ISO/TC 209
Cleanrooms and associated controlled environments

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ISO TC 209 14644-15 outreach article

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Background: Dear ISO/TC 209 Members:

Attached is the first in a series of outreach documents, proposed by the Strategy Study Group (SSG) and approved by the TC at the 2017 plenary meeting in Sydney, Australia. (See N341 Resolutions.)

It was the goal of the SSG to help TC 209's member bodies spread the word about the work of the Technical Committee on Cleanrooms and associated controlled environments and use of the standards within their own countries.

The article, written by WG11 Convenor Berthold Düthorn, offers an overview of the ISO 14644-15 standard on the assessment of cleanroom suitability of equipment and materials by airborne chemical concentration. The standard 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 article may be translated for use in your country and may be distributed in print or electronically.

Sincerely,
The ISO/TC 209 Secretariat Team

Committee URL: https://isotc.iso.org/livelink/livelink/open/tc209

Assessment of Cleanroom Suitability of Equipment and Materials by Chemical Concentration - ISO Standard Now Available for Designers, Suppliers, and Users

1. Introduction

International standards facilitate global trade by providing a common basis of communicating specifications in purchase transactions. The responsibility for cleanroom standardization within the International Organization for Standardization (ISO) is held by Technical Committee (TC) 209, Cleanrooms and associated controlled environments. In 1992, United States ISO Member ANSI proposed the formation of the technical committee to ISO at the recommendation of IEST, and has delegated the responsibility for the administration of ISO/TC 209 to IEST. ISO/TC 209 currently publishes standards as parts of the ISO 14644 and 14698 series. The objective of this paper is to announce the availability of a new ISO 14644 standard to facilitate assessing the suitability of equipment intended for operation in cleanrooms. The cleanroom standards are available from ISO and national standards organizations.

2. ISO 14644 — Part 15: Assessment of cleanroom suitability of equipment and materials by airborne chemical concentration

2.1. Position of ISO 14644-15 within the ISO 14644 series of standards

In 2017, ISO published standard ISO 14644-15, which is intended to cover a critical aspect of ISO/TC 209's scope. ISO 14644-15 addresses the need for testing of equipment and materials for use within controlled zones[1] or cleanrooms classified as described in ISO 14644-1, Classification of air cleanliness by particle concentration, when chemicals in the air are of special interest. This standard complements ISO 14644-14, Assessment of suitability for use of equipment by airborne particle concentration, which focuses on airborne particle emission by equipment.

2.2. Target audience

ISO 14644-15 is targeted for suppliers of equipment and materials as well as designers and users of cleanrooms and controlled associated environments. It enables contractual partners, or suppliers and users of equipment or materials to assess the chemical impact on a cleanroom environment prior to installation or during trouble shooting.

2.3. Content

ISO 14644-15 references the classification system of ISO 14644-8, Classification of air cleanliness by chemical concentration (ACC). Priority is given to volatile, total organic compounds (VOC), but other groups of contaminants as stated in ISO 14644-8 can be used for testing as well.

[1] Definitions according to ISO 14644-1:2015, 3.1.2 and 14644-15:2017, 3.9

ISO 14644-15 considers equipment as well as materials that are exposed to the environment. Equipment is identified without dimension (unit number 1), while materials' emission depends on surface area (unit m^2). ISO 14644-8 provides information on contaminants, generic analysis methods, levels and a logarithmic scale ($10^{-x}/g*m^3$ = ISO ACC $-x_{(X)}$) as the basis for airborne chemical cleanliness. Therefore, ISO 14644-15 focuses on the test method, sampling and assessment of results.

The specific emission rate for equipment (g/s; without dimension) and material (g/m^2*s) is introduced to allow comparisons between different equipment and different materials. As reference, chemical volatile organic compounds are chosen, if nothing else is stated. Other airborne chemical contaminations can be assessed as they are mentioned in ISO 14644-9, Classification of surface cleanliness by particle concentration.

ISO 14644-15 provides three different normative test set ups for sampling:

A) Closed Design
   This test set up is chosen for equipment that is of moderate size and movable. The approach is simplified and can be considered a chamber test using a purge gas for transporting chemicals to trapping systems.
B) Closed Design special application
   This test set up is intended for the testing of material samples with even surfaces.
C) Open Design
   This set up is written for larger equipment which cannot be easily tested with the Closed Design (see A) or for equipment, which has already been installed in a cleanroom or controlled environment.

All the test set ups have the following consideration in common: The intended use of the material or equipment must be defined as a precondition for testing. This is covered by the expression "representative mode" for equipment and "representative form" for material.

A detailed step-by-step test description guides the user of the standard from set up of the equipment or material for sampling to final test result (mass values), which consecutively are used to calculate the specific emission rate for the equipment or material.

In addition to chemical sampling and analyses results, a visual inspection is an important part of the cleanroom suitability assessment.

2.4. Application

After establishing the cleanroom suitability of the equipment or material, the specific emission rate can be used to evaluate the impact on a controlled zone or cleanroom in two major ways:

A) Prospectively, for a future installation

This approach considers the specific emission rate with proposed cleanroom/clean zone operational parameters such as internal volume, change rates for makeup and recirculated air, and efficiency of chemical filtration to predict a chemical mass concentration (g/m^3).

