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13.040.35	Brezprašni prostori in povezana nadzorovana okolja	Cleanrooms and associated controlled environments

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Cleanrooms and associated controlled environments —

Part 5: Operations

Salles propres et environnements maîtrisés apparentés —

Partie 5: Exploitation

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Contents

Page

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 of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 209 *Cleanrooms and associated controlled environments*, in collaboration with the European Committee for Standardisation (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 14644-5:2004), which has been technically revised. New normative content includes development of an impact assessment, development of an Operations Control Programme and the associated programmes that support cleanroom operation, and improved information concerning the movement of goods and materials into and out of the cleanrooms. Informative sections have been condensed so as not to duplicate information available in books and papers.

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.

Introduction

Cleanrooms and associated controlled environments provide for the control of contamination to air and surface cleanliness levels appropriate for accomplishing contamination-sensitive activities.

Consistent quality depends, in part, on cleanliness. Defined cleanliness levels for all contaminants addressed in ISO 14644 standards can be attained and maintained through a deliberate programme to establish and implement adequate design and operational procedures. Regulatory agencies that have authority over processes and products produced in the cleanroom may require additional procedures and measures.

Processes and products that benefit from the control of contamination include those in industries such as aerospace, automotive, assorted consumer products, defence, microelectronics, optics, nuclear, scientific research and life sciences (pharmaceuticals, biotechnology, medical devices, food, healthcare).

This part of ISO 14644 specifies basic requirements for cleanroom operations. It is intended for those who design, construct, start up or operate a cleanroom. For guidance about consumables and equipment used in cleanrooms refer to the ISO 14644 series of standards.

Cleanrooms and associated controlled environments —

Part 5: Operations

1 Scope

This part of ISO 14644 specifies requirements for the establishment of an Operations Control Programme to ensure efficient cleanroom operation within specified cleanliness levels. The Operations Control Programme includes management of personnel, entry and exit of personnel and materials, cleaning, maintenance and monitoring.

Normative operational requirements are presented that relate to:

— Providing a system that defines policies and operational procedures for maintaining cleanliness levels

— Training of personnel

— Transferring, installing and maintaining stationary equipment

— Transferring material and portable equipment into and out of the cleanroom

— Maintaining a personnel management programme that includes a gowning programme

— Maintaining a cleaning programme that addresses special cleaning

— Maintaining a cleanroom maintenance programme

— Establishing an appropriate monitoring programme.

Additional informative annexes are provided for:

— Personnel Management

— Gowning

— Training

— Cleaning.

Biocontamination control is not specifically addressed. For details, please refer to references [2], [3], and [4].

The following topics are omitted from this part of the standard:

— Aspects of health and safety management that have no direct bearing on contamination control

— Specific requirements for individual industries

— Specific requirements for equipment and materials used or associated with processes and products

— Design details of equipment

— Cleaning agent compatibility with cleanroom materials.

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 cited edition applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 14644, *Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration*

ISO 14644, *Cleanrooms and associated controlled environments — Part 3: Test methods*

ISO 14644, *Cleanrooms and associated controlled environments — Part 4: Design, construction and start-up*

ISO 14644, *Cleanrooms and associated controlled environments — Part 9: Assessment of surface cleanliness for particle concentration*

ISO 14644, *Cleanrooms and associated controlled environments — Part 10: Assessment of surface cleanliness for chemical contamination*

ISO 14644, *Cleanrooms and associated controlled environments — Part 13: Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications*

ISO 14644, *Cleanrooms and associated controlled environments — Part 14: Assessment of suitability for use of equipment by airborne particle concentration*

ISO 14644, *Cleanrooms and associated controlled environments — Part 15: Assessment of suitability for use of equipment and materials by airborne chemical concentration*

ISO 14644, *Cleanrooms and associated controlled environments — Part 16: Energy efficiency in cleanrooms and separative devices*

ISO 14644, *Cleanrooms and associated controlled environments — Part 17: Particle deposition rate applications*

ISO 14644, *Cleanrooms and associated controlled environments — Part 18: Assessment of suitability of consumables*

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

3.1
cleaning efficiency
fraction of specific contaminants removed from a surface by a cleaning process

Note 1 to entry: The fraction is determined by the accomplished surface cleanliness in respect to the initial surface cleanliness.

[SOURCE: ISO 14644-13:2017, 3.3]

3.2
cleanliness
condition not exceeding a specified level of contamination

[SOURCE: ISO 14644-15:2017, 3.5]

3.3
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]

3.4
clean zone
defined space which is constructed and operated in a manner to control the introduction, generation and retention of contaminants inside the space below a maximum concentration of airborne particles based on its designation

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
consumable
item selected for a prescribed, limited use and subsequent disposal, if applicable, within cleanrooms and controlled environments

[SOURCE: ISO 14644-18: 2023, 3.9]

3.6
contamination
unwanted matter in an undesirable location

[SOURCE: ISO 14644-13:2017, 3.4]

3.7
installation
cleanroom or one or more clean zones, together with all associated structures, air-treatment systems, services and utilities

[SOURCE: ISO 14644-1:2015, 3.1.3]

3.8
occupancy states: