
Cleanrooms and associated controlled environments —

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

Salles propres et environnements maîtrisés apparentés —

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



Reference number
ISO 14644-8:2013(E)

© ISO 2013

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
3.1 General	1
3.2 Contaminant categories	2
4 Classification	3
4.1 General	3
4.2 ISO-ACC descriptor format	3
5 Demonstration of compliance	5
5.1 Principle	5
5.2 Testing	5
5.3 Test report	6
Annex A (informative) Parameters for consideration	7
Annex B (informative) Typical contaminants	11
Annex C (informative) Typical methods of measurement	15
Annex D (informative) Consideration of specific requirements for separative devices	19
Bibliography	21

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 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).^[4] 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.

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/m³ 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

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](#).

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

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 ;

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

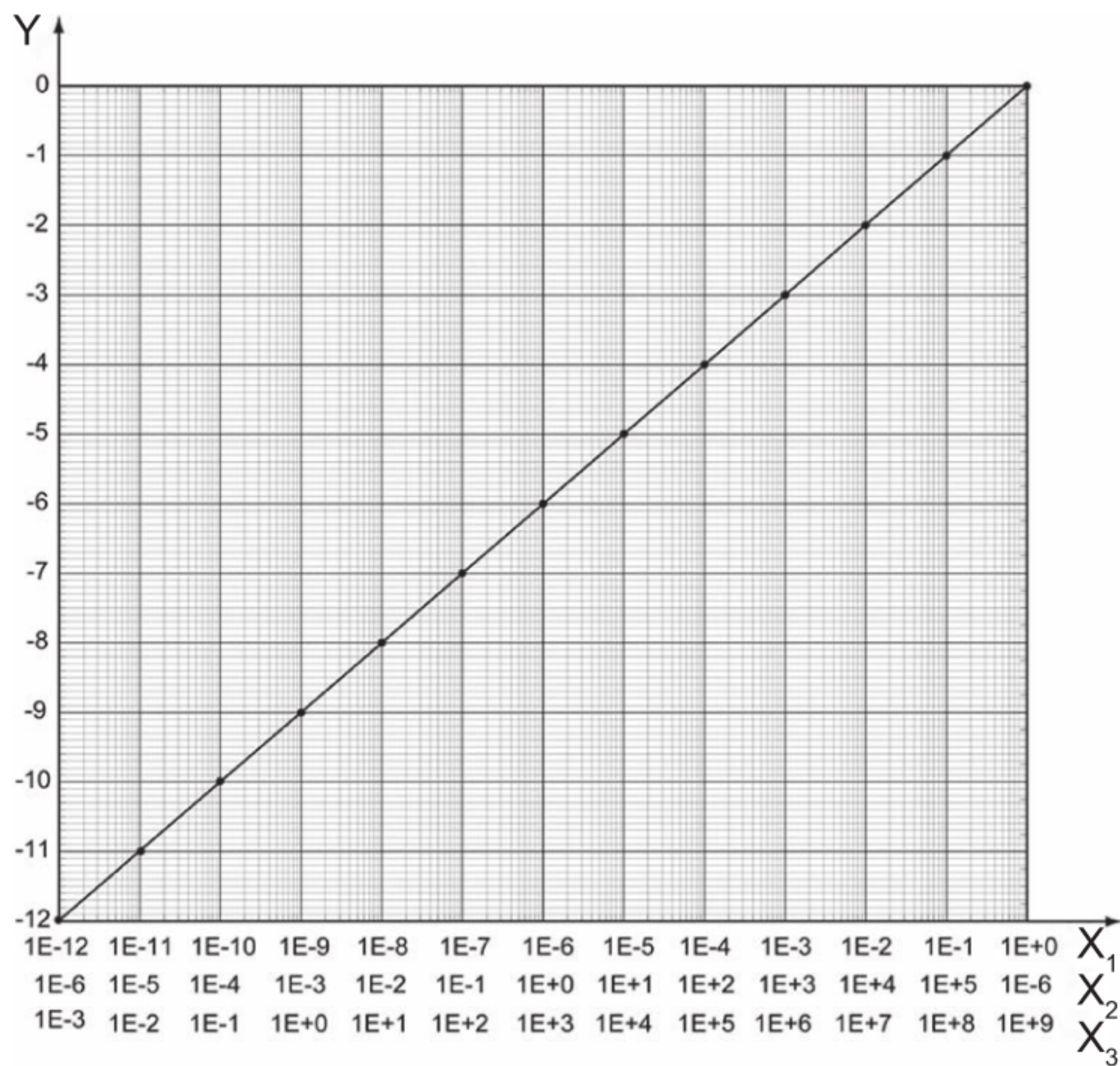
EXAMPLE 1 With an N-Methyl Pyrrolidone (NMP) sample, the measured value of air contamination was $8\text{E-}7 \text{ g/m}^3$; $N = -6,097$. This is within the class limit of $1\text{E-}6 \text{ g/m}^3$ for Class –6. The designation would be: “ISO-ACC Class –6 (NMP)”.

