DRAFT INTERNATIONAL STANDARD ISO/DIS 14644-12

ISO/TC **209** Secretariat: **ANSI**

Voting begins on **2013-04-04** Voting terminates on **2013-09-04**

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Cleanrooms and associated controlled environments —

Part 12:
Classification of air cleanliness by nanoscale particle concentration

Salles propres et environnements maîtrisés apparentés —

Partie 12: Classification de la propreté de l'air en fonction de la concentration des nanoparticules

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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Published in Switzerland

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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.

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 14644-12 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: 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*

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

— *Part 12: Classification of air cleanliness by nanoscale 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 the control of contamination to levels appropriate for accomplishing contamination-sensitive activities. Products and processes that benefit from the control of contamination include those in such industries as aerospace, microelectronics, pharmaceuticals, medical devices, healthcare and food.

ISO Technical Committee 209 Cleanrooms and associated controlled environments has issued standards ISO 14644-1 and ISO 14644-3 as listed in the Foreword. The normative requirements in these standards were limited to classification of particles greater than 100 nm. However, informative material was included in both documents for airborne particles smaller than 100 nm. At the time these documents were written, particles smaller than 100 nm were called ultrafine particles rather than the more recent term, nanoparticles.

In the course of current Revisions, sections on ultrafine particles have been removed from ISO 14644 Parts 1 and 3 and incorporated, in modified form, in the present document ISO 14644-12. ISO 14644-12 also extends the airborne particle classification scheme in ISO 14644-1 to particle sizes smaller than 100 nm. Supporting information has also been drawn from documents developed elsewhere, e.g. by ISO Technical Committee 229 Nanotechnologies.

Nanotechnology is a recently organized field, typically dealing with material in the size range of approximately 1 nm to 100 nm. As part of the long term trend of manufacturing products with ever smaller feature size to improve performance, many industries such as microelectrics and those related to health now have products in the nanoscale.

See Annex C for background information on particle size characteristics/properties.

NOTE In consideration of some similarities of rationale and structure between ISO 14644-12 and ISO 14644-1, it is conceivable that these two parts of ISO 14644 could be merged in the future. However, this is not envisaged at present.

Cleanrooms and associated controlled environments — Part 12: Classification of air cleanliness by nanoscale particle concentration

Caution

It is to be noted that the customary classification of cleanrooms by particle concentration requires the use of ISO 14644-1. Nanoscale particle classification using 14644-12 should under operational conditions only be used in addition to particle classification using 14644-1.

1 Scope

This part of ISO 14644 covers the classification of air cleanliness by particles (ACP) in terms of concentration of airborne nanoscale particles.

For classification purposes, only populations of particles with a lower size limit of 0.1 microns (100 nm) or less - "nanoscale" - are considered.

The classification given in this document is for use mainly in "in operation" states. This classification extrapolates the particulate classification equation specified in 14644-1 into the nanoscale (< 100 nm) region.

NOTE 1 For the purposes of this document, reference will be made to "nanoscale particles", which here signify all nano-objects having one (nanoplate), two (nanofibre) or three (nanoparticle) dimensions in the nanoscale.

NOTE 2 It should be noted that the actual behaviour of particles in the cleanroom depends on their sources and physical behaviour.

NOTE 3 Health and safety considerations are excluded from this document.

2 Normative references

ISO 14644-1:1999 Cleanrooms and associated controlled environments -- Part 1: Classification of air cleanliness by particle concentration

ISO 14644-3:2005 Cleanrooms and associated controlled environments -- Part 3: Test methods

ISO 15900:2009 Determination of particle size distribution -- Differential electrical mobility analysis for aerosol particles

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

ISO/TS 27687:2008 Nanotechnologies -- Terminology and definitions for nano-objects -- Nanoparticle, nanofibre and nanoplate[1]

[1] ISO/TS 80004-2, in preparation, will supersede ISO/TS 27687.

ISO 27891[2] Aerosol particle number concentration -- Calibration of condensation particle number counters

ISO/TS 80004-1:2010 Nanotechnologies -- Vocabulary -- Part 1: Core terms

3 Definitions

For the purposes of this part of ISO 14644, the definitions given in ISO 14644-1, ISO 14644-3, ISO/TS 27687 and ISO/TS 80004-1 and the following 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 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

[ISO 14644-1: definition 2.1.1]

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 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.

[ISO 14644-1: definition 2.1.2]

3.2 Size

3.2.1
nanoscale
size range from approximately 1 nm to 100 nm

NOTE 1 Properties that are not extrapolations from a larger size will typically, but not exclusively, be exhibited in this size range. For such properties the size limits are considered approximate.

NOTE 2 The lower limit in this definition (approximately 1 nm) is introduced to avoid single and small groups of atoms from being designated as nano-objects or elements of nanostructures, which might be implied by the absence of a lower limit.

