



SLOVENSKI STANDARD SIST EN ISO 14644-1:2000

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Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness (ISO 14644-1:1999)

Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness (ISO 14644-1:1999)

Reinräume und zugehörige Reinraumbereiche - Teil 1: Klassifizierung der Luftreinheit (ISO 14644-1:1999)

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Salles propres et environnements maîtrisés apparentés - Partie 1: Classification de la propreté de l'air (ISO 14644-1:1999)

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13.040.35	Brezprašni prostori in povezana nadzorovana okolja	Cleanrooms and associated controlled environments
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EUROPEAN STANDARD
NORME EUROPÉENNE
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EN ISO 14644-1

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Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness (ISO 14644-1:1999)

Salles propres et environnements maîtrisés apparentés -
Partie 1: Classification de la propreté de l'air (ISO 14644-
1:1999)

Reinräume und zugehörige Reinraumbereiche - Teil 1:
Klassifizierung der Luftreinheit (ISO 14644-1:1999)

This European Standard was approved by CEN on 3 March 1999.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Page 2
EN ISO 14644-1:1999

Foreword

The text of the International Standard ISO 14644-1:1999 has been prepared by Technical Committee ISO/TC 209 "Cleanrooms and associated controlled environments" in collaboration with Technical Committee CEN/TC 243 "Cleanroom technology", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 1999, and conflicting national standards shall be withdrawn at the latest by November 1999.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 14644-1:1999 was approved by CEN as a European Standard without any modification.

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INTERNATIONAL STANDARD

ISO
14644-1

First edition
1999-05-01

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*
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Contents

	Page
Foreword	iii
Introduction	iv
1 Scope	1
2 Definitions	1
3 Classification	3
4 Demonstration of compliance	4
Annexes	
Annex A (informative) Graphical illustration of the classes of Table 1	5
Annex B (normative) Determination of particulate cleanliness classification using a discrete-particle-counting, light-scattering instrument	6
Annex C (normative) Statistical treatment of particle concentration data	9
Annex D (informative) Worked examples of classification calculations	10
Annex E (informative) Considerations for the counting and sizing of particles outside the size range applicable for classification	13
Annex F (informative) Sequential sampling procedure	15
Bibliography	18
Figures	
Figure A.1 Graphical representation of ISO-class concentration limits for selected ISO classes	5
Figure F.1 Boundaries for pass or fail by the sequential sampling procedure	15
Tables	
Table 1 Selected airborne particulate cleanliness classes for cleanrooms and clean zones	3
Table C.1 Student's <i>t</i> distribution for the 95% upper confidence limit	9
Table F.1 Upper and lower limits for time at which <i>C</i> observed counts should arrive	16

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 (<i>N</i>)	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 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.

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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:

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

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