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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

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Contents

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.