SLOVENSKI STANDARD
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Biotehnologija - Merila za mikrobiološko varne prostore

Biotechnology - Performance criteria for microbiological safety cabinets

Biotechnik - Leistungskriterien für mikrobiologische Sicherheitswerkbänke

Biotechnologie - Criteres de performance pour les postes de sécurité microbiologique

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Biotechnology - Performance criteria for microbiological safety cabinets

Biotechnologie - Critères de performance pour les postes de sécurité microbiologique

Biotechnik - Leistungskriterien für mikrobiologische Sicherheitswerkbänke

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This European Standard exists 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 Central Secretariat has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 233 "Biotechnology", the secretariat of which is held by AFNOR.

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of an identical text or by endorsement, at the latest by November 2000, and conflicting national standards shall be withdrawn at the latest by November 2000.

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

Introduction

Microbiological safety cabinets are intended to reduce the risk to the operator when handling hazardous or potentially hazardous microorganisms. They do not necessarily protect the operator from all hazards involved. Some types of safety cabinet can also protect the materials being handled in them from environmental contamination.

1 Scope

This European Standard specifies basic requirements for microbiological safety cabinets (MSCs) with respect to safety and hygiene.

This European Standard sets the minimum performance criteria for safety cabinets for work with microorganisms and specifies test procedures for microbiological safety cabinets with respect to protection of the worker and the environment, product protection and cross contamination. Mechanical, electrical, chemical or radioactive safety precautions are not covered in the standard but are covered in EN 61010-1, EN 292-1 and EN 292-2 (see Bibliography [1], [2] and [3]).

This European Standard does not cover safety precautions for aspects not associated with the use of microorganisms such as those covering mechanical and electrical hazards, which are covered in EN 61010-1 (see Bibliography [1]), nor does it cover safety requirements regarding flammable gas and inert gases.

NOTE Some features of MSCs in addition to those for performance and safety are given for guidance in this European Standard and in EN 12741 (see Bibliography [4]).

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 1822-1	High efficiency air filters (HEPA and ULPA) - Part 1 : Classification, performance testing, marking
EN 12296	Biotechnology - Equipment - Guidance on testing procedures for cleanability
EN 12297	Biotechnology - Equipment - Guidance on testing procedures for sterilizability
EN 12298	Biotechnology - Equipment - Guidance on testing procedures for leaktightness
EN 13091:1999	Biotechnology - Performance criteria for filter elements and filtration assemblies

3 Definitions

For the purposes of this standard, the following definitions apply :

3.1 aperture protection factor (A_{pf})

Ratio of exposure to airborne contamination generated on the open bench, to the exposure resulting from the same dispersal of airborne contamination generated within the cabinet.

3.2 cross contamination

Unintended introduction of impurities of a chemical or microbiological nature from a material or product into another material or product.

3.3 microbiological safety cabinet (MSC)

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

3.4 MSC class I

Safety cabinet with an front aperture through which the operator can carry out manipulations inside the cabinet and which is constructed so that the worker is protected and the escape of airborne particulate contamination generated within the cabinet is controlled by means of an inward airflow through the working front aperture and filtration of the exhaust air.

3.5 MSC class II

Safety cabinet with a front aperture through which the operator can carry out manipulations inside the cabinet and which is constructed so that the worker is protected, the risk of product and cross contamination is low and the escape of airborne particulate contamination generated within the cabinet is controlled by means of an appropriate filtered internal airflow and filtration of the exhaust air.

NOTE A typical way of achieving this is by means of a uni-directional downward laminar airflow inside the cabinet and an air-curtain at the front aperture.

3.6 MSC class III

Safety cabinet in which the working area is totally enclosed and the operator is separated from the work by a physical barrier (i.e. gloves mechanically attached to the cabinet). Filtered air is continuously supplied to the cabinet and the exhaust air is treated to prevent release of microorganisms.

NOTE 1 Relevant provisions of this standard for class III microbiological safety cabinets may apply in respect of performance and construction to rigid or flexible film isolators. Further guidance specific to isolators is given in EN 12741 (see Bibliography [4]).

NOTE 2 The exhaust air can be cleaned by at least double in-line high efficiency particulate air filters and can be conducted through its own exhaust air system into the open air.

3.7 product protection

Ability of the MSC to prevent airborne contamination from outside entering the MSC through the front aperture.

3.8 retention efficiency

Ability of barrier to retain microorganisms and/or aerosols measured as the ratio of the concentration of a given marker substance between a challenged area and an adjacent area.

