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**Cleanrooms and associated controlled environments —**

**Part 15:  
Assessment of suitability for use of  
equipment and materials by airborne  
chemical concentration**

*Salles propres et environnements maîtrisés apparentés —*

*Partie 15: Évaluation de l'aptitude à l'emploi des équipements et  
des matériaux par la détermination de la concentration chimique  
aéroportée*

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# Contents

	Page
Foreword .....	iv
Introduction .....	v
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 Symbols</b> .....	<b>4</b>
<b>5 Test setup</b> .....	<b>5</b>
5.1 General .....	5
5.2 Closed design .....	5
5.3 Closed design special application .....	6
5.4 Open design .....	7
<b>6 Representative mode</b> .....	<b>7</b>
6.1 Equipment .....	7
6.2 Material .....	7
<b>7 Visual inspection</b> .....	<b>8</b>
7.1 General .....	8
7.2 Equipment .....	8
7.3 Material .....	8
<b>8 Test description</b> .....	<b>9</b>
<b>9 Calculation of the measured concentrations</b> .....	<b>9</b>
<b>10 Calculation of specific emission rate</b> .....	<b>10</b>
10.1 Calculation of specific emission rate — Closed design .....	10
10.2 Calculation of specific emission rate — Open design .....	11
<b>11 Assessment</b> .....	<b>11</b>
11.1 General .....	11
11.2 Required input data .....	12
11.3 Calculation to determine the effect on a cleanroom or controlled zone .....	12
11.4 Assessment of the suitability of material(s) or equipment for an existing cleanroom or controlled zone .....	13
<b>12 Documentation</b> .....	<b>13</b>
12.1 General .....	13
12.2 Common documentation requirements .....	13
12.3 Test documentation .....	14
12.4 Visual inspection .....	14
12.4.1 Equipment .....	14
12.4.2 Materials .....	14
<b>Annex A (informative) Example calculation for suitability assessment of one equipment (existing installation)</b> .....	<b>15</b>
<b>Annex B (informative) Example calculation for suitability assessment of wall material (existing cleanroom/clean zone installation)</b> .....	<b>17</b>
<b>Annex C (informative) Suitability assessment of a combination of equipment and floor material in a cleanroom to be designed</b> .....	<b>19</b>
<b>Bibliography</b> .....	<b>21</b>

## 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](http://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](http://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 on 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 the following URL: [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*.

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

## Introduction

Cleanrooms and associated controlled environments provide for the control of contamination to levels appropriate for accomplishing contamination-sensitive activities. Products and processes that benefit from the control of contamination include those in such industries as aerospace, microelectronics, optics, nuclear, and life sciences (pharmaceuticals, medical devices, food, healthcare).

This document addresses the cleanroom classification of air cleanliness by chemical concentration to the suitability of equipment for use in cleanrooms and associated controlled environments.

Examples and suitability assessments are given in [Annexes A, B and C](#).

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# Cleanrooms and associated controlled environments —

## Part 15:

# Assessment of suitability for use of equipment and materials by airborne chemical concentration

## 1 Scope

This document provides requirements and guidelines for assessing the chemical airborne cleanliness of equipment and materials which are foreseen to be used in cleanrooms and associated controlled environments which are linked to the ISO standard for cleanliness classes by chemical concentration (see ISO 14644-8).

The following are outside the scope of this document:

- health and safety requirements;
- compatibility with cleaning agents and techniques;
- cleanability;
- biocontamination;
- specific requirements of equipment and materials for processes and products;
- design details of equipment.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 14644-8:2013, *Cleanrooms and associated controlled environments — Part 8: Classification of air cleanliness by chemical concentration (ACC)*

## 3 Terms and definitions

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

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

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

### 3.1

#### air chemical contamination

any non-particulate chemical specie(s) in the air that can, by its chemical nature, adversely affect the product, process or equipment

[SOURCE: ISO 14644-8:2013, 3.1.3, modified — “substance” has been replaced by “non-particulate chemical specie(s)”.]

**3.2  
air cleanliness by chemical concentration**

ACC

level of air *cleanliness* (3.5) 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.

