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Cleanrooms and associated controlled environments - Part 7: Separative devices (ISO/DIS 14644-7:2026)

Reinräume und zugehörige Reinraumbereiche - Teil 7: SD-Module (Reinlufthauben, Handschuhboxen, Isolatoren und Minienvironments) (ISO/DIS 14644-7:2026)

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Salles propres et environnements maîtrisés apparentés - Partie 7: Dispositifs séparatifs (ISO/DIS 14644-7:2026)

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ICS:

13.040.35	Brezprašni prostori in povezana nadzorovana okolja	Cleanrooms and associated controlled environments

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DRAFT International Standard

ISO/DIS 14644-7

Cleanrooms and associated controlled environments —

Part 7: Separative devices

Salles propres et environnements maîtrisés apparentés —

Partie 7: Dispositifs séparatifs

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Foreword

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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 14644-7 was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*.

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Introduction

Cleanrooms and associated controlled environments provide for the control of airborne and surface contamination to levels appropriate for contamination-sensitive activities. Contamination control can be beneficial for protection of product or process in industries such as aerospace, microelectronics, pharmaceuticals, medical devices, healthcare, nuclear, fine finishing and food.

This part of ISO 14644 sets out considerations for the design and testing of separative devices and this edition of this part is in response to user and expert feedback validated by international enquiry. This edition has been updated to better integrate with the other parts of ISO 14644 and in particular the latest editions of parts 1, 2, 3 and 4.

The term ‘separative device’ was originally developed by Technical Committee ISO/TC 209 to encompass the wide continuum of configurations from open unrestricted air overspill to wholly physically contained systems. Separative devices provide protection in varying levels by utilising physical or aerodynamic means, or a combination of both, to create separation between an internal environment and the background environment. The original continuum of separative devices did not properly distinguish between prevention of ingress of contaminants (air cleanliness) within the device and prevention of egress of contaminants from the device (containment). The new continuum recognises that separative devices can provide a variety of combinations of air cleanliness and containment with varying degrees of effectiveness.

Part 1 of ISO 14644 defines cleanrooms and clean zones. Clean zones ‘can be a defined space within a cleanroom or might be achieved by a separative device. Such a device can be located inside or outside a cleanroom.’ This part of ISO 14644 is intended to apply to a broad range of devices, examples of which are given in the scope portion of this document. They may be integrated into the cleanroom structure or free-standing within it. Some separative devices can be independent of a cleanroom and some can be mobile.

Where a separative device provides air cleanliness, it can be classified, monitored, and tested in accordance with parts 1, 2, 3 and 4 of ISO 14644. Where it provides containment, the containment may be tested and monitored by part 3 or other methods. In all cases the effectiveness of separation can be expressed by a characterizing separation index, the basis for calculation and testing of this index is described herein.

ISO 14644 is intended to be broadly applicable; but, as isolators have special requirements, there is an emphasis in this Part 7 on physical separation – this should be considered when using this standard.

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Cleanrooms and associated controlled environments —

Part 7: Separative devices

1 Scope

This part of ISO 14644 specifies the minimum requirements for the design, construction, installation, test and setting to work of separative devices, in those respects where they differ from cleanrooms as described in ISO 14644-4.

It is intended to be complimentary to the requirements of other national and international standards and guidelines for separative devices as listed below.

This part includes devices providing segregation using either physical or aerodynamic separation for the purposes of preventing the ingress of contaminants to the device or preventing the egress of contaminants from the device. It provides design, testing and operational parameters to distinguish between devices with different purposes and performance characteristics.

Separative devices covered by this section addresses:

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— Unidirectional Airflow Devices

— Material Handling Booths

— Restricted Access Barrier Systems (with or without access devices)

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— Isolators (open or closed isolators, with or without transfer devices)

— Transfer Containers

— Biological Safety Cabinets Class II and III

— Gloveboxes

— Pass-Through Boxes or Transfer Hatches

— Minienvironments

Refer to Annex A for further information on the above devices.

