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Renhetsteknik – Renrum och tillhörande renhetskontrollerade miljöer –

Del 1: Klassificering av luftens renhet baserad på partikelkoncentration (ISO 14644-1:2015)

Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)

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Europastandarden EN ISO 14644-1:2015 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 14644-1:2015.

Denna standard ersätter SS-EN ISO 14644-1, utgåva 1.

The European Standard EN ISO 14644-1:2015 has the status of a Swedish Standard. This document contains the official English version of EN ISO 14644-1:2015.

This standard supersedes the Swedish Standard SS-EN ISO 14644-1, edition 1.

Förhållandet till övriga delar under samma huvudtitel - Utdrag ur Förord i ISO 14644-1:2015
Relations to other parts under the same general title - Extract from the Foreword of ISO 14644-1:2015

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: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration*
- *Part 3: Test methods*
- *Part 4: Design, construction and start-up*
- *Part 5: Operations*
- *Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)*
- *Part 8: Classification of air cleanliness by chemical concentration (ACC)*
- *Part 9: Classification of surface cleanliness by particle concentration*
- *Part 10: Classification of surface cleanliness by chemical concentration*

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Denna standard är framtagen av kommittén för Renhetsteknik, SIS/TK 108.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

EN ISO 14644-1

NORME EUROPÉENNE

EUROPÄISCHE NORM

December 2015

ICS 13.040.35

Supersedes EN ISO 14644-1:1999

English Version

Cleanrooms and associated controlled environments - Part
1: Classification of air cleanliness by particle concentration
(ISO 14644-1:2015)

Salles propres et environnements maîtrisés apparentés
- Partie 1: Classification de la propreté particulaire de
l'air (ISO 14644-1:2015)

Reinräume und zugehörige Reinraumbereiche - Teil 1:
Klassifizierung der Luftreinheit anhand der
Partikelkonzentration (ISO 14644-1:2015)

This European Standard was approved by CEN on 27 November 2015.

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 foreword

This document (EN ISO 14644-1:2015) 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 June 2016, and conflicting national standards shall be withdrawn at the latest by June 2016.

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.

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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 14644-1:2015 has been approved by CEN as EN ISO 14644-1:2015 without any modification.

Introduction

Cleanrooms and associated controlled environments provide for the control of contamination of air and, if appropriate, surfaces, to levels appropriate for accomplishing contamination-sensitive activities. Contamination control can be beneficial for protection of product or process integrity in applications in industries such as aerospace, microelectronics, pharmaceuticals, medical devices, healthcare and food.

This part of ISO 14644 specifies classes of air cleanliness in terms of the number of particles expressed as a concentration in air volume. It also specifies the standard method of testing to determine cleanliness class, including selection of sampling locations.

This edition is the result of a response to an ISO 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 ISO 14644. The nine ISO cleanliness classes are retained with minor revisions. [Table 1](#) defines the particle concentration at various particle sizes for the nine integer classes. [Table E.1](#) defines the maximum particle concentration at various particle sizes for intermediate classes. The use of these tables ensures better definition of the appropriate particle-size ranges for the different classes. This part of ISO 14644 retains the macroparticle descriptor concept; however, consideration of nano-scale particles (formerly defined as ultrafine particles) will be addressed in a separate standard.

The most significant change is the adoption of a more consistent statistical approach to the selection and the number of sampling locations; and the evaluation of the data collected. The statistical model is based on adaptation of the hypergeometric sampling model technique, where samples are drawn randomly without replacement from a finite population. The new approach allows each location to be treated independently with at least a 95 % level of confidence that at least 90 % of the cleanroom or clean zone areas will comply with the maximum particle concentration limit for the target class of air cleanliness. No assumptions are made regarding the distribution of the actual particle counts over the area of the cleanroom or clean zone; while in ISO 14644-1:1999 an underlying assumption was that the particle counts follow the same normal distribution across the room, this assumption has now been discarded to allow the sampling to be used in rooms where the particle counts vary in a more complex manner. In the process of revision it has been recognized that the 95 % UCL was neither appropriate nor was applied consistently in ISO 14644-1:1999. The minimum number of sampling locations required has been changed, compared with ISO 14644-1:1999. A reference table, [Table A.1](#), is provided to define the minimum number of sampling locations required based on a practical adaptation of the sampling model technique. An assumption is made that the area immediately surrounding each sampling location has a homogeneous particle concentration. The cleanroom or clean zone area is divided up into a grid of sections of near equal area, whose number is equal to the number of sampling locations derived from [Table A.1](#). A sampling location is placed within each grid section, so as to be representative of that grid section.

It is assumed for practical purposes that the locations are chosen representatively; a “representative” location (see [A.4.2](#)) means that features such as cleanroom or clean zone layout, equipment disposition and airflow systems should be considered when selecting sampling locations. Additional sampling locations may be added to the minimum number of sampling locations.

Finally, the annexes have been reordered to improve the logic of this part of ISO 14644 and portions of the content of certain annexes concerning testing and test instruments have been included from ISO 14644-3:2005.

The revised version of this part of ISO 14644 addresses the $\geq 5 \mu\text{m}$ particle limits for ISO Class 5 in the sterile products annexes of the EU, PIC/S and WHO GMPs by way of an adaptation of the macroparticle concept.

The revised version of this part of ISO 14644 now includes all matters related to classification of air cleanliness by particle concentration. The revised version of ISO 14644-2:2015 now deals exclusively with the monitoring of air cleanliness by particle concentration.

Cleanrooms may also be characterized by attributes in addition to the classification of air cleanliness by particle concentration. Other attributes, such as air cleanliness in terms of chemical concentration, may

be monitored and the attribute's grade or level may be designated along with the classification of the ISO Class of cleanliness. These additional attributes do not suffice alone to classify a cleanroom or clean zone.

Cleanrooms and associated controlled environments —

Part 1: Classification of air cleanliness by particle concentration

1 Scope

This part of ISO 14644 specifies the classification of air cleanliness in terms of concentration of airborne particles in cleanrooms and clean zones; and separative devices as defined in ISO 14644-7.

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 light scattering (discrete) airborne particle counters (LSAPC) 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 the specified lower threshold particle-size range, 0,1 μm to 5 μm . Concentrations of ultrafine particles (particles smaller than 0,1 μm) will be addressed in a separate standard to specify air cleanliness by nano-scale particles. An M descriptor (see [Annex C](#)) may be used to quantify populations of macroparticles (particles larger than 5 μm).

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

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 14644-2:2015, *Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration*

ISO 14644-7, *Cleanrooms and associated controlled environments — Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)*

3 Terms and definitions

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

3.1 General

3.1.1

cleanroom

room within which the number concentration of airborne particles is controlled and classified, and which is designed, constructed and operated in a manner to control the introduction, generation and retention of particles inside the room

Note 1 to entry: The class of airborne particle concentration is specified.