National Standards Authority of Ireland

IRISH STANDARD

CR 12739:1999

ICS 07.080

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BIOTECHNOLOGY - LABORATORIES FOR RESEARCH, DEVELOPMENT AND ANALYSIS - REPORT ON THE SELECTION OF EQUIPMENT NEEDED FOR BIOTECHNOLOGY LABORATORIES ACCORDING TO THE DEGREE OF HAZARD

This Irish Standard was published under the authority of the National Standards Authority of Ireland and comes into effect on:

Price Code F

Údarás um Chaighdeáin Náisiúnta na hÉireann

CEN REPORT

RAPPORT CEN

CEN BERICHT

CR 12739

October 1998

ICS

Descriptors:

English version

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

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

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

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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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.