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**Cleanrooms and associated controlled environments —**

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

**iTeh STANDARD PREVIEW**  
*Salles propres et environnements maîtrisés apparentés —*  
*(standards.iteh.ai)* **Partie 8: Classification de la propreté chimique de l'air**

[ISO 14644-8:2013](https://standards.iteh.ai/catalog/standards/sist/21568682-4383-4ae4-947e-11ac5bcb42ab/iso-14644-8-2013)

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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*:

- iTeh STANDARD PREVIEW**  
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- 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 [ISO 14644-8:2013  
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  - Part 4: Design, construction and start-up
  - Part 5: Operations
  - Part 6: Vocabulary
  - Part 7: Separative devices (clean air hoods, gloveboxes, isolators, mini-environments)
  - Part 8: Classification of air cleanliness by chemical concentration (ACC)
  - Part 9: Classification of surface cleanliness by particle concentration
  - Part 10: Classification of surface cleanliness by chemical concentration

This second edition cancels and replaces the first edition (ISO 14644-8:2006), which has been technically revised.

## 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, 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 otherwise generated sources.

Within this part of ISO 14644, 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 or construction material or 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 classification.

This part of ISO 14644 assigns ISO classification 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 classification purposes, this part of ISO 14644 is limited to a designated range of ACC and provides standard protocols for specifying such levels 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 devices: [Annex D](#).

This part of ISO 14644 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 are covered in some detail in other parts of the International Standards prepared by ISO/TC 209, including ISO 14698 (all parts).<sup>[4]</sup> In some circumstances, relevant regulatory agencies can impose supplementary policies or restrictions. In such situations, appropriate adaptations of this part of ISO 14644 can be required.

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# Cleanrooms and associated controlled environments —

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

### 1 Scope

This part of ISO 14644 establishes the classification 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 within the specification for classification.

This part of ISO 14644 currently considers only concentrations of air chemical contaminants between  $10^0$  and  $10^{-12}$  g/m<sup>3</sup> under cleanroom operational conditions.

This part of ISO 14644 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 part of ISO 14644 to describe the nature of air chemical contaminants.

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

### 2 Normative references

ISO 14644-8:2013

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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 document, the terms and definitions given in ISO 14644-6 and the following apply.

#### 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**

level of air cleanliness by chemical concentration, expressed in terms of an ISO-ACC Class 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 (ACC) class**

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 maximum allowable concentrations are defined in [Table 1](#) or determined by the equation for  $N$  in [4.2](#).

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Note 2 to entry: Classification in accordance with this part of ISO 14644 is limited to the range from 0 (the class with the lowest allowable cleanliness) to -12 (the cleanest specified class).

Note 3 to entry: The ACC class 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 classes (-1 to -12) is an integral part of the ACC class number  $N$  and must always be given. An air chemical cleanliness class without the negative sign (with the exception of the class 0) is not allowed.

Note 5 to entry: Intermediate ISO classification numbers may be specified, with 0,1 being the smallest permitted 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 Classification****4.1 General**

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

**4.2 ISO-ACC descriptor format** [ISO 14644-8:2013](https://standards.iteh.ai/catalog/standards/sist/21568682-4383-4ae4-947e-)

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

ISO-ACC Class  $N$  ( $X$ )

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 class, 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 permitted increment of  $N$ ;

