



SLOVENSKI STANDARD
SIST EN ISO 14644-8:2007
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Cleanrooms and associated controlled environments - Part 8: Classification of airborne molecular contamination (ISO 14644-8:2006)

Reinräume und zugehörige Reinraumbereiche - Teil 8: Klassifikation luftgetragener molekularer Kontamination (ISO 14644-8:2006)

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Salles propres et environnements maîtrisés apparentés (standard title) Partie 8: Classification de la contamination moléculaire aéroportée (ISO 14644-8:2006)

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ICS:

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

English Version

Cleanrooms and associated controlled environments - Part 8:
Classification of airborne molecular contamination (ISO 14644-
8:2006)

Salles propres et environnements maîtrisés apparentés -
Partie 8: Classification de la contamination moléculaire
aéroportée (ISO 14644-8:2006)

Reinräume und zugehörige Reinraumbereiche - Teil 8:
Klassifikation luftgetragener molekularer Kontamination
(ISO 14644-8:2006)

This European Standard was approved by CEN on 3 May 2006.

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, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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

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

Foreword

This document (EN ISO 14644-8:2006) 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 February 2007, and conflicting national standards shall be withdrawn at the latest by February 2007.

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, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 14644-8:2006 has been approved by CEN as EN ISO 14644-8:2006 without any modifications.

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**Cleanrooms and associated controlled
environments —**

**Part 8:
Classification of airborne molecular
contamination**

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*Salles propres et environnements maîtrisés apparentés —
(standards.iteh.ai)*

Partie 8: Classification de la contamination moléculaire aéroportée

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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 14644-8 was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*.

ISO 14644 consists of the following parts, under the general title *Cleanrooms and associated controlled environments*:

- Part 1: *Classification of air cleanliness*
- Part 2: *Specifications for testing and monitoring to prove continued compliance with ISO 14644-1*
- Part 3: *Test methods*
- Part 4: *Design, construction and start-up*
- Part 5: *Operations*
- Part 6: *Vocabulary*
- Part 7: *Separative enclosures (clean air hoods, gloveboxes, isolators, mini-environments)*
- Part 8: *Classification of airborne molecular contamination*

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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.

In some of these industries, the product or process can be sensitive to, or can be destroyed by, molecular contamination resulting from airborne molecules that are present due to external, process, or otherwise generated sources.

Within this part of ISO 14644, the presence of airborne molecules is expressed as airborne molecular contamination (AMC). Molecular contamination is a three-step event. The first step is *generation* due to external sources, process leakage or construction or human material outgassing. The second step is *transport* as AMC. The third step is *sorption* on the sensitive surface, which can be quantified as a surface molecular contamination (SMC).

The generating materials and the surfaces where sorption takes place will have a large influence on the steps of generation and sorption in addition to the actual AMC. Thus, for these two steps, not only the AMC but also the involved bulk and surfaces need to be defined. In order to make a standard generally applicable to any type of cleanroom or associated controlled environment, AMC has been chosen for the classification.

This part of ISO 14644 assigns ISO classification levels to be used to specify the limits of AMC concentrations within a cleanroom and associated controlled environment, where the product or process is deemed to be at risk from such contamination.

For classification purposes, this part of ISO 14644 is limited to a designated range of AMC concentrations and provides standard protocols for specifying such concentrations with regard to chemical compounds, methods of test and analysis, and time weighted factors.

Informative annexes are contained in this part of ISO 14644 covering

- parameters for consideration: Annex A;
- typical contaminating chemicals and substances: Annex B;
- typical methods of measurement and analysis: Annex C;
- considerations of specific requirements for separative enclosures: Annex D.

This part of ISO 14644 is one of a series of standards concerned with cleanrooms and contamination control. Many factors besides AMC need to 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 particular, attention is drawn to ISO 14698 (all parts)^[4]. In some circumstances, relevant regulatory agencies can impose supplementary policies or restrictions. In such situations, appropriate adaptations of this part of ISO 14644 may be required.

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Cleanrooms and associated controlled environments —

Part 8: Classification of airborne molecular contamination

1 Scope

This part of ISO 14644 covers the classification of airborne molecular contamination (AMC) in cleanrooms and associated controlled environments, in terms of airborne concentrations of specific chemical substances (individual, group or category) and provides a protocol to include test methods, analysis and time weighted factors within the specification for classification.

This part of ISO 14644 currently considers only concentrations of AMC between 10^0 and 10^{-12} g/m³ under cleanroom operational conditions.

This part of ISO 14644 is not relevant for application in those industries, processes or production, where the presence of airborne molecular substances is not considered a risk to the product or process.

It is not the intention of this part of ISO 14644 to describe the nature of airborne molecular contaminants.

This part of ISO 14644 does not give a classification of surface molecular contamination.

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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 14644-6, *Cleanrooms and associated controlled environments — Part 6: Vocabulary*

3 Terms and definitions

For the purposes of this part of ISO 14644, the terms and definitions given in ISO 14644-6 and the following apply.

3.1 General

3.1.1

molecular contamination

molecular (chemical, non-particulate) substances that can have a deleterious effect on the product, process or equipment