

Biotechnology — Laboratories for research, development and analysis — Guidance for handling, inactivating and testing of waste

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Biotechnik — Laboratorien für Forschung, Entwicklung und Analyse — Leitfaden für die Behandlung, Inaktivierung und Prüfung von Abfällen

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of an identical text or by endorsement, at the latest by January 2000, and conflicting national standards shall be withdrawn at the latest by January 2000.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

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Introduction

Compliance with this European Standard will minimize the risks associated with the collection, storage, packaging, intra-laboratory transport, treatment and disposal of waste including effluent and those arising from the treatment for re-use or recycling of contaminated items, equipment and materials.

This European Standard aims to harmonize the treatment of waste containing hazardous organisms. More extensive national and international legislative provisions should be observed. The principles for laboratories established in this European Standard are consistent with those relevant to large scale biotechnology processes.

The presence of hazardous organisms among the waste and the way in which it is handled should be determined by risk assessment in accordance with the national and European (see annex B [1], [2]) regulations.

1 Scope

This European Standard gives guidance on methods for handling, inactivating and testing of waste containing organisms arising from biotechnology laboratory activities and processes.

It is concerned with methods to reduce the risks arising from exposure to waste derived from laboratory-scale activities which contains organisms hazardous or potentially hazardous to humans, animals, plants or the environment. Such waste may include organisms whether as solid, liquid or gaseous by-products or effluent, together with items or equipment required to be disposed of and which may be contaminated with organisms.

Wastes may be generated by biotechnology, clinical, molecular biology, microbiology and other laboratories in activities where organisms are handled, genetically modified organisms are created or used or by laboratory processes involving material of human, animal or plant origin. This European Standard does not apply to other types of waste or waste from human healthcare or other medical treatment activities.

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 285, *Sterilization — Steam sterilizers — Large sterilizers*.

EN 866-1, *Biological systems for testing sterilizers and sterilization processes — Part 1: General requirements*.

EN 12128, *Biotechnology — Laboratories for research, development and analysis — Containment levels of microbiology laboratories, areas of risk, localities and physical safety requirements*.

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 61010-2-041:1996]

EN 12347, *Biotechnology — Performance criteria for steam sterilizers and autoclaves*.

3 Definitions

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

3.1

biohazardous waste

biological waste which can cause a hazard

3.2

decontamination

removal of microbiological contamination or reduction to an acceptable level

3.3

disinfectant

chemical agent which is able to reduce the number of viable microorganisms

3.4

disinfection

process of reducing the number of viable microorganisms by various physical and chemical methods

3.5

disposal

intentional and final burial, deposit, discharge, dumping, placing or release of any waste material into or on any air, land or water

3.6

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 to the environment.

3.7

inactivation

partial or full destruction of a given activity up to destruction of the microbiological system