

Cleanrooms and associated controlled environments - Part 5: Operations

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- Part 5: Operations

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 14644-5:2004 sisaldab Euroopa standardi EN ISO 14644-5:2004 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 26.10.2004 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 14644-5:2004 consists of the English text of the European standard EN ISO 14644-5:2004.</p> <p>This document is endorsed on 26.10.2004 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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<p>Käsitlusala:</p> <p>This part of ISO 14644 specifies basic requirements for cleanroom operations. It is intended for those planning to use and operate a cleanroom. Aspects of safety that have no direct bearing on contamination control are not considered in this part of ISO 14644 and national and local safety regulations must be observed. This document considers all classes of cleanrooms used to produce all types of products. Therefore, it is broad in application and does not address specific requirements for individual industries. Methods and programmes for routine monitoring within cleanrooms are not covered in detail in this part of ISO 14644 but reference is made to ISO 14644-2 and ISO 14644-3 for monitoring particles and ISO 14698-1 and ISO 14698-2 for monitoring micro-organisms.</p>	<p>Scope:</p> <p>This part of ISO 14644 specifies basic requirements for cleanroom operations. It is intended for those planning to use and operate a cleanroom. Aspects of safety that have no direct bearing on contamination control are not considered in this part of ISO 14644 and national and local safety regulations must be observed. This document considers all classes of cleanrooms used to produce all types of products. Therefore, it is broad in application and does not address specific requirements for individual industries. Methods and programmes for routine monitoring within cleanrooms are not covered in detail in this part of ISO 14644 but reference is made to ISO 14644-2 and ISO 14644-3 for monitoring particles and ISO 14698-1 and ISO 14698-2 for monitoring micro-organisms.</p>
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English version

**Cleanrooms and associated controlled environments - Part 5:
Operations (ISO 14644-5:2004)**

Salles propres et environnements maîtrisés apparentés -
Partie 5: Exploitation (ISO 14644-5:2004)

Reinräume und zugehörige Reinraumbereiche - Teil 5:
Betrieb (ISO 14644-5:2004)

This European Standard was approved by CEN on 29 July 2004.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

This document (EN ISO 14644-5:2004) 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 February 2005, and conflicting national standards shall be withdrawn at the latest by February 2005.

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

Endorsement notice

The text of ISO 14644-5:2004 has been approved by CEN as EN ISO 14644-5:2004 without any modifications.

Cleanrooms and associated controlled environments —

**Part 5:
Operations**

Salles propres et environnements maîtrisés apparentés —

Partie 5: Exploitation



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Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Specification of requirements	3
Annex A (informative) Operational systems	7
Annex B (informative) Cleanroom clothing	13
Annex C (informative) Personnel	18
Annex D (informative) Stationary equipment	22
Annex E (informative) Materials and portable equipment	26
Annex F (informative) Cleanroom cleaning	33
Bibliography	43

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 14644-5 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: 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 airborne molecular contamination*

The following part is under preparation:

- *Part 6: Terms and definitions*

Introduction

Industries and organizations of all kinds utilize cleanrooms. Operational procedures have a profound effect on the cleanliness levels achieved during the operation of the cleanroom and equipment. Consistent quality is cleanliness dependent. Operational cleanliness can only be attained and maintained through a deliberate programme established to specify, measure and enforce defined operational procedures. Regulatory agencies that have authority over processes and products produced in the cleanroom may require additional procedures and measures of cleanliness not covered in this general operating standard.

This part of ISO 14644 addresses normative and informative operational requirements related to:

- a) providing a system that defines policies and operational procedures;
- b) clothing used to isolate human-generated contamination from the cleanroom environment;
- c) training of personnel inside the cleanroom and monitoring their compliance to specified procedures and disciplines;
- d) transfer, installation and maintenance of stationary equipment (selection criteria is not discussed);
- e) selection and use of materials and portable equipment in the cleanroom;
- f) maintaining the cleanliness of the cleanroom through systematic cleaning and monitoring procedures.

Cleanrooms and associated controlled environments —

Part 5: Operations

1 Scope

This part of ISO 14644 specifies basic requirements for cleanroom operations. It is intended for those planning to use and operate a cleanroom. Aspects of safety that have no direct bearing on contamination control are not considered in this part of ISO 14644 and national and local safety regulations must be observed. This document considers all classes of cleanrooms used to produce all types of products. Therefore, it is broad in application and does not address specific requirements for individual industries. Methods and programmes for routine monitoring within cleanrooms are not covered in detail in this part of ISO 14644 but reference is made to ISO 14644-2 and ISO 14644-3 for monitoring particles and ISO 14698-1 and ISO 14698-2 for monitoring micro-organisms.

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 14644-1:1999, *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: Test methods*

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

ISO 14698-1:2003, *Cleanrooms and associated controlled environments — Biocontamination control — Part 1: General principles and methods*

ISO 14698-2:2003, *Cleanrooms and associated controlled environments — Biocontamination control — Part 2: Evaluation and interpretation of biocontamination data*

1) To be published.