

Puhasruumid ja nendega ühendatud kontrollitavad keskkonnad. Osa 1: Õhu puhtuse liigitus

Cleanrooms and associated controlled environments. Part 1: Classification of airborne particulate cleanliness for cleanrooms and clean zones

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 14644-1:2000 sisaldab Euroopa standardi EN ISO 14644-1:1999 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 11.01.2000 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 14644-1:2000 consists of the English text of the European standard EN ISO 14644-1:1999.</p> <p>This document is endorsed on 11.01.2000 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>
--	---

<p>Käsitlusala: This part of standard covers the classification of air cleanliness in cleanrooms and associated controlled environments. Classification in accordance with this standard is specified and accomplished exclusively in terms of concentration of airborne particles.</p>	<p>Scope: This part of standard covers the classification of air cleanliness in cleanrooms and associated controlled environments. Classification in accordance with this standard is specified and accomplished exclusively in terms of concentration of airborne particles.</p>
--	--

ICS 13.040.30

Võtmesõnad:

ICS 13.040.00

English version

Cleanrooms and associated controlled environments

Part 1: Classification of air cleanliness

(ISO 14644-1 : 1999)

Salles propres et environnements
maîtrisés apparentés – Partie 1:
Classification de la propreté de l'air
(ISO 14644-1 : 1999)

Reinräume und zugehörige Reinraum-
bereiche – Teil 1: Klassifizierung der
Luftreinheit (ISO 14644-1 : 1999)

This European Standard was approved by CEN on 1999-03-03.

CEN members are bound to comply with the CEN/GENELEC 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 14644-1 : 1999 Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness,

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 November 1999 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 14644-1 : 1999 was approved by CEN as a European Standard without any modification.

Contents

	Page
Foreword	2
Introduction	3
1 Scope	4
2 Definitions	4
3 Classification	6
4 Demonstration of compliance	7
Annexes	
Annex A (informative) Graphical illustration of the classes of Table 1	8
Annex B (normative) Determination of particulate cleanliness classification using a discrete-particle-counting, light-scattering instrument	9
Annex C (normative) Statistical treatment of particle concentration data	12
Annex D (informative) Worked examples of classification calculations	13
Annex E (informative) Considerations for the counting and sizing of particles outside the size range applicable for classification	16
Annex F (informative) Sequential sampling procedure	18
Bibliography	20
Figures	
Figure A.1 Graphical representation of ISO-class concentration limits for selected ISO classes	8
Figure F.1 Boundaries for pass or fail by the sequential sampling procedure	18
Tables	
Table 1 Selected airborne particulate cleanliness classes for cleanrooms and clean zones	6
Table C.1 Student's <i>t</i> distribution for the 95% upper confidence limit	12
Table F.1 Upper and lower limits for time at which <i>C</i> observed counts should arrive	19

Introduction

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 those in such industries as aerospace, microelectronics, pharmaceuticals, medical devices, food, and healthcare.

This part of ISO 14644 assigns ISO classification levels to be used for the specification of air cleanliness in cleanrooms and associated controlled environments. It also prescribes the standard method of testing as well as the procedure for determining the concentration of airborne particles.

For classification purposes, this part of ISO 14644 is limited to a designated range of considered particle sizes for determination of particle concentration limits. This part of ISO 14644 also provides standard protocols for the determination and designation of cleanliness levels that are based on airborne concentrations of particles smaller or larger than the size range designated for classification.

This part of ISO 14644 is one of a series of standards concerned with cleanrooms and contamination control. Many factors besides airborne particulate cleanliness must be considered in the design, specification, operation, and control of cleanrooms and other controlled environments. These are covered in some detail in other parts of the International Standards prepared by ISO/TC 209.

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.

This document is a preview generated by EVS

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) sizes ranging from 0,1 μm to 5 μm are considered for classification purposes.

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, respectively.

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

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

2 Definitions

For the purposes of this part of ISO 14644, the following definitions apply.

2.1 General

2.1.1

cleanroom

room in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimize the introduction, generation, and retention of parti-

cles inside the room, and in which other relevant parameters, e.g. temperature, humidity, and pressure, are controlled as necessary

2.1.2

clean zone

dedicated space in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the zone, and in which other relevant parameters, e.g. temperature, humidity, and pressure, are controlled as necessary

NOTE This zone may be open or enclosed and may or may not be located within a cleanroom.

2.1.3

installation

cleanroom or one or more clean zones, together with all associated structures, air-treatment systems, services, and utilities

2.1.4

classification

level (or the process of specifying or determining the level) of airborne particulate cleanliness applicable to a cleanroom or clean zone, expressed in terms of an ISO Class *N*, which represents maximum allowable concentrations (in particles per cubic metre of air) for considered sizes of particles

NOTE 1 The concentrations are determined by using equation (1) in 3.2.

NOTE 2 Classification in accordance with this International Standard is limited to the range extending from ISO Class 1 through ISO Class 9.

NOTE 3 The considered particle sizes (lower threshold values) applicable for classification in accordance with this International

generated by EVS