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Cleanrooms and associated controlled environments

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

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Cleanrooms and associated controlled environments - Part 15: Assessment of suitability for use of equipment and materials by airborne chemical concentration (ISO 14644-15:2017)

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 (ISO 14644-15:2017)

Reinräume und zugehörige Reinraumbereiche - Teil 15: Bewertung der Reinraumtauglichkeit von Geräten und Materialien anhand der chemischen Luft- und Oberflächenkonzentration (ISO 14644-15:2017)

This European Standard was approved by CEN on 27 October 2017.

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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 14644-15:2017 E

European foreword

This document (EN ISO 14644-15:2017) has been prepared by Technical Committee ISO/TC 209 "Cleanrooms and associated controlled environments" in collaboration with Technical Committee CEN/TC 243 "Cleanroom technology" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2018 and conflicting national standards shall be withdrawn at the latest by June 2018.

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Endorsement notice

The text of ISO 14644-15:2017 has been approved by CEN as EN ISO 14644-15:2017 without any modification.

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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.

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).

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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.

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.

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^{2}s) or g/(unit · 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
α	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 ±2 °C.

The tolerance of the flow meter shall be ±5 %.

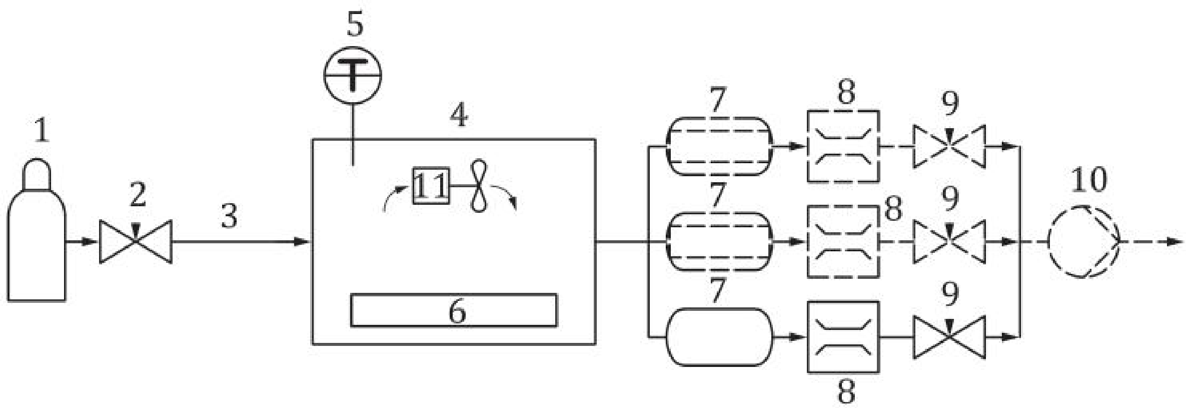
The humidity of the purge gas shall be specified and controlled.

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

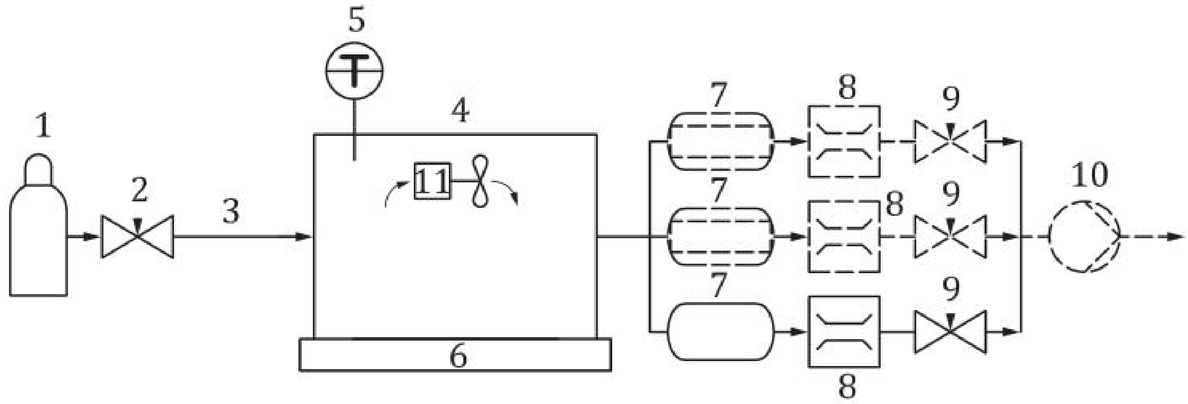
1 purge gas source
2 valve for purge gas supply
3 connection to chamber
4 test chamber
5 temperature sensor
6 material sample or equipment
7 trapping system(s)
8 flow meter(s)
9 valve(s) for flow control
10 pump (option)
11 mixing device (option)

