SLOVENSKI STANDARD
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Cleanrooms and associated controlled environments - Part 4: Design, construction and start-up (ISO 14644-4:2001)

Cleanrooms and associated controlled environments - Part 4: Design, construction and start-up (ISO 14644-4:2001)

Reinräume und zugehörige Reinraumbereiche - Teil 4: Planung, Ausführung und Erst-Inbetriebnahme (ISO 14644-4:2001)

Salles propres et environnements maîtrisés apparentés - Partie 4: Conception, construction et mise en fonctionnement (ISO 14644-4:2001)

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Cleanrooms and associated controlled environments - Part 4: Design, construction and start-up (ISO 14644-4:2001)

Salles propres et environnements maîtrisés apparentés - Partie 4: Conception, construction et mise en fonctionnement (ISO 14644-4:2001)

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This European Standard was approved by CEN on 1 April 2001.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

The text of the International Standard ISO 14644-4:2001 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 October 2001, and conflicting national standards shall be withdrawn at the latest by October 2001.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 14644-4:2001 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in annex ZA (normative).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates, by dated or undated reference, provisions from other publications. These normativereferences are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE Where an International Publication has been modified bycommon modifications, indicated by (mod.), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
ISO 14644-1	1999	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness	EN ISO 14644-1	1999
ISO 14644-2	2000	Cleanrooms and associated controlled environments — Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1	EN ISO 14644-2	2000

INTERNATIONAL STANDARD

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Cleanrooms and associated controlled environments —

Part 4: Design, construction and start-up

Salles propres et environnements maîtrisés apparentés —
Partie 4: Conception, construction et mise en fonctionnement

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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 3.

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 part of ISO 14644 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 14644-4 was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*.

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

— *Part 1: Classification of air cleanliness*

— *Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1*

— *Part 3: Metrology and test methods*

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

— *Part 5: Operations*

— *Part 6: Vocabulary*

— *Part 7: Separative enclosures (clean air hoods, glove boxes, isolators, mini-environments)*

Users should note that the titles listed for parts 3 and 5 to 7 are working titles at the time of the release of part 4. In the event that one or more of these parts are deleted from the work programme, the remaining parts may be renumbered.

Annexes A to H of this part of ISO 14644 are for information only.

Introduction

Cleanrooms and associated controlled environments provide for the control of airborne particulate contamination to levels appropriate for accomplishing contamination-sensitive activities. Products and processes that benefit from the control of airborne contamination include those in such industries as aerospace, microelectronics, pharmaceuticals, medical devices and healthcare.

This part of ISO 14644 specifies the requirements for the design and construction of cleanroom facilities. It is intended for use by purchasers, suppliers and designers of cleanroom installations and provides a check list of important parameters of performance. Construction guidance is provided, including requirements for start-up and qualification. Basic elements of design and construction needed to ensure continued satisfactory operation are identified through the consideration of relevant aspects of operation and maintenance.

This part of ISO 14644 is one of a series of standards concerned with cleanrooms and associated subjects. Many factors besides design, construction and start-up should be considered in the operation and control of cleanrooms and other controlled environments. These are covered in some detail in other International Standards prepared by ISO/TC 209.

Cleanrooms and associated controlled environments

Part 4:
Design, construction and start-up

1 Scope

This part of ISO 14644 specifies requirements for the design and construction of cleanroom installations but does not prescribe specific technological or contractual means to meet these requirements. It is intended for use by purchasers, suppliers and designers of cleanroom installations and provides a checklist of important parameters of performance. Construction guidance is provided, including requirements for start-up and qualification. Basic elements of design and construction needed to ensure continued satisfactory operation are identified through the consideration of relevant aspects of operation and maintenance.

NOTE Further guidance in respect of the above requirements is given in annexes A to H. Other parts of ISO 14644 may provide complementary information.

