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Renhetsteknik – Renrum och tillhörande renhetskontrollerade miljöer –
Del 14: Bedömning av lämplighet för användning av utrustning och material baserad på luftburen partikelkoncentration (ISO 14644-14:2016)

Cleanrooms and associated controlled environments –
Part 14: Assessment of suitability for use of equipment by airborne particle concentration (ISO 14644-14:2016)

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The European Standard EN ISO 14644-14:2016 has the status of a Swedish Standard. This document contains the official English version of EN ISO 14644-14:2016.

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Denna standard är framtagen av kommittén för Renhetsteknik, SIS/TK 108.

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EUROPEAN STANDARD
NORME EUROPÉENNE
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English Version

Cleanrooms and associated controlled environments - Part 14: Assessment of suitability for use of equipment by airborne particle concentration (ISO 14644-14:2016)

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 (ISO 14644-14:2016)

Reinräume und zugehörige Reinraumbereiche - Teil 14: Bewertung der Reinraumtauglichkeit von Geräten durch Partikelkonzentration in der Luft (ISO 14644-14:2016)

This European Standard was approved by CEN on 13 August 2016.

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European foreword

This document (EN ISO 14644-14:2016) has been prepared by Technical Committee ISO/TC 209 "Cleanrooms and associated controlled environments" in collaboration with Technical Committee CEN/TC 243 "Cleanroom technology" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2017, and conflicting national standards shall be withdrawn at the latest by April 2017.

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Endorsement notice

The text of ISO 14644-14:2016 has been approved by CEN as EN ISO 14644-14:2016 without any modification.

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

Cleanrooms and associated controlled environments —

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

1 Scope

This part of ISO 14644 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.

The following items are not covered by this part of ISO 14644:

— 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, 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 14644-1:2015, *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.

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

4 General outline of the assessment

Cleanroom suitability assessment has the following outline.

a) 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, 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.

b) A short description regarding how the equipment will be used in routine operation (with operating parameters) shall be given to promote setting the appropriate testing condition and parameters.

c) Visual inspection (see Clause 5).

d) The procedure described in Clause 6 shall be used in order to establish a link to the ISO 14644-1 classification system.

e) Execution of measurements (see 6.2).

f) The data gathered will be processed and the results linked to the ISO classification system (see 6.2.9 and 6.2.10).

g) The results obtained shall conclude the equipment's cleanroom suitability; the statement shall follow the defined designation (see 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 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 that 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 can include assessment for particles, surface films or inappropriately located lubricants.

The objectives of this inspection are the following:

— 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 will provide a measurement of surface cleanliness.

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

— recorded and available for comparison with the post-test visual inspection of surface cleanliness, and

— 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;