[SOURCE: ISO 14644-8:2013, 3.1.2]

**3.3  
breakthrough volume**

maximum *purge gas* (3.14) volume that can be drawn through a trapping system without loss of analyte at a specific temperature

**3.4  
chemical contamination**

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

[SOURCE: ISO 14644-8:2013, 3.1.1]

**3.5  
cleanliness**

condition not exceeding a specified level of contamination

**3.6  
cleanroom**

room within which the number concentration of airborne particles is controlled and classified, and which is designed, constructed and operated in a manner to control the introduction, generation, and retention of particles inside the room

Note 1 to entry: The class of airborne particle concentration is specified.

Note 2 to entry: Levels of other cleanliness attributes such as chemical, viable or nanoscale concentrations in the air, and also surface cleanliness in terms of particle, nanoscale, chemical and viable concentrations may also be specified and controlled.

Note 3 to entry: Other relevant physical parameters may also be controlled as required, e.g. temperature, humidity, pressure, vibration and electrostatic.

[SOURCE: ISO 14644-1:2015, 3.1.1]

**3.7  
cleanroom suitability**

ability to maintain the critical control attributes or condition of any *clean zone* (3.8) when used as intended

Note 1 to entry: For the purposes of this document, the assessment is based on air chemical concentration.

Note 2 to entry: The definition refers to the use of equipment and materials.

[SOURCE: ISO 14644-14:2016, 3.3, modified — Note 2 has been added.]

**3.8  
clean zone**

defined space within which the number concentration of airborne particles is controlled and classified, and which is constructed and operated in a manner to control the introduction, generation, and retention of contaminants inside the space

Note 1 to entry: The class of airborne particle concentration is specified.

Note 2 to entry: Levels of other cleanliness attributes such as chemical, viable or nanoscale concentrations in the air, and also surface cleanliness in terms of particle, nanoscale, chemical and viable concentrations may also be specified and controlled.

Note 3 to entry: A clean zone(s) may be a defined space within a cleanroom or may be achieved by a separative device. Such a device may be located inside or outside a cleanroom.

Note 4 to entry: Other relevant physical parameters may also be controlled as required, e.g. temperature, humidity, pressure, vibration and electrostatic.

[SOURCE: ISO 14644-1:2015, 3.1.2]

### 3.9 controlled zone

designated space in which the concentration of at least one contamination category (particles, chemical, biocontamination) in air and/or on surfaces is controlled and specified and which is constructed and used in a manner to minimize the introduction and impact of contamination

Note 1 to entry: Levels of cleanliness attributes such as chemical and viable concentrations in the air or cleanliness in terms of particle, chemical and viable concentrations on surfaces may be specified by class(es).

Note 2 to entry: Other relevant parameters may also be controlled as necessary, e.g. temperature, humidity and pressure, vibration and electrostatic.

Note 3 to entry: A controlled zone can be a defined space within a cleanroom or may be achieved by a separative device. Such a device may be located inside or outside a cleanroom.

### 3.10 emission

contaminants that are discharged into the environment

[SOURCE: ISO 2889:2010, 3.30]

Note 1 to entry: For the purposes of this document, only chemical emission is considered.

### 3.11 emission rate

rate describing the mass of one or more volatile chemical(s) emitted from the equipment or material per time unit

### 3.12 equipment

system designed for specific function(s), integrating materials, components and/or controls

EXAMPLE Testing and manufacturing equipment and machinery; equipment for transport and handling; storage units; tools; furniture; doors; ceilings; IT hardware; handling robots.

[SOURCE: ISO 14644-14:2017, 3.6]

### 3.13 material

single substance or composite

Note 1 to entry: It might be necessary to provide material in a representative form to enable testing.

### 3.14 purge gas

gas or gas mixture to carry contaminant to a defined outlet

Note 1 to entry: In a controlled or *clean zone* (3.8) or a *cleanroom* (3.6), filtered air might be used as purge gas.

Note 2 to entry: A *test environment* (3.18) might be purged with air or other gases or gas mixtures to carry the contaminant to a trapping system or measurement device.

**3.15**

**representative form**

material sample produced to represent the intrinsic physical and chemical properties of an object

**3.16**

**representative mode**

mode of operation that reflects the intended use of the equipment

**3.17**

**specific emission rate**

normalized mass flow of chemical contaminants emitted from a test object

Note 1 to entry: Material-specific *emission rate* (3.11) is based on surface area.

Note 2 to entry: Equipment-specific emission rate is based on one single unit of equipment.

