SLOVENSKI STANDARD
SIST CR 12739:1999

01-december-1999

Biotehnologija - Raziskovalni, razvojni in analitski laboratoriji - Poročilo o izbiri opreme za biotehnološke laboratorije glede na stopnjo nevarnosti

Biotechnology - Laboratories for research, development and analysis - Report on the selection of equipment needed for biotechnology laboratories according to the degree of hazard

Biotechnik - Laboratorien für Forschung, Entwicklung und Analyse - Bericht zur Auswahl der je nach Gefährdungsgrad erforderlichen Ausstattung biotechnischer Laboratorien

Biotechnologie - Laboratoires de recherche, développement et analyse - Rapport sur le choix des équipements nécessaires dans les laboratoires de biotechnologie en fonction du degré de danger

Ta slovenski standard je istoveten z: **CR 12739:1998**

ICS:

07.080	Biologija. Botanika. Zoologija	Biology. Botany. Zoology
11.100.01	Laboratorijska medicina na splošno	Laboratory medicine in general

SIST CR 12739:1999 **en**

CEN REPORT

RAPPORT CEN

CEN BERICHT

CR 12739

October 1998

ICS

Descriptors:

English version

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This CEN Report was approved by CEN on 8 July 1998. It has been drawn up by the Technical Committee CEN/TC 233.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. CR 12739:1998 E

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Foreword

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

Introduction

A standard for the equipment used in biotechnology laboratories is important because equipment is at the heart of laboratory work, providing an operational resource for the worker to carry out research, development and production work on the laboratory scale. To create and maintain a biosafe working environment in biotechnology laboratories, as required by Directive 90/679/EEC, the equipment should be of a quality that enables the procedures for safe biotechnology to be carried out satisfactorily. The requirements for safe equipment for use in biotechnology laboratories can only be determined by an analysis of the hazards and the probability of their occurrence. For this reason, a risk assessment approach is recommended. The risk assessment should at least facilitate the selection of appropriate equipment which minimizes risks and therefore ensures that European and national biosafety requirements are taken into account.

In addition to the equipment performance criteria standards produced by CEN/TC233, which set out the biosafety attributes required for safe biotechnology, all equipment used in a laboratory should be of high quality and should meet European Standards in respects other than biosafety, for failure in use may have serious biosafety implications. The standards produced by CEN/TC 233, other relevant European and international standards, and other CEN Technical committees considering standardization of equipment relevant to biotechnology are listed in annex A.

1 Scope

This CEN Report gives guidance on the principles for the selection of equipment to be used in a biotechnology laboratory.

2 Hazard analysis

2.1 General

Work in a biotechnology laboratory consists of sequences of operations in which more than one, and often many, units of equipment are commonly used. The work pattern as a whole should be examined and described in detail to assess whether there are potential hazards, the probability of these affecting people and the environment, and the attributes of equipment which are required for minimizing risks.

2.2 Specific hazards

Biological, chemical and physical hazards should be assessed as part of a complete risk assessment, and it is necessary to ensure that safety measures taken do not cause conflict or replacement of one type of hazard by another.

Hazards resulting from work in biotechnology laboratories are described in a number publications and a selection of these is listed in annex A.

Specific hazards associated with individual units of equipment are described in other standards produced by CEN and these should be consulted (see annex A).

3 Risk assessment

Laboratory work usually involves several operations using more than one type of equipment. Accordingly, biosafety issues may arise which are not normally associated with individual items of equipment. Interaction between items of equipment during operations may be responsible for these. At the simplest, the need to link pieces of equipment may impose physical stresses which are absent when the items are used in a stand-alone way.

The complexity of laboratory work is such that a written risk assessment should be made to identify hazards and the probability of exposure of people and the environment to these hazards. The method of risk assessment used should be subject to national regulations for the protection of workers and of the environment. The risk assessment should be stored and should be readily available.

The objective of the risk assessment is to ensure that the equipment selected and made available to workers in biotechnology laboratories should remove or as far as necessary reduce the identified hazards, while allowing the laboratory operation to continue so that the objectives of the work are realized. As objectives change and as equipment design alters, the risk assessment should be repeated to ensure that any new hazards are identified and appropriate action taken.

The nature of the assessment will depend on many factors, including :

a) the type and severity of the hazards involved ;

b) the experience gained from previous work ;

c) practical evidence of the safe use of equipment ;

d) the novelty or otherwise of the operation.

The risk assessment identifies where the major hazards exist and indicates whether the factors of leaktightness, sterilizability and cleanability are significant factors affecting the likelihood of exposure of people and the environment to that hazard. If so, equipment of suitable performance in these respects should be selected or alternative equipment or process operations chosen to eliminate or reduce the risk.

Guidance to risk assessment for the contained use of genetically modified microorganisms is being developed by the European Commission.

Annex A (Informative)

Bibliography

The following is a non-exclusive list of monographs which discuss the hazards associated with biological laboratories.

