SLOVENSKI STANDARD
SIST EN 12740:1999

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Biotehnologija - Raziskovalni, razvojni in analitski laboratoriji - Navodilo za ravnanje z odpadki, njihovo inaktivacijo in preskušanje

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

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

Biotechnologie - Laboratoires de recherche, développement et analyse - Guide pour la manipulation, l'inactivation et le contrôle des déchets

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

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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of an identical text or by endorsement, at the latest by January 2000, and conflicting national standards shall be withdrawn at the latest by January 2000.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

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.

3.8 microorganism

Any microbiological entity, cellular or non cellular, capable of replication or of transferring genetic material [EN1619].

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.

3.9 monitoring

Regular or continuous observation or collection of data with respect to an organism, process or procedures.

3.10 organism

Biological entity capable of replication or transferring genetic material.

3.11 risk

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

3.12 sharps

Items whether intact or broken which may cause lacerations or puncture wounds.

NOTE : Examples of sharps are hypodermic needles, disposable blades, forceps, knives, probes, scalpels and scissors, glass pipettes, slides and cover glasses, broken glass or plastic ware.

3.13 sterile

State of being free from viable microorganisms.

NOTE 1 : In practice no such absolute statement regarding the absence of viable microorganisms can be proven. However, sterile conditions can be regarded as established by using an accepted or recognized method of sterilization.

NOTE 2 : The process of inactivation of viable microorganisms during a sterilization procedure is usually described by an empirical mathematical function, commonly an exponential function. By their mathematical nature, such functions can be reduced to very low numbers, but not to zero. However, these empirical functions can be applied to control or assess the process parameters of a sterilization procedure to realize a desired degree of inactivation of viable microorganisms.

3.14 sterilization

Process used to reach a sterile state.

3.15 validation

Documented procedure for obtaining, recording and interpreting the results needed to show that a process will constantly yield a product complying with pre-determined specifications.

3.16 waste

By-product arising from a process or unwanted substance or article derived from any activity.

NOTE : Examples of waste are scrap material, effluent, unwanted residue or surplus arising from any process or activity or any substance or article which is discarded or to be disposed of as being broken, contaminated, spoiled, or worn out.

4 Waste management

A documented waste management policy should be established describing the measures for the prevention, minimization, segregation, handling, storage, treatment, transportation and final disposal of biohazardous waste from laboratory activities. The policy should commit the laboratory to minimize the production of waste and where possible the recovery of materials. The waste management system should be part of the overall risk assessment of the laboratory's activities. This should assure that it is appropriate to the work carried out and the wastes generated.

The waste management policy and system and the responsibilities and duties allocated to laboratory managers, researchers and technical personnel should be specified in a waste management plan. The arrangements for effective control of biohazardous waste should be integral with the general management and supervisory organization.

Documented operational procedures describing the methods used for effective waste management should be established. These documents should be reviewed at regular intervals and updated if necessary.

A description should be given of the methods and procedures for handling, inactivating and treating biohazardous waste under both normal conditions and deviations. Procedures should also be described for the commissioning, maintenance and use of plant and equipment used for waste treatment in accordance with appropriate European Standards and guidelines.

Comprehensive information should be provided on the risks to human health and safety and to the environment arising from waste which contains organisms together with details of its treatment and the prevention and control measures used in normal procedures and in emergencies. This information should be understandable to technical and non-technical personnel alike.

The quality of the waste management system should be assured by periodic monitoring of the various arrangements and procedures. These include operating conditions and control devices of laboratories and equipment, the composition and characterization of the waste

loads and adherence to approved standard operating procedures. Test and inspection results should be documented together with details of any action taken to correct deviations from the intended operating conditions.

5 Segregation of waste

The following essential elements with regard to the segregation of waste should be considered during risk assessment of the laboratory's activities and should be included and documented :

a) identification of wastes which need different treatment methods ;

b) methods for the segregation of biohazardous from non-biohazardous waste at the point of origin, if possible ;

c) methods for the segregation of other categories of waste (such as hazardous chemical or radioactive products) which do not contain organisms when there is incompatibility with the biohazardous waste treatment methods.

NOTE 1 : Combination wastes containing biological and other hazardous materials (e.g. toxic chemicals and radioactive substances) should need special attention. For example, for biological and radioactive waste the risk to be first treated should be determined by risk assessment.

NOTE 2 : In cases of small quantities of waste and in laboratories of containment level 3 or 4, segregation may not be useful.

Segregation methods or procedures including designated containers for the waste should facilitate differentiation and identification of the wastes streams and prevent the inadvertent mixing of the various types.

NOTE 3 : Hazardous and non-hazardous wastes which do not contain organisms will generally be subject to other European or National legal controls and should be handled accordingly.

NOTE 4 : Segregation of wastes at the point of generation can reduce the risk of exposure of waste handlers to organisms and by preventing the contamination of other wastes by such agents reduce the total quantity of biohazardous waste generated by the laboratory.

6 Waste containers

Containers used for the collection of biohazardous waste in the laboratory should be selected after consideration of the following factors and, where appropriate, specifying validated methods for decontaminating containers :

a) the nature of the waste as a liquid, slurry, solid or a sharp ;

b) the handling and transportation methods and procedures ;

c) the treatment methods for the waste ;

d) the decontamination of the container for re-use ;

e) the means of identifying different wastes ;

f) the ability to provide the necessary degree of physical containment.

Adequate supplies of containers should be provided so that the waste can be discarded immediately into an appropriate container to eliminate subsequent sorting, repackaging and other handling operations.

NOTE 1 : Considerations relating to containers for sharps, liquid and solid waste are given in annex A.

Suitable means should be provided to identify containers for different waste types, for example by colour coding, permanent and legible wording or securely fixed and clearly worded labels.

In the case of re-usable containers, the colour coding or labels should be unaffected by any decontamination process.

The container or its label should be marked with the international biohazard sign, unless it is used only for waste from containment level 1.

There should be an effective closure device or means for sealing the container so as to maintain containment during subsequent handling.

NOTE 2 : Closure devices include, for example, integral closure devices, plastics or wire ties, and thermal sealing devices.

Containers should be made of a material which is permeable to the sterilant if the contents are to be sterilized with steam or gaseous fumigant or constructed in such a way that the sterilant is able to penetrate the load.

Biohazardous waste containers should not be used for other waste items, materials or substances.

NOTE 3 : Containers for laboratory waste should conform to National regulations with regard colour coding, materials of construction, shape and size. In particular, waste containers which are used for off-site transportation should be constructed and labelled in accordance with the European Agreement on the international Carriage of Dangerous Goods by Road (ADR).

7 Waste collection

7.1 General requirements

Waste should be inactivated or rendered safe before final disposal or discharge. If treatment is not undertaken within the laboratory the waste should be conveyed in sealed robust containers to a separate treatment area and in accordance with any packaging and transport requirements for off-site conveyance.

Waste containers should be removed from the laboratory when their safe capacity has been reached or at periodic intervals and transported to a storage or holding area pending