NOTE For MSCs, the protection of operators, environment and products is achieved by various barriers such as housing, filters or adequate flow patterns. The function of those barriers is to prevent or minimize the transfer of microorganisms/aerosols between adjacent areas being separated by a barrier. Depending on the direction of the transfer to be considered, the challenge area can be the cabinet working space, the upstream side of filters or the laboratory environment.

3.9 working space

Part of the interior of the cabinet within which manipulations are carried out.

4 Hazards

The following hazards shall be taken into account :

- release of microorganisms during operation for example through the front aperture, exhaust, piping or carcass;

- release of microorganisms during dismantling or maintenance e.g. filter replacement of MSCs or parts thereof following improper sterilization ;

- release of microorganisms by removal of contaminated material from the MSC after product- or cross contamination.

5 Performance classes

5.1 Leaktightness

The performance classes for leaktightness of MSCs are given in table 1.

Table 1 - Leaktightness performance

Performance class for leaktightness Leaktightness Index (LI)	Description of performance class
LI-A	leakage of target microorganism not defined
LI-B	leakage[1)] of target microorganism detected and quantified under defined conditions
LI-C	leakage[1)] of target microorganism tested under defined conditions and leakage below detection limit or threshold value[2)]

1) Based on leakage assessment by BATNEEC (Best Available Technique Not Entailing Excessive Costs)*.
2) Prescribed threshold value should be based on the required safety level and can for example be the detection limit of an approved BATNEEC.

5.2 Cleanability

The performance classes for cleanability of MSCs are given in table 2.

Table 2 - Cleanability performance

Performance class for cleanability Cleanability Index (CI)	Description of performance class
CI-A	visible soil or cleanliness not defined
CI-B	cleanability[1)] tested and quantified under defined conditions or MSC designed with regard to specified technical criteria
CI-C	cleanability[1)] tested and quantified under defined conditions and soil below detection limit or threshold value [2)]

1) Based on assessment by BATNEEC (Best Available Technique Not Entailing Excessive Costs)*.
2) Prescribed threshold value should be based on the required safety level and can for example be the detection limit of an approved BATNEEC.

The performance for cleanability shall be CI-B or better for all classes of MSCs.

Cleanability applies as a performance criterion for MSCs where :

- deposits of soil in MSCs could jeopardize the sterilization procedure if the sterilization media do not reach all parts of the MSC or if the required temperature is not reached ;

- cleaning procedures are intended to remove and inactivate microorganisms to make MSCs safe for handling without using any other sterilization or inactivation procedure.

5.3 Sterilizability

The performance classes for sterilizability of MSCs are given in table 3.

* Use of BATNEEC does not mean that financial issues moderate the degree of safety. Where several methods are available, the user can choose the most convenient, provided that it gives results of the necessary quality.

Table 3 - Sterilizability performance

Performance class for sterilizability Sterilizability Index (SI)	Description of performance class
SI-A	MSC not suitable or not tested for reduction of viable target microorganisms
SI-B	MSC can be treated for a specified reduction of viable target microorganisms
SI-C	MSC can be sterilized
NOTE In this table the result (performance) of an inactivation procedure is described and not the way or means of achieving the result.	

The performance for sterilizability shall be SI-B or better for all classes of MSCs.

5.4 Minimum requirements for performance

Table 4 gives requirements of performance with respect to leaktightness and microbial containment for the three classes of MSCs.

Table 4 - Minimum requirements of performance for three classes of MSCs

Class	Retention at front aperture[1]	Leaktightness	Product protection	Cross contamination
I	≤ 10 CFU per operator's test[2] and ≤ 5 CFU per non-disturbance test[3]; or $A_{pf} \geq 1 \times 10^5$	LI-C for carcass	Not applicable	Not applicable
II	≤ 10 CFU per operator's test[2] and ≤ 5 CFU per non-disturbance test[3]; or $A_{pf} \geq 1 \times 10^5$	LI-C for carcass	≤ 5 CFU per test	≤ 2 CFU per test
III	Not applicable	≤ 10 % loss of test overpressure of 500 Pa in the whole enclosed system after 30 min	Not applicable	Not applicable

1) Expressed in A_{pf} or egress of microorganisms.
2) At operator's position.
3) At side positions and inward flow at front aperture established by a non-disturbance test.

6 Classification and verification of performance

6.1 General

MSCs covered by this European Standard shall be classified in accordance with the tables 1, 2 and 3. The performance of MSCs is determined and verified by the manufacturer or by the user.

In general three types of performance testing can be distinguished :

- type testing ;

- installation testing after commissioning or at change of installation, or change of environment ; and

- routine maintenance testing.

