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Cleanrooms and associated control environments - Part 8: Classification of airborne molecular contamination

Salles propres et environnements maîtrisés apparentés - Partie 8: Classification de la contamination moléculaire aéroportée

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 243.

If this draft becomes a European Standard, 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.

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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

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Foreword

This document (prEN ISO 14644-8:2004) 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 document is currently submitted to the parallel Enquiry.

Endorsement notice

The text of ISO/DIS 14644-8:2004 has been approved by CEN as prEN ISO 14644-8:2004 without any modifications.

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Cleanrooms and associated controlled environments —

Part 8: Classification of airborne molecular contamination

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ISO/CEN PARALLEL ENQUIRY

The CEN Secretary-General has advised the ISO Secretary-General that this ISO/DIS covers a subject of interest to European standardization. **In accordance with the ISO-lead mode of collaboration as defined in the Vienna Agreement, consultation on this ISO/DIS has the same effect for CEN members as would a CEN enquiry on a draft European Standard.** Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month FDIS vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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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: Terms and definitions*

— *Part 7: Separative enclosures (clean air hoods, gloveboxes, isolators, minienvironments)*

— *Part 8: Classification of airborne molecular contamination*

Users should note that the titles listed for parts 3 and 5 to 8 are working titles at the time of the release of part 8. In the event that one or more of these parts are deleted from the work programme, the remaining parts may be renumbered.

Attention is also drawn to *ISO 14698, Cleanrooms and associated controlled environments — Biocontamination control*.

Annexes A to D of this part of ISO 14644 are for information only.

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 may be sensitive to 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 in air. 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 in air 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 some circumstances, relevant regulatory agencies may impose supplementary policies or restrictions. In such situations appropriate adaptations of this part of ISO 14644 may be required.

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 species (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 considers only concentrations of AMC between 10^{0} and 10^{-12} g/m^{3} 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 species 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.

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: Terms and definitions*

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 (non-particulate) species that may have a deleterious effect on the product, process or equipment

3.1.2
airborne molecular contamination (AMC)
presence in the atmosphere of a cleanroom or controlled environment of molecular (chemical, non-particulate) species in the gaseous or vapour state that may have a deleterious effect on the product, process or equipment in the cleanroom or controlled environment

NOTE This definition does not include biomolecules, which are judged to be particulates.

3.1.3
surface molecular contamination (SMC)
presence on the surface of a product or analytical instrument of molecular (chemical, non-particulate) species in the sorbed state that may have a deleterious effect on the product, process or equipment in the cleanroom or controlled environment

3.1.4
contaminant category
common name for a group of compounds with a specific and similar deleterious effect when deposited on the surface of interest

3.1.5
outgassing
release of a molecular species in the gaseous or vapour state from a material

3.2 Contaminant categories

3.2.1
acid
species whose chemical reaction characteristic is to establish new bonds by the acceptance of electron pairs

3.2.2
base
species whose chemical reaction characteristic is to establish new bonds by the donation of electron pairs

3.2.3
biotoxic
contaminant species that is obnoxious to the development and preservation of the life of organisms, micro-organisms, tissues or individual cells

3.2.4
condensable
species capable of depositing on a surface by condensation, under cleanroom operating conditions

3.2.5
corrosive
species that causes destructive chemical change of a surface

3.2.6
dopant
species that, after sorption, is incorporated in the bulk of a product and is capable of changing the properties of materials, even in trace amounts

NOTE Typical examples of dopants are bulk modifiers in microelectronics and critical metal contaminants, e.g. Na, Cu or Fe.

3.2.7
organic
species based on carbon and also containing hydrogen, with or without oxygen, nitrogen or other elements

3.2.8
oxidant
species that, upon deposition to a product or surface of interest, results in the formation of an oxide