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BS EN ISO 14644-14:2016



BSI Standards Publication

Cleanrooms and associated controlled environments

Part 14: Assessment of suitability for use of equipment by airborne particle concentration (ISO 14644-14:2016)

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This British Standard is the UK implementation of EN ISO 14644-14:2016.

BSI, as a member of CEN, is obliged to publish EN ISO 14644-14:2016 as a British Standard. However, attention is drawn to the fact that during the development of this European Standard, the UK committee voted against its approval as a European Standard. The UK committee is of the opinion that a lack of emphasis has been placed on the importance and value of the optional "Total emission measurement method" described in informative clause B.4. In particular, this method provides important information that can be used to determine the required supply air volume in non-unidirectional airflow cleanrooms to mitigate the airborne particle load in the room. Calculated supply air volume requirements are an essential part of BS EN ISO 14644-4:2001 and the forthcoming ISO 14644-16 standard. In addition, the UK committee views that the method specified in clause 6 described as "measurement of airborne particle emissions at critical locations", should be used with caution. High levels of particle generation from some equipment can be mitigated by the use of local exhaust ventilation to prevent an adverse effect on the room class at critical control points due to migration of airborne particles.

In light of these concerns, the UK committee refers users of this standard to the paragraph at the end of clause 4 which states, "The method described in B.4 may be used to determine the average total emission of equipment and provides data that may be used to determine the particle load on a cleanroom". The UK committee advises that clause B.4 be utilised to allow the customer and supplier to select this method when it is more appropriate than the method described in clause 6. The reason for this decision should be documented when claiming conformance with BS EN ISO 14644-14:2016.

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.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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Cleanrooms and associated controlled environments - Part 14: Assessment of suitability for use of equipment by airborne particle concentration (ISO 14644-14:2016)

Salles propres et environnements maîtrisés apparentés
- Partie 14: Évaluation de l'aptitude à l'emploi des
équipements par la détermination de la concentration
de particules en suspension dans l'air (ISO 14644-
14:2016)

Reinräume und zugehörige Reinraumbereiche - Teil
14: Bewertung der Reinraumtauglichkeit von Geräten
durch Partikelkonzentration in der Luft (ISO 14644-
14:2016)

This European Standard was approved by CEN on 13 August 2016.

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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

European foreword

This document (EN ISO 14644-14:2016) 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 April 2017, and conflicting national standards shall be withdrawn at the latest by April 2017.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 14644-14:2016 has been approved by CEN as EN ISO 14644-14:2016 without any modification.

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Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 General outline of the assessment	3
5 Visual inspection	3
6 Assessment of suitability by airborne particle concentration measurements	4
6.1 General.....	4
6.2 Assessment procedure.....	4
6.2.1 Overview.....	4
6.2.2 Requirements and considerations.....	5
6.2.3 Representative mode of operation.....	6
6.2.4 Considerations for the test environment.....	6
6.2.5 Determination of the test environment.....	6
6.2.6 Approximate identification of HPC location(s).....	6
6.2.7 Precise determination of HPC location(s).....	7
6.2.8 Suitability measurement(s).....	7
6.2.9 Data processing.....	8
6.2.10 Reference to ISO 14644-1 classification system.....	10
7 Documentation	10
7.1 General.....	10
7.2 Common documentation requirements.....	10
7.3 Documentation for visual inspection.....	11
7.4 Documentation for assessment of test environment.....	11
7.5 Documentation for classification measurement.....	12
8 Statement on cleanroom suitability	12
Annex A (informative) Example for data processing deriving from measurements	14
Annex B (informative) Additional optional tests	18
Bibliography	21

This is a preview of "BS EN ISO 14644-14:2...". Click here to purchase the full version from the ANSI store.

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.

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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 209, *Cleanrooms and associated controlled environments*.

A list of all part in the ISO 14644 series, published under the general title *Cleanrooms and associated controlled environments*, can be found on the ISO website.

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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 and healthcare).

This part of ISO 14644 links the cleanroom classification of air cleanliness by particle concentration to the suitability of equipment for use in cleanrooms and associated controlled environments.

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Cleanrooms and associated controlled environments —

Part 14:

Assessment of suitability for use of equipment by airborne particle concentration

1 Scope

This part of ISO 14644 specifies a methodology to assess the suitability of equipment (e.g. machinery, measuring equipment, process equipment, components and tools) for use in cleanrooms and associated controlled environments, with respect to airborne particle cleanliness as specified in ISO 14644-1. Particle sizes range from 0,1 μm to equal to or larger than 5 μm (given in ISO 14644-1).

NOTE Where regulatory agencies impose supplementary guidelines or restrictions, appropriate adaptation of the assessment methodology can be required.

The following items are not covered by this part of ISO 14644:

- assessment of suitability with respect to biocontamination;
- testing for suitability of decontamination agents and techniques;
- cleanability of equipment and materials;
- requirements on design of equipment and selection of materials;
- physical properties of materials (e.g. electrostatic, thermal properties);
- optimizing performance of equipment for specific process applications;
- selection and use of statistical methods for testing;
- protocols and requirements for local safety regulations.

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 14644-1:2015, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

cleanliness

condition not exceeding a specified level of contamination