INTERNATIONAL STANDARD

ISO 14644-1

Redline version
compares Second edition to
First edition

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

Reference number
ISO 14644-1:redline:2015(E)

IMPORTANT — PLEASE NOTE

This is a mark-up copy and uses the following colour coding:

Text example 1	— indicates added text (in green)
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1.x ...	— Heading numbers containg modifications are highlighted in yellow in the Table of Contents

All changes in this document have yet to reach concensus by vote and as such should only be used internally for review purposes.

DISCLAIMER

This Redline version provides you with a quick and easy way to compare the main changes between this edition of the standard and its previous edition. It doesn't capture all single changes such as punctuation but highlights the modifications providing customers with the most valuable information. Therefore it is important to note that this Redline version is not the official ISO standard and that the users must consult with the clean version of the standard, which is the official standard, for implementation purposes.

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

~~International Standard ISO 14644-1 was prepared by Technical Committee~~The committee responsible for this document is ISO/TC 209, *Cleanrooms and associated controlled environments*.

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

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 testing and monitoring to prove continued compliance with~~Monitoring to provide evidence of cleanroom performance related to ~~ISO 14644-1~~ air cleanliness by particle concentration*

— *Part 3: ~~Metrology and test~~Test methods*

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

— *Part 5: Operations*

— *Part ~~6: Terms and definitions~~7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)*

— *Part ~~7: Enhanced clean devices~~8: Classification of air cleanliness by chemical concentration (ACC)*

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

— *Part 10: Classification of surface cleanliness by chemical concentration*

~~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~~Attention is also drawn to ISO ~~14644~~14698. ~~Annexes A, D, E,~~ *Cleanrooms and ~~F are for information only.~~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 ~~airborne particulate contamination~~contamination of air and, if appropriate, surfaces, to levels appropriate for accomplishing contamination-sensitive activities. ~~Products and processes that benefit from the control of airborne contamination include those in such industries~~Contamination control can be beneficial for protection of product or process integrity in applications in industries such as aerospace, microelectronics, pharmaceuticals, medical devices, ~~food, and healthcare~~healthcare and food.

This part of ISO 14644 ~~assigns ISO classification levels to be used for the specification~~specifies classes of air cleanliness in ~~cleanrooms and associated controlled environments~~terms of the number of particles expressed as a concentration in air volume. It also ~~prescribes~~specifies the standard method of testing ~~as well as the procedure for determining the concentration of airborne particles~~to determine cleanliness class, including selection of sampling locations.

This edition is the result of a response to an ISO 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 ISO 14644. The nine ISO cleanliness classes are retained with minor revisions. Table 1 defines the particle concentration at various particle sizes for the nine integer classes. Table E.1 defines the maximum particle concentration at various particle sizes for intermediate classes. The use of these tables ensures better definition of the appropriate particle-size ranges for the different classes. This part of ISO 14644 retains the macroparticle descriptor concept; however, consideration of nano-scale particles (formerly defined as ultrafine particles) will be addressed in a separate standard.

The most significant change is the adoption of a more consistent statistical approach to the selection and the number of sampling locations; and the evaluation of the data collected. The statistical model is based on adaptation of the hypergeometric sampling model technique, where samples are drawn randomly without replacement from a finite population. The new approach allows each location to be treated independently with at least a 95 % level of confidence that at least 90 % of the cleanroom or clean zone areas will comply with the maximum particle concentration limit for the target class of air cleanliness. No assumptions are made regarding the distribution of the actual particle counts over the area of the cleanroom or clean zone; while in ISO 14644-1:1999 an underlying assumption was that the particle counts follow the same normal distribution across the room, this assumption has now been discarded to allow the sampling to be used in rooms where the particle counts vary in a more complex manner. In the process of revision it has been recognized that the 95 % UCL was neither appropriate nor was applied consistently in ISO 14644-1:1999. The minimum number of sampling locations required has been changed, compared with ISO 14644-1:1999. A reference table, Table A.1, is provided to define the minimum number of sampling locations required based on a practical adaptation of the sampling model technique. An assumption is made that the area immediately surrounding each sampling location has a homogeneous particle concentration. The cleanroom or clean zone area is divided up into a grid of sections of near equal area, whose number is equal to the number of sampling locations derived from Table A.1. A sampling location is placed within each grid section, so as to be representative of that grid section.

