SLOVENSKI STANDARD
oSIST prEN ISO 14644-2:2011

01-april-2011

Čiste sobe in podobna nadzorovana okolja - 2. del: Specifikacije za nadzor in periodične preskuse za dokazovanje stalne skladnosti z ISO 14644-1 (ISO/DIS 14644-2:2010)

Cleanrooms and associated controlled environments - Part 2: Specifications for monitoring and periodic testing to prove continued compliance with ISO 14644-1 (ISO/DIS 14644-2:2010)

Reinräume und zugehörige Reinraumbereiche - Teil 2: Festlegungen für die Überwachung und periodische Prüfung zum Nachweis der fortlaufenden Übereinstimmung mit ISO 14644-1 (ISO/DIS 14644-2:2010)

Salles propres et environnements maîtrisés apparentés - Partie 2: Exigences pour la surveillance et les contrôles périodiques en vue de démontrer le maintien de la conformité avec l'ISO 14644-1 (ISO/DIS 14644-2:2010)

Ta slovenski standard je istoveten z: **prEN ISO 14644-2**

ICS:

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

oSIST prEN ISO 14644-2:2011 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN ISO 14644-2

December 2010

ICS 13.040.35

Will supersede EN ISO 14644-2:2000

English Version

Cleanrooms and associated controlled environments - Part 2: Specifications for monitoring and periodic testing to prove continued compliance with ISO 14644-1 (ISO/DIS 14644-2:2010)

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Reinräume und zugehörige Reinraumbereiche - Teil 2: Festlegungen für die Überwachung und periodische Prüfung zum Nachweis der fortlaufenden Übereinstimmung mit ISO 14644-1 (ISO/DIS 14644-2:2010)

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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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Ref. No. prEN ISO 14644-2:2010: E

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Foreword

This document (prEN ISO 14644-2:2010) 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 14644-2:2000.

Endorsement notice

The text of ISO/DIS 14644-2:2010 has been approved by CEN as a prEN ISO 14644-2:2010 without any modification.

DRAFT INTERNATIONAL STANDARD ISO/DIS 14644-2

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 2:
Specifications for monitoring and periodic testing to prove continued compliance with ISO 14644-1

Salles propres et environnements maîtrisés apparentés —

Partie 2: Exigences pour la surveillance et les contrôles périodiques en vue de démontrer le maintien de la conformité avec l'ISO 14644-1

[Revision of first edition (ISO 14644-2:2000)]

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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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 14644-2 was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*.

This second edition cancels and replaces in whole the first edition (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*

— *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*

Introduction

This part of ISO 14644 provides a process to prove continued compliance with ISO 14644-1:XXXX and specifies minimum requirements for testing and monitoring. In any testing plan, consideration should also be given to the particular operational requirements, risk assessment of the installation, and its use.

Cleanrooms and associated controlled environments provide for the control of airborne particulate contamination to levels appropriate for accomplishing contamination-sensitive activities. Products and processes that benefit from the control of airborne contamination include aerospace, microelectronics, pharmaceuticals, medical devices, healthcare, food and others. Many factors besides airborne particulate cleanliness should be considered in the design, specification, operation and control of cleanrooms and other controlled environments.

In some circumstances, relevant regulatory agencies may impose supplementary policies or restrictions. In such situations, appropriate adaptations of the standard testing procedures may be required.