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Cleanrooms and associated controlled environments —

Part 8: Assessment of air cleanliness by chemical concentration (ACC)

Salles propres et environnements maîtrisés apparentés —

Partie 8: Évaluation de la propreté chimique de l'air

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Contents

Page

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 243, *Cleanroom technology*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 14644-8:2013), of which it constitutes a minor revision. The changes are as follows:

— the term class (classification, classified) changed to grade or assessment where appropriate;

— 3.1.2, definition revised;

— Bibliography updated;

— minor editorial changes.

A list of all parts in the ISO 14644 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Cleanrooms and associated controlled environments provide for the control of airborne particulate contamination to levels of cleanliness appropriate for accomplishing process activities sensitive to a range of contaminants. Products and processes that benefit from the control of airborne contamination include those in such industries as aerospace, microelectronics, pharmaceuticals, medical devices, food, healthcare, optics, instrumentation, vacuum technology, coatings, photovoltaics, displays, LEDs, coatings, automotive and surface analysis.

In some of these industries, the product or process can be sensitive to, or can be destroyed by, chemical contamination resulting from chemicals that are present due to external, process or other generated sources.

Within this document, the presence of chemicals is expressed as air chemical contamination. Chemical contamination is a three-step event. The first step is *generation* due to external sources such as process leakage, construction material, personnel or material outgassing. The second step is *transport* as airborne chemical contamination. The third step is *sorption* on the sensitive surface, which can be quantified as a surface chemical contamination.

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 air contamination. Thus, for these two steps, not only the contaminants 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, air chemical cleanliness (ACC) has been chosen for the level assessment.

This document assigns ISO grading levels to be used to specify the level of ACC within a cleanroom and associated controlled environment, where the product or process is deemed to be at risk from air chemical contamination.

For level assessment purposes, this document provides guidance for a range of ACC levels and provides standard protocols for specifying such levels with regard to chemical compounds, methods of test and analysis, and time weighted factors.

Annexes A to D contain the following information:

— 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 devices: Annex D.

This document is one of a series of standards concerned with cleanrooms and contamination control. Many factors besides ACC need to be considered in the design, specification, operation and control of cleanrooms and other controlled environments. These features are recognized in this document and covered in some detail in other parts of the International Standards prepared by ISO/TC 209, including the ISO 14698 series. In some circumstances, relevant regulatory agencies can impose supplementary policies or restrictions. In such situations, appropriate adaptations of this document can be required.

NOTE When assessment of ACC at critical control point(s) is used as an additional cleanliness attribute to classification of air cleanliness by airborne particle concentration in accordance with ISO 14644-1, then the space can be described as a *cleanroom* or *clean-zone*. If ACC is used alone, then the space must be described as a *controlled zone*.

Cleanrooms and associated controlled environments —

Part 8: Assessment of air cleanliness by chemical concentration (ACC)

1 Scope

This document establishes typical assessment processes to determine grading levels of air chemical cleanliness (ACC) 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 for their determination. This document currently considers only concentrations of air chemical contaminants between 10^0 g/m^3 and 10^{-12} g/m^3 under cleanroom operational conditions.

This document is not relevant for application in those industries, processes or productions where the presence of airborne chemical substances is not considered a risk to the product or process.

It is not the intention of this document to describe the nature of air chemical contaminants.

This document does not give a classification of surface chemical contamination.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1 General

3.1.1
chemical contamination
non-particulate substances that can have a deleterious effect on the product, process or equipment

3.1.2
air cleanliness by chemical concentration
ACC
quantity of chemical detected in the air, expressed in terms of an ISO-ACC level N, which represents the maximum allowable concentration of a given chemical species or a group of chemical species, expressed in grams per cubic metre

Note 1 to entry: This definition does not include macromolecules of biological origin, which are judged to be particles.

3.1.3
air chemical contamination
any substance in the air that can, by its chemical nature, adversely affect the product, process or equipment

3.1.4
surface cleanliness by chemical concentration
SCC
condition of the surface cleanliness with respect to its chemical concentration

3.1.5
surface chemical contamination
any substance on the surface that can, by its chemical nature, adversely affect the product, process or equipment

3.1.6
contaminant category
common name for a group of compounds with a specific and similar deleterious effect when deposited on the surface of interest

3.1.7
outgassing
release of chemical substances in the gaseous or vapour state from a material

3.1.8
air cleanliness by chemical concentration level
grading number stating the maximum allowable concentration of a given chemical species or a group of chemical species in grams per cubic metre

Note 1 to entry: The range of concentrations are defined in Table 1 or determined by the formula for *N* in 4.2.