**3.18**

**test environment**

space in which the test is carried out, described by a set of parameters

[SOURCE: ISO 14644-14:2017, 3.7]

**4 Symbols**

Symbol	Meaning	Unit
$p_b$	Background concentration in the test environment without the test object	$g/m^3$
$p_o$	Concentration in the test environment with the test object	$g/m^3$
$p_c$	Chemical mass concentration in the cleanroom/controlled zone	$g/m^3$
$p_m$	Chemical mass concentration of the make up air	$g/m^3$
$F_b$	Sampling flow rate background measurement	$m^3/s$
$F_o$	Sampling flow rate object measurement	$m^3/s$
$m_o$	Total sampled mass emitted from the test environment with test object	g
$m_b$	Total sampled mass emitted from the test environment without test object	g
$t_o$	Sampling duration object measurement	s
$t_b$	Sampling duration background measurement	s
$x$	Specific metric related to the test object	$m^2$ for materials "unit" for equipment
$x$	Quantity related to the assessed object	$m^2$ for materials "unit" for equipment
$q_o$	Specific emission rate of the test object	$g/(m^2s)$ or $g/(unit \cdot s)$
$n_t$	Air change rate through the test environment	1/s
$n_m$	Make up air change rate	1/s
$n_r$	Recirculated air change rate	1/s
$V_c$	Volume of air in the cleanroom/ controlled zone	$m^3$
$V_t$	Volume of the test environment	$m^3$
$\alpha$	Specified efficiency of the chemical filtration system	—

## 5 Test setup

### 5.1 General

The test setup shall be designed for collecting representative samples of contaminants within the test environment in order to assess specific emission rates from equipment and/or materials. It can be designed as closed (see [Figure 1](#)), closed special application (see [Figure 2](#)) or open (see [Figure 3](#)).

Closed design is used for low specific emission rates and is the preferred method. Larger test objects and equipment in operation may require the use of an open design test setup (see [5.4](#)).

The tolerance of the temperature sensor shall be  $\pm 2$  °C.

The tolerance of the flow meter shall be  $\pm 5$  %.

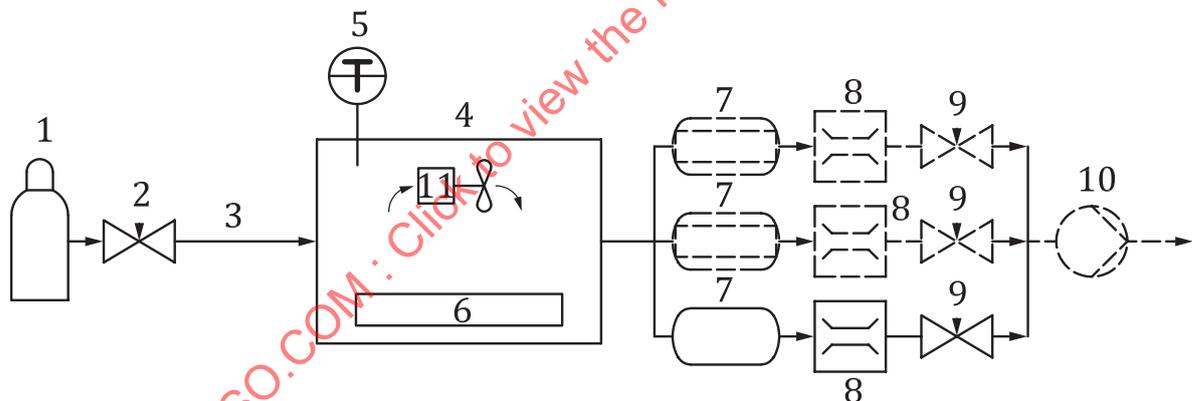
The humidity of the purge gas shall be specified and controlled.

The sampling of ACC-emissions is performed by purging a defined gas volume onto a suitable trapping system, e.g. an adsorber. Multiple trapping systems can be used to collect different species of contaminants.

ISO 14644-8:2013, Annex C gives an overview regarding trapping and measuring techniques.

NOTE For considerations regarding VOC-sampling, see ISO 16000-6 and ISO 16017-1.

