SWEDISH STANDARDS INSTITUTE

SVENSK STANDARD
SS-EN ISO 14644-3:2005

Fastställd 2005-12-22

Utgåva 1

Renhetsteknik – Renrum och tillhörande renhetskontrollerade miljöer –
Del 3: Provningsmetoder (ISO 14644-3:2005)

Cleanrooms and associated controlled environments –
Part 3: Test methods (ISO 14644-3:2005)

ICS 13.040.35

Språk: engelska

Publicerad: februari 2006

Europastandarden EN ISO 14644-3:2005 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 14644-3:2005.

The European Standard EN ISO 14644-3:2005 has the status of a Swedish Standard. This document contains the official English version of EN ISO 14644-3:2005.

Upplysningar om **sakinnehållet** i standarden lämnas av SIS, Swedish Standards Institute,
telefon 08 - 555 520 00.

Standarder kan beställas hos SIS Förlag AB som även lämnar **allmänna upplysningar** om svensk och utländsk standard.
Postadress: SIS Förlag AB, 118 80 STOCKHOLM
Telefon: 08 - 555 523 10. *Telefax*: 08 - 555 523 11
E-post: sis.sales@sis.se. *Internet*: www.sis.se

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14644-3

December 2005

ICS 13.040.35

English Version

Cleanrooms and associated controlled environments - Part 3: Test methods (ISO 14644-3:2005)

Salles propres et environnements maîtrisés apparentés - Partie 3: Méthodes d'essai (ISO 14644-3:2005)

Reinräume und zugehörige Reinraumbereiche - Teil 3: Prüfverfahren (ISO 14644-3:2005)

This European Standard was approved by CEN on 12 September 2005.

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.

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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN ISO 14644-3:2005: E

Contents

Page

Foreword

This document (EN ISO 14644-3:2005) 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 2006, and conflicting national standards shall be withdrawn at the latest by June 2006.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 14644-3:2005 has been approved by CEN as EN ISO 14644-3:2005 without any modifications.

Introduction

Cleanrooms and associated controlled environments provide for the control of airborne 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, healthcare and food.

This part of ISO 14644 sets out test methods that may be used for the purpose of characterizing a cleanroom as described and specified in other parts of ISO 14644.

NOTE Not all cleanroom parameter test procedures are shown in this part of ISO 14644. The procedures and apparatus to characterize other parameters, of concern in cleanrooms and clean zones used for specific products or processes, are discussed elsewhere in other documents prepared by ISO/TC 209 [for example, procedures for control and measurement of viable materials (ISO 14698), testing cleanroom functionality (ISO 14644-4), and testing of separative devices (ISO 14644-7)]. In addition, other standards can be considered to be applicable.

Statements in this part of ISO 14644 reference the standards of ASTM, CEN, DIN, IEST, JACA, JIS and SEMI.

Cleanrooms and associated controlled environments —

Part 3:
Test methods

WARNING — The use of this part of ISO 14644 may involve hazardous materials, operations and equipment. This part of ISO 14644 does not purport to address all of the safety problems associated with its use. It is the responsibility of the user of this part of ISO 14644 to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.

1 Scope

This part of ISO 14644 specifies test methods for designated classification of airborne particulate cleanliness and for characterizing the performance of cleanrooms and clean zones. Performance tests are specified for two types of cleanrooms and clean zones: those with unidirectional flow and those with non-unidirectional flow, in three possible occupancy states: as-built, at-rest and operational. The test methods recommend test apparatus and test procedures for determining performance parameters. Where the test method is affected by the type of cleanroom or clean zone, alternative procedures are suggested. For some of the tests, several different methods and apparatus are recommended to accommodate different end-use considerations. Alternative methods not included in this part of ISO 14644 may be used if based on agreement between customer and supplier. Alternative methods do not necessarily provide equivalent measurements.

This part of ISO 14644 is not applicable to the measurement of products or of processes in cleanrooms or separative devices.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7726:1998, *Ergonomics of the thermal environment — Instruments for measuring physical quantities*

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

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

ISO 14644-4:2001, *Cleanrooms and associated controlled environments — Part 4: Design, construction and start-up*

3 Terms and definitions

For the purposes of this document, the following terms and 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 minimize 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

[ISO 14644-1:1999, 2.1.1]

3.1.2
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.

[ISO 14644-1:1999, 2.1.2]

3.1.3
installation
cleanroom or one or more clean zones, together with all associated structures, air-treatment systems, services, and utilities

[ISO 14644-1:1999, 2.1.3]

3.1.4
separative device
equipment utilizing constructional and dynamic means to create assured levels of separation between the inside and outside of a defined volume

NOTE Some industry-specific examples of separative devices are clean air hoods, containment enclosures, glove boxes, isolators and mini-environments.

3.2 Airborne particle measurement

3.2.1
aerosol generator
instrument capable of generating particulate matter having appropriate size range (e.g. 0,05 µm to 2 µm) at a constant concentration, which may be produced by thermal, hydraulic, pneumatic, acoustic or electrostatic means

3.2.2
airborne particle
solid or liquid object suspended in air, viable or non-viable, sized (for the purpose of this part of ISO 14644) between 1 nm and 100 µm

NOTE For classification purposes, refer to ISO 14644-1:1999, 2.2.1.