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

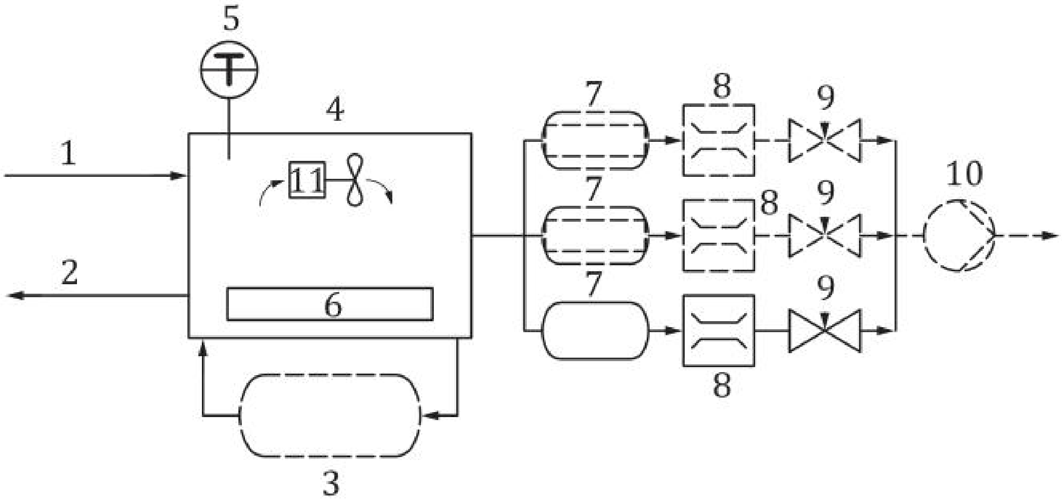
1 purge gas source
2 valve for purge gas supply
3 connection to chamber
4 test chamber
5 temperature sensor
6 material sample
7 trapping system(s)
8 flow meter(s)
9 valve(s) for flow control
10 pump (option)
11 mixing device (option)

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

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 ± 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 ±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^3;

p_o is the concentration in the test environment with the test object in g/m^3;

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^3/s;

F_o is the sampling flow rate object measurement in m^3/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_{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 $g/(m^2\ s)$ or $g/(unit \cdot s)$;

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^2 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_{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 g/(m^2 s) or g/(unit s);

p_b is the background concentration in the test environment without the test object in g/m^3;

p_o is the concentration in the test environment with the test object in g/m^3;

n_t is the air change rate through the test environment in 1/s;

V_t is the volume of the test environment in m^3;

x is the specific metric, x, related to the test object in m^2 or unit.

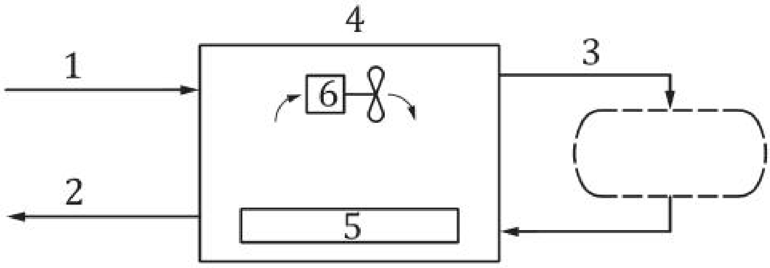
The specific emission rate shall always be stated with the chemical or chemical group it has been assessed for.

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, α)
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): α;

— 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:

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

where

q_o is the specific emission rate of all considered objects (material or/and equipment) in g/(m^2 s) or g/(unit s);

p_c is the chemical mass concentration in the cleanroom/controlled zone in g/m^3;

p_m is the chemical mass concentration of the make up air in g/m^3;

n_m is the make up air change rate in 1/s;

n_r is the recirculated air change rate in 1/s;

V_c is the volume of air in the cleanroom/controlled zone in m^3;

x is the quantity related to the assessed object in m^2 or unit;

α is the efficiency of the chemical filtration system.

NOTE If there is no chemical filtration system in the recirculated air, α 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	$1,0 \times 10^{-4}$	g/m³
q_e	Equipment specific emission rate[a]	$5,0 \times 10^{-4}$	g/unit · 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	m³
α	Chemical filtration efficiency	0,9	—

[a] 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):

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

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

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

Result:

$p_c = 1,58 \times 10^{-5}$ g/m³ ≤ 1×10^{-4} g/m³ (limit for ISO ACC class −4)

Since the calculated p_c is lower than the reference concentration of ISO ACC class −4 (1×10^{-4} g/m³), 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.

Annex B
(informative)

Example calculation for suitability assessment of wall material (existing cleanroom/clean zone installation)

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

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

Chemical group of interest is: total organic.

