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Biološke varnostne omare - 1. del: Razredi in osnovne zahteve

Biological safety cabinets - Part 1: Classes and basic requirements

Biologische Sicherheitswerkbänke - Teil 1: Klassen und grundlegende Anforderungen

Postes de sécurité biologique - Partie 1: Types et exigences fondamentales

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English Version

Biological safety cabinets - Part 1: Classes and basic requirements

Biotechnologie - Critères de performance pour les postes de sécurité microbiologique

Biotechnik - Leistungskriterien für mikrobiologische Sicherheitswerkbänke

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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prEN 12469-1:2024 (E)

European foreword

This document (prEN 12469-1:2024) has been prepared by Technical Committee CEN/TC 332 “Laboratory Equipment”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

This document, together with prEN 12469-2:2024, prEN 12469-3:202X, prEN 12469-4:202X and prEN 12469-5:2024, will partially supersede EN 12469:2000.

prEN 12469-1:2024 includes the following significant technical changes with respect to EN 12469:2000:

- the structure has been changed to emphasize different classes of biological safety cabinets (BSC);
- the text of the entire document has been revised and references have been updated.

prEN 12469 consists of the following parts, under the general title *Biological safety cabinets*:

- Part 1: Classes, terminology and basic requirements
- Part 2: BSC class II
- Part 3: BSC class III¹
- Part 4: BSC class I²
- Part 5: Installation, commissioning and routine testing

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¹ Under preparation.

² Under preparation.

Introduction

Biological safety cabinets (BSC) are designed to reduce the risk to the operator when using biological materials. Dependent on type, they can protect the operator, the product, and the environment from biological aerosols.

BSC class I and class II are ventilated enclosures with an open front aperture.

A BSC class III is a fully enclosed workspace with gloves attached to the front port normally with an additional pass-through box attached.

A BSC class I provides operator and environment protection.

A BSC class II provides operator, product, and environment protection. In addition, it offers cross-contamination protection.

A BSC class III provides operator, environment and product protection. It is normally used in high level containment facilities for the highest risk group agents.

The type of BSC required is usually based on risk group, risk assessment and application.

This document describes the design and testing of these BSC for use in laboratories handling biological agents.

This document is a product standard. Occupational health and safety assessments methods are not included.

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1 Scope

This document specifies the minimum requirements for BSC with respect to design, construction, safety and hygiene and gives general test methods for their verification.

The requirements for the different classes are given in the respective parts of prEN 12469.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

EN 842, *Safety of machinery – Visual danger signals – General requirements, design and testing*

EN 1822-1, *High efficiency air filters (EPA, HEPA and ULPA) - Part 1: Classification, performance testing, marking*

EN 12600, *Glass in building - Pendulum test - Impact test method and classification for flat glass*

EN ISO 5349-2, *Mechanical vibration - Measurement and evaluation of human exposure to hand-transmitted vibration - Part 2: Practical guidance for measurement at the workplace (ISO 5349-2)*

EN ISO 7731, *Ergonomics - Danger signals for public and work areas - Auditory danger signals (ISO 7731)*

EN ISO 8041-1, *Human response to vibration - Measuring instrumentation - Part 1: General purpose vibration meters (ISO 8041-1)*

EN ISO 11201:2010, *Acoustics - Noise emitted by machinery and equipment - Determination of emission sound pressure levels at a work station and at other specified positions in an essentially free field over a reflecting plane with negligible environmental corrections (ISO 11201:2010)*

EN 13792, *Colour coding of taps and valves for use in laboratories*

EN ISO 14644-3, *Cleanrooms and associated controlled environments - Part 3: Test methods (ISO 14644-3)*

EN ISO 14738, *Safety of machinery - Anthropometric requirements for the design of workstations at machinery (ISO 14738)*

EN 61010-1, *Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements*

EN IEC/IEEE 82079-1, *Preparation of instructions for use - Structuring, content and presentation - Part 1: General principles and detailed requirements*

ISO 6706, *Plastics laboratory ware — Graduated measuring cylinders*

ISO/CIE 19476, *Characterization of the performance of illuminance meters and luminance meters*

EN 61672-1, *Electroacoustics - Sound level meters - Part 1: Specifications*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp/>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1

biological agent

any microbiological entity, cellular or non-cellular, naturally occurring or engineered, capable of replication or of transferring genetic material that could be able to provoke infection, allergy, toxicity or other adverse effects in humans, animals, or plants

EXAMPLE Bacteria, fungi, viruses, viroids, endo-, and ectoparasites.

Note 1 to entry: The definition of biological agents covers commonly used terms, such as pathogens, quarantine microorganisms, microorganisms of dual-use potential.

Note 2 to entry: For the purpose of this document, prions are regarded as biological agents.

Note 3 to entry: The term “engineered” includes biological agents that are synthetically derived.

3.2

biological safety cabinet

BSC

ventilated enclosure intended to offer protection to the operator and the environment from the aerosols, arising from the handling of potentially hazardous and hazardous microorganisms, with air discharged to the atmosphere being filtered

Note 1 to entry: There are different classes of BSCs (see Clause 4).

3.3

carcass

cabinet body that includes e.g. the exterior surface welds, gaskets and seals

3.4

cleaning

removal of unwanted material from an object

3.5

containment

state achieved by separative devices with high degree of separation between operator and operation

[SOURCE: EN ISO 14644-7, 3.6]

3.6

cross-contamination

transfer of contaminants from one surface or component to another within the designated working area

3.7

decontamination

overall process of removal or reduction of any contaminants (chemical, waste, residue or microorganisms) from the inner or outer space of the cabinet

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Note 1 to entry: The method of decontamination used (e.g. cleaning, disinfections) should be chosen to the intended use of the item decontaminated.

3.8**designated working area**

area within the BSC workspace as described in the operating manual where performance is measured in accordance with this document to establish operating performance relevant to protection of the worker, and/or product protection including cross-contamination as necessary for the classes of BSC

3.9**disinfection**

process to reduce the number of viable biological agents, by a suitable method to a desired level suitable for further safe handling or use

Note 1 to entry: Suitable methods are wiping, spraying, radiation or fumigation.

3.10**downflow**

unidirectional airflow, flowing downward through the designated working area

3.11**filter system**

system including filter, fittings, seals and other connecting parts

3.12**front aperture**

opening to the working area on the front side of the BSC, which is limited by the front window

3.13**inflow**

airflow from the outside of the BSC through the front aperture

3.14**inner measurement plane**

plane of sash at the type test opening, except where the plane of sash does not meet the work surface of the BSC

Note 1 to entry: In the latter case, it is a non-vertical plane bounded

- at the top by the lowest point of the upper edge of the type test opening in the plane of the sash,
- at the bottom by the uppermost point of the lower edge of the opening closest to the plane of sash, and
- at the sides by the side edges of the opening.

3.15**inner space of the cabinet**

possibly contaminated area

Note 1 to entry: This includes all areas which can be reached and accessed through the work opening without using a tool.

Note 2 to entry: This includes all areas which cannot be reached through the work opening and are only allowed to be opened by using a tool.