[ISO 27687: definition 2.1]

3.2.2
nano-object
material with one, two or three external dimensions in the nanoscale

NOTE Generic term for all discrete nanoscale objects.

[ISO 27687: definition 2.2]

[2] To be published .

3.2.3
particle size cutoff
D_{50}
particle size at which the counting efficiency is 50 %

NOTE See annex B for explanation of counting efficiency.

3.3 Airborne particles

3.3.1
nanoparticle
nano-object with all three external dimensions in the nanoscale

NOTE If the lengths of the longest to the shortest axes of the nano-object differ significantly (typically by more than three times), the terms nanorod or nanoplate are intended to be used instead of the term nanoparticle.

[ISO 27687: definition 4.1]

3.3.2
particle size distribution
cumulative distribution of particle concentration as a function of particle size

[ISO 14644-1: definition 3.2.4]

3.3.3
aerosol
system of solid or liquid particles suspended in gas

[ISO 15900: definition 2.1]

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

[14644-1: definition 2.4.1]

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

[14644-1: definition 1.4.2]

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

[14644-1: definition 2.4.3]

3.5 Measuring apparatus

3.5.1
condensation particle counter
CPC
instrument that measures the airborne particle number concentration by condensing a liquid onto the particles from a supersaturated vapour and counting the resulting droplets

NOTE 1 The sizes of particles detected are usually smaller than several hundred nanometres and larger than a few nanometres.

NOTE 2 A CPC is one possible detector for use with a differential electrical mobility analyser.

NOTE 3 In some cases, a condensation particle counter may be called a condensation nucleus counter (CNC).

3.5.2
differential electrical mobility classifier
DEMC
classifier that is able to select aerosol particles according to their electrical mobility and pass them to its exit

NOTE A DEMC classifies aerosol particles by balancing the electrical force on each particle with its aerodynamic drag force in an electrical field. Classified particles are in a narrow range of electrical mobility determined by the operating conditions and physical dimensions of the DEMC, while they can have different sizes due to differences in the number of charges that they have

[ISO 15900: definition 2.7]

3.5.3
differential mobility analyzing system
DMAS
system to measure the size distribution of submicrometre aerosol particles consisting of a DEMC, flow meters, a particle detector, interconnecting plumbing, a computer and suitable software

[ISO 15900: definition 2.8]

3.5.4
Counting efficiency
ratio of the reported concentration of particles in a given size range to the actual concentration of such particles

[ISO 14644-3: definition 3.6.5]

4 Classification

4.1 General

For the purposes of this classification document the term "nanoscale particles" will be used instead of the generic term "nano-objects". This is necessary because, for measurement purposes, the only important particle characteristic is its "equivalent diameter". In this document, "nanoscale particle" signifies any object with one, two or three dimensions in the nanoscale.

4.2 Occupancy states

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

4.3 Classification number

The air particle cleanliness class in a cleanroom or associated controlled environment shall be designated by a classification number, *N*, specifying the maximum total particle concentration in air permitted for a considered nanoscale particle size.

NOTE This is an extension of the considered particle size range of the classification described in 14644-1 into the nanoscale.

Airborne particulate cleanliness shall be designated by a classification number, N. The maximum permitted concentration of particles Cn, for each considered particle size, D, is determined by the formula [ISO 4644-1]:

$$C_{n,m} = 10^{N} \times (0.1/D)^{2.08} \qquad (1)$$

where:

$C_{n,m}$ represents the maximum permitted concentration (in particles/m^3) of airborne particles at a specific class that are equal to or larger than the considered particle size. $C_{n,m}$ 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.

D is the considered particle size in µm.

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

NOTE 1 Equation 1 was used to compute particle concentrations expected for classifications of particles smaller than 0,1 µm extending the classes in ISO 14644-1. It is acknowledged that metrology may not be available at the present time to quantify all the presented classes.

NOTE 2 A given facility may have a classification for microscale cleanliness under ISO 14644-1 and nanoscale cleanliness under ISO 14644-12.

NOTE 3 The cleanroom is tested in an operational state – see C.3.

The maximum permitted concentration of particles, $C_{n,m}$, for each considered particle size, *D*, is determined from Table 1.

Table 1 – Classification table for ISO-ACP classes

Classification	Particle sizes				
	0,001µm (1nm)[d]	0,005µm (5nm)	0,01µm (10nm)	0,05µm (50nm)	0,1 µm
1	145 000 [d]	5 080	1 200	[c]	*10* [a]
2	1 450 000 [d]	50 800	12 000	423	100
3	14 500 000 [d]	508 000	120 000	4 230	1 000
4	145 000 000[d]	5 080 000	1 200 000	42 300	10 000
5	[b]	50 800 000	12 000 000	423 000	100 000
6	[b]	[b]	[b]	4 230 000	1 000 000
7	[b]	[b]	[b]	[b]	[b]
8	[b]	[b]	[b]	[b]	[b]
9	[b]	[b]	[b]	[b]	[b]
Notes:					