It is assumed for practical purposes that the locations are chosen representatively; a “representative” location (see A.4.2) means that features such as cleanroom or clean zone layout, equipment disposition and airflow systems should be considered when selecting sampling locations. Additional sampling locations may be added to the minimum number of sampling locations.

Finally, the annexes have been reordered to improve the logic of this part of ISO 14644 and portions of the content of certain annexes concerning testing and test instruments have been included from ISO 14644-3:2005.

~~For classification purposes,~~The revised version of this part of ISO 14644 ~~is limited to a designated range of considered particle sizes for determination of particle concentration limits. This part of~~addresses the ≥ 5 µm particle limits~~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~~for ISO Class 5 in the sterile products annexes of the EU, PIC/S and WHO GMPs by way of an adaptation of the macroparticle concept.

ThisThe revised version of 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 ofnow includes all matters related to classification of air cleanliness by particle concentration. The revised version of ISO 14644-2:2015the International Standards prepared by ISO/TC 209 now deals exclusively with the monitoring of air cleanliness by particle concentration.

In some circumstances, relevant regulatory agencies may impose supplementary policies or restrictions. In such situations, appropriate adaptations of the standard testing procedures may be requiredCleanrooms may also be characterized by attributes in addition to the classification of air cleanliness by particle concentration. Other attributes, such as air cleanliness in terms of chemical concentration, may be monitored and the attribute's grade or level may be designated along with the classification of the ISO Class of cleanliness. These additional attributes do not suffice alone to classify a cleanroom or clean zone.

Cleanrooms and associated controlled environments —

Part 1:
Classification of air cleanliness by particle concentration

1 Scope

This part of ISO 14644 specifies the classification of air cleanliness in terms of concentration of airborne particles in cleanrooms and clean zones; and separative devices as defined in ISO 14644-7.

~~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 light scattering (discrete) airborne particle counters (LSAPC) 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 lower threshold 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~~ will be addressed in a separate standard to specify air cleanliness by nano-scale particles. An M descriptor (see Annex C) may be used to quantify populations of macroparticles (particles larger than 5 µm).

This part of ISO 14644 cannot be used to characterize the physical, chemical, radiological, viable or ~~viable~~ other 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 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14644-2:2015, *Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration*

ISO 14644-7, *Cleanrooms and associated controlled environments — Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)*

~~2~~3 ~~Definitions~~ Terms and definitions

For the purposes of this ~~part of ISO 14644~~ document, the following terms and definitions apply.

~~2.1~~3.1 General

~~2.1.1~~3.1.1
cleanroom
room ~~in~~within which the number concentration of airborne particles is controlled and classified, and which is designed, constructed and ~~used~~operated in a manner to ~~minimize~~control 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~~

Note 1 to entry: The class of airborne particle concentration is specified.

Note 2 to entry: Levels of other cleanliness attributes such as chemical, viable or nanoscale concentrations in the air, and also surface cleanliness in terms of particle, nanoscale, chemical and viable concentrations might also be specified and controlled.

Note 3 to entry: Other relevant physical parameters might also be controlled as required, e.g. temperature, humidity, pressure, vibration and electrostatic.

~~2.1.2~~3.1.2
clean zone
~~dedicated space in~~defined space within which the number concentration of airborne particles is controlled and classified, and which is constructed and ~~used~~operated in a manner to ~~minimize~~control 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~~contaminants inside the space

Note 1 to entry: The class of airborne particle concentration is specified.

Note 2 to entry: Levels of other cleanliness attributes such as chemical, viable or nanoscale concentrations in the air, and also surface cleanliness in terms of particle, nanoscale, chemical and viable concentrations might also be specified and controlled.

Note 3 to entry: ~~This zone may be open or enclosed and may or may not be located within~~A clean zone(s) can be a defined space within a cleanroom or might be achieved by a separative device. Such a device can be located inside or outside a cleanroom.