EXAMPLE 2 With an organic compound sample, the measured value was $6\text{E-}5 \text{ g/m}^3$ of total organic compounds (TOC). This is within the class limit of $1\text{E-}4 \text{ g/m}^3$ 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 g/m^3	Concentration $\mu\text{g/m}^3$	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/m³)
 X_2 airborne concentration (µg/m³)
 X_3 airborne concentration (ng/m³)
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.

Annex A (informative)

Parameters for consideration

A.1 Principles

This annex is intended to give guidance to consideration of parameters affecting or contributing to ACC within a cleanroom or associated controlled environment. It is important to consider the development of such parameters at the initial stages of design and control requirements, along with any special considerations for operation of the facility.

A.2 Concepts for establishing parameters

The following principles permit the establishment of the parameters which influence the ACC or which contribute to it and which should be taken into account.

- a) First, establish if the product or process is affected by chemical contamination, as in many industries consideration of chemical contamination is not a governing factor.
- b) Establish the contaminant categories that affect the product or process and if any particular substances or substance groups require special consideration.
- c) Establish the maximum concentrations of contaminant categories and/or substances or substance groups permitted for the product or process and designate the associated ISO-ACC descriptor in accordance with [4.2](#).
- d) Establish sources of chemical contamination and concentration levels that can occur from
 - 1) outdoor air (providing fresh air to the facility);
 - 2) construction materials in the facility, especially those in contact with recirculating and make-up air streams;
 - 3) cross-contamination that can occur within the facility;
 - 4) operation and maintenance of the facility;
 - 5) personnel, cleanroom apparel and auxiliary materials;
 - 6) process media and tooling.

Further guidance on these occurrences is given in A.3 to A.8.

- e) Establish the design requirements to avoid or reduce chemical contamination generated as per A.2 d) to achieve the ISO-ACC class for the product or process.

A.3 Outdoor air

A.3.1 Where outdoor air is provided as fresh air to the facility to which the product or process is exposed, the outdoor air quality and any seasonal variation should be established with regard to the concentration of compounds or substances affecting the product or process. In addition, the construction materials of heating, ventilation or air conditioning equipment, including cabling, should be taken into account.

A.3.2 The analysis of the concentration should be conducted over a period of time sufficient to evaluate its variability, along with consideration of any future developments that can affect the outdoor air quality.

A.3.3 In some cases, due to prevailing winds, proximity of contaminating sources, etc., chemical contamination concentrations can be minimized by selective positioning of the fresh-air intake(s) to the facility.

A.3.4 Outdoor air contamination levels entering the incoming air to a building can include variable contamination levels from the same building exhaust, exhaust from neighbouring buildings, or other contamination sources including farms, sewer plants, dumps, highways, airports, train yards, local industry, and other sources. These levels can vary dramatically with wind direction, wind velocity, time of day, precipitation, temperature, sunlight or other factors. Thus it is important to use continuous monitoring where possible for the most important parameters, or to do periodic sampling on different dates and with sampling for many hours or days, so that atypical average or highest level can be assessed, rather than just a single data point.

Long-term average data is useful for predicting chemical filter lifetimes, and real-time data is valuable to assess the highest levels encountered to assess if they will affect the most sensitive products.

A.4 Construction materials

A.4.1 Construction materials serving the facility can be sources of chemical contamination because of outgassing.

Examples of suitable cleanroom construction materials are given in Annex E of ISO 14644-4:2001.^[1]

A.4.2 The degree of material outgassing can be dependent upon the temperature, relative humidity and pressure of the cleanroom or controlled environment, and these effects should be established specific to the design of the facility.

A.4.3 Outgassing from materials of construction can, in many cases, decay exponentially and asymptotically over a period of time. Thinner materials (e.g. coatings) and more volatile compounds (e.g. solvents) tend to decay more rapidly, but thicker materials (floor tiles, insulation, ULPA filter potting compounds) and higher boiling compounds (plasticisers, antioxidants, organophosphorus fire retardants, larger silicones) can decay much more slowly, and possibly outgas at significant levels for many years.

