ rounded to } 382 \text{ particles/m}^3
 \end{aligned}$$

D.1.10

The standard errors of the means are calculated (C.3.3):

$$SE(D_1) = \frac{2154}{\sqrt{9}} = 718 \text{ particles/m}^3$$

$$SE(D_2) = \frac{382}{\sqrt{9}} = 127,3 \text{ rounded to } 127 \text{ particles/m}^3$$

D.1.11

The 95% upper confidence limits (UCL) are calculated (C.3.4). As the number of individual averages is Y = 9, the t factor taken from Table C.1 is t = 1.9.

$$\begin{aligned}
 95\% \text{ UCL } (>0,3 \mu\text{m}) &= 6349 + (1.9 \times 718) \\
 &= 7713,2 \\
 &\text{rounded to } 7713 \text{ particles/m}^3
 \end{aligned}$$

$$\begin{aligned}
 95\% \text{ UCL } (\geq 0,5 \mu\text{m}) &= 706 + (1.9 \times 127) \\
 &= 947,3 \\
 &\text{rounded to } 947 \text{ particles/m}^3
 \end{aligned}$$

D.1.12

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.1.11, 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

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

D.2.1

A cleanroom is specified for a particulate cleanliness of ISO Class 3 in operation. The number of sampling locations has been determined to be 5. As the number of sampling locations is more than one and less than ten, the calculation of the 95% UCL according to the Annex C is applicable.

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

D.2.2

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

$$C_n (\geq 1 \mu\text{m}) = 1000 \text{ particles/m}^3$$

D.2.3

At each sampling location, only one single sample volume is taken (B.5.1.1). The number of particles/m³, P, is calculated for each location and tabulated below:

Sampling location	P ($D \geq 0,1 \mu\text{m}$)
1	926
2	958
3	937
4	963
5	214

Each value of the concentration for $D=0,1 \mu\text{m}$ 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 mean of the averages is calculated (C.3.1):

$$\begin{aligned} M &= \frac{1}{5} (926 + 958 + 937 + 963 + 214) \\ &= \frac{1}{5} \times 3998 \\ &= 799,6 \text{ rounded to } 800 \text{ particles/m}^3 \end{aligned}$$

D.2.5

The standard deviation of the mean is calculated (C.3.2):

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

$$SD = \sqrt{107\,394} = 327,7 \text{ rounded to } 328 \text{ particles/m}^3$$

D.2.6

The standard error of the mean is calculated (C.3.3):

$$SE = \frac{328}{\sqrt{5}} = 146,7 \text{ rounded to } 147 \text{ particles/m}^3$$

D.2.7

The 95% UCL is calculated (C.3.4):

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

$$\begin{aligned} 95\% \text{ UCL} &= 800 + (2,1 \times 147) \\ &= 1108,7 \text{ rounded to } 1109 \text{ particles/m}^3 \end{aligned}$$

D.2.8

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

The 95% UCL calculation results in the room not meeting the specified classification limit.

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

E.1 Application

In some situations, typically 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 M descriptors) and E.3 (for U descriptors).

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

E.2.1

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.2.2

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/m³ of air)
- b is the equivalent diameter (or diameters) associated with the specified method for measuring macroparticles.
- c is the specified measurement method.

NOTE: 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.

Examples:

1) To express an airborne particle concentration of 10 000 particles/m³ 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”.

2) To express an airborne particle concentration of 1 000 particles/m³ 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(1000; 10 µm to 20 µm); cascade impactor followed by microscopic sizing and counting”.

NOTE 1: Suitable methods of test for concentrations of airborne particles larger than 5 µm are given in the Institute of Environment Sciences publication IES-TechPub-1003, *Measurement of Airborne Macroparticles*.

NOTE 2: 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/m³) applicable to the considered size of 5 µm for the specified ISO class.

E.3 Consideration of particles smaller than 0,1 µm (ultrafine particles) —U descriptor

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).

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/m³ of air).
- y is the size in micrometers 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/m³ in the particle size range $\geq 0,01 \mu\text{m}$, the designation would be: "U (140 000 : 0,01)."

