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Čiste sobe in podobna nadzorovana okolja - 1. del: Klasifikacija čistosti zraka s pomočjo koncentracije delcev (ISO/DIS 14644-1:2010)

Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO/DIS 14644-1:2010)

Reinräume und zugehörige Reinraumbereiche - Teil 1: Klassifizierung der Luftreinheit anhand der Partikelkonzentration (ISO/DIS 14644-1:2010)

Salles propres et environnements maîtrisés apparentés - Partie 1: Classification de la propreté particulaire de l'air (ISO/DIS 14644-1:2010)

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Ta slovenski standard je istoveten z: prEN ISO 14644-1

ICS:

13.040.35	Brezprašni prostori in povezana nadzorovana okolja	Cleanrooms and associated controlled environments

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN ISO 14644-1

December 2010

ICS 13.040.35

Will supersede EN ISO 14644-1:1999

English Version

Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO/DIS 14644-1:2010)

Salles propres et environnements maîtrisés apparentés - Partie 1: Classification de la propreté particulaire de l'air (ISO/DIS 14644-1:2010)

Reinräume und zugehörige Reinraumbereiche - Teil 1: Klassifizierung der Luftreinheit anhand der Partikelkonzentration (ISO/DIS 14644-1:2010)

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 243.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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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Contents

Page

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Foreword

This document (prEN ISO 14644-1:2010) 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 document is currently submitted to the parallel Enquiry.

This document will supersede EN ISO 14644-1:1999.

Endorsement notice

The text of ISO/DIS 14644-1:2010 has been approved by CEN as a prEN ISO 14644-1:2010 without any modification.

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DRAFT INTERNATIONAL STANDARD ISO/DIS 14644-1

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

Voting begins on **2010-12-02** Voting terminates on **2011-05-02**

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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

[Revision of first edition (ISO 14644-1:1999)]

ICS 13.040.35

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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.

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oSIST prEN ISO 14644-1:2011

Contents

Page

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SIST EN ISO 14644-1:2016
https://standards.iteh.ai/catalog/standards/sist/505acaf6-dc19-4e80-af71-67d5df8a5ad3/sist-en-iso-14644-1-2016

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Foreword

This edition is the result of a 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 the standard. The nine ISO cleanliness classes are retained unchanged, but Table 1 defines the particle concentration at various particle sizes for the nine integer classes. The use of Table 1 ensures better definition of the appropriate particle-size ranges for the different classes. A formula is retained to allow definition of intermediate decimal classes. The standard retains the concept of ultrafine and macroparticle descriptors for particle sizes outside the range appropriate for measurement using airborne particle counters.

The most significant change is the adoption of a more consistent statistical approach to the selection of number of sample locations and the evaluation of the data collected. The number of sample locations compared with the 1999 version of the standard have been changed. The approach allows each location to be treated independently with a 95 % level of confidence that at least 90 % of the cleanroom or clean zone will comply with the maximum particle concentration limit for the target class of air cleanliness. A reference table is provided to define the number of sample locations required. Because a degree of randomness is required, the cleanroom or clean zone is then divided into equal sectors and the sample location placed randomly within each sector.

Finally, the annexes have been reordered to improve the logic of the standard.

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 14644-1 was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*.

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

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 monitoring and periodic testing to prove continued compliance with ISO 14644-1:XXXX*

— *Part 3: Test methods*

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— *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*

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 of air or surfaces to levels appropriate for accomplishing contamination-sensitive activities. Contamination control can be beneficial for protection of product or process integrity in applications such as aerospace, microelectronics, pharmaceuticals, medical devices and healthcare.

This part of ISO 14644 specifies ISO classes of air cleanliness in terms of particle concentration in air volume. It also specifies the standard method of testing to determine classification, including selection of sampling locations, and evaluation of class from the data collected.

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Cleanrooms and associated controlled environments —

Part 1:
Classification of air cleanliness by particle concentration

1 Scope

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 discrete-particle airborne counting and sizing instruments 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 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 (see 3.3.1 and 3.3.2), respectively.

This part of ISO 14644 cannot be used to characterise the physical, chemical, radiological or viable nature of airborne particles.

NOTE The actual distribution of particle concentrations within incremental size ranges is normally not predictable and is typically variable over time.

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2 Normative reference

The following normative document contains provisions, which, through reference in this text, constitute provisions of this part of ISO 14644. Subsequent amendments to or revisions of this publication do not apply. However, parties to agreements based on this part of ISO 14644 are encouraged to investigate the possibility of applying the most recent editions of the normative document indicated below.

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

3 Definitions

For the purposes of this part of ISO 14644, the following definitions 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 minimise 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

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