Note 2 to entry: Testing and monitoring in accordance with this document is limited to the range from 0 (the grade with the lowest cleanliness) to –12 (the cleanest level).

Note 3 to entry: The ACC grading number is only valid in connection with the ACC descriptor that specifies to which chemical species or group of chemical species it is related.

Note 4 to entry: The negative sign of the air chemical cleanliness levels (–1 to –12) is an integral part of the ACC level number *N* and shall always be used.

Note 5 to entry: Intermediate ISO grade numbers may be specified, with 0,1 being the smallest practical increment.

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
species based on carbon-containing compounds

Note 1 to entry: Inorganic carbon-containing compounds are excluded.

3.2.8
oxidant
substance that, upon deposition onto a surface or product of interest, results in the formation of an oxide or participates in a redox reaction

4 Testing and monitoring using grading levels

4.1 General

Testing or monitoring shall be specified by use of a descriptor as described in 4.2. This descriptor is designated "ISO-ACC" and indicates the maximum total chemical concentration for a contaminant category, an individual substance or a group of substances.

4.2 ISO-ACC descriptor format

An ACC grading number is only valid in connection with the ACC descriptor that specifies the chemical substance or group of substances for which this level number is valid. The ISO-ACC descriptor is expressed in the format:

ISO-ACC Level N (*X*)

where

X is a chemical substance or a group of chemical substances which includes, but is not limited to:

- acid (ac);
- base (ba);
- biotoxic (bt);
- condensable (cd);
- corrosive (cr);
- dopant (dp);
- organic, total (or);
- oxidant (ox); or
- a group of substances or an individual substance;

N is the ISO-ACC level, which is the logarithmic index of concentration, c_x, expressed in grams per cubic metre, and falls within a limiting range of 0 to −12. Intermediate concentrations may be specified, with 0,1 being the smallest practical increment of *N*;

$N = \log_{10}[c_x]$.

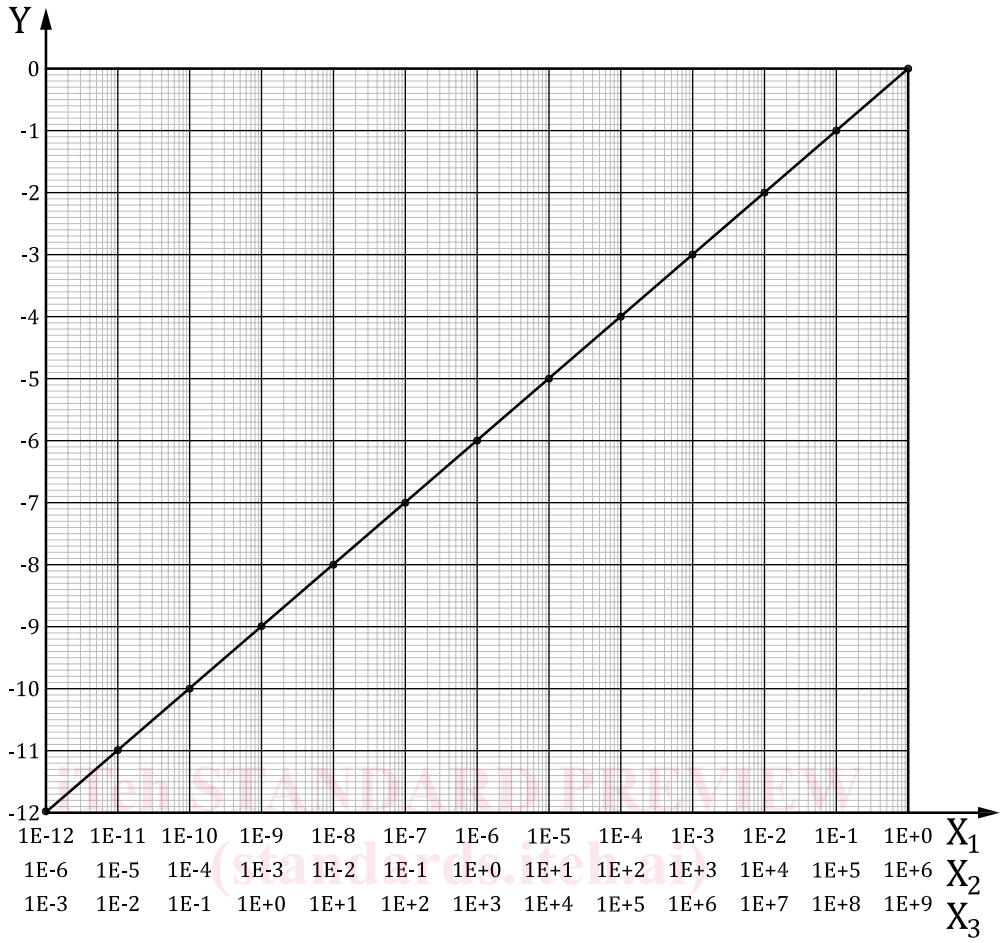
EXAMPLE 1 With an N-Methyl Pyrrolidone (NMP) sample, the measured value of air contamination was 8E-7 g/m^3; N = −6,097. This is within the level limit of 1E-6 g/m^3 for grade −6. The designation would be: "ISO-ACC Level −6 (NMP)".

