SLOVENSKI STANDARD
SIST EN 12741:1999

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Biotehnologija - Raziskovalni, razvojni in analitiski laboratoriji - Navodilo za delovanje biotehnoloških laboratorijev

Biotechnology - Laboratories for research, development and analysis - Guidance for biotechnology laboratory operations

Biotechnik - Laboratorien für Forschung, Entwicklung und Analyse - Leitfaden für biotechnologische Laborpraxis

Biotechnologie - Laboratoires de recherche, développement et analyse - Guide pour les opérations de laboratoires biotechnologiques

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English version

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

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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of an identical text or by endorsement, at the latest by January 2000, and conflicting national standards shall be withdrawn at the latest by January 2000.

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.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

Users of this European Standard, prepared in the field of application of Article 118A of the EC Treaty, should be aware that standards have no formal legal relationship with Directives which may have been made under Article 118A of the Treaty. In addition, national legislation in the Member states may contain more stringent requirements than the minimum requirements of a Directive based on Article 118A. Information on the relationship between the national legislation implementing Directives based on Article 118A and this European Standard may be given in a national foreword of the national standard implementing the European Standard.

Introduction

Good biotechnology laboratory practice covers all aspects of the organization of biotechnology work and the conditions under which it is planned, executed, validated and supervised as well as aspects relating to education and training of personnel.

It is recognized that good biotechnology laboratory practice requires suitable education and training of personnel and the standard is written on the basis that staff have received appropriate training. Staff should have access to relevant sources of information, including the results of biological risk assessment which determines the safe working procedures and practices in a given situation. A non-exclusive sample of relevant literature is given in annex B. There are many other texts relevant to specific items of biotechnology laboratory operations which are not quoted.

1 Scope

This European Standard gives guidance for practice for biotechnology operations in research, development and analysis laboratories of containment levels 1, 2, 3 and 4 (see EN 12128 and EN 12738).

This European Standard aims at the protection of workers from biological hazards as well as the environment including plants and animals.

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.

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
prEN 12469	Biotechnology - Performance criteria for microbiological safety cabinets
EN 12738	Biotechnology - Laboratories for research, development and analysis - Guidance for containment of animals inoculated with microorganisms in experiments
EN 12740	Biotechnology - Laboratories for research, development and analysis - Guidance for handling, inactivating and testing of waste
CR 12739	Biotechnology - Laboratories for research, development and analysis - Report on the selection of equipment needed for biotechnology laboratories according to the degree of hazard
ISO 3864	Safety colours and safety signs

ISO 7000 Graphical symbols for use on equipment - Index and synopsis

3 Definitions

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

3.1 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.

3.2 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 [EN 12128].

3.3 microorganism

Any 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.

3.4 risk

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

4 Basic practices for biotechnology laboratories

4.1 General

All staff should be informed that good practice is fundamental to safety.

Practices that could transfer hazardous material to mouth or skin should be avoided. Food and drink (other than samples submitted for scientific investigation) should not be taken into, consumed or stored in any area where organisms are handled. Smoking, the use of personal medications or the application of cosmetics should not be permitted in these areas.

Personnel should respect elementary rules of hygiene, should wash their hands when beginning work, whenever they have handled hazardous materials and on leaving the laboratory, after protective clothing has been removed. Hand drying should be carried out

using disposable towels or other suitable materials. Disinfection and cleaning should be carried out as necessary.

Hazards involved in operating laboratory equipment include long hair, jewellery, certain types of footwear and loose clothing that may be a factor in laboratory accidents. Therefore proper attire including protective clothing appropriate for the hazard should be worn at all times.

Mouth pipetting should be expressly forbidden. Pipetting devices should always be used for pipetting.

Aerosol release into the workplace should be minimized. If hazardous aerosols are likely to be generated, the work should be carried out in a microbiological safety cabinet (see prEN 12469).