B) Assessment for an existing cleanroom/clean zone

This approach considers the specific emission rate(s) with existing cleanroom/clean zone operational parameters such as internal volume, change rates for makeup and recirculated air, mass concentration of the makeup air, and efficiency of chemical filtration to predict a chemical mass concentration (g/m^3).

Both options show the versatility of ISO 14644-15, since it gives guidance for designers, suppliers of equipment and materials and their users.

3. Standardization work of ISO/TC 209 and CEN/TC 243

3.1. Overview on ISO/TC 209 standardization work

Since 1993, ISO/TC 209 has been responsible for International standards on cleanrooms and associated controlled environments.

The use of cleanrooms and associated controlled environments is becoming more and more common and a key enabling technology for production. In response, ISO/TC 209 working groups (WGs) have contributed standards for design, testing and use of cleanrooms and associated controlled environments to aid in the acceptance of this beneficial technology by different user groups and regions.

There are currently 23 participating member (P members) countries, which are eligible to nominate experts for WGs and vote on standards in development or systematic review. There are currently 22 countries (O members) that can observe the work of ISO/TC 209.

Up to the present, a series of 15 standards has been published under the responsibility of ISO/TC 209 in the14644 and 14698 series. Three standards are under development or revision at present.

ISO/TC 209 standards are written generically in that they can be applied for testing and monitoring, or in a broader sense to control cleanliness in various industries such as

- automotive,
- aerospace,
- electronics,
- semiconductors,
- food,
- life sciences (e.g. pharmaceuticals, health care, hospitals),
- scientific research.

In addition, industry or national standards and guidelines are sometimes used to provide deviating or more specific requirements and aspects.

ISO/TC 209 has established formal liaisons with five other ISO TCs and the International Confederation of Contamination Control Societies (ICCCS) to ensure transparency and consistency in its standardization efforts.

In 2017, ISO/TC 209 revised its business plan and scope to capture and address current and future standardization needs of consumers, regulators and industry regarding cleanrooms. The revised scope reflects technical progress and the recognition that cleanroom technology has become more widely applied in various industries and the applications have become more diverse. Additional information can be retrieved from the websites of ISO[2], CEN[3] and ISO/TC 209[4].

4. Summary

ISO/TC 209 advances applicability and use of cleanrooms and associated controlled environments by providing standards for specification, design, testing/monitoring and operation. In 2017, ISO 14644-15 was published as one of a series of 15 standards. This new standard addresses the cleanroom suitability for use of equipment and materials by quantifying airborne chemical concentration. ISO 14644.15 can be used by designers of facilities, suppliers of equipment and materials and users in various phases during the lifetime of an installation to support decisions on acceptance or to assess the impact of equipment or material(s) in the design of a future installation when chemical contamination is of interest.

5. Bibliography

1. ISO/TC 209, http://www.iso.org/iso/iso_technical_committee?commid=54874, last visit 30th of May 2018
2. VDI 2083, https://www.vdi.de/technik/fachthemen/bauen-und-gebaeudetechnik/fachbereiche/technische-gebaeudeausruestung/richtlinienarbeit/richtlinienreihe-vdi-2083-reinraumtechnik/ last visit 2nd of Jan 2018
3. IEST, http://www.iest.org/ last visit 2nd of Jan 2018
4. ISO Glossary, https://www.iso.org/glossary.html, last visit 2nd of Jan 2018

2 http://www.iso.org/iso/home.html, last visit on Dec 30th, 2017

3 https://www.cen.eu/Pages/default.aspx, , last visit on Dec 30th, 2017

4 http://www.iso.org/iso/iso_technical_committee?commid=54874, last visit on Jan 02nd, 2018

Abstract:

Within the International Organization for Standardization (ISO), Technical Committee (TC) 209 is chartered with standardization of cleanrooms and associated controlled environments. A series of 15 international standards (thirteen parts under ISO 14644 and ISO 14698 Part 1 – 2) has been established for controlling contamination by means of cleanroom technology. The documents address design, classification and support operation of cleanrooms.

The recently published standard ISO 14644-15:2017 specifies assessment of the suitability of equipment and materials with respect to airborne chemical concentration. Three sampling procedures are described as well as calculation procedures for emission rate and specific emission rate in g/s for equipment(s) or g/(m²s) for material(s). The emission rate and specific emission rate and proscribed inspection result are used for the cleanroom suitability assessment.

The specific emission rate can be used by designers, suppliers and users for acceptance or impact evaluation of equipment and materials considered for use in existing or future applications of cleanroom technology.

About the author

Dr. Berthold Düthorn, pharmacist by education received a PhD from the faculty of natural sciences of University Erlangen-Nürnberg. He is holding the position as vice president of Robert Bosch Technology GmbH and Managing Director of Valicare GmbH. His responsibilities are the product areas qualification and validation services, plant design and industry 4.0.

For more than 20 years he has been engaged in national and international standardization of cleanrooms and associated controlled environments as a nominated expert, convenor of ISO/TC 209 WG 11 and the German mirror group, and head of the German delegation in ISO/TC 209 and CEN/TC 243.

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