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Cleanrooms and associated controlled environments —

Part 9: Classification of surface cleanliness by particle concentration

Salles propres et environnements maîtrisés apparentés —

Partie 9: Classification de la propreté des surfaces par la concentration de particules

Reference number
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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 14644-9 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 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 air cleanliness by chemical concentration*

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

— *Part 10: Classification of surface cleanliness by chemical 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 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, optics, nuclear, and life sciences (pharmaceuticals, medical devices, food, healthcare).

ISO 14644-1 to ISO 14644-8 and ISO 14698-1 and ISO 14698-2 (biological contamination) deal exclusively with airborne particle and chemical contamination. Many factors, besides the classification of surface cleanliness, should be considered in the design, specification, operation and control of cleanrooms and other controlled environments. These factors are covered in some detail in other parts of ISO 14644 and ISO 14698.

This part of ISO 14644 provides a classification for the determination and designation of surface cleanliness levels based on particle concentrations. This part of ISO 14644 also lists some methods of testing, as well as procedure(s) for determining the concentration of particles on surfaces.

Where regulatory agencies impose supplementary guidelines or restrictions, appropriate adaptations of the testing procedures might be required.

Cleanrooms and associated controlled environments —

Part 9:
Classification of surface cleanliness by particle concentration

1 Scope

This part of ISO 14644 establishes the classification of cleanliness levels on solid surfaces by particle concentration in cleanrooms and associated controlled environment applications. Recommendations on testing and measuring methods, as well as information about surface characteristics, are given in Annexes A to D.

This part of ISO 14644 applies to all solid surfaces in cleanrooms and associated controlled environments, such as walls, ceilings, floors, working environments, tools, equipment and products. The classification of surface cleanliness by particle concentration (SCP) is limited to particles between 0,05 µm and 500 µm.

The following issues are not considered in this part of ISO 14644:

— requirements for the cleanliness and suitability of surfaces for specific processes;

— procedures for the cleaning of surfaces;

— material characteristics;

— references to interactive bonding forces or generation processes that are usually time-dependent and process-dependent;

— selection and use of statistical methods for classification and testing;

— other characteristics of particles, such as electrostatic charge, ionic charges, microbiological state, etc.

2 Normative references

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

ISO 14644-6:2007, *Cleanrooms and associated controlled environments — Part 6: Vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14644-6:2007 and the following apply.

3.1
descriptor for specific particle size ranges
differential descriptor that expresses SCP level within specific particle size ranges

NOTE The descriptor may be applied to particle size ranges of special interest or those particle size ranges that are outside the range of the classification system, and specified independently or as a supplement to the SCP classes.

3.2
direct measurement method
assessment of the contamination without any intermediate steps

3.3
indirect measurement method
assessment of the contamination with intermediate steps

3.4
solid surface
boundary between the solid and a second phase

3.5
surface particle
solid and/or liquid matter adhered and discretely distributed on a surface of interest, excluding film-like matter that covers the whole surface

NOTE Surface particles are adhered via chemical and/or physical interactions.

3.6
surface cleanliness by particle concentration
SCP
condition of a surface with respect to its particle concentration

NOTE The surface cleanliness depends upon material and design characteristics, stress loads (complexity of loads acting on a surface) and prevailing environmental conditions, along with other factors.

3.7
surface cleanliness by particle concentration class
SCP class

grading number stating the maximum allowable surface concentration, in particles per square metre, for a considered size of particles (SCP Classes 1 to 8)

3.8
surface cleanliness by particle concentration classification
SCP classification
level (or the process of specifying or determining the level) that represents maximum allowable surface concentrations, in particles per square metre, for considered sizes of particles, expressed in terms of an ISO SCP Class N

3.9
surface particle concentration
number of individual particles per unit of surface area under consideration

4 Abbreviated terms

For the purposes of this document, the following abbreviated terms apply.

