

	<b>Cleanrooms and associated controlled environments</b> Part 4: Design, construction and start-up (ISO 14644-4 : 2001) English version of DIN EN ISO 14644-4	<b>DIN</b> <b>EN ISO 14644-4</b>
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ICS 13.040.30

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

**European Standard EN ISO 14644-4 : 2001 has the status of a DIN Standard.**

*A comma is used as the decimal marker.*

### National foreword

This standard has been published in accordance with a decision taken by CEN/TC 243 to adopt, without alteration, International Standard ISO 14644-4 as a European Standard.

The responsible German body involved in its preparation was the DIN/VDI-Gemeinschaftsarbeitsausschuss *Reinraumtechnik* (DIN/VDI Joint Committee on cleanroom technology).

DIN EN ISO 14644-1 and DIN EN ISO 14644-2 are the standards corresponding to International Standards ISO 14644-1 and ISO 14644-2, respectively, referred to in clause 2 of the EN.

### National Annex NA

#### Standards referred to

(and not included in **Normative references**, **Bibliography** and **Annex ZA**)

DIN EN ISO 14644-1 Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness (ISO 14644-1 : 1999)

DIN EN ISO 14644-2 Cleanrooms and associated controlled environments – Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1 (ISO 14644-2 : 2000)

EN comprises 55 pages.



**English version**

**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)

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

This European Standard was approved by CEN on 2001-04-01.

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.

The European Standards exist 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.

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**CEN**

European Committee for Standardization  
Comité Européen de Normalisation  
Europäisches Komitee für Normung

**Management Centre: rue de Stassart 36, B-1050 Brussels**

## Foreword

International Standard

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

which was prepared by ISO/TC 209 'Cleanrooms and associated controlled environments' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 243 'Cleanroom technology', the Secretariat of which is held by BSI, as a European Standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by October 2001 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the 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 publications are listed in Annex ZA (normative).

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## 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.

## 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:— <sup>1)</sup>, *Cleanrooms and associated controlled environments — Part 3: Metrology and test methods.*

ISO 14698-1:— <sup>1)</sup>, *Cleanrooms and associated controlled environments — Biocontamination control — Part 1: General principles*

ISO 14698-2:— <sup>1)</sup>, *Cleanrooms and associated controlled environments — Biocontamination control — Part 2: Evaluation and interpretation of biocontamination data.*

ISO 14698-3:— <sup>1)</sup>, *Cleanrooms and associated controlled environments — 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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<sup>1)</sup> To be published.