Application of this part of ISO 14644 is restricted in the following:

— user requirements are represented by purchaser or specifier;

— specific processes to be accommodated in the cleanroom installation are not specified;

— fire and safety regulations are not considered specifically; the appropriate national and local requirements should be respected;

— process media and utility services are only considered with respect to their routing between and in the different zones of cleanliness;

— regarding initial operation and maintenance, only cleanroom construction-specific requirements are considered.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 14644. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 14644 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 14644-1:1999, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness.*

ISO 14644-2:2000, *Cleanrooms and associated controlled environments — Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1.*

ISO 14644-3:— [1], *Cleanrooms and associated controlled environments — Part 3: Metrology and test methods.*

ISO 14698-1:— [1], *Cleanrooms and associated controlled environments — Biocontamination control — Part 1: General principles*

ISO 14698-2:— [1], *Cleanrooms and associated controlled environments — Biocontamination control — Part 2: Evaluation and interpretation of biocontamination data.*

ISO 14698-3:— [1], *Cleanrooms and associated controlled environements — Biocontamination control — Part 3: Measurement of the efficiency of processes of cleaning and/or disinfection of inert surfaces bearing biocontaminated wet soiling or biofilms.*

3 Terms and definitions

For the purposes of this part of ISO 14644, the terms and definitions given in ISO 14644-1 and the following apply.

3.1
changing room
room where people using a cleanroom may change into, or out of, cleanroom apparel

3.2
clean air device
stand-alone equipment for treating and distributing clean air to achieve defined environmental conditions

3.3
cleanliness
condition of a product, surface, device, gas, fluid, etc. with a defined level of contamination

NOTE Contamination can be particulate, non-particulate, biological, molecular or of other consistency.

3.4
commissioning
planned and documented series of inspections, adjustments and tests carried out systematically to set the installation into correct technical operation as specified

3.5
contaminant
any particulate, molecular, non-particulate and biological entity that can adversely affect the product or process

3.6
non-unidirectional airflow
air distribution where the supply air entering the clean zone mixes with the internal air by means of induction

3.7
particle
minute piece of matter with defined physical boundaries

NOTE For classification purposes refer to ISO 14644-1.

3.8
pre-filter
air filter fitted upstream of another filter to reduce the challenge on that filter

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[1] To be published.

3.9
process core
location at which the process and the interaction between the environment and the process occurs

3.10
start-up
act of preparing and bringing an installation into active service, including all systems

EXAMPLE Systems may include procedures, training requirements, infrastructure, support services, statutory undertakings requirements.

3.11
unidirectional airflow
controlled airflow through the entire cross-section of a clean zone with a steady velocity and approximately parallel streamlines

NOTE This type of airflow results in a directed transport of particles from the clean zone.

4 Requirements

4.1 The parameters listed in 4.2 to 4.18 shall be defined and agreed between purchaser and supplier:

NOTE In the requirements stated below, references are made to annexes A to H which are for information only.

4.2 The number, edition and date of publication of this part of ISO 14644 shall be given.

4.3 The role of other relevant parties to the project (e.g. consultants, designers, regulatory authorities, service organizations) shall be established (see examples in annex C).

4.4 The general purpose for which the cleanroom is to be used, the operations to be carried out therein and any constraint imposed by the operating requirements (see examples in annexes A, B and D).

4.5 The required airborne particulate cleanliness class or demands for cleanliness in accordance with the relevant International Standard (ISO 14644-1, ISO 14698-1, ISO 14698-2 and ISO 14698-3) (see examples in annex B).

4.6 The critical environmental parameters, including their specified set points, alert and action levels to be measured to ensure compliance, together with the measurement methods to be used, including calibration (ISO 14644-2 and ISO 14644-3) (see examples in annex F).

4.7 The contamination control concept, including installation, operating and performance criteria, to be used to achieve the required cleanliness level (see examples in annex A).

4.8 The methods of measurement, control, monitoring and documentation required to meet the parameters agreed (see examples in annexes C and F).

4.9 The entry or exit of equipment, apparatus, supplies and personnel required to support the installation (see examples in annex D).

4.10 The specified occupancy states selected from "as-built", "at-rest" and "operational" under which the required parameters shall be achieved and maintained including variations with time, and the methods of control (see examples in annex C).

4.11 The layout and configuration of the installation (see examples in annex D).

4.12 Critical dimensions and mass restrictions, including those related to available space (see examples in annex D).