This part of ISO 14644 excludes:

— Devices designed solely for containment, not associated with cleanrooms or clean zones.

— Environmental health or safety requirements which might drive the need for containment.

— Application-specific requirements

— Specific processes to be accommodated in the separative-device installation.

— Fire, safety and other regulatory matters, specifically where appropriate national and local regulations apply.

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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, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration*

ISO 14644-2, *Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration*

ISO 14644-3, *Cleanrooms and associated controlled environments — Part 3: Test methods*

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

ISO 14644-14, *Cleanrooms and associated controlled environments — Part 14: Assessment of suitability for use of equipment by airborne particle concentration*

ISO 14644-15, *Cleanrooms and associated controlled environments — Part 15: Assessment of suitability for use of equipment and materials by airborne chemical concentration*

ISO 14644-16, *Cleanrooms and associated controlled environments — Part 16: Energy efficiency in cleanrooms and separative devices*

ISO 14644-18, *Cleanrooms and associated controlled environments — Part 18: Assessment of suitability of consumables*

3 Terms and definitions

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For the purposes of this document, the terms and definitions given in ISO 10648-2, 14644-1, 14644-2 14644-4, and 14644-14 and the following apply

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3.1
access device
component of a separative device which allows an operator outside the barrier to manipulate materials, equipment or products within the separative device without compromising the separation.

3.2
barrier
means employed to provide separation

3.3
breach velocity
speed of air through an aperture in a barrier

Note 1 to entry: Sufficient airflow through a breach will prevent movement of airborne contamination in the opposite direction (aerodynamic separation)

3.4
containment
resistance to egress of airborne contaminant

Note 1 to entry: The contaminant can be airborne particles, microorganisms or chemicals

3.5
decontamination
reduction of unwanted matter to a defined level

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3.6
glove (of separative devices)
component of an access device that maintains an effective barrier while enabling the hands of an operator to enter the enclosed volume of a separative device.

Note 1 to entry: Gloves can be two-piece glove and sleeve systems or one-piece glove and sleeve (gauntlet).

3.7
glove port
attachment site for glove sleeve system

3.8
glove sleeve system
multi-component access device that maintains an effective barrier while enabling the replacement of sleeve piece, connecting cuff piece and the glove

3.9
Isolator
enclosure providing separation by physical and aerodynamic means which is operated via access devices.

Note 1 to entry: isolators for aseptic processing are capable of being subject to reproducible interior bio-decontamination.

[SOURCE: ISO 11139:2018, modified]

3.10
leak (of a separative device)
defect allowing egress from or ingress to the working zone

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3.11
pressure integrity
capability to provide a quantifiable leakage rate repeatable under quantitative leak test conditions

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3.12
Separation
Reduction of ingress or egress of contaminants between a working zone and the surrounding environment.

3.13
Separation index SI_i,
numerical abbreviation expressing the prevention of ingress into a working zone from the surrounding environment of the separative device under specified test conditions

Note 1 to entry: for formula see section 9.3.2, Formula A.1

Note 2 to entry: the index can be applied for contaminants such as particles, chemicals or microorganisms

3.14
Separation index SI_e,
numerical abbreviation expressing the prevention of egress of a contaminant from the internal volume of a separative device into the surrounding environment under specified test conditions

Note 1 to entry: for formula see 9.3.2 , Formula A.2

Note 2 to entry: the index can be applied for contaminants such as particles, chemicals or microorganisms

3.15
separative device
equipment utilizing a physical barrier or aerodynamic means to create assured levels of separation described by separation indices

Note 1 to entry: The device has the purpose of preventing egress from or ingress into a specified area or volume (e.g. work zone) or both

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Note 2 to entry: Some industry specific examples of separative devices are unidirectional airflow devices, containment enclosures, glove boxes, isolators and minienvironments.

