SLOVENSKI STANDARD
oSIST prEN ISO 14644-14:2014

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Čiste sobe in podobna nadzorovana okolja - 14. del: Ocenjevanje primernosti za uporabo opreme s koncentracijo lebdečih delcev (ISO/DIS 14644-14)

Cleanrooms and associated controlled environments - Part 14: Assessment of suitability for use of equipment by airborne particle concentration (ISO/DIS 14644-14)

Reinräume und zugehörige Reinraumbereiche - Teil 14: Bewertung der Reinraumtauglichkeit von Geräten durch Partikelkonzentration in der Luft (ISO/DIS 14644-14:2014)

Salles propres et environnements maîtrisés apparentés - Partie 14: Evaluation de la compatibilité des équipments en termes d'émission particulaire pour une utilisation en salle propre (ISO/DIS 14644-14:2014)

Ta slovenski standard je istoveten z: **prEN ISO 14644-14**

ICS:

13.040.35	Brezprašni prostori in povezana nadzorovana okolja	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

Salles propres et environnements maîtrisés apparentés —

Partie 14: Evaluation de la compatibilité des équipments en termes d'émission particulaire pour une utilisation en salle propre

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 five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

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.

Reference number
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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 14644-14 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 and surface chemical concentration*

Attention is also drawn to *ISO 14698, Cleanrooms and associated controlled environments — Bio-contamination 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 links the cleanroom classification of air cleanliness by particle concentration (referred to by the initialism ACP) to the suitability of equipment for use in cleanrooms and associated controlled environments.

Table 1 gives guidance to the user and explains the links between the area of interest ("Contamination of interest"), the assessment standards ("Applicable assessment standard") and the related ISO 14644 standard ("Reference classification standard").

Table 1 — Links between contamination of interest and assessment standard

Contamination of interest	Category	Item to be assessed	Applicable assessment standard	Reference classification standard	Designation
particle	airborne	equipment	14644-14	14644-1	ISO *N*
particle	airborne	materials	-[a]	14644-1	ISO *N*
particle	surface	equipment	-[a]	14644-9	ISO-SCP
particle	surface	materials	-[a]	14644-9	ISO-SCP
chemical	airborne	equipment	14644-15[b]	14644-8	ISO-ACC
chemical	airborne	materials	14644-15 [b]	14644-8	ISO-ACC
chemical	surface	equipment	-[a]	14644-10	ISO-SCC
chemical	surface	materials	-[a]	14644-10	ISO-SCC

[a] There might be future "Applicable assessment standards".

[b] ISO 14644-15 is under preparation by ISO/TC 209/WG 11

1 Scope

This part of ISO 14644 specifies a methodology to assess the suitability of equipment (e. g. machinery, measuring equipment, process equipment, components, 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.

The following items are not covered by ISO 14644-14:

- Assessment of suitability with respect to bio-contamination;
- 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 referenced documents are indispensable for the application 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:XXXX, *Cleanroom and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration*

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

3 Terms and definitions

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

3.1
equipment
materials, components and controls, in a system, designed and integrated for a specific function

EXAMPLE testing and manufacturing equipment and machinery; equipment for transport and handling; storage units; tools; furniture; doors; ceilings; IT hardware; handling robots

3.2
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.

3.3
test environment
space in which the test is carried out, described by a set of parameters

3.4
cleanliness
condition not exceeding a specified level of contamination

3.5
decontamination
removal of undesirable material down to a specified level

[ISO 14644-7:2004]

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.

[ISO 14644-1:XXXX]

3.7
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.
Note 5 to entry: A clean zone might also be subject to control of air cleanliness in terms of chemical, viable or nanoscale concentrations, as also to control of surface cleanliness in terms of particle, nanoscale, chemical and viable concentrations.

[ISO 14644-1:XXXX]

4 General outline of the assessment

Cleanroom suitability assessment has the following outline:

1. Before the assessment can be executed, the customer and supplier shall agree upon the particle size range(s), with reference to air cleanliness by particle concentration (ACP), designated by ISO Class *N* as given in ISO 14644-1 and item to be tested including the modes of operation(s). Each selected mode of operation shall be assessed separately.
2. A short description how the equipment will be used in routine operation (with operating parameters) shall be given to promote setting the appropriate testing condition and parameters.
3. Visual inspection (see clause 5)
4. The procedure described in clause 6 shall be used in order to establish a link to the ISO 14644-1 classification system.

   NOTE For particle sizes larger than 5 µm the procedure for M descriptor according to ISO 14644-1 should be used.

5. Execution of measurements (see 6.2)

6. The data gathered will be processed and the results linked to the ISO classification system (see 6.2.9 – 6.2.10)
7. The results obtained shall conclude the equipment's clean room suitability; the statement shall follow the defined designation (clause 8)

Additional optional tests (not linked to ISO class *N*) such as total emission of particles or operational life cycle test are described in Annex B.

The method described in Annex B.4 may be used to determine the average total emission of equipment and provides data that may be used to determine the particle load on a cleanroom.

5 Visual inspection

Visual inspection of the equipment shall be carried out before and after any measurement based assessment.

The visual inspection shall ensure that all packaging has been removed and the equipment is undamaged and that it is correctly assembled and appropriately connected to its required utilities.

Visual surface cleanliness shall be qualitatively assessed such that any subsequent quantifiable tests shall not be compromised. This part of the visual inspection may include assessment for particles, surface films or inappropriately located lubricants.

The objectives of this inspection are:

— Identify contamination, such as particles and films originated from manufacturing, packaging, transportation or initial assembly.

— Identify contamination that has withstood any prior decontamination process.

It is not intended that this inspection provides a measurement of surface cleanliness.

Depending on the location of the contamination, the results from visual inspection should be:

— Recorded and available for comparison with the post- test visual inspection of surface cleanliness.

— Be used as basis to direct a repeat or improved decontamination process.

Detection efficiency of visible contamination on equipment will depend upon the following factors:

— The accessibility and orientation of the surface to be inspected.

— Materials used for equipment construction, their surface condition and treatment.

— Viewing parameters (e. g. illumination, field of view, vision magnification, viewing distance).

For particle contamination in particular it may be useful to assess particle mobility. The use of probes, forced clean dry air, vacuum device or tape lift could be used.

6 Assessment of suitability by airborne particle concentration measurements

6.1 General

The objective of this clause is to describe a suitability methodology using measurement of airborne particle emissions at critical locations. By including measurement locations at, or close to, the locations of high particle concentration (HPC) suitability can be derived related to the intended application cleanroom classification.

This assessment methodology enables a link to the classification system of ISO 14644-1, in one or more particle size ranges to be established.

In order to assess the cleanroom suitability of equipment, it is intended that the location(s) with HPC emitted by the equipment are identified and included in the final suitability measurement. Since the size distribution of

