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Cleanrooms and associated controlled environments —

Part 14: Assessment of suitability for use of equipment by airborne particle concentration

Salles propres et environnements maîtrisés apparentés —

Partie 14: Évaluation de l'aptitude à l'emploi des équipements par la détermination de la concentration de particules en suspension dans l'air

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Foreword

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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 document 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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This document was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 243, *Cleanroom technology*,in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 14644-14:2016), of which it constitutes a minor revision. The changes are as follows:

— updated reference document;

— corrected title in Bibliography;

— removed references that are not mentioned in the text from the Bibliography.

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

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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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 and healthcare).

This part of the ISO 14644 series links the cleanroom classification of air cleanliness by particle concentration to the suitability of equipment for use in cleanrooms and associated controlled environments.

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Cleanrooms and associated controlled environments —

Part 14: Assessment of suitability for use of equipment by airborne particle concentration

1 Scope

This document specifies a methodology to assess the suitability of equipment (e.g. machinery, measuring equipment, process equipment, components and tools) for use in cleanrooms and associated controlled environments, with respect to airborne particle cleanliness as specified in ISO 14644-1. Particle sizes range from 0,1 µm to equal to or larger than 5 µm (given in ISO 14644-1).

NOTE Where regulatory agencies impose supplementary guidelines or restrictions, appropriate adaptation of the assessment methodology can be required.

This document is not applicable to the following items:

— assessment of suitability with respect to biocontamination;

— testing for suitability of decontamination agents and techniques;

— cleanability of equipment and materials;

— requirements on design of equipment and selection of materials;

— physical properties of materials (e.g. electrostatic, thermal properties);

— optimizing performance of equipment for specific process applications;

— selection and use of statistical methods for testing;

— protocols and requirements for local safety regulations.

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 14644-1:2015, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration*

3 Terms and definitions

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

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

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

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3.1
cleanliness
condition not exceeding a specified level of contamination

3.2
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 might also be specified and controlled.

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

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

3.3
cleanroom suitability
ability to maintain the critical control attributes or condition of any clean zone when used as intended

Note 1 to entry: For the purposes of this part of ISO 14644, the assessment is based on airborne particle concentration.

3.4
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 might also be specified and controlled.

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

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

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

3.5
decontamination
reduction of unwanted matter to a defined level

[SOURCE: ISO 14644-7:2004, 3.7]

3.6
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, Information Technology (IT) hardware and handling robots.

3.7
test environment
space in which the test is carried out, described by a set of parameters

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