### 5.2 Closed design



#### Key

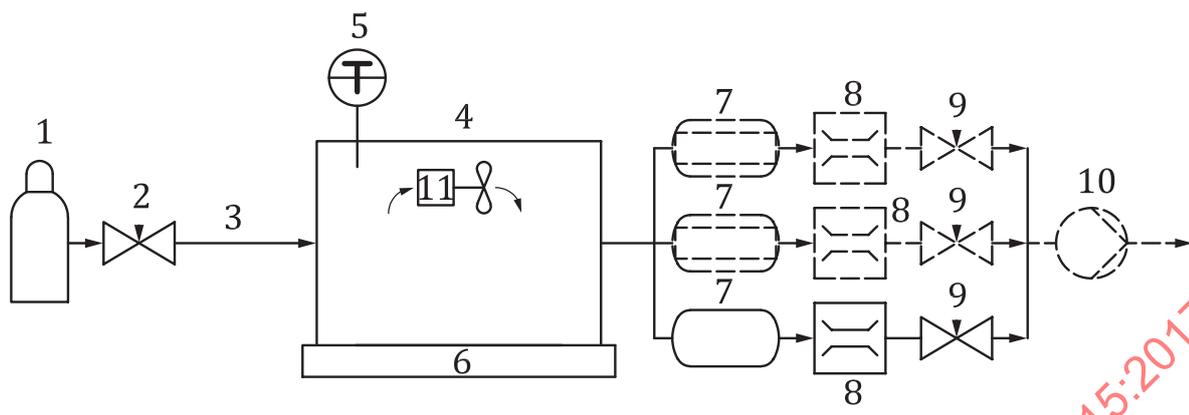
1	purge gas source	7	trapping system(s)
2	valve for purge gas supply	8	flow meter(s)
3	connection to chamber	9	valve(s) for flow control
4	test chamber	10	pump (option)
5	temperature sensor	11	mixing device (option)
6	material sample or equipment		

NOTE Depending on the size of the test environment, a mixing device can be installed to enable homogeneous mixing.

**Figure 1 — Closed design**

Using a closed design requires a flow-controlled purge gas supply and a flow meter installed after the trapping system. The purge gas flow shall be controlled by a valve. In addition, a pump may be used downstream of the flow meter.

5.3 Closed design special application



Key

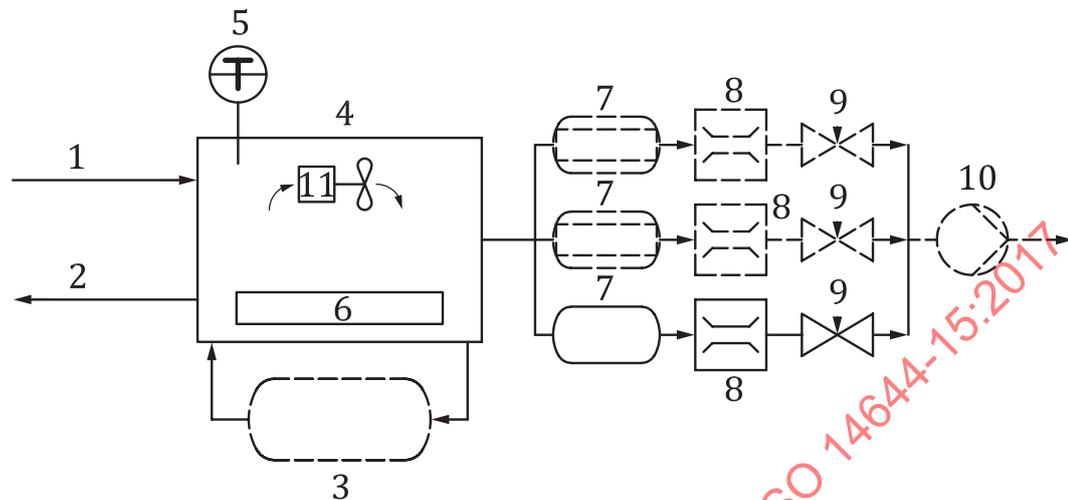
- |   |                            |    |                           |
|---|----------------------------|----|---------------------------|
| 1 | purge gas source           | 7  | trapping system(s)        |
| 2 | valve for purge gas supply | 8  | flow meter(s)             |
| 3 | connection to chamber      | 9  | valve(s) for flow control |
| 4 | test chamber               | 10 | pump (option)             |
| 5 | temperature sensor         | 11 | mixing device (option)    |
| 6 | material sample            |    |                           |

Figure 2 — Closed design special application

This setup is used for material samples with even surfaces. Both the enclosure and the material sample surface shall form a gastight test environment.

To obtain a background analysis, substitute test material with glass or stainless steel plate that can be chemically cleaned to the same extent as the chamber walls.