Collins, C.H., Laboratory acquired Infections. Buterworths, 3rd edition. London 1993.

Fleming, Diane O., et al., Laboratory safety, Principles and Practices, American Society for Microbiology, Wahington D.C., 1994, (2nd Edition).

Furr, A. Keith, CRC Handbook of Laboratory Safety, CRC Press Inc, Boca Raton, 1945, (4th Edition).

Liberman, D.F, and J.G. Gordon, Biohazards Management Handbook, Marcel Decker, New York, 1995, (2nd Edition).

US Department of Health, Education and Welfare, Biosafety in Microbiological and Biomedical Laboratories, Centers for Disease Control and Prevention, Atlanta, Georgia and NIH, Bethesda, Maryland. U.S. Government Printing Office, Washington, 3rd Edition, 1993.

US Department of Health, Education and Welfare, Laboratory Safety at the Centre for Disease Control, Publication N° CDC 75-818, September 1994.

US Department of Health, Education and Welfare, National Cancer Institute Safety Standards for Research involving Ongogenic Viruses, Publication N° NIH 75-790, October 1994.

World Health Organization, Laboratory Biosafety Manual, Geneva, 1993, 2nd Edition.

List of relevant standards.

CEN equipment standards related to biosafety in biotechnology which should be consulted :

a) Standards produced by CEN/TC 233

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
EN 12462	Biotechnology - Performance criteria for pumps
prEN 12469	Biotechnology - Performance criteria for microbiological safety cabinets
prEN 13092	Biotechnology - Equipment - Guidance on sampling and inoculation procedures
prEN 12690	Biotechnology - Performance criteria for shaft seals

prEN 12884	Biotechnology - Performance criteria for centrifuges
prEN 12885	Biotechnology - Performance criteria for cell disruptors
prEN 13312-2	Biotechnology - Performance criteria for piping and instrumentation - Part 2 : Couplings
prEN 13312-3	Biotechnology - Performance criteria for piping and instrumentation - Part 3 : Sampling and inoculation devices
prEN 13312-4	Biotechnology - Performance criteria for piping and instrumentation - Part 4 : Tubes and pipes
prEN 13312-5	Biotechnology - Performance criteria for piping and instrumentation - Part 5 : Valves
prEN 13312-6	Biotechnology - Performance criteria for piping and instrumentation - Part 6 : Equipment probes
prEN 13091	Biotechnology - Performance criteria for filter elements and filtration equipment
prEN 13095	Biotechnology - Performance criteria for off gas systems
prEN 13311-2	Biotechnology - Performance criteria for vessels - Part 2 : Pressure protection devices
prEN 13311-3	Biotechnology - Performance criteria for vessels - Part 3 : Glass pressure vessels
prEN 13311-4	Biotechnology - Performance criteria for vessels - Part 4 : Bioreactors
prEN 13311-5	Biotechnology - Performance criteria for vessels - Part 5 : Kill tanks
prEN 13311-6	Biotechnology - Performance criteria for vessels - Part 6 : Chromatography columns
prEN 12738	Biotechnology - Laboratories for research, development and analysis - Guidance for the containment of animals inoculated with microorganisms in experiments
prEN 12740	Biotechnology - Laboratories for research, development and analysis - Guidance for handling, inactivating and testing of waste
prEN 12741	Biotechnology - Laboratories for research, development and analysis - Guidance for good practice for biotechnology laboratory operations
	Biotechnology - Laboratories for research, development and analysis - Guidance for the containment of plants in experiments [WI 00233 053][1]

[1] Under preparation

b) Other European procedural and general standards.

Section 1 : Safety equipment

Protective clothing and the like

EN 143	Respiratory protective devices - Particle filters - Requirements, testing and marking
prEN 166	Personal eye protection - Specifications
EN 340	Protective clothing - General requirements
EN 374-1	Protective gloves against chemicals and microorganisms - Part 1 : Terminology and performance requirements
EN 374-2	Protective gloves against chemicals and microorganisms - Part 2 : Determination of resistance to penetration
EN 374-3	Protective gloves against chemicals and microorganisms - Part 3 : Determination of resistance to permeation by chemicals
EN 467	Protective clothing - Protection against liquid chemicals - Performance requirements for garments providing protection to parts of the body

Steam sterilizers

EN 285	Sterilization - Steam sterilizers - Large sterilizers
prEN 290	Sterilization - Steam sterilizers - Big sterilizers - Terminology

EN 61010-2-041	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]
EN 61010-2-042	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-042 : Particular for autoclaves and sterilizers using toxic gas for the treatment of medical materials and for laboratory processes [IEC 1010-2-042:1997]
BS 2646-1	Autoclaves for sterilization in laboratories ; specification for design and construction
BS 2646- 2	Autoclaves for sterilization in laboratories ; guide to planning and installation
DIN 58 946 - 5	Sterilization ; steam sterilizers, small sterilizers, requirements

Biosafety cabinets

BS 5726 199	Microbiological safety cabinets