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

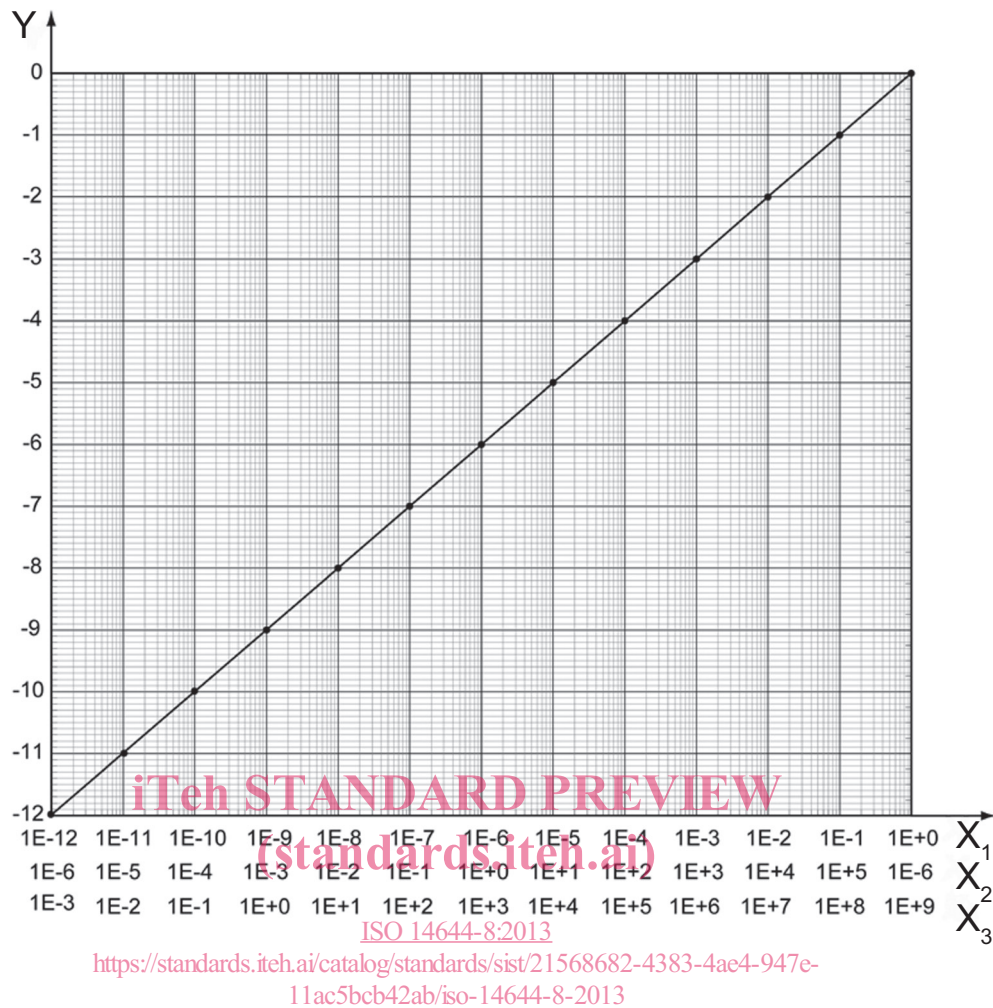
EXAMPLE 1 With an N-Methyl Pyrrolidone (NMP) sample, the measured value of air contamination was  $8E-7 \text{ g/m}^3$ ;  $N = -6,097$ . This is within the class limit of  $1E-6 \text{ g/m}^3$  for Class -6. The designation would be: "ISO-ACC Class -6 (NMP)".

EXAMPLE 2 With an organic compound sample, the measured value was  $6E-5 \text{ g/m}^3$  of total organic compounds (TOC). This is within the class limit of  $1E-4 \text{ g/m}^3$  for Class -4. The designation would be: "ISO-ACC Class -4 (TOC)."

Table 1 and Figure 1 further illustrate the ISO-ACC classification as a function of contaminant concentration.

Table 1 — ISO-ACC classes

ISO-ACC class	Concentration $\text{g/m}^3$	Concentration $\mu\text{g/m}^3$	Concentration $\text{ng/m}^3$
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 ( $\text{g}/\text{m}^3$ )  
 $X_2$  airborne concentration ( $\mu\text{g}/\text{m}^3$ )  
 $X_3$  airborne concentration ( $\text{ng}/\text{m}^3$ )  
 $Y$  ISO-ACC class

**Figure 1 — ISO-ACC classes as a function of concentration**

## 5 Demonstration of compliance

### 5.1 Principle

Compliance with classification (ISO-ACC class) requirements 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 supplier.

It is recommended to carry out replicate sampling 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, except 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 class(es).

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 part of ISO 14644, i.e. ISO 14644-8:2013;
- 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 class or classes, the specified test method(s) and, where applicable, the substances, substance group or category(ies), the elapsed time period and the designated particulate class;
- 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.