Note 4 to entry: Other relevant physical parameters might also be controlled as required, e.g. temperature, humidity, pressure, vibration and electrostatic.

~~2.1.3~~3.1.3
installation
cleanroom or one or more clean zones, together with all associated structures, air-treatment systems, services and utilities

~~2.1.4~~3.1.4
classification
~~level (or the process of specifying or determining the level) of airborne particulate cleanliness applicable to~~method of assessing level of cleanliness against a specification for 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 to entry: The concentrations are determined by using equation (1) in 3.2~~.

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

Note 1 to entry: ~~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)~~Levels should be expressed 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~~an ISO Class, which represents maximum allowable concentrations of particles in a unit volume of air.

~~Note 4 to entry: 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 to entry: Classification may be specified or accomplished in any of three occupancy states (see 2.4).~~

~~2.2~~3.2 Airborne particles

~~2.2.1~~3.2.1
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~~minute piece of matter with defined physical boundaries

~~2.2.2~~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 1 to entry: For discrete-particle ~~counting~~, light-scattering instruments, the equivalent optical diameter is used.

~~2.2.3~~3.2.3
particle concentration
number of individual particles per unit volume of air

~~2.2.4~~3.2.4
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~~3.2.5
macroparticle
particle with an equivalent diameter greater than 5 µm

3.2.6
M descriptor
designation for 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 1 to entry: The M descriptor can be regarded as an upper limit for the averages at sampling locations. M descriptors cannot be used to define ISO Classes, but the M descriptor may be quoted independently or in conjunction with ISO Classes.

~~2.2.7~~3.2.7
~~fibre~~unidirectional airflow
~~particle having an aspect (length-to-width) ratio of 10 or more~~controlled airflow through the entire cross-section of a cleanroom or a clean zone with a steady velocity and airstreams that are considered to be parallel

3.2.8
non-undirectional airflow
air distribution where the supply air entering the cleanroom or clean zone mixes with the internal air by means of induction

~~2.3 Descriptors~~

~~2.3.1~~
~~U descriptor~~
~~measured or specified concentration, of particles per cubic metre of air, including the ultrafine particles~~

~~Note 1 to entry: 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 1 to entry: 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~~3.3 Occupancy states

~~2.4.1~~3.3.1
as-built
condition where the ~~installation~~cleanroom or clean zone is complete with all services connected and functioning but with no ~~production~~ equipment, ~~materials~~furniture, materials or personnel present

~~2.4.2~~3.3.2
at-rest
condition where the ~~installation~~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

~~2.4.3~~3.3.3
operational
agreed condition where the ~~installation~~cleanroom or clean zone is functioning in the specified manner, with equipment operating and 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						

3.4 Testing instrumentation (see Annex F)

3.4.1
resolution
smallest change in a quantity being measured that causes a perceptible change in the corresponding indication

Note 1 to entry: Resolution can depend on, for example, noise (internal or external) or friction. It may also depend on the value of a quantity being measured.

[SOURCE: ISO/IEC Guide 99:2007, 4.14]

3.4.2
maximum permissible measurement error
extreme value of measurement error, with respect to a known reference quantity value, permitted by specifications or regulations for a given measurement, measuring instrument, or measuring system

Note 1 to entry: Usually, the term "maximum permissible errors" or "limits of error" is used where there are two extreme values.

Note 2 to entry: The term "tolerance" should not be used to designate "maximum permissible error".

[SOURCE: ISO/IEC Guide 99:2007, 4.26]

~~2.5~~ 3.5 ~~Roles~~ Instrument specifications

~~2.5.1~~ 3.5.1
~~customer~~ LSAPC
light scattering airborne particle counter
light scattering discrete airborne particle counter
~~organization, or the agent thereof, responsible for specifying the requirements of a cleanroom or clean zone~~ instrument capable of counting and sizing single airborne particles and reporting size data in terms of equivalent optical diameter

Note 1 to entry: The specifications for the LSAPC are given in ISO 21501-4:2007.