## 5.4 Open design



### Key

1	make up air	7	trapping system(s)
2	exhaust air	8	flow meter(s)
3	optional air recirculation (without chemical filtration)	9	valve(s) for flow control
4	test chamber	10	pump (option)
5	temperature sensor	11	mixing device (option)
6	material sample or equipment		

**Figure 3 — Open design**

This setup is intended for larger equipment and equipment in operation. It typically represents a cleanroom or controlled zone; therefore air is used as purge gas. Chemical filtration, make up air and background emission can influence the capability of this test setup. The sampled amount of gas is a defined portion of the purge gas going through the test environment. The remaining excess purge gas is released by the exhaust air (leakage of the test environment and exhaust air passing the HVAC-system).

## 6 Representative mode

### 6.1 Equipment

The representative mode of operation has to reflect the intended use of the equipment. Representative equipment parameters of operation shall be defined and agreed upon before testing.

### 6.2 Material

Materials shall be assessed in a form directly related to its intended use (including the material characteristics such as layers, composite thickness, porosity and surface texture) by considering following parameters:

- age of material:  $28 \pm 2$  days (see ISO 16000-9);
- physical state: solid or liquid;
- surface area of the sample, derived from measurement or from projection (for porous and granular materials).

If such a material sample cannot be obtained, the proxy sample shall be manufactured with the same chemical composition and shall have undergone a similar forming process as the finished component.

Materials of different age can be assessed, but this deviation shall be clearly highlighted. A comparison of materials can only be performed based on using the same material age.

## 7 Visual inspection

### 7.1 General

Visual surface cleanliness shall be qualitatively assessed, before and after any quantitative assessment, such that the quantitative tests shall not be compromised. The visual inspection should focus on chemical sources that may have been inadvertently introduced during manufacture, packaging, shipment or, in the case of equipment, installation.

The results from visual inspection should be documented and be available for comparison with any post-test visual inspection results. The outcome of a visual inspection may be used as basis to direct a repeat or improved decontamination process for equipment, or the submission of a replacement material sample.

It is not intended that this inspection provides a measurement of sample cleanliness.

### 7.2 Equipment

The visual inspection shall ensure that all packaging has been removed and that the equipment is undamaged, is correctly assembled and appropriately connected to its required utilities.

Inspection should identify contamination, such as particles and films that may have originated from manufacturing, packaging, transportation or initial assembly, which has withstood any prior decontamination process.

Detection efficiency of visible contamination for equipment will depend upon the following factors:

- the accessibility and orientation of the surface to be inspected;
- materials used for equipment construction, their surface condition and treatment;
- viewing parameters (e.g. illumination type, field of view, vision magnification, viewing distance).

### 7.3 Material

This visual inspection should focus on chemical sources that may have been inadvertently introduced during manufacture, shipment, re-sizing or other preparation actions undergone by the material.

Therefore, the objectives of this inspection are to

- identify visual characteristics of the material that could influence subsequent testing. These characteristics could include sample homogeneity, surface roughness, texture and porosity. Following quantifiable testing, the inspection should assess samples for any degradation due to test environment factors such as temperature or humidity, and
- conduct visual inspection parameters such as viewing distance and illumination type, since these can be more consistent than those for equipment due to smaller sample size. Again, inspection parameters, along with the results of inspection, shall be documented.

## 8 Test description

The following outline describes the necessary sampling and analysis steps.

- 1) Select the test environment with regards to the sample size, geometry and mode of operation.
- 2) Select a suitable trapping system (type and capacity), purge gas and analysis technique to obtain mass values with regard to the contaminant to be investigated.

NOTE ACC analysis techniques are mentioned in ISO 14644-8:2013, Annex C.

Depending on the airborne chemical contaminant or contaminant group to be measured, direct techniques without any trapping may be suitable (PTR-MS, FTIR, FID, CRDS).

From sample collection to analysis (packaging and transportation), consideration should be given to the incorporation of transport blank samples.

- 3) Define the sampling time and volume with regard to the expected emission of the test object. The detection limit of the measurement device and the breakthrough volume of the trapping system need to be taken into account. Set the temperature of the test environment at the agreed temperature (guidance value 22 °C) and maintain it  $\pm 2$  °C.

Sampling at elevated temperatures may be performed for gathering additional information.

- 4) Install the trapping system and start the purge gas flow through the test environment without any installed test object for the defined sampling time.