3.2.3
count median particle diameter
CMD
median particle diameter based on the number of particles

NOTE For the count median, one half of the particle number is contributed by the particles with a size smaller than the count median size, and one half by particles larger than the count median size.

3.2.4
macroparticle
particle with an equivalent diameter greater than 5 µm

[ISO 14644-1:1999, 2.2.6]

3.2.5
M descriptor
measured or specified concentration of macroparticles per cubic metre of air, expressed in terms of the equivalent diameter that is characteristic of the measurement method used

NOTE The M descriptor may be regarded as an upper limit for the averages at sampling locations (or as an upper confidence limit, depending upon the number of sampling locations used to characterize the cleanroom or clean zone). M descriptors cannot be used to define airborne particulate cleanliness classes, but they may be quoted independently or in conjunction with airborne particulate cleanliness classes.

[ISO 14644-1:1999, 2.3.2]

3.2.6
mass median particle diameter
MMD
median particle diameter based on the particle mass

NOTE For the mass median, one half of mass of all particles is contributed by particles with a size smaller than the mass median size, and one half by particles larger than the mass median size.

3.2.7
particle concentration
number of individual particles per unit volume of air

[ISO 14644-1:1999, 2.2.3]

3.2.8
particle size
diameter of a sphere that produces a response, by a given particle-sizing instrument, that is equivalent to the response produced by the particle being measured

NOTE For discrete-particle-counting, light-scattering instruments, the equivalent optical diameter is used.

[ISO 14644-1:1999, 2.2.2]

3.2.9
particle size distribution
cumulative distribution of particle concentration as a function of particle size

[ISO 14644-1:1999, 2.2.4]

3.2.10
test aerosol
gaseous suspension of solid and/or liquid particles with known and controlled size distribution and concentration

3.2.11
U descriptor
measured or specified concentration in particles per cubic metre or air, including the ultrafine particles

NOTE The U descriptor may be regarded as an upper limit for the averages at sampling locations (or as an upper confidence limit, depending upon the number of sampling locations used to characterize the cleanroom or clean zone). U descriptors cannot be used to define airborne particulate cleanliness classes, but they may be quoted independently or in conjunction with airborne particulate cleanliness classes.

[ISO 14644-1:1999, 2.3.1]

3.2.12
ultrafine particle
particle with an equivalent diameter less than 0,1 µm

[ISO 14644-1:1999, 2.2.5]

3.3 Air filters and systems

3.3.1
aerosol challenge
challenging of a filter or an installed filter system by test aerosol

3.3.2
designated leak
maximum allowable penetration, which is determined by agreement between customer and supplier, through a leak, detectable during scanning of an installation with discrete-particle counters or aerosol photometers

3.3.3
dilution system
system wherein aerosol is mixed with particle-free dilution air in a known volumetric ratio to reduce concentration

3.3.4
filter system
system composed of filter, frame and other support system or other housing

3.3.5
final filter
filters in a final position before the air enters the cleanroom

3.3.6
installed filter system
filter system mounted in the ceiling, wall, apparatus or duct

3.3.7
installed filter system leakage test
test performed to confirm that the filters are properly installed by verifying that there is absence of bypass leakage in the installation, and that the filters and the grid system are free of defects and leaks

3.3.8
leak
〈of air filter system〉 penetration of contaminants that exceed an expected value of downstream concentration through lack of integrity or defects

3.3.9
scanning
method for disclosing leaks in filters and parts of units, whereby the probe inlet of an aerosol photometer or discrete-particle counter is moved in overlapping strokes across the defined test area

3.3.10
standard leak penetration
leak penetration detected by a discrete-particle counter or aerosol photometer with a standard sample flow-rate when the sampling probe is stationary in front of the leak

NOTE Penetration is the ratio of the particle concentration downstream of the filter to the concentration upstream.

3.4 Airflow and other physical states

3.4.1
air exchange rate
rate of air exchange expressed as number of air changes per unit of time and calculated by dividing the volume of air delivered in the unit of time by the volume of the space

3.4.2
average airflow rate
averaged volume of air per unit of time, to determine the air exchange rate in a cleanroom or clean zone

NOTE Airflow rate is expressed in cubic metres per hour (m^3/h).

3.4.3
measuring plane
cross-sectional area for testing or measuring a performance parameter such as the airflow velocity

3.4.4
non-unidirectional airflow
air distribution where the supply air entering the clean zone mixes with the internal air by means of induction

[ISO 14644-4:2001, 3.6]

3.4.5
supply airflow rate
air volume supplied into an installation from final filters or air ducts in unit of time

3.4.6
total airflow rate
air volume that passes through a section of an installation in unit of time

3.4.7
unidirectional airflow
controlled airflow through the entire cross-section of a clean zone with a steady velocity and approximately parallel streamlines

NOTE This type of airflow results in a directed transport of particles from the clean zone.

[ISO 14644-4:2001, 3.11]

3.4.8
uniformity of airflow
unidirectional airflow pattern in which the point-to-point readings of velocities are within a defined percentage of the average airflow velocity

3.5 Electrostatic measurement

3.5.1
discharge time
time required to reduce the voltage to the level, positive or negative, to which an isolated conductive monitoring plate was originally charged

3.5.2
offset voltage
voltage that will accumulate upon an initially uncharged isolated conductive plate when that plate is exposed to an ionized air environment