BS EN ISO 14644-9:2012

BSI Standards Publication

Cleanrooms and associated controlled environments

Part 9: Classification of surface cleanliness by particle concentration (ISO 14644-9:2012)

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National foreword

This British Standard is the UK implementation of EN ISO 14644-9:2012.

The UK participation in its preparation was entrusted to Technical Committee LBI/30, Cleanroom technology.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Foreword

This document (EN ISO 14644-9:2012) 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of an identical text or by endorsement, at the latest by February 2013, and conflicting national standards shall be withdrawn at the latest by February 2013.

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Endorsement notice

The text of ISO 14644-9:2012 has been approved by CEN as a EN ISO 14644-9:2012 without any modification.

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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.

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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*

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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.

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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

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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

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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, $C_{\mathrm{SCP;D}}$, in particles per square metre of surface, for each considered particle size, D:

$$C_{\mathrm{SCP;D}} = k \frac{10^{N}}{D} \tag{1}$$

where

$C_{\mathrm{SCP;D}}$ 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; $C_{\mathrm{SCP;D}}$ 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 $C_{\mathrm{SCP;D}}$, 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.

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