A.4.4 All materials forming the construction of a facility where air chemical contamination is of concern should be assessed with regard to their combined chemical characteristics and selected accordingly for their use. This analysis can be constructed as a table.

A.5 Cross-contamination

A.5.1 Chemical contamination can occur by migration between services, partial pressure change transfer systems and/or processes within the facility.

A.5.2 The degree of such contamination should be assessed and evaluated as part of the initial design concept.

A.5.3 In some cases, cross-contamination can be minimized or avoided by isolation, enclosure or barrier technology to contain the service or process or to provide protection to the product or process. Examples of such concepts are given in [Annex A](#) of ISO 14644-4:2001^[1] and in ISO 14644-7.^[3]

A.5.4 A significant source of cross-contamination can include the facility's exhaust or external operations. Maintaining emissions, for example below regulatory limits, may not be adequate to protect incoming air, especially on calm days, for those processes that are sensitive to air chemical contamination

at levels much lower than regulatory limits. Similarly, some compounds that are not regulated can still be very detrimental to sensitive processes.

A.6 Operation and maintenance

Chemical contamination sources from facility operation and maintenance can be prevented or minimized by scheduling disciplines, over and above those stated within ISO 14644-5,^[2] typically as below:

- facemasks or ventilated/filtered helmets worn during working process;
- qualified chemical analysis of garments, gloves and packaging materials thereof;
- qualified chemical analysis of cleaning liquids and other cleaning materials;
- qualified chemical analysis of any product packaging materials, taking into consideration operations such as outgassing during heat-sealing of bags;
- operational disciplines to minimize chemical contamination from the use of any portable equipment or temporary materials;
- temporary isolation barriers for use during maintenance or repair of machinery or services;
- operative protocols instated to minimize chemical contamination.

For the areas most sensitive to air chemical contamination effects, positive pressurization or carefully controlled air flow is required. This includes ensuring all exhaust lines are under negative pressure relative to the room to prevent air chemical contamination from more contaminated areas — which can include plenums, trenches, vents, hollow walls, tunnels and conduit — from intruding into the critical areas.

A.7 Personnel

Chemical contamination sources from personnel can be prevented or minimized by rules to control the following:

- use of cosmetics, deodorants, hand lotions, soaps perfumes and hair products;
- practice of smoking;
- use of medication;
- consumption of certain foods and drugs;
- entry and exit procedures;
- personal use of cleaning and disinfectant materials.

This list is not exhaustive.

NOTE The degree of control needed depends on the process concerned. Attention is drawn to relevant clauses of ISO 14644-5.^[2]

A.8 Other sources

These can include

- consumables;
- equipment;
- chemicals;

- reaction by-products, especially from etching or chemical vapour deposition (CVD);
- heaters, insulation, computers, displays, printers, electronics;
- leaks of chemicals, coolants, waste streams, sewer gases, antistatic treatments.

A.9 Air treatment processes for the abatement of air chemical contamination

Several processes are available in order to control or reduce the concentration of specific chemical contamination categories. These include

- sorption on suitable materials (activated carbon, treated activated carbon, ion exchange resin, zeolites, etc.);
- photoelectron ionization and electrostatic ion removal;
- catalytic photo oxidation;
- wet scrubbers or sprays, air washes using water and/or chemicals.

Annex B (informative)

Typical contaminants

B.1 Principle

The categorization of airborne chemical contaminants is a complex subject. Many compounds have chemical attributes that fit into multiple categories and therefore categorization of contaminants should be a function of the deleterious chemical reaction that the specific chemical compound of interest has on the final product that is manufactured in the cleanroom environment. [Table B.1](#) gives typical examples of contaminating chemicals and categories that can be of concern to a product or process. Users are encouraged to categorize the chemicals or substances that are specific to their concern in application in a similar manner.

[Table B.1](#) is given as guidance only and it is not intended to be exhaustive or comprehensive.