EXAMPLE 2 With an organic compound sample, the measured value was 6E-5 g/m^3 of total organic compounds (TOC). This is within the level limit of 1E-4 g/m^3 for grade −4. The designation would be: "ISO-ACC Level −4 (TOC)."

Table 1 and Figure 1 further illustrate the suggested ISO-ACC concentration levels as a function of contaminant concentration for the specified species.

Table 1 — ISO-ACC grades

ISO-ACC level	Concentration g/m^3	Concentration µg/m^3	Concentration ng/m^3
0	10^0	10^6 (1 000 000)	10^9 (1 000 000 000)
−1	10^{-1}	10^5 (100 000)	10^8 (100 000 000)
−2	10^{-2}	10^4 (10 000)	10^7 (10 000 000)
−3	10^{-3}	10^3 (1 000)	10^6 (1 000 000)
−4	10^{-4}	10^2 (100)	10^5 (100 000)
−5	10^{-5}	10^1 (10)	10^4 (10 000)
−6	10^{-6}	10^0 (1)	10^3 (1 000)
−7	10^{-7}	10^{-1} (0,1)	10^2 (100)
−8	10^{-8}	10^{-2} (0,01)	10^1 (10)
−9	10^{-9}	10^{-3} (0,001)	10^0 (1)
−10	10^{-10}	10^{-4} (0,000 1)	10^{-1} (0,1)
−11	10^{-11}	10^{-5} (0,000 01)	10^{-2} (0,01)
−12	10^{-12}	10^{-6} (0,000 001)	10^{-3} (0,001)



Key

X_1 airborne concentration (g/m^3)

X_2 airborne concentration (µg/m^3)

X_3 airborne concentration (ng/m^3)

Y ISO-ACC level

Figure 1 — ISO-ACC levels as a function of concentration

5 Demonstration of compliance with an ISO-ACC level

5.1 Principle

Compliance with an ISO-ACC level requirement specified by the customer is verified by performing specified testing procedures agreed between the customer and supplier and by providing specified documentation of the results and conditions of testing.

5.2 Testing

Example test methods are given in Annex C. The list of typical methods described is not exhaustive. Alternative methods of comparable accuracy may be specified by agreement.

NOTE 1 Analysis by different methods, even when correctly applied, can produce different results of equal validity.

Tests performed to demonstrate compliance shall be conducted using suitable test methods and calibrated instruments.

Sampling locations shall be determined by agreement between the customer and the supplier.

It is recommended that replicate sampling is carried out at the locations agreed.

NOTE 2 In analytical measurement, the contribution of particulate contamination cannot always be excluded.

NOTE 3 For trace analysis using grab sampling, the incorporation of a shipping blank sample, prepared and analysed in the same batch as the actual sample, is required to assess contamination from the overall process, excluding the air sampling.

The elapsed time period shall be agreed between the customer and supplier. See A.4.3.

5.3 Test report

The results from testing each cleanroom or associated controlled environment shall be recorded and submitted as a comprehensive report, along with a statement of compliance or non-compliance with the specified ISO-ACC level or levels.

The test report shall include the following:

a) name of the test operator, the name and address of the testing organization, and the date, time and duration of sampling;

b) number and year of publication of this document, i.e. ISO 14644-8:2022;

c) clear identification of the physical location of the cleanroom or controlled environment tested (including reference to adjacent areas if necessary) and specific designations for coordinates of all sampling locations;

d) specified designation criteria for the cleanroom or controlled environment, including the occupancy state, the ISO-ACC level or levels, the specified test method(s) and, where applicable, the substances, substance group or categories, the elapsed time period and the designated particulate type;

e) details of the test procedure used, with any available data describing the test circumstances or departures from the test method, and identification of the test instrument(s) and its current calibration certificate(s);

f) test results, including air chemical concentration(s) data, for all sampling locations.