Table B.1 — Input data

Symbol	Meaning	Values	Unit
p_m	Mass concentration of the make up air	$1,0 \times 10^{-4}$	g/m³
q_m	Material specific emission rate[a]	$1,0 \times 10^{-5}$	g/m² · s
x	Area (of the material)	100	m²
n_m	Calculated air exchange rate achieved by the purge air	0,01	1/s
n_r	Calculated air exchange rate achieved by the re-circulated air	0,2	1/s
V_c	Volume of air in the cleanroom	250	m³
α	Chemical filtration efficiency	0,9	—

[a] 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 (B.1):

$$p_c = \frac{p_m \cdot n_m + \frac{q_m \cdot x}{V_c}}{n_m + n_r \cdot \alpha} \tag{B.1}$$

$$p_c = \frac{1,0 \cdot 10^{-4} \frac{g}{m^3} \cdot 0,01 \frac{1}{s} + \frac{\Sigma \left(1,0 \cdot 10^{-5} \frac{g}{m^2 \cdot s} \cdot 100\ m^2 \right)}{250\ m^3}}{0,01 \frac{1}{s} + 0,2 \frac{1}{s} \cdot 0,9} \tag{B.2}$$

$$p_c = 2,63 \cdot 10^{-5} \frac{g}{m^3} \tag{B.3}$$

Result:

$p_c = 2,63 \times 10^{-5}$ g/m³ ≤ 1×10^{-4} g/m³ (limit for ISO ACC class −4)

Since the calculated p_c is lower than the reference concentration of ISO ACC class −4 (1×10^{-4} g/m^3), the wall material is suitable for being installed with a quantity of 100 m^2 in the cleanroom/controlled zone with its given operating parameters.

NOTE 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.

Annex C
(informative)

Suitability assessment of a combination of equipment and floor material in a cleanroom to be designed

A new equipment and a new floor material are to be introduced into a future cleanroom with ACC-filtration.

An ISO-ACC class of −4 should be achieved. Therefore, the total emission rate, q_o, from the equipment and the floor material together should not exceed the calculated limit.

Chemical group of interest is total organic.

Table C.1 — Input data

Symbol	Meaning	Values	Unit
p_m	Mass concentration of the make up air	$1{,}0 \times 10^{-4}$	g/m^3
q_e	Equipment specific emission rate[a]	$5{,}0 \times 10^{-4}$	g/unit · s
x_e	Number of equipment	3	unit
q_m	Material specific emission rate[a]	$9{,}0 \times 10^{-5}$	g/m^3 s
x_m	Area (floor material)	100	m^2
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	m^3
α	Chemical filtration efficiency	0,8	—

[a] 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, which is the combined mass concentration derived from the flooring material and equipment, can be calculated using Formula (C.1):

$$p_c = \frac{p_m \cdot n_m + \frac{\Sigma(q_e \cdot x_e)}{V_c}}{n_m + n_r \cdot \alpha} + \frac{p_m \cdot n_m + \frac{q_m \cdot x_m}{V_c}}{n_m + n_r \cdot \alpha} \quad \text{(C.1)}$$

$$p_c = \frac{1{,}0 \cdot 10^{-4}\,\frac{\text{g}}{\text{m}^3} \cdot 0{,}01\,\frac{1}{\text{s}} + \frac{\Sigma\left(5{,}0 \cdot 10^{-4}\,\frac{\text{g}}{\text{unit} \cdot \text{s}} \cdot 3\ \text{unit}\right)}{250\ \text{m}^3}}{0{,}01\,\frac{1}{\text{s}} + 0{,}2\,\frac{1}{\text{s}} \cdot 0{,}8} + \frac{1{,}0 \cdot 10^{-4}\,\frac{\text{g}}{\text{m}^3} \cdot 0{,}01\,\frac{1}{\text{s}} + \frac{\Sigma\left(9{,}0 \cdot 10^{-5}\,\frac{\text{g}}{\text{m}^2 \cdot \text{s}} \cdot 100\ \text{m}^2\right)}{250\ \text{m}^3}}{0{,}01\,\frac{1}{\text{s}} + 0{,}2\,\frac{1}{\text{s}} \cdot 0{,}8} \tag{C.2}$$

$$p_c = 2{,}59 \cdot 10^{-4}\,\frac{\text{g}}{\text{m}^3} \tag{C.3}$$

Result:

Since $P_{c\ total}$ $2{,}59 \times 10^{-4}$ g/m³ > 1×10^{-4} g/m³, the foreseen combination of equipment and wall installation material exceeds the limit and will not comply with the requirement of ISO ACC class −4.

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.

In order to stay within the limits, either the use of different material or equipment parameters (amount or kind) or an adjustment in the cleanroom design parameters can be considered, e.g.

— design for higher the volume for recirculated air (n_r),

— design for make up air with lower mass concentration (p_m), e.g. by ACC filtration,

— foresee higher filter efficiency α in the recirculation air, and

— design for higher make up air exchange rate (n_m).

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