Nederlandse

norm

NEN-EN 12128

Biotechnologie - Laboratoria voor onderzoek, ontwikkeling en analyse - Veiligheidsniveaus voor microbiologische laboratoria, risicogebieden, localiteiten, en technische veiligheidseisen

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

april 1998
ICS 07.080

Vervangt NEN-EN 12128:1995 Ontw.

Als Nederlandse norm is aanvaard:
- EN 12128:1998

Normcommissie 370 233 "Biotechnologie"

Nederlands Normalisatie-instituut

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Nederlands Voorwoord

Voor de in deze norm vermelde normatieve verwijzingen bestaan in Nederland de volgende equivalenten:

Vermelde norm	Nederlandse norm	Titel
prEN 12347:1996	NEN-EN 12347:1996 Ontw.	Biotechnologie - Apparaten en uitrusting - Prestatie-eisen voor autoclaven
prEN 12469:1996	NEN-EN 12469:1996 Ontw.	Biotechnologie - Prestatie-eisen voor microbiologische veiligheidswerkkasten
prEN 12740:1997	Ontw. NEN-EN 12740:1997	Biotechnologie - Laboratoria voor onderzoek, ontwikkeling en analyse - Leidraad voor de behandeling, de inactivering en de beproeving van afval
EN 61010-2-041	NEN 11010-2-041	Veiligheidseisen voor elektrische materieel voor meet- en regeltechniek en laboratoriumgebruik - Deel 2-041: Bijzondere eisen voor autoclaven met gebruik van stoom voor de behandeling van medische benodigdheden en voor laboratoriumprocessen
EN 61010-2-042	NEN-EN-IEC 61010-2-042	Veiligheidseisen voor elektrisch materieel voor meet- en regeltechniek en laboratoriumgebruik - Deel 2-042: Bijzondere eisen voor autoclaven en sterilisatoren met gebruik van giftige gassen voor de behandeling van medische benodigdheden en voor laboratoriumproeven
EN 61010-2-043	NEN-EN-IEC 61010-2-043	Veiligheidseisen voor elektrisch materieel voor meet- en regeltechniek en laboratoriumgebruik - Deel 2-043: Bijzondere eisen voor sterilisatoren met gebruik van hetzij hete lucht hetzij heet inert gas voor de behandeling van medische benodigdheden en voor laboratoriumprocessen
ISO 3864	-	-
ISO 7000	NEN 3529	Microfilmtechniek - Grafische symbolen voor microfilm
ISO 8995	-	-

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 12128

March 1998

ICS

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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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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EUROPÄISCHES KOMITEE FÜR NORMUNG

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

Ref. No. EN 12128:1998 E

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 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

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.

3.3 genetically modified microorganism

Microorganism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

NOTE : Within the terms of this definition genetic modification occurs at least through the use of the techniques listed in the Directive 90/219/EEC or its appropriate annexes (see annex C [1]).

3.4 hazard

Intrinsic potential property or ability of something (e.g. any agent, equipment, material or process) to cause harm [EN 1620].

NOTE : Harm is an injury or damage to health of people and/or the environment.

3.5 laboratory suite

One or more laboratories within a building, not necessarily of the same discipline or containment level, with ancillary rooms and with shared use of facilities.

3.6 laboratory unit

Separate building, or self-contained suite within a building, containing one or more laboratories and with ancillary rooms such as airlocks, changing rooms, showers, preparation rooms, sterilizer rooms, and storage rooms.

NOTE : A microbiology laboratory (or suite, or unit) may be divided so as to provide separate areas for particular purposes, e.g. for media and reagent preparation, sterilization, microscopy.

3.7 microorganism

Microbiological entity, cellular or non cellular, capable of replication or of transferring genetic material [EN 1619].

NOTE : For the purposes of this standard, the term microorganism covers the term of biological agent, according to the Directive 90/679/EEC : microorganisms, including those which have been genetically modified, cell cultures and human endoparasites which may be able to provoke any infection, allergy or toxicity.

3.8 physical containment

System for confining a microorganism or organism or other entity within a defined space [EN 1620].

3.9 physical containment level

Standard of accommodation suitable for the containment of microorganisms according to the hazard they present.

3.10 primary physical containment

System of physical containment which limits the escape of a microorganism or organism into the working environment.

NOTE : This can involve the use of closed containers or appropriate equipment together with secure operating procedures.

3.11 risk

Probability of occurrence of a hazard causing harm and the degree of severity of the harm.

3.12 secondary physical containment

System of physical containment which limits the escape of a microorganism or organism into the environment or into other working areas.

NOTE : This can involve the use of rooms with specially designed air handling, the existence of airlocks and/or sterilizers for the removal of materials and secure operating procedures. In many cases it can add to the effectiveness of primary physical containment.

4 Physical containment level classification

A microbiology laboratory shall be classified as belonging to one of four basic physical containment levels. These levels are designated PCL1, indicating the lowest, to PCL4, indicating the highest level of containment. The requirements for each physical containment level are given in clause 5 to clause 8 and are summarized in table 1.

NOTE 1 : Generally the containment requirements of a higher level include those of the lower level(s).

NOTE 2 : Microorganisms are allocated into risk groups on the basis of their potential to cause harm.

Microorganisms shall be handled in the appropriate laboratory containment level as indicated by an assessment of risk.

5 Physical containment level 1 laboratory (PCL1)

5.1 Location and physical provisions (PCL1)

Microbiological work shall be carried out in laboratories specified for the purpose.

NOTE 1 : It is recommended that the PCL1 status is clearly marked on the outside of the laboratory door.

There shall be adequate space for each worker.

NOTE 2 : Guidance on the space needs and dimensions are given in annex A. In determining the amount of space required consideration should be given to factors such as the intended nature of the work and space for bench-mounted and free-standing equipment.

5.2 Cleanability (PCL1)

Bench surfaces shall be impervious to water, shall be easy to clean and shall be resistant to disinfectants, cleaning agents, acids, alkalis, solvents and other chemicals which may be expected in normal use.

NOTE 1 : A method of test for the assessment of surface resistance to cold liquids is given in ISO 4211.

The laboratory shall be designed to facilitate effective cleaning.

NOTE 2 : Surfaces should be accessible for maintenance.

5.3 Installations and washing facilities (PCL1)

Hand washing and emergency eye washing facilities shall be provided.

NOTE 1 : Facilities for hand disinfection should be provided.

NOTE 2 : Personnel showers are not required for biological safety. However, showers may be required for other purposes.

NOTE 3 : Facilities for the temporary storage of laboratory clothing, such as laboratory coats, should be provided.

5.4 Illumination (PCL1)

Illumination shall conform to ISO 8995.

5.5 Equipment (PCL1)

Any microbiological safety cabinet provided shall conform to prEN 12469.

Bestelformulier

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Normalisatie: de wereld op één lijn.

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