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Cleanrooms and associated controlled environments —

Part 1:
Classification of air cleanliness by particle concentration

Salles propres et environnements maîtrisés apparentés —

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

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

ICS 13.040.35

ISO/CEN PARALLEL PROCESSING

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

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

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

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

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

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Foreword

This edition is the result of a systematic review and includes changes in response to user and expert feedback validated by international enquiry. The title has been revised to “Classification of air cleanliness by particle concentration” to be consistent with other parts of the standard. The nine ISO cleanliness classes are retained unchanged, but Table 1 defines the particle concentration at various particle sizes for the nine integer classes. The use of Table 1 ensures better definition of the appropriate particle-size ranges for the different classes. A formula is retained to allow definition of intermediate decimal classes. The standard retains the concept of ultrafine and macroparticle descriptors for particle sizes outside the range appropriate for measurement using airborne particle counters.

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

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

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

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

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

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

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

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

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

— *Part 3: Test methods*

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

— *Part 5: Operations*

— *Part 6: Vocabulary*

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

— *Part 8: Classification of airborne molecular contamination*

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

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

— *Part 1: General principles and methods*

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

Introduction

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

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

Cleanrooms and associated controlled environments —

Part 1:
Classification of air cleanliness by particle concentration

1 Scope

This part of ISO 14644 covers the classification of air cleanliness in cleanrooms and associated controlled environments exclusively in terms of concentration of airborne particles. Only particle populations having cumulative distributions based on threshold (lower limit) particle sizes ranging from 0,1 µm to 5 µm are considered for classification purposes.

The use of discrete-particle airborne counting and sizing instruments is the basis for determination of the concentration of airborne particles, equal to and greater than the specified sizes, at designated sampling locations.

This part of ISO 14644 does not provide for classification of particle populations that are outside of the specified particle-size range, 0,1 µm to 5 µm. Concentrations of ultrafine particles (particles smaller than 0,1 µm) and macroparticles (particles larger than 5 µm) may be used to quantify these populations in terms of U descriptors and M descriptors (see 3.3.1 and 3.3.2), respectively.

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

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

2 Normative reference

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

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

3 Definitions

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

3.1 General

3.1.1
cleanroom
room in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimise the introduction, generation, and retention of particles inside the room, and in which other relevant parameters, e.g. temperature, humidity, and pressure, are controlled as necessary

3.1.2
clean zone
dedicated space in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimise the introduction, generation, and retention of particles inside the zone and in which other relevant parameters, e.g. temperature, humidity and pressure, are controlled as necessary

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

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

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

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

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

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

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

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

3.2 Airborne particles

3.2.1
particle
minute piece of matter with defined physical boundaries

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

NOTE For discrete-particle light-scattering instruments, the equivalent optical diameter is used.

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

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

3.2.5
ultrafine particle
particle with an equivalent diameter less than 0,1 µm

3.2.6
macroparticle
particle with an equivalent diameter greater than 5 µm

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

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

3.3 Descriptors

3.3.1
U descriptor
measured or specified concentration, in particles per cubic metre of air, including the ultrafine particles

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

3.3.2
M descriptor
measured or specified concentration of macroparticles per cubic metre of air, expressed in terms of the equivalent diameter that is characteristic of the measurement method used

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

3.4 Occupancy states

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

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

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

3.5 Roles

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

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

4 Classification

4.1 Occupancy state(s)

The air cleaniness class by particle concentration of air in a cleanroom or clean zone shall be defined in one or more of three occupancy states, viz. “as-built,” “at-rest,” or “operational” (see 3.4).

4.2 Classification number

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

Table 1 — Air cleanliness classification table by particle concentration

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

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

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

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

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

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

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

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

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

where

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

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

D is the considered particle size, in micrometres.

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

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

4.3 Designation

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

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

b) the occupancy state to which the classification applies;

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

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

If measurements are to be made at more than one considered particle size, each larger particle diameter (e.g. *D*2) shall be at least 1,5 times the next smaller particle diameter (e.g. *D*1), i.e. $D2 \geq 1{,}5 \times D1$.

Example designations:

ISO Class 4; at rest; 0,2 µm 0,5 µm

ISO Class 7,5; in operation; 0.5 µm

5 Demonstration of compliance

5.1 Principle

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

5.2 Testing

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

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

5.3 Airborne particle concentration evaluation

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

be averaged and the average concentration must not exceed the concentration limits given in Table 1 or derived from Equation (1) for intermediate decimal classes.

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

5.4 Test report

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

The test report shall include:

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

b) the number and year of publication of this part of ISO 14644, i.e. ISO 14644-1:date of current issue;

c) a clear identification of the physical location of the cleanroom or clean zone tested (including reference to adjacent areas if necessary), and specific designations for coordinates of all sampling locations;

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

e) details of the test method used, with any special conditions relating to the test, or departures from the test method, and identification of the test instrument and its current calibration certificate;

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

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