In case a closed design special application (see 5.3) is used, the test material shall be replaced with suitable material, e.g. glass or stainless steel plate matching the chamber wall chemical emission properties.

- 5) Record the flow rate and sampling time.
- 6) Stop gas the flow after the predefined sampling time and remove the trapping system for analysis.
- 7) Perform an analysis of the trapping system to obtain background mass values (in g).

Potential condensation on the interior surfaces of the test environment can have an influence on the test results

- 8) Introduce the test object into the test environment in its representative mode.
- 9) Allow purge that is at least three times the volume of the test environment before entering the next step. Record the time.
- 10) Record the flow rate and sampling time.
- 11) Install the trapping system and start the purge gas flow of the test environment for the defined sampling time. Record the sampling time.
- 12) Stop the gas flow after the predefined sampling time and remove the trapping system for analysis.
- 13) Perform an analysis of the trapping system to obtain test object mass values emitted (in g).

Depending on the analytical methods used, appropriate quality control elements should be considered.

## 9 Calculation of the measured concentrations

The concentration values can be calculated from their corresponding analysed mass values,  $m$ , sampling flow rates,  $F$ , and sampling duration values,  $t$ , obtained during the test.

For interpretation of the result, the uncertainty of each parameter used has to be considered, as shown in [Formulae \(1\)](#) and [\(2\)](#):

$$p_o = \frac{m_o}{F_o \cdot t_o} \quad (1)$$

$$p_b = \frac{m_b}{F_b \cdot t_b} \quad (2)$$

where

$p_b$  is the background concentration in the test environment without the test object in g/m<sup>3</sup>;

$p_o$  is the concentration in the test environment with the test object in g/m<sup>3</sup>;

$m_b$  is the total sampled mass emitted from the test environment without the test object in g;

$m_o$  is the total sampled mass emitted from the test environment with the test object in g;

$F_b$  is the sampling flow rate background measurement in m<sup>3</sup>/s;

$F_o$  is the sampling flow rate object measurement in m<sup>3</sup>/s;

$t_b$  is the sampling duration background measurement in s;

$t_o$  is the sampling duration object measurement in s.

## 10 Calculation of specific emission rate

### 10.1 Calculation of specific emission rate — Closed design

The specific emission rate of the test object,  $q_{\text{object}}$ , is calculated from the mass values,  $m_o$  and  $m_b$ , the sampling duration,  $t_o$ , and the specific metric,  $x$ . Any detected background mass shall be subtracted.

The mass value of the test object has to be at least ten times higher than the background mass value. If this criterion is not fulfilled, the selection of the parameters applied and the sampling/measurement devices need to be reconsidered, as shown in [Formula \(3\)](#):

$$q_o = \frac{m_o - m_b}{x \cdot t_o} \quad (3)$$

where

$q_o$  is the specific emission rate of the test object in g/(m<sup>2</sup> s) or g/(unit · s);

$m_o$  is the total sampled mass from the test environment with the test object in g;

$m_b$  is the total sampled mass from the test environment without the test object in g;

$t_o$  is the sampling duration object measurement in s;

$x$  is the specific metric,  $x$ , related to the test object (area or unit) in m<sup>2</sup> or unit.

The specific emission rate shall always be stated with the chemical or chemical group it has been assessed for.

## 10.2 Calculation of specific emission rate — Open design

The specific emission rate of the test object  $q_{\text{object}}$ , depends on the calculated mass concentrations,  $p_o$  and  $p_b$ , the volume of the test environment,  $V_t$ , the air change rate through the test environment,  $n_t$ , and the specific metric,  $x$ , related to the test object. Any detected background mass shall be subtracted.

The mass concentration value of the test object has to be at least ten times higher than the background mass concentration value. If this criterion is not fulfilled, the selection of the parameters applied and the sampling/measurement devices need to be reconsidered, as shown in [Formula \(4\)](#):

$$q_o = \frac{V_t \cdot n_t \cdot (p_o - p_b)}{x} \quad (4)$$

where

$q_o$  is the specific emission rate of the test object in  $\text{g}/(\text{m}^2 \text{ s})$  or  $\text{g}/(\text{unit s})$ ;

$p_b$  is the background concentration in the test environment without the test object in  $\text{g}/\text{m}^3$ ;

$p_o$  is the concentration in the test environment with the test object in  $\text{g}/\text{m}^3$ ;

$n_t$  is the air change rate through the test environment in  $1/\text{s}$ ;

$V_t$  is the volume of the test environment in  $\text{m}^3$ ;

$x$  is the specific metric,  $x$ , related to the test object in  $\text{m}^2$  or unit.

