SLOVENSKI STANDARD
SIST EN 14065:2003

01-februar-2003

Tekstilije - Tekstilije v postopku pranja - Sistem kontrole biokontaminacije

Textiles - Laundry processed textiles - Biocontamination control system

Textilien - In Wäschereien aufbereitete Textilien - Kontrollsystem Biokontamination

Textiles - Textiles traités en blanchisserie - Systeme de maîtrise de la biocontamination

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Ta slovenski standard je istoveten z: **EN 14065:2002**

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ICS:

07.100.99	Drugi standardi v zvezi z mikrobiologijo	Other standards related to microbiology
59.080.01	Tekstilije na splošno	Textiles in general

SIST EN 14065:2003 **en**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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English version

Textiles - Laundry processed textiles - Biocontamination control system

Textiles - Textiles traités en blanchisserie - Système de maîtrise de la biocontamination

Textilien - In Wäschereien aufbereitete Textilien - Kontrollsystem Biokontamination

This European Standard was approved by CEN on 23 September 2002.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

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 Management Centre has the same status as the official versions.

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SIST EN 14065:2003

Contents

iTeh STANDARD PREVIEW
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SIST EN 14065:2003
https://standards.iteh.ai/catalog/standards/sist/5c2cf581-cd7f-4218-97d6-e67d7b14f707/sist-en-14065-2003

SIST EN 14065:2003

Foreword

This document EN 14065:2002 has been prepared by Technical Committee CEN /TC 248 "Textiles and textile products", the secretariat of which is held by BSI.

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 May 2003, and conflicting national standards shall be withdrawn at the latest by May 2003.

Annexes A, B and C are informative.

This document contains a bibliography.

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, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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SIST EN 14065:2003
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Introduction

General

The sensory cleanliness of laundry processed textiles is important for the laundry industry and their customers. Processed textiles should be visibly clean, free from stains and correctly dried or ironed; they should also be pleasant to the touch and fragrant or at least free from any unpleasant odours, etc.

Sensory cleanliness is obtained during the laundry cycle through physico-chemical treatments such as mechanical action, temperature, addition of detergents and auxiliary products, bleaching agents, dilutions and rinses in successive baths, in combination with sufficient time. With these procedures, most micro-organisms have a low probability of survival.

Nowadays the need for the prevention of microbiological contamination of individuals, products, materials or environment is of increasing significance. Consequently, assured microbiological quality becomes necessary. Therefore the laundry industry is adopting new process control techniques to assure the microbiological quality of laundered textiles.

The purpose of this standard is to provide a management system to deliver an agreed level of microbiological quality according to the intended use of the textile.

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The microbiological quality of textiles is determined by their intended use, e.g. consistent with the level of risk for individuals, products, materials or an environment exposed to biocontamination. In certain cases, where very high microbiological quality is required, for example in operating theatres and immune-deficiency or burns departments in hospitals, etc., processing is completed by sterilisation.

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Soiled textiles entering a laundry are contaminated with varying numbers of micro-organisms from the environment in which they have been used. In this context, the objective of the launderer is to decontaminate the textiles using a disinfecting process and then protect them from subsequent recontamination up to the moment they become the responsibility of the customer.

Good manufacturing practice in the laundry is a prerequisite for achieving microbiological quality; some countries already possess national guidelines to assist with this.

Working practices for dealing with hazards and controlling risks prior to washing should be common to all laundry operations. However from the point of maximum decontamination (by thermal, chemical and physical means) the textiles will be subject to microbiological recontamination. The awareness of a ‘micro-organism exchange’ is important in assessing the impact recontamination may have in the use of the textile.

Different strategies are used for controlling recontamination in terms of investment, plant design, construction and operation. Laundry operations and the market sector they supply will determine which is most appropriate.

The true performance of the complete laundry processes may only be validated after adequate in-process microbiological testing has been carried out. It may be necessary to modify plant lay out and revalidate processes as a result.