AFM atomic force microscopy

CNC condensation nucleus counter

EDX energy dispersive X-ray spectroscopy

ESCA electron spectroscopy for chemical analysis

ESD electrostatic discharge

IR infrared (absorption spectroscopy)

OPC optical particle counter

PET polyethylene terephthalate

SCP surface cleanliness by particle concentration

SEM scanning electron microscopy

UV ultraviolet (spectroscopy)

WDX wavelength-dispersive X-ray spectroscopy

5 Classification system

5.1 ISO-SCP classification format

The class of surface cleanliness by particle concentration (SCP) in a cleanroom or associated controlled environment shall be designated by a classification number, N, specifying the maximum total particle concentration on surfaces permitted for a considered particle size. N shall be determined from the following equation with the maximum permitted total particle concentration on the surface, $C_{\text{SCP;D}}$, in particles per square metre of surface, for each considered particle size, D:

$$C_{\text{SCP;D}} = k\,\frac{10^{N}}{D} \qquad (1)$$

where

$C_{\text{SCP;D}}$ is the maximum permitted total surface concentration, in particles per square metre of surface, of particles that are equal to or larger than the considered particle size; $C_{\text{SCP;D}}$ is rounded to the nearest whole number, using no more than three significant figures;

N is the SCP classification number, which is limited to SCP Class 1 through SCP Class 8; SCP Class number N is represented by the measured particle diameter D, in micrometres;

NOTE N refers to the exponent base 10 for the concentration of particles at the reference particle size of 1 µm.

D is the considered particle size, in micrometres.

k is a constant 1, in micrometres.

NOTE 1 The SCP class based on the particle concentration can be a time- and process-dependent value due to the dynamic characteristics of particle generation and transportation.

NOTE 2 Due to the complexity of statistical evaluations and readily available additional references, the selection and use of statistical methods for classification and testing are not described in this part of ISO 14644.

The concentration $C_{\text{SCP;D}}$, as derived from Equation (1), shall serve as the definitive value. Table 1 presents selected SCP classes and corresponding maximum cumulative permitted total surface concentrations for considered particle sizes.

Figure 1 provides a representation of the selected classes in graphical form.

Table 1 — Selected SCP classes for cleanrooms and associated controlled environments

Units in particles per square metre

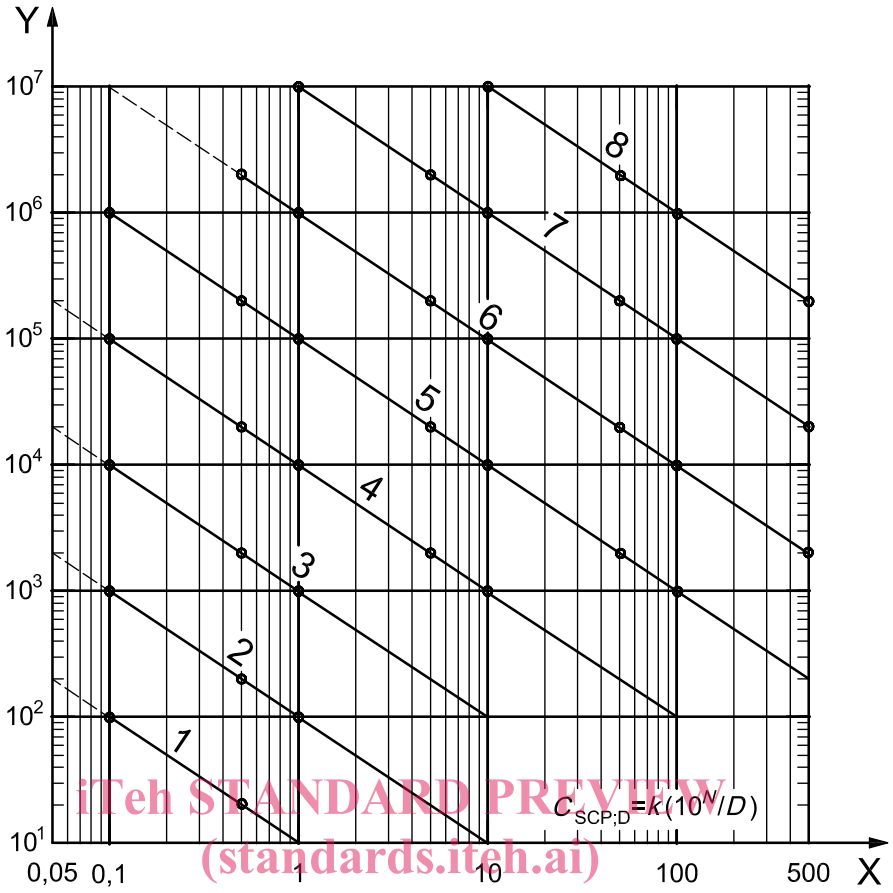
SCP Class	Particle size								
	≥ 0,05 µm	≥ 0,1 µm	≥ 0,5 µm	≥ 1 µm	≥ 5 µm	≥ 10 µm	≥ 50 µm	≥ 100 µm	≥ 500 µm
SCP Class 1	(200)	100	20	(10)					
SCP Class 2	(2 000)	1 000	200	100	(20)	(10)			
SCP Class 3	(20 000)	10 000	2 000	1 000	(200)	(100)			
SCP Class 4	(200 000)	100 000	20 000	10 000	2 000	1 000	(200)	(100)	
SCP Class 5		1 000 000	200 000	100 000	20 000	10 000	2 000	1 000	(200)
SCP Class 6		(10 000 000)	2 000 000	1 000 000	200 000	100 000	20 000	10 000	2 000
SCP Class 7				10 000 000	2 000 000	1 000 000	200 000	100 000	20 000
SCP Class 8						10 000 000	2 000 000	1 000 000	200 000