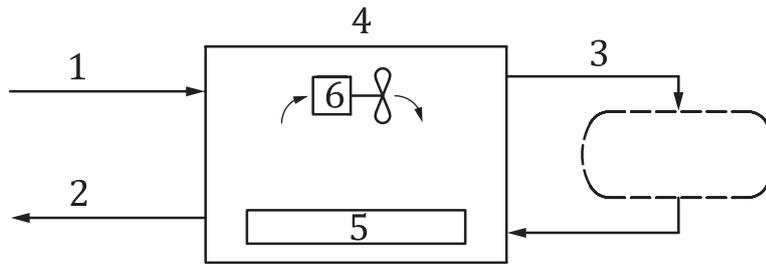
The specific emission rate shall always be stated with the chemical or chemical group it has been assessed for.

## 11 Assessment

### 11.1 General

The specific emission rate is used to assess the impact on air cleanliness by chemical concentration (ACC) of a controlled zone. This can be used either for a given installation or during design of a cleanroom or controlled zone. [Figure 4](#) illustrates the individual parameters needed for the assessment of a controlled zone.

NOTE Efficiency of chemical filtration changes over time.



**Key**

- 1 make up air ( $P_m, n_m$ )
- 2 exhaust air
- 3 optional air recirculation ( $n_{re}$ ) with or without chemical filtration (efficiency,  $\alpha$ )
- 4 cleanroom or controlled zone ( $V_c, p_c$ )
- 5 material sample or equipment
- 6 mixing device (option)

**Figure 4 — Cleanroom or controlled zone with its corresponding parameters as a typical example for an open design environment**

**11.2 Required input data**

- temperature;
- dimensions of controlled zone:  $V_c$ ;
- air change rate of make up air:  $n_m$ ;
- air change rate of recirculated air (if applicable):  $n_r$ ;
- chemical mass concentration of make up air:  $p_m$ ;
- efficiency of chemical filtration in recirculation (if applicable):  $\alpha$ ;
- chemical mass concentration of the air in the cleanroom/controlled zone:  $p_c$ ;
- specific emission rate of all considered objects (material and/or equipment), if the final ISO-ACC-class has to be assessed:  $q_o$ ;
- metric,  $x$  (surface area for material and unit count for equipment);
- targeted ISO ACC class number,  $N$ , in the controlled zone, if upper limit of the specific emission rate of all considered objects has to be assessed.

**11.3 Calculation to determine the effect on a cleanroom or controlled zone**

The chemical mass concentration,  $p_c$ , of the controlled zone can be calculated as shown in [Formula \(5\)](#) in the case a chemical filtration system is used:

$$p_c = \frac{p_m \cdot n_m + \frac{\Sigma(q_o \cdot x)}{V_c}}{n_m + n_r \cdot \alpha} \tag{5}$$

where

$q_0$  is the specific emission rate of all considered objects (material or/and equipment) in  $\text{g}/(\text{m}^2 \text{ s})$  or  $\text{g}/(\text{unit s})$ ;

$p_c$  is the chemical mass concentration in the cleanroom/controlled zone in  $\text{g}/\text{m}^3$ ;

$p_m$  is the chemical mass concentration of the make up air in  $\text{g}/\text{m}^3$ ;

$n_m$  is the make up air change rate in  $1/\text{s}$ ;

$n_r$  is the recirculated air change rate in  $1/\text{s}$ ;

$V_c$  is the volume of air in the cleanroom/controlled zone in  $\text{m}^3$ ;

$x$  is the quantity related to the assessed object in  $\text{m}^2$  or unit;

$\alpha$  is the efficiency of the chemical filtration system.

NOTE If there is no chemical filtration system in the recirculated air,  $\alpha$  is 0.

#### 11.4 Assessment of the suitability of material(s) or equipment for an existing cleanroom or controlled zone

The assessment of suitability can be performed on matching chemicals or chemical groups only.

An assessment is only allowed if the temperature during sampling for the specific emission rate has been equal or higher than the temperature of the cleanroom installation to be evaluated.

The calculated chemical mass concentration of the cleanzone,  $p_c$ , is compared to ISO ACC class number  $N$  that shall be determined according to ISO 14644-8:2013, 4.2.

