SLOVENSKI STANDARD
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Čiste sobe in podobna nadzorovana okolja - 13. del: Čiščenje površin za doseganje določenih ravni čistoče po klasifikaciji delcev in kemikalij (ISO/DIS 14644-13:2016)

Cleanrooms and associated controlled environments - Part 13: Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications (ISO/DIS 14644-13:2016)

Reinräume und zugehörige Reinraumbereiche - Teil 13: Reinigung von Oberflächen zur Erreichung definierter Reinheitsgrade hinsichtlich Partikel- und Chemikalienklassifikationen (ISO/DIS 14644-13:2016)

Salles propres et environnements maîtrisés apparentés - Partie 13: Nettoyage des surfaces afin d'obtenir des niveaux de propreté par rapport aux classifications particulaire et chimique (ISO/DIS 14644-13:2016)

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Cleanrooms and associated controlled environments —

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

Salles propres et environnements maîtrisés apparentés —

Partie 13: Nettoyage des surfaces afin d'obtenir des niveaux de propreté par rapport aux classifications particulaire et chimique

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.

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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 14644-13 was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*, and by Technical Committee 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 classification*

— *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

‘Surface’ refers to the interface between two phases. For the purpose of this document, the surface is a solid. “Clean surface” is where one or more of the contamination categories (particles, chemical) are under control due to cleaning / decontamination. The degree of cleanliness is specified in the corresponding surface cleanliness classifications (ISO 14644-9:2012 Surface cleanliness by particle concentration SCP; ISO 14644-10:2013 Surface cleanliness by chemical concentration SCC). Different cleaning methods are necessary depending on the degree of cleanliness (cleanliness class) required. This standard gives guidance on the selection of cleaning methods to achieve specified cleanliness levels. For the selection procedure, the aspects of surface description, cleanliness specifications, types of contamination, cleaning techniques, material compatibility, and assessment methodology are taken into consideration. Most of the methods are suitable for removal of more than one contamination category at the same time therefore a common standard for the selection of a cleaning method for both particles as well as chemical contamination is needed.

Cleanrooms and associated controlled environments — Part 13: Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classification

1 Scope

The standard addresses the cleaning to a specified degree on cleanroom surfaces, surfaces of equipment in a cleanroom and surfaces of materials in a cleanroom. It provides guidance on the assessment of cleaning methods for achieving the required surface cleanliness by particle concentration (SCP) and surface cleanliness by chemical concentration (SCC) classes and which techniques should be considered to achieve these specified levels.

The efficacy of cleaning techniques will make reference to the cleanliness classes and associated test methods found in ISO 14644-9:2012 and ISO 14644-10:2013.

The following matters of general guidance will be provided:

— expected surface cleanliness levels;

— suitability of cleaning methods;

— compatibility of surfaces with the cleaning technique;

— assessment of cleaning efficacy.

The following will be excluded from the standard:

— classification of cleaning methods

— product produced within a cleanroom;

— specific surface related cleaning methods;

— detailed description of cleaning mechanisms, methods and procedures of various cleaning methods;

— detailed material characteristics;

— description of damage mechanisms by cleaning processes and time-dependent effects;

— references to interactive bonding forces between contaminants and surfaces or generation processes that are usually time-dependent and process-dependent;

— other characteristics of particles such as electrostatic charge, ionic charges etc.;

— chemical reactions between molecular contaminants and surfaces;

— microbiological aspects of surface cleanliness;

— radioactive aspects of contamination;

— health and safety considerations;

— environmental aspects such as waste disposal, emissions etc.;

— selection and use of statistical methods.

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 14644-8:2013, *Cleanrooms and associated controlled environments — Part 8: Classification of air cleanliness by chemical concentration (ACC)*

ISO 14644-9:2012, *Cleanrooms and associated controlled environments — Part 9: Classification of surface cleanliness by particle concentration*

ISO 14644-10:2013, *Cleanrooms and associated controlled environments — Part 10: Classification of surface cleanliness by chemical concentration*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply. Where a term has been defined in all parts of ISO 14644 and the following apply:

3.1
cleanliness (of a solid surface)
condition of a solid surface where the amount of contamination (particle, chemical or viable) is controlled to a specific level.

3.2
cleaning efficacy
the relation between the required cleanliness and the accomplished cleanliness under controlled conditions

Note to entry: In case of real operational conditions or monitoring, the term cleaning effectiveness is used.

3.3
cleaning efficiency
the fraction of specific contaminants removed from a surface by a cleaning process. The fraction is determined by the accomplished surface cleanliness in respect to the initial surface cleanliness.

3.4
contamination
unwanted matter in an undesirable location.

3.5
chemical contamination
chemical (non-particulate) substances that can have a deleterious effect on the product, process or equipment

3.6
descriptor for specific particle size ranges
differential descriptor that expresses SCP level within specific particle size ranges

Note to entry: The descriptor may be applied to particle size ranges of special interest or those particle size ranges that are outside the range of the classification system, and specified independently or as a supplement to the SCP classes.

3.7
direct measurement method
assessment of the contamination without any intermediate steps

3.8
indirect measurement method
assessment of the contamination with intermediate steps

3.9
particle
minute piece of matter with defined physical boundaries

3.10
particle contamination
particles having the potential to affect the process, the product, the personnel or the facilities

3.11
particle size
length dimension describing the size of a three-dimensional particle

Note to entry 1: The particle size depends on the measurement method.

Note to entry 2: Different methods can be used to determine the particle size, e. g. the largest dimension, equivalent diameter, smallest enclosed box.

3.12
particle size distribution
cumulative distribution of particle concentration as a function of particle size
[ISO 14644-9:2012]

3.13
solid surface
boundary between the solid and a second phase

3.14
surface
boundary between two phases; one of them is normally a solid phase and the other a gas, a liquid or another solid

3.15
surface particle
solid and/or liquid matters adhered and discretely distributed on a surface of interest, excluding film-like matters that cover the whole surface. They are adhered via chemical and/or physical interactions

3.16
surface cleanliness by particle concentration classification (SCP)
level (or the process of specifying or determining the level) that represents maximum allowable surface concentrations, in particles per square metre, for considered sizes of particles, expressed in terms of an ISO SCP Class *N* [ISO 14644-9:2012].

3.17
surface cleanliness by particle concentration class (SCP class)
grading number stating the maximum allowable surface concentration, in particles per square metre, for a considered size of particles (SCP Classes 1 to 8)

3.18
surface particle concentration
number of individual particles per unit of area of surface under consideration