> NOTE : Open-fronted cabinets (Class I and II) allow some escape of airborne material. Inward airflow may be disturbed by, for example, people passing behind the operator, turbulence of air around equipment within the cabinet or sudden changes in air pressure within the room. Disturbances of this kind may reduce the validity of operator protection and validation of operator safety may be required in specific cases.

The laboratory should be tidy and clean and should not contain anything that is not related to the work.

Working surfaces, including those of biological safety cabinets, should be decontaminated using a validated procedure whenever biological material is accidentally spilled, when an item of work has been completed and at the end of the working day (see clause 10).

The wearing of laboratory coats and/or appropriate special clothing should be compulsory. When personnel leave the laboratory suite the protective clothing should be removed and left in the changing area. Outdoor clothing should be kept separate from the working areas. When hazardous organisms are, or may be, present in laboratory suites, care should be taken to avoid distributing hazardous material from one unit to another.

In some work areas or while certain operations are being carried out, it may be necessary to ensure that adequate measures exist for contacting workers.

A suitable control policy for insects and rodents should be implemented (see EN 12128).

The use of hypodermic needles and other sharps should be minimized and where possible, avoided. Every worker handling them should develop a safe routine for their use, transport and disposal.

All items of equipment within the laboratory should conform to the requirements of appropriate European Standards (for example, see EN 12347, prEN 12469 and CR 12739). Equipment should be selected on the basis of the possibility of decontamination and of prevention or minimization of internal contamination. The maintenance and repair of equipment and apparatus should only be undertaken by personnel with appropriate experience, who should be issued with a permit to work and who should be made aware of the possibility of contamination with hazardous organisms. Equipment should be positioned so that it is stable and not prone to tipping.

Minor incidents, for example, spillage of small volumes of culture medium containing hazardous material, should be dealt with effectively e.g. by covering the affected area and equipment with swabs of disinfectant. Disposable gloves should be worn during this operation; contaminated clothing should be discarded and autoclaved. Broken glass should

be swept carefully into a suitable container; all contaminated items of debris and equipment used to collect it should be decontaminated by a validated procedure. Action in the event of accidents and emergencies is considered in clause 8.

All material contaminated with hazardous material should be decontaminated. If this is done away from the laboratory, the material should be transferred in a durable, leakproof, closed container.

The person in charge of the laboratory should be informed immediately of any accident.

4.2 Instruction and training

Personnel should receive appropriate training for the work that is required of them. Information about safety measures should form an integral part of the induction training of new workers in laboratories. It is important to ensure that the basis of these safety measures is well understood in order to prevent human error and incorrect practices.

Initial training should be supplemented by refresher or continuous training so as to keep up with developments in techniques and equipment.

The role of heads of laboratories and of management in training the personnel for which they are responsible should be defined.

The person or persons in charge of safety should take part in any in-house personnel teaching or training and preparation of training material. It is desirable that they should be familiar with laboratory work and the techniques for handling relevant potentially harmful organisms.

A copy of safety instructions should always be available in working areas.

4.3 Hazard management

The work practices of personnel should be designed to ensure safety in respect of general, physical, chemical and microbiological hazards.

Personnel should be instructed and trained in methods to cope with general hazards and they should be informed and instructed of the terms of local and national requirements.

NOTE 1 : Methods for controlling the hazards of handling hazardous material should, in most instances, be also sufficient to prevent the hazard of toxicity or allergy. However, such specific hazard may exist in other operations where pathogenicity is not an issue. In such situations attention to appropriate hygiene conditions should be given. Specific protective clothing and equipment to guard against allergy hazards may be appropriate in some instances. Medical screening may also be appropriate.

Biotechnological work may involve the use of hazardous chemicals, for example mutagens, carcinogens, and teratogenic, radioactive and other toxic products. Personnel should be instructed and know how to apply relevant safety techniques.

All personnel should be instructed on safety measures relating to specific classes of pathogenic microorganisms. Procedures to be applied when using microorganisms handled