INTERNATIONAL STANDARD

ISO 14644-15

First edition
2017-10

Cleanrooms and associated controlled environments —

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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
https://standards.iteh.ai/catalog/standards/sist/e788b640-c704-444b-8457-0ebd13545ce1/iso-14644-15-2017

Reference number
ISO 14644-15:2017(E)

© ISO 2017

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO 14644-15:2017
https://standards.iteh.ai/catalog/standards/sist/e788b640-c704-444b-8457-0ebd13545ce1/iso-14644-15-2017

COPYRIGHT PROTECTED DOCUMENT

© ISO 2017, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

© ISO 2017 – All rights reserved

Contents

Page

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO 14644-15:2017
https://standards.iteh.ai/catalog/standards/sist/67a6b640-c784-444b-8457-0ebdf3543ce1/iso-14644-15-2017

© ISO 2017 – All rights reserved

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

For an explanation 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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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

ISO 14644-15:2017
https://standards.iteh.ai/catalog/standards/sist/e788b640-c704-444b-8457-0abd13515ed1/iso-14644-15-2017

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

 © ISO 2017 – All rights reserved

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO 14644-15:2017
https://standards.iteh.ai/catalog/standards/sist/e788b640-c704-444b-8457-0ebd13545ce1/iso-14644-15-2017

© ISO 2017 – All rights reserved

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO 14644-15:2017
https://standards.iteh.ai/catalog/standards/sist/e788b640-c704-444b-8457-0ebd13545ce1/iso-14644-15-2017

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO 14644-15:2017
https://standards.iteh.ai/catalog/standards/sist/e788b640-c704-444b-8457-0ebd13545ce1/iso-14644-15-2017

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)”.]

© ISO 2017 – All rights reserved

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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

ISO 14644-15:2017
https://standards.iteh.ai/catalog/standards/sist/e788b640-c704-444b-8457-0ebd13545ce1/iso-14644-15-2017

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.

© ISO 2017 – All rights reserved

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

3.10
emission
contaminants that are discharged into the environment

[SOURCE: ISO 2889:2010, 3.30]

ISO 14644-15:2017
https://standards.iteh.ai/catalog/standards/sist/e788b640-c704-444b-8457-0ebd15345ce1/iso-14644-15-2017

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.

© ISO 2017 – All rights reserved

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	—

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO 14644-15:2017
https://standards.iteh.ai/catalog/standards/sist/e788b640-c704-444b-8457-0ebd13545ce1/iso-14644-15-2017

© ISO 2017 – All rights reserved

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.

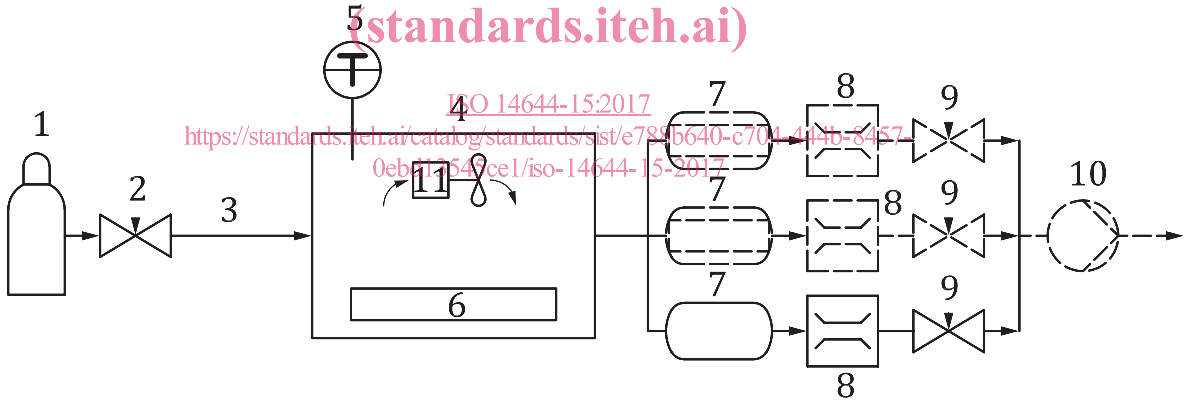
The sampling of ACC-emissions is performed by purging a defined gas volume onto a suitable trapping system, e.g. an adsorber. Multiple trapping systems can be used to collect different species of contaminants.

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO 14644-15:2017
https://standards.iteh.ai/catalog/standards/sist/e7886640-c704-444b-8457-0eb41154ce1/iso-14644-15-2017



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.

© ISO 2017 – All rights reserved