NOTE 1: Suitable methods of test for concentrations of airborne particles smaller than $0,1 \mu\text{m}$ are given in the Institute of Environmental Sciences publication IES-TechPub-1002, *Determination of the Concentration of Airborne Ultrafine Particles*.

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/m³) applicable to the considered size of $0,1 \mu\text{m}$ for the specified ISO class.

Annex F (normative)

Sequential sampling procedures

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 qualify as ISO Class 4 or cleaner.

NOTE: For further information on sequential sampling, see the Institute of Environmental Sciences publication *IES-TechPub-1004, Sequential Sampling Procedures for Classification of Air in Cleanrooms and Clean Zones*.

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 formulas for upper and lower limit boundaries:

$$\text{Upper limits: } C = 3,96 + 1,03E.$$

$$\text{Lower limits: } C = -3,96 + 1,03E.$$

Where C is the observed count, and 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 that corresponds to the volume that has been sampled, the air 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

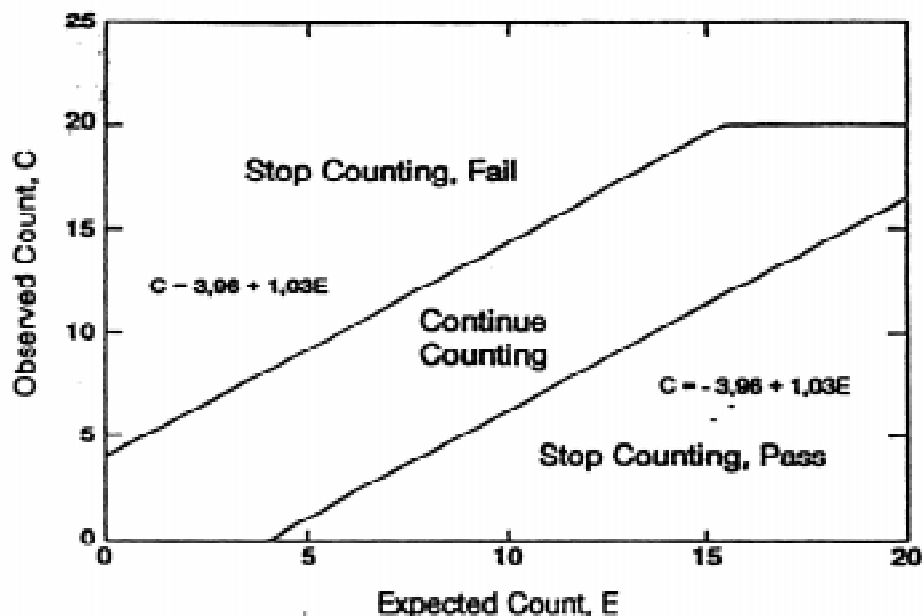


Figure F.1—Boundaries for pass or fail by the sequential sampling procedure

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 on 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

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.3.1

Figure F.1 illustrates the boundaries established by the equation of 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 which has 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 must 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 also judged to have complied with the class limit.

F.3.2

Table F.1 provides an equivalent method for use with sequential sampling, also based on the equations of F.2. The time, t, on the table is assigned a value of "1,0000" 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

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

NOTE: Fractional times are given as the fraction of total times (t = 1,0000 at the class limit).

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
0,0019	4	0,1922	0
0,0505	5	0,2407	1
0,0992	6	0,2893	2
0,1476	7	0,3378	3
0,1961	8	0,3864	4
0,2447	9	0,4349	5
0,2932	10	0,4834	6
0,3417	11	0,5320	7
0,3902	12	0,5805	8
0,4388	13	0,6291	9
0,4873	14	0,6676	10
0,5359	15	0,7262	11
0,5844	16	0,7747	12
0,6330	17	0,8233	13
0,6815	18	0,8718	14
0,7300	19	0,9203	15
0,7786	20	0,9689	16
1,0000	21	1,0000	17

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 passes the specified limit. If the cumulative observed count continuously arrives between the times shown in the two columns, sampling must 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.