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Cleanrooms and associated controlled environments —

Part 8: Classification of airborne molecular contamination

Salles propres et environnements maîtrisés apparentés —

Partie 8: Classification de la contamination moléculaire aéroportée



Reference number
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Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Classification	3
5 Demonstration of compliance	5
Annex A (informative) Parameters for consideration	7
Annex B (informative) Typical contaminants	10
Annex C (informative) Typical methods of measurement	13
Annex D (informative) Consideration of specific requirements for separative devices	17
Bibliography	18

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*

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.

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.

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

ISO 14644-8:2006(E)

3.1.2

airborne molecular contamination

AMC

presence in the atmosphere of a cleanroom or controlled environment of molecular (chemical, non-particulate) substances 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 macromolecules of biological origin that, which are judged to be particles.

3.1.3

surface molecular contamination

SMC

presence of molecular (chemical, non-particulate) substances in the sorbed state that may have a deleterious effect on the product, or surface of interest, 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 molecular substances in the gaseous or vapour state from a material

3.2 Contaminant categories

3.2.1

acid

substance whose chemical reaction characteristic is to establish new bonds by the acceptance of electron pairs

3.2.2

base

substance whose chemical reaction characteristic is to establish new bonds by the donation of electron pairs

3.2.3

biotoxic

contaminant substance that is obnoxious to the development and preservation of the life of organisms, microorganisms, tissues or individual cells

3.2.4

condensable

substance capable of depositing on a surface by condensation under cleanroom operating conditions

3.2.5

corrosive

substance that causes destructive chemical change of a surface

3.2.6

dopant

substance that, after sorption and/or diffusion, is incorporated in the bulk of a product and is capable of changing the properties of materials, even in trace amounts

3.2.7

organic

substance based on carbon and also containing hydrogen, with or without oxygen, nitrogen or other elements