SLOVENSKI STANDARD
oSIST prEN ISO 14644-15:2016

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Čiste sobe in podobna nadzorovana okolja - 15. del: Ocena ustreznosti uporabe opreme in materialov na osnovi koncentracije onesnaževal v zraku (ISO/DIS 14644-15:2016)

Cleanrooms and associated controlled environments - Part 15: Assessment of suitability for use of equipment and materials by airborne chemical concentration (ISO/DIS 14644-15:2016)

Reinräume und zugehörige Reinraumbereiche - Teil 15: Bewertung der Reinraumtauglichkeit von Geräten und Materialien anhand der chemischen Luft- und Oberflächenkonzentration (ISO/DIS 14644-15:2016)

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/DIS 14644-15:2016)

Ta slovenski standard je istoveten z: **prEN ISO 14644-15**

ICS:

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

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DRAFT INTERNATIONAL STANDARD

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Cleanrooms and associated controlled environments —

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

Salles propres et environnements maîtrisés apparentés —

Partie 15: Évaluation de la compatibilité des équipements à l'emploi en salle propre en termes de propreté chimique de l'air et des surfaces

ICS: 13.040.35

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel three month enquiry.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 14644-15 was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*, and by Technical Committee CEN/TC 243, *Cleanroom technology* in collaboration.

ISO 14644 consists of the following parts, under the general title *Cleanrooms and associated controlled environments*:

— *Part 1: Classification of air cleanliness by particle concentration*

— *Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration*

— *Part 3: Test methods*

— *Part 4: Design, construction and start-up*

— *Part 5: Operations*

— *Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)*

— *Part 8: Classification of air cleanliness by chemical concentration (ACC)*

— *Part 9: Classification of surface cleanliness by particle concentration*

— *Part 10: Classification of surface cleanliness by chemical concentration*

— *Part 12: Classification of air cleanliness by nanoscale particle concentration*

— *Part 13: Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications*

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

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

Attention is also drawn to *ISO 14698, Cleanrooms and associated controlled environments — Biocontamination control*:

— *Part 1: General principles and methods*

— *Part 2: Evaluation and interpretation of biocontamination data*

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.

1 Scope

This standard provides requirements and guidance 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 (ISO 14644-8).

Health and safety requirements are not covered by this document and may be covered by legal documents of the specific country.

The following issues are excluded:

— 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, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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, *Cleanroom and associated controlled environments — Part 8: Classification of air cleanliness by chemical concentration.*

3 Terms and definitions

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

3.1
air chemical contamination
any substance in the air that can, by its chemical nature, adversely affect the product, process or equipment

[ISO 14644-8:2013]

3.2
air cleanliness by chemical concentration
ACC
level of air cleanliness 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 meter

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 volume that can be drawn through an adsorber 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 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]

3.7
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 standard, the assessment is based on airborne particle concentration.

[SOURCE: ISO/FDIS 14644-14:2015, 3.3]

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 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]

3.9
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 should 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 separate device. Such a device can 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 standard only chemical emission is considered.

3.11
emission rate
rate describing the mass of one or more volatile chemical(s) emitted from 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/FDIS 14644-14:2015, 3.6]

3.13
material
single substance or composite

Note 1 to entry: It may 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 or a cleanroom, filtered air can be used as purge gas.

Note 2 to entry: A test environment may be purged with air or other gases or gas mixtures to carry the contaminant to an adsorber 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