Table B.1 — Typical examples of contaminating chemicals and categories that can be of concern to a product or process

CAS No.	Substance	Rational formula	Contaminant category ^a									
			ac	ba	or	bt	cd			cr	dp	ox
							H	M	L			
7664-41-7	Ammonia	NH ₃		x		x		x		x		
141-43-5	2-Aminoethanol	H ₂ NCH ₂ CH ₂ OH		x	x				x	x		
78-91-1	2-Amino-propanol	CH ₃ (NH ₂)CHCH ₂ OH		x	x			x				
7782-50-5	Chlorine	Cl ₂				x				x		x
128-37-0	BHT:di(<i>t</i> -butyl)hydroxytoluene	CH ₃ C ₆ H ₂ (<i>t</i> -C ₄ H ₉) ₂ OH			x	x		x				
85-68-7	Butyl benzylphthalate	H ₉ C ₄ OCOC ₆ H ₄ COOCH ₂ C ₆ H ₅			x		x					
7637-07-2	Borontrifluoride	BF ₃	x							x	x	
1303-86-2	Boron oxide	B ₂ O ₃				x					x	
108-91-8	Cyclo hexylamine	C ₆ H ₁₁ NH ₂		x	x			x				
—	Cyclopoly dimethylsiloxanes	(-Si(CH ₃) ₂ O-) _{<i>n</i>}			x		x	x				
106-46-7	<i>p</i> -Dichloro benzene	ClC ₆ H ₄ Cl			x	x		x				
100-37-8	Diethyl aminoethanol	(C ₂ H ₅) ₂ NCH ₂ CH ₂ OH		x	x			x				
117-84-0	Dioctylphthalate	C ₆ H ₄ (C=OOC ₈ H ₁₇) ₂			x		x					
84-66-2	Diethylphthalate	C ₆ H ₄ (C=OOC ₂ H ₅) ₂			x		x					
84-74-2	Dibutylphthalate	C ₆ H ₄ (C=OOC ₄ H ₉) ₂			x		x					
117-81-7	Di(2-ethylhexyl)phthalate	C ₆ H ₄ (C=OOCCH ₂ CHC ₂ H ₅ C ₄ H ₉) ₂			x		x					
84-61-7	Dicyclohexylphthalate	C ₆ H ₄ (C=OOC ₆ H ₁₁) ₂			x		x					
103-23-1	Di(2-ethylhexyl)adipate	C ₄ H ₈ (C=OOCCH ₂ CHC ₂ H ₅ C ₄ H ₉) ₂			x		x					
84-76-4	Dinonylphthalate	C ₆ H ₄ (C=OOC ₉ H ₁₉) ₂			x		x					
84-77-5	Didecylphthalate	C ₆ H ₄ (C=OOC ₁₀ H ₂₁) ₂			x		x					
541-02-6	Decamethylcyclopentasiloxane	(-Si(CH ₃) ₂ O-) ₅			x		x					
540-97-6	Dodecamethylcyclohexasiloxane	(-Si(CH ₃) ₂ O-) ₆			x		x					
104-76-7	2-Ethylhexanol	CH ₃ (CH ₂) ₃ C ₂ H ₅ CHCH ₂ OH			x			x				
75-21-8	Ethylene oxide	C ₂ H ₄ O				x			x			
^a ac: acid; ba: base; bt: biotoxic; cd: condensable; cr: corrosive; dp: dopant; or: organic; ox: oxidant. H: Highly condensable, boiling point > 200 °C; M: Moderately condensable, 200 °C ≥ <i>T</i> _b ≥ 100 °C; L: weakly condensable, 100 °C > <i>T</i> _b (<i>T</i> _b is the boiling point).												

Table B.1 (continued)

CAS No.	Substance	Rational formula	Contaminant category ^a									
			ac	ba	or	bt	cd			cr	dp	ox
							H	M	L			
50-00-0	Formaldehyde	HCHO			X	X			X			
142-82-5	Heptane	C ₇ H ₁₆			X				X			
66-25-1	Hexanal	C ₆ H ₁₂ O			X	X			X			
7647-01-0	Hydrochloric acid	HCl	X			X			X	X		
766-39-3	Hydrofluoric acid	HF	X			X			X	X		
10035-10-6	Hydrobromic acid	HBr	X			X			X	X		
7783-06-4	Hydrogen sulfide	H ₂ S	X			X			X	X		
999-97-3	Hexamethyldisilazane	(CH ₃) ₃ SiNHSi(CH ₃) ₃		X	X			X				
541-05-9	Hexamethylcyclotrisiloxane	(-Si(CH ₃) ₂ O-) ₃			X			X				
67-63-0	Isopropyl alcohol	(CH ₃) ₂ CHOH			X	X			X			
10102-43-9	Nitrogen monoxide	NO	X			X			X	X		
10102-44-0	Nitrogen dioxide	NO ₂	X			X			X	X		
872-50-4	N-Methylpyrrolidone	-(NCH ₃)(C=O)(CH ₂) ₃ -		X	X			X				
644-31-5	Ozone	O ₃				X				X		X
556-67-2	Octamethylcyclotetrasiloxane	(-Si(CH ₃) ₂ O-) ₄			X			X				
7803-51-2	Phosphine	PH ₃				X			X		X	
7446-09-5	Sulfur dioxide	SO ₂	X			X			X	X		
75-50-3	Trimethylamine	(CH ₃) ₃ N		X	X					X		
121-44-8	Triethylamine	(C ₂ H ₅) ₃ N		X	X				X	X		
45-40-0	Triethyl phosphate	(C ₂ H ₅ O) ₃ P=O			X		X				X	
6145-73-9	Tris(2-chloro-1-propyl) phosphate	(CH ₃ ClCHCH ₂ O) ₃ P=O			X			X		X	X	
13674-73-9	Tris(1-chloro-2-propyl) phosphate	((CH ₃)(ClCH ₂)CH-O-) ₃ P=O			X			X		X	X	
78-30-8	Tricresyl phosphate	(CH ₃ C ₆ H ₄ O) ₃ P=O			X		X				X	
126-73-8	Tri(n-butyl) phosphate	(C ₄ H ₉ O) ₃ P=O			X		X				X	

^a ac: acid; ba: base; bt: biotoxic; cd: condensable; cr: corrosive; dp: dopant; or: organic; ox: oxidant.

H: Highly condensable, boiling point > 200 °C;

M: Moderately condensable, 200 °C ≥ T_b ≥ 100 °C; L: weakly condensable, 100 °C > T_b (T_b is the boiling point).

Table B.1 (continued)

CAS No.	Substance	Rational formula	Contaminant category ^a									
			ac	ba	or	bt	cd			cr	dp	ox
							H	M	L			
20405-30-5	Tris(2,2,2-trichloroethyl) phosphate	(Cl ₃ CH ₂) ₃ P=O			x		x				x	
115-96-8	Tris(chloroethyl) phosphate	(ClC ₂ H ₄ O) ₃ P=O			x		x			x	x	
75-59-2	Tetramethylammonium hydroxide	(CH ₃) ₄ N+OH ⁻		x	x		x					
95-47-6	Xylene	(CH ₃) ₂ C ₆ H ₄			x	x		x				
57-13-6	Urea	C=O(NH ₂) ₂		x								
	Total phthalates	R ₁ OCOC ₆ H ₄ COOR ₂			x		x					
	Total phosphates	(RO) ₃ P=O			x		x				x	
	Total siloxanes, linear plus cyclic				x		x	x	x			
	Total silicon compounds, organic + inorganic				x		x	x	x			
	Total sulfur		x		x	x	x	x	x	x		
	Total cyclosiloxanes	(-Si(CH ₃) ₂ O-) _n			x		x					
	Total hydrocarbon derivatives	C _m H _n O _p X _y (where X is any other element)			x		x	x	x			
	Total non-methane hydrocarbon derivatives	C _m H _n O _p X _y , minus CH ₄ (where X is any other element)			x		x	x	x			
	Total unsaturated hydrocarbon derivatives	C _m H _n O _p X _y (where X is any other element, with $n \leq 2m$ and C = O)			x		x	x	x			
^a ac: acid; ba: base; bt: biotoxic; cd: condensable; cr: corrosive; dp: dopant; or: organic; ox: oxidant. H: Highly condensable, boiling point > 200 °C; M: Moderately condensable, 200 °C ≥ T _b ≥ 100 °C; L: weakly condensable, 100 °C > T _b (T _b is the boiling point).												

Annex C (informative)

Typical methods of measurement

C.1 Principle

C.1.1 This annex is intended to give guidance on the various methods of measurement and analysis of chemical contamination, in consideration of the compounds and the compounds' anticipated concentrations.

C.1.2 The instruments referred to in this annex are not intended to form an exhaustive or comprehensive list, but merely represent examples in relation to the parameters of current technology as listed in [Table C.1](#).

C.2 Method concepts

C.2.1 Methods can be broadly divided into two categories:

- methods of direct analysis, including online or continuous monitors;
- methods where the sample collection is separate or even remote from the analysis of the sample.

C.2.2 Direct analysing instruments provide the possibility of relatively instantaneous measurement. Sample collection instruments, by necessity, provide a value integrated over the sample collection time period.

C.2.3 Sample-collection instruments can be further subdivided into passive sampling or active sampling, which utilizes a form of pump.

C.2.4 Passive diffusive samplers (DIFF) employ a specially prepared surface that selectively collects one or more gas component(s). This method requires extended sampling time periods for low concentration levels of ACC.