The values in Table 1 are concentrations of particles of the related particle size and SCP class per surface area of one square metre (1 m^2) equal to or larger than the considered particle size ($C_{SCP;D}$).

For figures in parentheses, the corresponding particle sizes should not be used for classification purposes; select another particle size for classification.

The minimum area for testing should be statistically representative of the surface under consideration.

NOTE Classification of the lower SCP classes requires numerous measurements to establish a significant value.



Key

X considered particle size, D (µm)

Y particle concentration on a surface $\geq D$, $C_{SCP;D}$ (particles/m^2)

1 SCP Class 1
2 SCP Class 2
3 SCP Class 3
4 SCP Class 4
5 SCP Class 5
6 SCP Class 6
7 SCP Class 7
8 SCP Class 8

The solid classification lines shown on the graph shall be used for classification purposes. The dashed lines should not be used for classification purposes.

NOTE Particle distribution on surfaces typically is not a normal distribution, but is affected by different factors, such as roughness, porosity, electrostatic charge, deposition mechanisms, etc. (see Annex A).

EXAMPLE SCP Class 5 (1 µm) signifies that 1 m^2 of surface may carry a maximum of 10^5 particles with a considered particle size ≥ 1 µm (D = 1). SCP Class 5 (10 µm) signifies that 1 m^2 of surface may carry a maximum of 10^4 particles per square metre with a considered particle size ≥ 10 µm (D = 10). Any other measured particle size ($D = x$) which leads to a concentration that lies below the relevant SCP class line is within the specification of SCP Class 5 (x µm).

Figure 1 — SCP classes

For particle sizes out of the classification system and in cases where only a narrow particle range or individual particle sizes are of interest, a descriptor can be used (see Annex B).

5.2 Designation

The SCP class number shall be formatted as follows: SCP Class N (D µm).

The designation of the SCP class for cleanrooms and associated controlled environments shall also include the following:

a) the surface type measured;

b) the surface area measured;

c) the measurement method applied.

Details of measurement methods applied, including sampling techniques and measurement devices, should be retrieved from test reports.

The considered particle size should be determined by agreement between the customer and supplier.

The SCP classification shall be stated in relation to the measured particle size diameter.

EXAMPLE 1 SCP Class 2 (0,1 µm); wafer or glass substrate, surface area: 310 cm^2; surface particle counter.

EXAMPLE 2 SCP Class 5 (0,5 µm); inner wall of a bottle, surface area: 200 cm^2; liquid dispersion — liquid particle counter.

5.3 General information on surface cleanliness by particle concentration

Airborne particle concentration and surface particle concentration are generally related. The relationship is dependent on many factors, such as airflow turbulence, rate of deposition, time of deposition, deposition velocity, concentration within the air, and surface characteristics such as electrostatic charge (see A.2.4).

To determine surface cleanliness by particle concentration, various parameters (see Annex C) and surface characteristics (see Annex A) that influence testing should be taken into account.

6 Demonstration of compliance

6.1 Principle

Compliance with SCP class requirements, as specified by the customer, is verified by performing tests and by providing documentation of the results and conditions of the testing.

Details for demonstrating compliance (see 6.3) shall be agreed upon between the customer and supplier in advance of testing.

6.2 Testing

Tests performed to demonstrate compliance shall be conducted in a controlled environment using suitable test methods and calibrated instruments, whenever possible.

Direct and indirect test methods can be used for demonstrating compliance and are given in Annex D. The list of typical methods described is not exhaustive. Alternative methods of comparable accuracy may be specified by agreement.

NOTE Measurement by different methods, even when correctly applied, can produce different results of equal validity.

Repeated measurements are recommended.