

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)

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

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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of an identical text or by endorsement, at the latest by February 2005, and conflicting national standards shall be withdrawn at the latest by February 2005.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.

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Cleanrooms and associated controlled environments —

Operations

Salles propres et environnements maîtrisés apparentés —



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Cleanrooms and associated controlled environments — Biocontamination control —

3 Terms and definitions

3.1 General Terms

3.1.1
biocleanroom

3.1.2
changing room

3.1.3
cross-over bench

3.1.4
disinfection

3.1.5
fibre

3.1.6
operator

3.1.7
particle

3.1.8
personnel

3.1.9
separative device

3.1.10
unidirectional airflow

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3.2.1
as-built

3.2.2
at-rest

3.2.3
operational

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4.1.1

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4.1.3

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4.1.6

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4.2 Cleanroom clothing

4.2.1

4.2.2

4.2.3

4.2.4

4.2.5

4.2.6

4.2.7

4.2.8

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4.3 Personnel

4.3.1

4.3.2

4.3.3

4.3.4

4.3.5

4.4 Stationary equipment

4.4.1

4.4.2

4.4.3

4.4.4

4.4.5

4.4.6

4.5 Materials and portable and mobile equipment

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4.5.2

4.5.3

4.5.4

4.5.5

4.6 Cleanroom cleaning

4.6.1

4.6.2

4.6.3

4.6.4

4.6.5

4.6.6

Annex A

Operational systems

A.1 General

A.2 Assessing contamination risks

A.2.1 Methods for assessing risks

A.2.2 Determining operational risks

A.2.2.1 General

A.2.2.2 Cleanroom clothing

A.2.2.3 Personnel

A.2.2.4 Stationary equipment

A.2.2.5 Materials and portable and mobile equipment

A.2.2.6 Cleanroom cleaning

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A.4 Education and training

A.4.1 Involvement

A.4.2 Training course contents

A.4.3 Monitoring of cleanroom personnel and corrective action

A.4.4 Training documentation

A.5 Cleanroom support services

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A.5.2 Record of the installation

A.5.3 Operating and maintenance instructions

A.5.4 Performance monitoring

A.5.5 Maintenance procedures

A.5.6 Maintenance records

A.6 Upgrading and modifying the cleanroom

A.7 Safety

Annex B

Cleanroom clothing

B.1 Function of cleanroom clothing

B.2 General choice of cleanroom clothing

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B.3 Properties of fabric

B.3.1 Barrier properties

B.3.2 Durability

B.3.3 Electrostatic properties

measured by checking the fabric's surface resistivity. Such methods are

B.3.4 Other physical properties

B.4 Design and construction of cleanroom clothing

B.4.1 Construction of clothing

B.4.2 General design

B.4.3 Dispersal chamber (body box)

B.5 Thermal comfort

B.6 Cleanroom clothing cleaning process and frequency of change

B.7 Gloves

B.8 Face masks and other headgear

B.9 Storage of clothing

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B.9.4

Annex C

Personnel

C.1 Training

C.2 Access by personnel

C.3 Clothing and personal items

C.4 Hygiene

- d) in a biocleanroom — high microbial bioburden on personnel.

C.5 Cleanroom clothing changing procedures

C.6 Discipline and conduct

Methods should be devised for moving or manipulating the product. “No-touch” techniques should be

C.7 Safety

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C.8 Personnel initiatives

Annex D

Stationary equipment

D.1 General

D.2 Clean entry process

D.2.1 Planning

cleanroom that is “as-built” or “at-rest” should be properly unpacked and cleaned. Failure to do so will require into an “operational” cleanroom. Failure to do so will expose not only the cleanroom to contamination risks but

D.2.2 Inspection and removal of non-cleanroom packaging

D.2.3 Removing cleanroom packaging

D.3 Transporting equipment

D.4 Installation procedures

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D.5 Maintenance and repair

D.6 Equipment removal

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Materials and portable equipment

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E.4.3.1 Personal and small equipment

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E.5.3 Solutions and finishes used in cleaning

E.5.4 Wipers

E.5.5 Vacuum cleaners, hoses and handles

E.5.6 Mops

E.5.7 Buckets and wringers

E.5.8 Floor scrubbers, buffing and waxing machines

E.5.9 Stepladders

E.5.10 Brooms or brushes

E.5.11 Receptacles for rubbish and recycling

E.5.12 Cleanroom mats and sticky flooring

- a) Disposable — Multiple layers of adhesive, plastic film with the sticky surface facing up. Layers are
- b) Reusable — Resilient polymeric mat with a naturally sticky surface, to be cleaned when it becomes dirty.

E.5.13 Clean containers and packaging

E.5.14 Hand tools, boxes and maintenance equipment

E.5.15 Safety equipment

E.5.16 Written documentation

E.5.17 Electronic documentation

E.5.18 Other materials

E.6 Storage

Annex F

Cleanroom cleaning

F.1 Overview

F.2 Surface classification

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F.2.2 Critical surfaces

F.2.3 General cleanroom surfaces

are considered “general”. They should be cleaned on a regular basis to prevent transfer of contamination onto

F.2.4 Surfaces of changing rooms and transfer areas

F.3 Basic cleaning

F.3.1 General

F.3.2 Basic cleaning categories

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F.3.3 Vacuum cleaning

F.3.4 Wet cleaning

F.3.5 Damp cleaning

F.4 Cleaning specific surfaces

F.4.1 Identifying surfaces to be cleaned

F.4.2 Floors and subfloors

F.4.3 Walls, doors, return grilles, windows and vertical surfaces

F.4.4 Ceilings, diffusers and lamp fixtures

F.4.5 Tables and other critical horizontal surfaces

F.4.6 Cleanroom chairs, furniture and ladders

F.4.7 Stationary equipment

F.4.8 Carts and trolleys

F.4.9 Hazardous processing surfaces

F.4.10 Cross-over benches, supply and cleanroom clothing supply cabinets, lockers and other compartmented surfaces

F.4.11 Rubbish bins and containers

F.4.12 Cleanroom mats and sticky flooring

Cleanroom mats and sticky flooring should be serviced according to the manufacturer's instructions as

F.5 Surface treatment

F.5.1 General

F.5.2 Anti-static treatment

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F.5.3 Disinfection

F.6 Cleaning personnel

F.7 Cleaning programme

F.7.1 Preparing a cleaning programme

F.7.2 Scheduling the cleaning programme

F.7.3 Regular cleaning

F.7.4 Periodic cleaning

F.7.5 Cleaning during and after construction or maintenance

F.7.6 Cleaning during emergency situations

F.8 Monitoring cleaning effectiveness and testing

F.8.1 Particle contamination

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F.8.2 Microbiological contamination

F.9 Construction-related cleaning programme

Table F.1 — Stages of construction-related cleaning programme

Stage	Purpose	Responsible party	Method	Standard
Stage 1 —				
Stage 2 —			-	
Stage 3 —			-	
Stage 4 —				
Stage 5 —				
Stage 6 —				
Stage 7 —	-			
Stage 8 —				

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Stage	Purpose	Responsible party	Method	Standard
Stage 9 —				
Stage 10 —				

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