C.2.5 Active sampling collects contamination by drawing a determined volume of air through an adsorptive medium. This technique allows sampling of low concentration levels of chemical contamination within a reduced time period. Active sampling instruments can involve complex apparatus, and considerations have to be made for uptake efficiencies and handling.

C.2.6 Typical collection methods may be sorbent tube (SOR), employing a steel or glass tube filled with a suitable adsorbent, e.g. Tenax¹⁾, activated charcoal, silica gel, etc.;

- coated filter, impregnated with a suitable chemical reagent that specifically adsorbs the contaminant;
- impinger (IMP), comprising a single or series of gas-washing bottles filled with deionized water or suitable liquid reagent;
- sample bag (SB), for use at high concentrations of air chemical contamination that can be directly sampled by analysis equipment. The SB does not normally employ adsorptive media. For bag sampling, the following factors must be considered for accurate analysis: stability of sample in

1) Tenax is an example of a suitable product available commercially. This information is given for the convenience of users of this part of ISO 14644 and does not constitute an endorsement by ISO of this product.

sample bag due to factors including diffusion of analytes into or out of the bag, adsorption onto the bag, reactions between analytes, and carryover from previous samples. This method is not as useful for very high boiling point compounds that adsorb onto the polymer bags;

- canister (CAN) or cylinder sampling, using either evacuated canister that has a valve that is opened at location to be sampled, thus requiring no pump, or a cylinder that is purged using valves at both ends for many volumes, before sealing at one atmosphere, or higher pressures if available from compressed air lines. The surfaces of the sampling vessels must be appropriately passivated to avoid loss of analytes during the typical delay time between sampling and analysis, at the concentrations of interest.

C.3 Selection of typical sampling devices and analysis methods

C.3.1 Typical sampling methods

These can include, but are not limited to

- passive diffusive sampler (DIFF);
- filter collector (FC);
- impinger (IMP) set in series filled with suitable solvent, ultrapure water, or other trapping fluids that can also contain reagents;
- sample bag (SB), canister/container (CAN) for direct sampling of air;
- sorbent tube (SOR);
- witness wafer (WW) or plate used as sample collector;
- droplet scanning extraction (DSE);
- diffusion tube (DT).

C.3.2 Typical analysis methods

C.3.2.1 Off-line analysis methods

These can include, but are not limited to

- atomic absorption spectroscopy (AA-S);
- atomic absorption spectroscopy – graphite furnace (AA-GF);
- atomic emission spectroscopy (AES), or more broadly, optical emission spectrometry (OES);
- vapor phase decomposition – TXRF;
- vapor phase decomposition – ICP-MS;
- drop scan extraction – ICP-MS;
- Mass gain detection (MGD) with resonators including quartz crystal microbalances (QCM), surface acoustic wave (SAW) and similar devices;
- chemiluminescence (CL);
- capillary zone electrophoresis (CZE);
- gas chromatography – flame ionization detector (GC-FID);
- gas chromatography – mass spectroscopy (GC-MS);

- ion chromatography (IC);
- inductively coupled plasma – mass spectroscopy (ICP-MS);
- infrared spectroscopy (IR);
- mass spectroscopy (MS);
- ultraviolet spectroscopy (UVS);
- Fourier Transform infrared spectroscopy (FTIR);
- total reflection X-ray fluorescence spectroscopy (TXRF);
- vapour phase decomposition – total reflection X-ray fluorescence (VPD-TXRF);
- time of flight – secondary ion mass spectrometry (TOF-SIMS);
- atmospheric pressure ionization – mass spectroscopy (API-MS).

C.3.2.2 Online monitors

These can include, but are not limited to

- colourimetric detection on chemically impregnated paper reel-type analyser (CPR);
- ion mobility spectroscopy (IMS);
- mass gain detector (MGD) (of condensed organic build-up) using different types of piezoelectric resonators;
- portable gas chromatograph equipment (PGC);
- sensors of electrochemical cell type (ECS);
- ion chromatography monitoring system (ICS);
- chemiluminescence monitoring system (CLS);
- fluoride ion monitor (FIM);
- surface acoustic wave (SAW);
- quartz crystal microbalance (QCM);
- cavity ringdown spectroscopy (CRDS).

The user should note the detection limits and remain within them. The recovery should be between 75 % and 125 %. [Table C.1](#) illustrates a selection matrix for examples of measurement methods given above.

NOTE The applicable analysis method for a given contaminant concentration is dependent on sampling rate and duration.

