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Cleanrooms and associated controlled environments - Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 14644-2:2001 sisaldab Euroopa standardi EN ISO 14644-2:2000 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 16.02.2001 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 14644-2:2001 consists of the English text of the European standard EN ISO 14644-2:2000.</p> <p>This document is endorsed on 16.02.2001 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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<p>Käsitlusala: This part of the Standard specifies requirements for periodic testing of a cleanroom or clean zone to prove its continued compliance with ISO 14644-1 for the designated classification of airborne particulate cleanliness.</p>	<p>Scope: This part of the Standard specifies requirements for periodic testing of a cleanroom or clean zone to prove its continued compliance with ISO 14644-1 for the designated classification of airborne particulate cleanliness.</p>
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Võtmesõnad: air purity, clean rooms, clean-room technology, definitions, impurities, particles, specification (approval), specifications, testing

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English version

Cleanrooms and associated controlled environments

Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
(ISO 14644-2 : 2000)

Salles propres et environnements maîtrisés apparentés – Partie 2: Spécifications pour les essais et la surveillance en vue de démontrer le maintien de la conformité avec l'ISO 14644-1 (ISO 14644-2 : 2000)

Reinräume und zugehörige Reinraumbereiche – Teil 2: Festlegungen zur Prüfung und Überwachung zum Nachweis der fortlaufenden Übereinstimmung mit ISO 14644-2 (ISO 14644-2 : 2000)

This European Standard was approved by CEN on 2000-09-15.

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 Central Secretariat or to any CEN member.

The European Standards exist 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Foreword

International Standard

ISO 14644-2 : 2000 Cleanrooms and associated controlled environments – Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1,

which was prepared by ISO/TC 209 'Cleanrooms and associated controlled environments' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 243 'Cleanroom technology', the Secretariat of which is held by BSI, as a European Standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by March 2001 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 14644-2 : 2000 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to international publications are listed in Annex ZA (normative.)

Contents

	Page
Foreword.....	2
Introduction.....	2
1 Scope.....	3
2 Normative references.....	3
3 Terms and definitions.....	3
3.1 General terms.....	3
3.2 Terms concerning frequency intervals.....	4
4 Demonstration of continued compliance.....	4
4.1 Principle.....	4
4.2 Testing for continued compliance.....	4
4.3 Monitoring.....	6
4.4 Documentation.....	6
4.5 Records.....	7
Annex A (informative) Optional tests.....	7
Annex B (informative) Guidance on the influence of risk assessment on cleanroom or clean zone tests and monitoring.....	7

Introduction

This part of ISO 14644 provides a process to prove continued compliance with ISO 14644-1 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.

1 Scope

This part of ISO 14644 specifies requirements for periodic testing of a cleanroom or clean zone to prove its continued compliance with ISO 14644-1 for the designated classification of airborne particulate cleanliness.

These requirements invoke the test described in ISO 14644-1 for classification of a cleanroom or clean zone. Additional tests are also specified, to be carried out in accordance with the requirements of this part of ISO 14644. Optional tests, to be applied at the user's discretion, are also identified.

This part of ISO 14644 also specifies requirements for monitoring of a cleanroom or clean zone (hereafter referred to as an installation) to provide evidence of its continued compliance with ISO 14644-1 for the designated classification of airborne particulate cleanliness.

2 Normative references

The following normative document contains provisions which, through reference in this text, constitute provisions of this part of ISO 14644. For dated references, subsequent amendments to, or revisions of, any of these publications 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 documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 14644-1:1999, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness*.

ISO 14644-3:—¹⁾, *Cleanrooms and associated controlled environments — Part 3: Metrology and test methods*.

3 Terms and definitions

For the purposes of this part of ISO 14644, the terms and definitions given in ISO 14644-1 and the following apply.

3.1 General terms

3.1.1

requalification

execution of the test sequence specified for the installation to demonstrate compliance with ISO 14644-1 according to the classification of the installation, including the verification of the selected pre-test conditions

1) To be published.