3.16
transfer device
mechanism to effect movement of materials into or out of a separative devices while minimizing ingress or egress of contamination

3.17
work zone
designated part of a separative device in which specified activities are carried out

3.18
cleanliness
condition not exceeding a specified level of contamination

[SOURCE: ISO 14644-14:2016, 3.1]

Note 1 to entry: In this document, contamination refers to particles, chemicals or viables.

3.19
cleanroom
room within which the number concentration of airborne particles is controlled and classified, and which is designed, constructed and operated in a manner to control the introduction, generation, and retention of particles inside the room

Note 1 to entry: The class of airborne particle concentration is specified.

Note 2 to entry: Levels of other cleanliness attributes such as chemical, viable or nanoscale concentrations in the air, and also surface cleanliness in terms of particle, nanoscale, chemical and viable concentrations might also be specified and controlled.

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Note 3 to entry: Other relevant physical parameters might also be controlled as required, e.g. temperature, humidity, pressure, vibration and electrostatic.

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[SOURCE: ISO 14644-1:2015, 3.1.1]

3.20
clean zone
defined space within which the number concentration of airborne particles is controlled and classified, and which is constructed and operated in a manner to control the introduction, generation, and retention of contaminants inside the space

Note 1 to entry: The class of airborne particle concentration is specified.

Note 2 to entry: Levels of other cleanliness attributes such as chemical, viable or nanoscale concentrations in the air, and also surface cleanliness in terms of particle, nanoscale, chemical and viable concentrations might also be specified and controlled.

Note 3 to entry: A clean zone(s) can be a defined space within a cleanroom or might be achieved by a separative device. Such a device can be located inside or outside a cleanroom.

Note 4 to entry: Other relevant physical parameters might also be controlled as required, e.g. temperature, humidity, pressure, vibration and electrostatic.

[SOURCE: ISO 14644-1:2015, 3.1.2]

3.21
contamination
unwanted matter in an undesirable location

[SOURCE: ISO 14644-13:2017, 3.4]

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3.22
controlled zone
designated space in which the concentration of at least one contamination category (particles, chemical, biocontamination) in air and on surfaces is controlled and specified and which is constructed and used in a manner to minimize the introduction and impact of contamination

Note 1 to entry: Levels of cleanliness attributes such as chemical and viable concentrations in the air or cleanliness in terms of particle, chemical and viable concentrations on surfaces should be specified by level(s) as described in the ISO standard series.

Note 2 to entry: Other relevant parameters may also be controlled as necessary, e.g. temperature, humidity and pressure, vibration and electrostatic.

Note 3 to entry: A controlled zone can be a defined space within a cleanroom or may be achieved by a separative device. Such a device can be located inside or outside a cleanroom.

[SOURCE: ISO 14644-15:2016, 3.9]

3.23
service life
length of time or number of cycles an item is suitable for use

Note 1 to entry: In this document, items are considered as consumable.

Note 2 to entry: Service life is depending on appropriate use.

[SOURCE: ISO 14644-18:2023, 3.19]

3.24
verification
confirmation, through the provision of objective evidence that specified requirements have been fulfilled

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Note 1 to entry: The objective evidence needed for a verification can be the result of an Inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

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Note 2 to entry: The activities carried out for verification are sometimes called a qualification Process.

Note 3 to entry: The word “verified” is used to designate the corresponding status.