Table C.1 — Selection matrix illustrating examples of measurement methods in relation to expected air chemical concentrations

ISO-ACC Class N 10 ⁿ g/m ³	Contaminant category						
	Acid	Base	Organics	Biotoxics	Condensables	Corrosives	Dopants
0	IMP, IC, UVS, DIFF, ECS	IMP, IC, UVS, DIFF, ECS	DIFF, SOR, SB, GC-FID, GC-MS, IR	IMP, IC, UVS, SB, DIFF, SOR, GC-FID, GC-MS, IR, CPR, ECS	SOR, GC-FID, GC-MS, IR	IMP, IC, UVS, DIFF, SOR, GC-FID, GC-MS, IR, ECS	SOR, GC-FID, GC-MS, IR, IMP, IC, ICP-MS, GF-AAS, UVS
-1							
-2							
-3							
-4	IMP, IC, UVS, CLS, IR, CPR, DIFF	IMP, IC, UVS, CLS, IR, CPR, DIFF		IMP, IC, UVS, CLS, IR, CPR, DIFF		IMP, IC, UVS, CLS, IR, CPR, DIFF	
-5							
-6	IMP, IC, UVS, IR, CLS, CPR, DIFF	IMP, IC, UVS, IR, CLS, CPR, DIFF	SOR, GC-FID, GC-MS, IMS	IMP, IC, UVS, IR, CLS, CPR, DIFF, SOR, GC-MS, ICP-MS	SOR, GC-FID, GC-MS, MGD	IMP, IC, UVS, IR, CLS, CPR, DIFF, SOR, GC- FID, GC-MS	IC, SOR, GC-MS, IMP, ICP, MS
-7							
-8	IMP, IC	IMP, IC, IMS		IMP, IC, SOR, GC-MS, ICP-MS		IMP, IC, SOR, GC-MS	
-9	IMP, IC, CZE, IMS		SOR, GC-MS	IMP, IC, CZE, IMS, SOR, GC-MS, ICP-MS	SOR, GC-MS	IMP, IC, CZE, IMS, SOR, GC-MS	
-10	IMP, CZE	IMP, IC, CZE		IMP, CZE, SOR, GC-MS, ICP-MS		IMP, CZE, SOR, GC-MS	
-11							
-12							
NOTE Methods corresponding to these abbreviations are listed in C.3.							

Annex D (informative)

Consideration of specific requirements for separative devices

D.1 Principle

D.1.1 This annex is intended to give guidance for separative devices that, by their nature and application, embody special design features that require consideration when classifying to the requirements of air chemical contamination. Details of the various types and applications of such devices are given within ISO 14644-7.

D.1.2 Consideration should be given to the possibility of contamination from a separative device itself.

In some cases, where no direct measurement of the ACC is possible (e.g. in a volume too small), measurements of the surface cleanliness by chemical concentration are the only possible way of characterizing the degree of cleanliness.

NOTE The relation between SCC (expressed in concentration/unit of area) and ACC (expressed in concentration/unit of volume of air) is generally not known. In cases where the relationship between the measured SCC and the ACC has been determined experimentally (or by another way) and is known, SCC results can be used to calculate units of ACC and thereby used for classification.

D.2 Specific considerations

D.2.1 The design of the barrier technology employed can restrict choices in the method of sampling and measuring ACC. The optimum testing method should be established and agreed between customer and supplier, and provisions made as necessary concerning the design of the device for any fittings or fixings required for testing purposes.

D.2.2 The materials used in the construction of the device should be considered in conjunction with [Annex A](#) of this part of ISO 14644. Many such devices employ flexible screens or barriers in conjunction with flexible gloves, bags or manipulative devices. These materials and their potential sources of chemical contamination should be considered.

D.2.3 Any retrofitted materials or extensions to the device and their potential sources of chemical contamination should be considered.

D.2.4 Where the product is of particular concern, it may be decided to verify the performance of the device by a process of measurement and analysis of the surface chemical cleanliness of the product (see D.1.2).

Where verification is performed by evaluating surface cleanliness by chemical concentration, the time period in which the product remains in the device can be a major influencing factor and should be considered.

D.2.5 Pumped sampling of small enclosure using a feed gas to make up for the gas sampled can significantly dilute the air chemical contaminant's concentration at the start of sampling, especially if the sampling volume is much larger than the enclosure. This can lead to artificially low values for the concentration calculated based on sampling volume vs. the actual concentration prior to sampling.

D.2.6 While the ACC tests in this part of ISO 14644 are for cleanroom air, similar principles can be applied to other devices, enclosures, and potentially environments purged with gases including clean dry

air, nitrogen, inert gases or gas mixtures. Similar concepts could also be applied to pressurized sampling locations, but these are not covered in this part of ISO 14644.