This document has been developed using the principles of a Risk Analysis and Biocontamination Control (RABC) system, presented in prEN ISO 14698–1. This method is essentially based on preventative measures, as opposed to inspection procedures on the end product.

This standard does not take into account the measures required for the protection of personnel.

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Process approach

This European Standard, which describes a process approach to quality management, is consistent with ISO 9001:2000, except clause 7.3 (according to permissible exclusions given in 1.2 of ISO 9001:2000).

In the RABC system, a risk analysis has been added to a quality assurance process.

Compatibility with other quality management systems

This European Standard is compatible with other internationally recognised quality management system standards.

This European Standard may be integrated into an existing quality management system.

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SIST EN 14065:2003
https://standards.iteh.ai/catalog/standards/sist/5c2cf581-cd7f-4218-97d6-e67d7b14f707/sist-en-14065-2003

SIST EN 14065:2003

1 Scope

This European Standard describes a management system for ensuring the microbiological quality of laundry processed textiles used in specifically defined sectors in which it is necessary to control biocontamination. This document describes a Risk Analysis and Biocontamination Control (RABC) system to enable laundries to continuously assure the microbiological quality of the laundered textiles.

It applies to textiles processed in laundries and used in specific sectors, e.g. pharmaceuticals, medical devices, food, healthcare and cosmetics and excludes those aspects relating to worker safety and sterility of the final product.

2 Normative references

Not applicable.

3 Terms and definitions

For the purposes of this European Standard, the following terms and definitions apply.

3.1
action level
established level of a CP monitoring variable set by the RABC team at which remedial procedures are activated to bring the laundry process back into control

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https://standards.iteh.ai/catalog/standards/sist/5a2c89bd-7f4d-4210-97d6-e67d7b14f707/sist-en-14065-2003

3.2
alert level
established level of a CP monitoring variable set by the RABC team giving early warning of a change from normal conditions

3.3
biocontamination
contamination with viable micro-organisms

3.4
control measure
action or procedure required to control a biocontamination risk

3.5
control point (CP)
any point or step in a process at which control is applied in order to contain, eliminate or reduce biocontamination risk

3.6
corrective action
action to be taken, when the results of monitoring indicate that alert or action levels are exceeded, in order to restore control of the process

3.7
flow diagram
graphical representation of all the steps in the process

3.8
hazard
in the context of this standard, any element or factor that may adversely affect the achievement of the agreed microbiological quality of textiles

SIST EN 14065:2003

3.9
laundry
plant where soiled/used textiles are given an appropriate series of processes, e.g. washing, drying/finishing, ironing folding and packing, in order to deliver these articles fit for reuse

3.10
laundering cycle
all or a combination of the following operations carried out firstly in a machine, in an aqueous medium, wetting out, preliminary washing, washing, bleaching, rinsing, neutralisation followed by extraction, drying, finishing, folding, packing

3.11
microbiological quality (of textiles)
number and if required types of micro-organisms present on textiles

NOTE The intended end-use will determine the agreed level of microbiological quality.

3.12
monitoring programme
identification of the variables to be monitored at the control points, together with the frequency of observation

3.13
processed textiles
textiles which have undergone a laundry cycle

3.14
RABC logbook
chronicle of all monitoring data, observations and actions taken and their consequences

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3.15
RABC manual
record of all the administrative and implementation documentation for the RABC system

SIST EN 14065:2003
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3.16
risk
likelihood of a harmful effect occurring as a consequence of a hazard

3.17
risk analysis
investigation of available information to identify hazards and to estimate the consequential risks

3.18
Risk Analysis and Biocontamination Control System (RABC system)
quality management system with an additional risk analysis for the control of risks of biocontamination of laundry processed textiles

3.19
target level
defined level for the variables which shall be monitored at the control points

3.20
viable micro-organisms
isolated, naturally occurring or accumulated micro-organisms capable of multiplying to produce demonstrable growth

3.21
washing supplies
products used in the machine during washing to assist the removal of soiling and stains and keep them in suspension in an aqueous medium

NOTE These include in particular soaps and surface-active agents, complexing agents, alkaline products and bleaching agents.

