

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

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British Standard

ICS 07.080; 07.100.01

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Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 12, an inside back cover and a back cover.

This British Standard, having been prepared under the direction of the Sector Board for Materials and Chemicals, was published under the authority of the Standards Board and comes into effect on 15 August 1998

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ISBN 0 580 30066 8

Amendments issued since publication

Amd. No.	Date	Text affected

ICS 07.080; 07.100.01

Descriptors: Biotechnology, biology, microbiological analysis, laboratories, research, micro-organisms, safety, accident prevention, level: quality, hazards, specifications, classifications

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

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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of an identical text or by endorsement, at the latest by September 1998, and conflicting national standards shall be withdrawn at the latest by September 1998.

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Contents

	Page
Foreword	2
Introduction	3
1 Scope	3
2 Normative references	3
3 Definitions	3
4 Physical containment level classification	4
5 Physical containment level 1 laboratory (PCL1)	4
6 Physical containment level 2 laboratory (PCL2)	6
7 Physical containment level 3 laboratory (PCL3)	7
8 Physical containment level 4 laboratory (PCL4)	8
Annex A (informative) Guidance on space needs and dimensions	10
Annex B (informative) Method of test for the determination of pressure differences	11
Annex C (informative) Bibliography	12

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 micro-organisms; 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 micro-organisms 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 micro-organisms (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 micro-organisms of different risk groups.

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

It applies to microbiology laboratories where the handling of micro-organisms 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 micro-organisms.

The requirements given in this European Standard are to minimize risks that may result from handling micro-organisms or materials which contain them. They are applicable to premises where there is an intention to manipulate or propagate micro-organisms 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.*

EN 61010-2-041, *Particular requirements for autoclaves using steam for the treatment of medical materials, and for laboratory processes.*
(IEC 1010-2-041:1996)

EN 61010-2-042, *Particular requirements for autoclaves and sterilizers using toxic gas for the treatment of medical materials, and for laboratory processes.*
(IEC 1010-2-042:1997)

EN 61010-2-043, *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.*

3 Definitions

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

3.1

autoclave

apparatus designed to make materials and/or equipment sterile by exposure to steam at a pressure above the atmospheric pressure

3.2

cell culture

in-vitro growth of cells derived from multicellular organisms