INTERNATIONAL STANDARD

ISO 14644-1

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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

Reference number
ISO 14644-1:1999(E)

Contents

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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 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 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
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:

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

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 cleanrooms and clean zones shall include:

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

b) the occupancy state to which the classification applies;

c) the considered particle size(s), and the related 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.

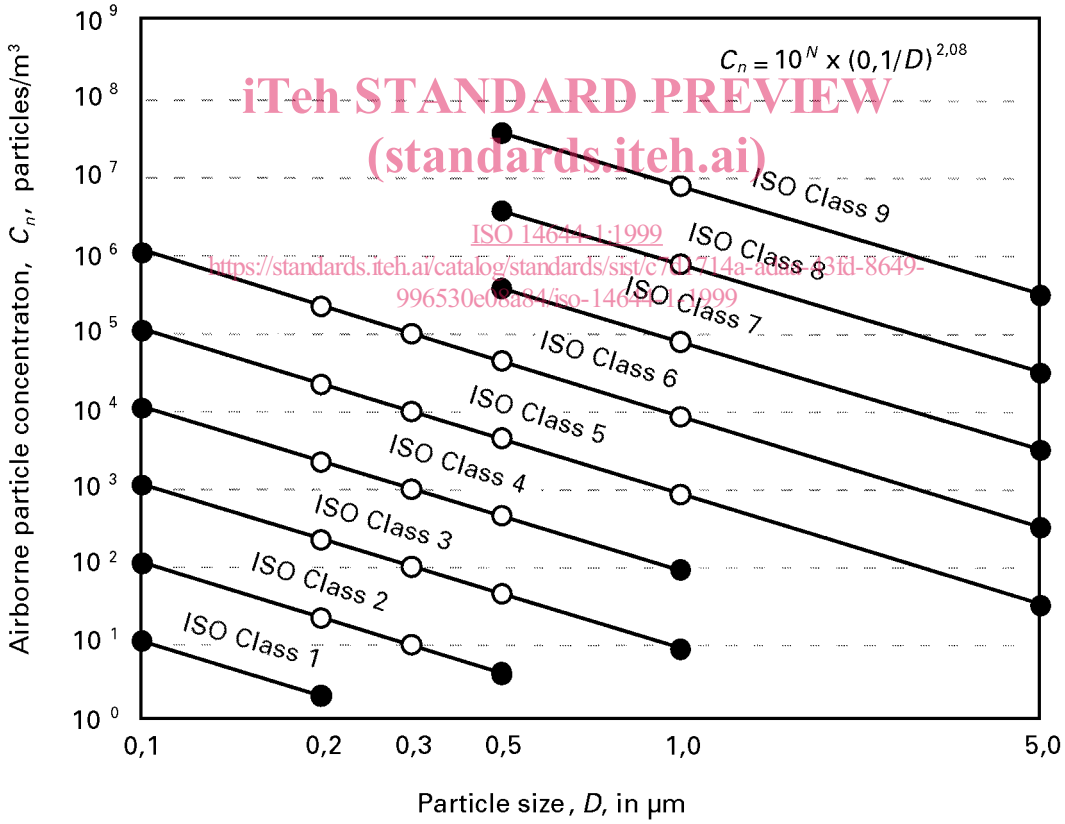

Figure A.1 — Graphical representation of ISO-class concentration limits for selected ISO classes

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;