If the concentration,  $p_c$ , does not exceed the concentration given for the respective ISO ACC class number,  $N$ , then the material(s) or equipment(s) is (are) suitable for use in this ISO ACC environment with its given parameters.

## 12 Documentation

### 12.1 General

The documentation shall contain required test setup and analysis information to enable reproduction of the testing for suitability assessment.

### 12.2 Common documentation requirements

- description of the test including selection of test chamber design;
- reference to standards and/or guidelines used;
- date;
- place where assessment is carried out;
- person(s) performing the test;

- customer;
- marking/identification of test object;
- type designation of equipment used and applicable calibration dates or records.

### 12.3 Test documentation

- for equipment, a full description including mode(s) of operation;
- for materials, form of sample, its age and surface area presented for assessment;
- for the test setup design that has been selected, all key parameters are to be documented for example,
  - purge gas selected and its flow rate,
  - chamber temperature,
  - trapping system type,
  - sampling time, and
  - in open design, all relevant clean room parameters including specified efficiency for any chemical filtration used;
- records for transportation of the trapping system(s) to the analytical setup including details for transport blanks;
- setup for analysis for example,
  - equipment description used for analysis, and
  - respective results.

### 12.4 Visual inspection

#### 12.4.1 Equipment

- Record equipment condition, any damage and compatibility with the utilities and services connection.
- For visual artefacts, record surfaces affected and inspection conditions.

#### 12.4.2 Materials

- Record observations of the material to be tested; its representative form, any packaging used and sample general condition.
- Sample homogeneity, surface appearance and edge condition.

## Annex A (informative)

### Example calculation for suitability assessment of one equipment (existing installation)

A new equipment with a known specific emission rate is introduced in an existing installation with ACC-filtration in the recirculation air.

An ISO-ACC class N of -4 should be maintained.

Chemical group of interest is: total organic.

**Table A.1 — Input data**

Symbol	Meaning	Values	Unit
$p_m$	Mass concentration of the make up air	$1,0 \times 10^{-4}$	$\text{g}/\text{m}^3$
$q_e$	Equipment specific emission rate <sup>a</sup>	$5,0 \times 10^{-4}$	$\text{g}/\text{unit} \cdot \text{s}$
$x$	Number of equipment	1	unit
$n_m$	Calculated air exchange rate achieved by the purge air	0,01	1/s
$n_r$	Calculated air exchange rate achieved by the recirculated air	0,2	1/s
$V_c$	Volume of air in the cleanroom	250	$\text{m}^3$
$\alpha$	Chemical filtration efficiency	0,9	—

<sup>a</sup> It is assumed that no other objects are contributing to the chemicals of interest.

With these parameters, the chemical mass concentration in the cleanroom,  $p_c$ , can be calculated using [Formula \(A.1\)](#):

$$p_c = \frac{p_m \cdot n_m + \frac{\Sigma(q_e \cdot x)}{V_c}}{n_m + n_r \cdot \alpha} \quad (\text{A.1})$$

$$p_c = \frac{1,0 \cdot 10^{-4} \frac{\text{g}}{\text{m}^3} \cdot 0,01 \frac{1}{\text{s}} + \frac{\Sigma \left( 5,0 \cdot 10^{-4} \frac{\text{g}}{\text{unit} \cdot \text{s}} \cdot 1 \text{ unit} \right)}{250 \text{ m}^3}}{0,01 \frac{1}{\text{s}} + 0,2 \frac{1}{\text{s}} \cdot 0,9} \quad (\text{A.2})$$

$$p_c = 1,58 \cdot 10^{-5} \frac{\text{g}}{\text{m}^3} \quad (\text{A.3})$$

#### Result:

$$p_c = 1,58 \times 10^{-5} \text{ g}/\text{m}^3 \leq 1 \times 10^{-4} \text{ g}/\text{m}^3 \text{ (limit for ISO ACC class -4)}$$

Since the calculated  $p_c$  is lower than the reference concentration of ISO ACC class -4 ( $1 \times 10^{-4} \text{ g}/\text{m}^3$ ), the equipment is suitable for being installed and operated in the cleanroom/controlled zone with its given operating parameters.

NOTE 1 Mode of operation in the suitability measurement and the foreseen use need to match.

NOTE 2 This assessment is only valid if the temperature during sampling for the specific emission rate has been equal to or higher than the temperature of the cleanroom/controlled zone installation.

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