SIST EN 14065:2003

4 Prerequisites and general principles of biocontamination control

It is necessary for a laundry to follow good manufacturing practices as a prerequisite to implementing this standard. These can form part of an existing quality management system.

Examples of the topics to be considered are given in annex A.

A formal system shall be established, implemented and maintained in order to assess and control risks that can affect the microbiological quality of the process and product.

In such a system, specific microbiological hazards shall be identified. The control measures and their effectiveness shall be determined, analysed and documented.

The principles of a Risk Analysis and Biocontamination Control system (RABC) are :

4.1 Principle 1 : List of microbiological hazards and list of control measures

a) Identification of the microbiological hazard(s) associated with each step of the process, with the product or with staff ;

b) assessment and classification of levels of risk(s) of biocontamination of textiles at each step of the process as a consequence of the hazard ;

NOTE Classification of risk(s) can be performed according to relevant national guidelines or regulations where these exist.

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c) identification of control measures to eliminate or reduce the risk(s) of biocontamination of textiles to reach the agreed microbiological quality for the end-use of the textiles.

4.2 Principle 2 : Determination of the control points

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Determination of the points/steps/environmental conditions that can be controlled (control points) to eliminate or reduce the risk(s).

4.3 Principle 3 : Target levels and limits - Tolerances

Establishment of limits at each control point which shall not be exceeded to assure microbiological quality of textiles.

4.4 Principle 4 : Monitoring system

Establishment of scheduled testing or observation to monitor the control points.

4.5 Principle 5 : Corrective actions

Establishment of corrective actions to be taken when monitoring indicates that a particular point/procedure/operational step/environmental condition is not under control.

4.6 Principle 6 : RABC System checking procedures

Establishment of procedures to verify that the system is working effectively.

4.7 Principle 7 : Documentation

Establishment and maintenance of appropriate documentation.

SIST EN 14065:2003

5 Alignment with a quality management system

In order to improve efficiency and reduce the amount of documentation required, the documentation of the RABC system in accordance with 6.2.7 can be integrated with that of the existing compatible quality management system

6 Application of the Risk Analysis and Biocontamination Control system to laundries

The Risk Analysis and Biocontamination Control (RABC) system shall be used throughout the entire textile laundering process, from collection of the soiled articles to delivery of articles fit for use. Besides increasing the microbiological quality of textiles delivered to the users, its advantage is to improve process management.

Prerequisites and several preliminary actions are required for implementation of the RABC system to the laundry (6.1) before applying the seven principles of the RABC system (6.2).

6.1 Prerequisites and preliminary actions for establishing an RABC system

6.1.1 Management commitment

The management shall provide evidence of its commitment to the development and the improvement of the RABC system by conducting management reviews and ensuring the availability of necessary resources.

6.1.2 Constitution of the RABC team

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The management shall constitute a RABC team. This team shall be multidisciplinary with specific knowledge and experience appropriate to the process considered and end product requirements. If an experienced team cannot be constituted from the staff resources on site, additional expertise may be called upon from outside.

The responsibility of the RABC team shall be to implement and manage the RABC system.

SIST EN 14065:2003
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NOTE Possible members of a multidisciplinary team (depending on the organisation of the laundry) could be :

- the laundry unit manager ;
- the laundry workshop manager ;
- a representative of each department of the laundry ;
- a representative of the hygiene department ;
- a representative of the cleaning and maintenance department ;
- the quality manager ;
- a qualified microbiologist.

6.1.3 Facilities and work environment

The management shall identify, provide and maintain the facilities it needs to achieve the control of biocontamination. The RABC team shall identify the human and physical factors of the work environment needed to achieve control of biocontamination and recommend appropriate improvements.