Biotechnology - Laboratories for research, development and analysis - Guidance for good practice for biotechnology laboratory operations

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EESTI STANDARDI EESSÕNA

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NATIONAL FOREWORD

Käsitlusala: This European Standard describes the elements of good practice which will prevent and control hazards to humans and the environment in the operation of biotechnology laboratories.	**Scope:** This European Standard describes the elements of good practice which will prevent and control hazards to humans and the environment in the operation of biotechnology laboratories.

ICS 07.080, 07.100.01

Võtmesõnad:

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English version

Biotechnology – Laboratories for research, development and analysis
Guidance for biotechnology laboratory operations

Biotechnologie – Laboratoires de recherche, développement et analyse – Guide pour les opérations de laboratoires biotechnologiques

Biotechnik – Laboratorien für Forschung, Entwicklung und Analyse – Leitfaden für biotechnologische Laborpraxis

This European Standard was approved by CEN on 1999-06-19.

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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.

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CEN

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

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Contents

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of an identical text or by endorsement, at the latest by January 2000, and conflicting national standards shall be withdrawn at the latest by January 2000.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

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

Users of this European Standard, prepared in the field of application of Article 118A of the EC Treaty, should be aware that standards have no formal legal relationship with Directives which may have been made under Article 118A of the Treaty. In addition, national legislation in the Member states may contain more stringent requirements than the minimum requirements of a Directive based on Article 118A. Information on the relationship between the national legislation implementing Directives based on Article 118A and this European Standard may be given in a national foreword of the national standard implementing the European Standard.

Introduction

Good biotechnology laboratory practice covers all aspects of the organization of biotechnology work and the conditions under which it is planned, executed, validated and supervised as well as aspects relating to education and training of personnel.

It is recognized that good biotechnology laboratory practice requires suitable education and training of personnel and the standard is written on the basis that staff have received appropriate training. Staff should have access to relevant sources of information, including the results of biological risk assessment which determines the safe working procedures and practices in a given situation. A non-exclusive sample of relevant literature is given in annex B. There are many other texts relevant to specific items of biotechnology laboratory operations which are not quoted.

1 Scope

This European Standard gives guidance for practice for biotechnology operations in research, development and analysis laboratories of containment levels 1, 2, 3 and 4 (see EN 12128 and EN 12738).

This European Standard aims at the protection of workers from biological hazards as well as the environment including plants and animals.

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 12128	Biotechnology - Laboratories for research, development and analysis - Containment levels of microbiology laboratories, areas of risk, localities and physical safety requirements
EN 12347	Biotechnology - Performance criteria for steam sterilizers and autoclaves
prEN 12469	Biotechnology - Performance criteria for microbiological safety cabinets
EN 12738	Biotechnology - Laboratories for research, development and analysis - Guidance for containment of animals inoculated with microorganisms in experiments
EN 12740	Biotechnology - Laboratories for research, development and analysis - Guidance for handling, inactivating and testing of waste
CR 12739	Biotechnology - Laboratories for research, development and analysis - Report on the selection of equipment needed for biotechnology laboratories according to the degree of hazard
ISO 3864	Safety colours and safety signs