The design, construction and materials of MSCs shall be adequate for safe operation within the MSC. Illumination, sound level, vibration, stability, temperature, electrical and gas supply shall be adequate for safe operation within the MSC. MSCs shall incorporate continuous monitoring systems linked to alarms, suitable for indicating safe and unsafe conditions.

NOTE Guidance on how to achieve such conditions is given in annex A.

6.2 Leaktightness

6.2.1 General

MSCs shall be tested for leaktightness in accordance with EN 12298. The requirements for leaktightness and retention at front aperture are given in table 4. Tests shall be performed under representative process conditions. The two main aspects for microbial leaktightness for MSCs are described in 6.2.2 and 6.2.3.

NOTE A suitable test method for leakage of the carcass is described in annex B. A suitable test method for retention at front aperture is described in annex C. Any other test method may be used provided a validated correlation is established with these test methods.

6.2.2 Leaktightness for air

6.2.2.1 Leakage of carcass (class I and class II)

MSCs shall fulfil the requirements given in table 4. The carcass of MSCs in which contaminated air is under positive pressure and can leak directly to the outside shall be tested for leaks. MSCs shall be tested for leaks under positive pressure.

6.2.2.2 Leakage of carcass (class III)

The design working pressure in MSCs shall be at least 200 Pa below the air pressure of the laboratory. MSCs shall fulfil the requirements given in table 4.

6.2.3 Leaktightness for liquid spillage

MSCs shall have adequate provisions to collect spilled liquids.

6.2.4 Testing for leaktightness aspects and microbiological contamination

Direct or indirect test methods, for example flow measurement of exhaust or supply air, shall be used for installation testing and routine maintenance testing of MSCs.

NOTE 1 Table 5 summarizes test methods for type testing, installation testing and routine maintenance testing of the various aspects of leaktightness of MSCs.

Installation testing shall be carried out when MSCs are installed or at change of installation, or change of environment. If the ventilation in the room is changed, no (re)installation testing is required if the user can demonstrate, verify and document that the environment and the set up of MSCs are within the conditions of classification after type testing as specified by the manufacturer. In this case filter testing is still required. Measurement of volumetric airflow rate and visualization of airflow patterns are required but can be supplemented by retention testing at front aperture.

NOTE 2 Attention is drawn to relevant National regulations concerning routine maintenance testing.

6.3 Cleanability

MSCs shall be tested for cleanability in accordance with EN 12296. All corners and angles inside the cabinet working space and other normally accessible areas (e.g. during cleaning) likely to come into contact with microorganisms shall be rounded for proper cleaning. When surfaces inside the working space are examined without magnification by normal or corrected vision, there shall be no cracks or surface defects.

6.4 Sterilizability

MSCs shall be tested for sterilizability in accordance with EN 12297.

NOTE Annex J describes a method for fumigation MSCs.

Table 5 - Test methods for type testing, installation testing and routine maintenance testing for class I and II MSCs

Testing	Retention at front aperture	Leaktightness of carcass	Filters*	Product protection (class II only)	Cross contamination (class II only)
Type testing	- microbiological or KI method (see annex C)	- soap solution test method (see annex B)	- aerosol challenge method (see annex D)	- microbiological method (see annex E)	- microbiological method (see annex F)
Installation testing	- check that manufacturer's specification is met ; - check volumetric airflow rate measurements (see for example annexes G and H) ; and - check airflow patterns (visualization) ; - optional : retention testing (microbiological method [see annex E], or alternative methods such as KI, light scattering, after validation)	not applicable	- aerosol challenge method (see annex D) ; or - when appropriate, natural aerosol challenge method*	- check that manufacturer's specification is met ; - check volumetric airflow rate measurements (see for example annexes G and H) ; and - check airflow patterns (visualization) ; - optional : retention testing microbiological method [see annex E], or alternative methods such as KI, light scattering, after validation)	- check that manufacturer's specification is met
Routine maintenance testing (see annex K)	- check manufacturer's requirements for maintenance ; - check volumetric airflow rate measurements (see for example annexes G and H) ; and - check airflow patterns (visualization)	not applicable	- as for installation testing	- check manufacturer's requirements for maintenance ; - check volumetric airflow rate measurements (see for example annexes G and H) ; and - check airflow patterns (visualization)	- check manufacturer's requirements for maintenance ; - check volumetric airflow rate measurements (see for example annexes G and H) ; and - check airflow patterns (visualization)

NOTE National regulations may require risk assessment and may demand additional requirements in special cases, e.g. if highly hazardous microorganisms are to be used or if there is a higher danger of infection via the airborne route.

* Information on filters is given in EN 13091:1999.