[SOURCE: ISO 9000:2015, 3.8.12, modified: Cross-references to other terms deleted]

3.25
contaminant
particle, chemical or microorganism that adversely affects the product or process

[SOURCE: ISO 14644-4:2022, 3.1.7]

Note 1 to entry: For this standard, contaminant can also adversely affect the environment, personnel or other materials

4 Symbols and abbreviations

The following symbols and abbreviations are used in this part of ISO 14644

Table 1 — Common symbols used in cleanrooms and associated controlled environments

Symbol	Meaning
BD	Basic Design
BSC	Biological Safety Cabinet
BMS	Building Management System
CD	Concept Design
DD	Detailed Design

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Table 1 *(continued)*

Symbol	Meaning
EMS	Environmental Monitoring System
FAT	Factory Acceptance Testing
HEPA filter	High Efficiency Particulate Air filter
LSAPC	Light-scattering airborne particle counter
RABS	Restricted Access Barrier System
SAT	Site Acceptance Testing
SI	Separation index
SMIF	Standard Mechanical Interfaces
UDAF	Unidirectional Airflow
ULPA	Ultra Low Penetration Air filter

5 Requirements

5.1 General Requirements

Taking into consideration the contamination control concepts and overall strategy for contamination control, an initial risk assessment shall be conducted to establish the requirements with respect to product quality and safety aspects for personnel and environment.

The following items listed shall be considered and specified as appropriate, by customer and supplier before, or in the early stages of, the design process.

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5.1.1 Usage

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a) The intended use of the separative device and the operations to be carried out therein;

Note 1 *Intended use can include purpose of containment*

Note 2 *Considerations include material compatibility, residues and effluents.*

b) Entry and exit of equipment, materials and waste, in terms of quantity, movement and controls applied such as decontamination;

Note 1 *Access devices and transfer devices can be part of these considerations*

Note 2 *Ergonomics are an integral part of entry and exit of materials*

c) Intended life cycle of the separative device

d) Changes of the separative device anticipated over time to be provided for in the design

e) Intended operational cycles and turn-down periods;

Note *When systems are planned to be turned off, a detailed process impact assessment should be documented and an appropriate shutdown and return to service procedure outlined. Shutting systems off generally result in loss of separation and loss of cleanliness.*

f) The intended location of the separative device and any constraints of the *installation*

g) The identification of surrounding environmental influences;

h) Critical dimensions and weight restrictions, including those related to available space.

Note *This includes circulation space and access for personnel and material movements.*

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i) Process and product requirements that affect the separative device such as air velocity, light sensitivity or radioactivity.

j) Cleaning and decontamination requirements.

k) Utility requirements

l) Process hazards;

m) Internal surfaces and finish requirements (including request for smooth, impervious finishes which are cleanable and resistant to cleaning and decontamination agents and free of gaps to uncontrolled areas);

n) Required availability, reliability level and back-up strategy;

o) Strategy of maintenance operations, space and time needed to maintain the installations during the process cycle;

p) Access of personnel over all phases of operation, including PPE, access devices and the like.

5.1.2 References

a) Regulatory requirements;

b) The number, edition and year of publication of the relevant parts of ISO 14644 that will be used;

c) Methods of testing, measurement and monitoring, to meet the acceptance criteria *and* related documentation.

Note *It might be necessary to have special provisions (access or connections) for testing and monitoring of separative devices.*

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5.1.3 Conditions

a) The air cleanliness class at the designated particle size(s) and the defined occupancy states in accordance with ISO 14644-1;

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b) Any other requirements with respect to particles or other contaminants in air or on surfaces (e.g. particle number concentration and particle deposition rate);

c) Considerations of any other influences e.g., electrostatic discharge (ESD), vibration;

d) Sources of contamination and their source strength data;

5.1.4 Control / Monitoring

a) Performance parameters and their acceptance criteria with any specific requirements for alert (warning) and action (alarm) limits and their management;

Note *Management includes initial acceptance testing as well as ongoing monitoring*

b) Cleanroom environmental control by stand-alone systems or integrated into building management system (BMS);

c) Requirements for monitoring of environmental and other parameters, both inside and outside of the separative device.;

Note *Guidance for monitoring to provide evidence of cleanroom and separative performance related to air cleanliness by particle concentration can be found in ISO 14644-2.*

It is recommended for critical parameters to be continuously monitored and alarmed.

d) The preferred contamination control concepts and overall strategy for contamination control, including physical or chemical decontamination processes;

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