D.2.7 Specific industries can have specific recommended test methods or specifications, or guidelines for control of air chemical contamination. See the Bibliography.



Bibliography

- [1] ISO 14644-4:2001, *Cleanrooms and associated controlled environments — Part 4: Design, construction and start-up*
- [2] ISO 14644-5:2004, *Cleanrooms and associated controlled environments — Part 5: Operations*
- [3] ISO 14644-7:2004, *Cleanrooms and associated controlled environments — Part 7: Separative devices (clean air hoods, glove boxes, isolators and mini-environments)*
- [4] ISO 14698 (all parts), *Cleanrooms and associated controlled environments — Biocontamination control*
- [5] SEMI F21-1102, *Classification of Airborne Molecular Contaminant Levels in Clean Environments*
- [6] Technology Roadmap for Semiconductors, Yield Enhancement Groups, Section on Wafer Environmental Contamination Control
- [7] IEST-G-CC035.1, *Design Considerations for AMC Filtration Systems in Cleanrooms*
- [8] ASTM D5127-99, *Standard Guide for Ultra Pure Water Used in the Electronics and Semiconductor Industry*
- [9] JACA No. 34-:2000, *Standard for Evaluation of Airborne Molecular Contaminants Emitted from Construction/Composition Materials for Clean Room*
- [10] JACA No. 35A-2003, *Standard for Classification of Air Cleanliness for Airborne Molecular Contaminant (AMC) Level in Cleanrooms and Associated Controlled Environments and its Evaluation Methods*
- [11] JACA No. 43-2006, *Standard for Evaluation Methods on Substrate Surface Contamination in Cleanrooms and Associated Controlled Environments*
- [12] SEMI E108-0307, *Test Method for the Assessment of Outgassing Organic Contamination from Minienvironments using Gas Chromatography/Mass Spectrometry*
- [13] IEST-RP-CC031.2, *Method for Characterising Outgassed Compounds from Cleanroom Materials and Components*
- [14] IDEMA Standard M11-99, *General Outgas Test Procedure by Dynamic Headspace Analysis*
- [15] JIS B9917-8:2010, *Standard for Classification of Air Cleanliness for Airborne Molecular Contaminants (AMC) Level in Cleanrooms and Associated Controlled Environments and its Evaluation Methods*
- [16] *Airborne Molecular Contamination*. Fujimoto.T, Takeda, K and Nonaka, T. - 'Developments in Surface Contamination and Cleaning' - William Andrew Publishing 2007
- [17] SEMI E45-1101, *Test Method for the Determination of Inorganic Contamination from Minienvironments Using Vapour Phase Decomposition-Total Reflection X-Ray Spectroscopy (VPD-TXRF), VPD-Atomic Absorption Spectroscopy (VPD-AAS), or VPD/Inductively Coupled Plasma-Mass Spectrometry (VPD/ICP-MS)*
- [18] SEMI E460307, *Test Method for the Determination of Organic Contamination from Minienvironments Using Ion Mobility Spectrometry (IMS)*
- [19] Takeda K., Mochizuki A., Nonaka T., Matsumoto I., Fujimoto T., Nakahara T. Evaluation of Outgassing Compounds from Cleanroom Construction Materials. *J. IEST*. 2001, **44** (No. 1) pp. 28–32
- [20] Tamura H., Fujii S., Yuasa K. and Kagi N. Evaluation Method of VOC Emissions from Cleanroom Materials using the Double Cylinder Chamber. *Journal of Architecture, Planning and Environmental Engineering*, No. 520, pp. 55-59 (1999)

- [21] Tamura H., Fujii S., Kagi N. *Estimate of the Time Change of the Gas Emission Flux*. Proceedings of the 48th IEST Annual Technical Meeting and the 16th International Symposium on Contamination Control, ESTECH 2002 Proceedings, pp 7-15, Anaheim, California U.S. (2002), BUEE 2001, Seoul, Korea (2001)



医课汇
公众号
专业医疗器械资讯平台
WECHAT OF
HLONGMED



hlongmed.com
医疗器械咨询服务
MEDICAL DEVICE
CONSULTING
SERVICES



医课培训平台
医疗器械任职培训
WEB TRAINING
CENTER



医械宝
医疗器械知识平台
KNOWLEDG
ECENTEROF
MEDICAL DEVICE



MDCPP.COM
医械云专业平台
KNOWLEDG
ECENTEROF MEDICAL
DEVICE