EESTI STANDARD EVS-EN 12128:1999

Biotehnoloogia. Laborid uuringuks, arendustegevuseks ja analüüsiks. Mikrobioloogialaborite ettevaatusabinõude tasandid, ohuga seotud piirkonnad, tegevuskohad ja füüsikalised ohutusnõuded

Biotechnology - Laboratories for research, development and analysis - Containment levels of microbiology laboratories, areas of risk, localities and physical safety requirements

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 12128:1999 sisaldab Euroopa standardi EN 12128:1998 ingliskeelset teksti. Käesolev dokument on jõustatud 12.12.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 12128:1999 consists of the English text of the European standard EN 12128:1998. This document is endorsed on 12.12.1999 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: Käesolev Euroopa standard määrab kindlaks laboritele bioloogilise ohutuse osas esitatavate füüsikaliste nõuete miinimumi neljal füüsikaliste ettevaatusabinõude viitetasandil, mis sobivad erinevatesse ohurühmadesse kuuluvate mikroorganismide käsitlemiseks.	**Scope:**

ICS 07.080

Võtmesõnad: bioloogia, biotehnoloogia, klassifikatsioon, kvaliteet, laborid, mikrobioloogiline analüüs, mikroorganismid, ohud, ohutus, tase, tehnilised andmed, uuring, õnnetuste vältimine

EUROPEAN STANDARD
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Descriptors: Biotechnology, laboratories, microbiological analysis, safety.

English version

Biotechnology – Laboratories for research, development and analysis

Containment levels of microbiology laboratories, areas of risk, localities and physical safety requirements

Biotechnologie – Laboratoires de recherche, de développement et d'analyse – Niveaux de confinement des laboratoires de microbiologie, zones à risque, situations et exigences physiques de sécurité

Biotechnik – Laboratorien für Forschung, Entwicklung und Analyse – Sicherheitsstufen mikrobiologischer Laboratorien, Gefahrenbereich, Räumlichkeiten und technische Sicherheitsanforderungen

This European Standard was approved by CEN on 1998-02-28.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of 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.

CEN

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

Central Secretariat: rue de Stassart 36, B-1050 Brussels

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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 September 1998, and conflicting national standards shall be withdrawn at the latest by September 1998.

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

This European Standard sets minimum physical containment requirements for biological safety based on the principles of the prevention and control of microbiological hazards to humans, animals, plants and the environment, which should be complied with as a prerequisite for the setting up and continued operation of a microbiology laboratory.

Compliance with the physical safety requirements set out in this standard should minimize the risks associated with the handling of microorganisms ; hence they serve to protect people, animals, plants and the environment.

The physical containment level to be used is determined by risk assessment (see annex C [1], [2]).

The requirements laid down may act as primary or secondary containment measures to protect the worker or the environment. For microorganisms which are primarily animal or plant pathogens which present minimal or no risk to human health, differing primary and secondary containment measures may be applicable. There are special containment requirements for genetically modified microorganisms (GMMs) under Council Directive 90/219/EEC (see annex C [1]). The requirements need to be selected on the basis of risk assessment from the four reference physical containment levels described. Secondary containment measures, in addition to those given in this European Standard, can be required in some special circumstances.

1 Scope

This European Standard specifies minimum physical requirements for biological safety for laboratories at four reference physical containment levels which are appropriate for handling microorganisms of different risk groups.

This European Standard primarily addresses the containment of microorganisms which can present a risk to human health.

It applies to microbiology laboratories where the handling of microorganisms in bacteriology, mycology, virology, parasitology and/or genetic modification is carried out.

> NOTE : Some aspects can also be applicable to laboratories specializing in disciplines other than microbiology which deal with specimens or other material not intended for cultivation but which may contain microorganisms.

The requirements given in this European Standard are to minimize risks that may result from handling microorganisms or materials which contain them. They are applicable to premises where there is an intention to manipulate or propagate microorganisms of known or unknown identity.

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.

prEN 12347	Biotechnology - Equipment - Performance criteria for autoclaves
prEN 12469	Biotechnology - Performance criteria for microbiological safety cabinets
prEN 12740	Biotechnology - Laboratories for research, development and analysis - Guidance for handling, inactivating and testing of waste
EN 61010	Safety requirements for electrical equipment for measurement, control and laboratory use
Part 2-041	Particular requirements for autoclaves using steam for the treatment of medical materials, and for laboratory processes (IEC 1010-2-041:1996)
Part 2-042	Particular requirements for autoclaves and sterilizers using toxic gas for the treatment of medical materials, and for laboratory processes (IEC 1010-2-042:1997)
Part 2-043	Particular requirements for dry heat sterilizers using either hot air or hot inert gas for the treatment of medical materials and for laboratory processes (IEC 1010-2-043:1997)
ISO 3864	Safety colours and signs
ISO 7000	Graphical symbols for use on equipment - Index and synopsis
ISO 8995	Principles of visual ergonomics - The lighting of indoor work systems