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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.

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

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Contents

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of an identical text or by endorsement, at the latest by May 2003, and conflicting national standards shall be withdrawn at the latest by May 2003.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.

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.

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.

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.

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.

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

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

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

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

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.

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.

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

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.

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

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.

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.

6.1.4 Determination of the intended end use of the textile

The RABC team shall identify and record the intended end use of the textile taking into account customer requirements or specifications.

6.1.5 Preparation of a laundry flow diagram

The RABC team shall prepare a laundry flow diagram after examination of the relevant technical information e.g. textiles, machines and local procedures. It may subsequently be necessary to modify the laundry lay-out on site.

6.1.6 Process specification

The RABC team shall specify the process according to the type of textile. Different process specifications may be necessary depending on the nature of the soiling.

6.1.7 Training awareness and competency

The management shall :

a) identify competency needs for personnel performing activities affecting bio-contamination ;

b) provide training to satisfy these needs ;

c) evaluate the effectiveness of the training provided ;

d) ensure that its employees are aware of the relevance and importance of their activities and how they contribute to the achievement of the microbiological objectives ;

e) maintain appropriate records of education, experience, training and qualifications.

6.1.8 Purchasing information

The microbiological quality depends on adequate products being used in the laundry process. Specifications for these products shall be referenced in the purchasing documents.

6.2 Application of the seven principles for implementing the RABC system

The application of the RABC principles requires the documentation of procedures and the recording of information e.g. monitoring results, corrective actions. This is the basis for the preparation of the RABC manual described in 6.2.7.

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

6.2.1.1 Identification of the hazard(s) associated with the process, product or staff

The RABC team shall draw up a list of all the microbiological hazards which can occur at each step of the process.

Only those hazards of such a nature that their elimination or reduction to agreed levels is essential with regard to the microbiological quality of textiles shall be listed (see informative annex B).

6.2.1.2 Assessment and classification of levels of risk(s) of biocontamination of textiles resulting from the hazards

The RABC team shall assess and record the probability of each hazards presenting a risk and its consequences to the microbiological quality of the textile.

Classification of risks according to the level of biocontamination can be assessed, for example, as :

— low or negligible risk ;

— medium risk ;

— high risk ;

— very high risk.

6.2.1.3 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

Where required, the team shall then consider control measures that can be applied to each hazard (see informative annex C).

NOTE Control measures correspond to actions and activities required to eliminate the hazards or reduce their impact or occurrence to agreed levels. More than one control measure can be required to control a given hazard ; several hazards can be controlled by the same control measure.

6.2.2 Principle 2 : Determine the Control Points

For each hazard (6.2.1.1), the RABC team shall determine the locations, steps and environmental conditions that shall be controlled in order to eliminate or reduce the risks to agreed levels. These shall be documented as the Control Points (CP) and control measures of the process.

If a hazard presents a risk to the microbiological quality of textiles a control measure shall be introduced to reduce/eliminate the risk.

6.2.3 Principle 3 : Establish the target levels and tolerance limits for each Control Point

The RABC team shall determine the target levels and tolerance limits for normal operating conditions for the control measures at each Control Point. These shall be included in the RABC manual.

Target levels and tolerance limits shall be reviewed (6.2.6).

6.2.4 Principle 4 : Establish a monitoring system for each Control Point (CP)

The RABC team shall develop and document a monitoring system for the observation of the normal operating conditions of each CP, with reference to tolerance limits agreed in clause 6.2.3. The monitoring procedures shall enable the detection of any deviation from the target level. The monitoring system shall supply this information in sufficient time for corrective action to be taken to restore control of the laundry process and to deal with affected textiles.

If deviations from normal operating conditions are detected (alert level), the monitoring programme shall be intensified. If the tolerance limits are exceeded (action level), corrective action shall be implemented as soon as the condition becomes known.

The results of the monitoring programme shall be interpreted by a designated individual, possessing the requisite expertise and authority to take corrective actions. If continuous monitoring is not possible, the quantity and frequency of the monitoring programme shall be kept under review (6.2.6), but shall guarantee sufficient control of the CP.

NOTE Most CP monitoring procedures should be capable of being performed currently. Direct inspection is preferred where the time required for long analytical tests is not available. Visual inspection and physical or chemical measurements are preferred to microbiological analyses; their rapid implementation and the results obtained should demonstrate that the conditions for controlling the microbiological characteristics of the textiles have been maintained.

All recordings associated with CP monitoring shall be signed by the person(s) performing the monitoring operations and by the designated person(s) responsible for interpreting the results.

6.2.5 Principle 5 : Establish corrective actions

The RABC team shall develop and document the specific corrective actions which shall be implemented for each CP when the results of monitoring shows deviation from target levels and tolerance limits. Action shall be taken as soon as the condition becomes known, in order to restore control of the laundry process.

Monitoring shall be increased until it has been shown that target levels and tolerance limits for the CP have been met again. A decision shall also be required by the designated person on the destination of affected textiles e.g. remedial treatment. The reasons for corrective action and the decision on the destination of textiles shall be documented in the RABC logbook.

6.2.6 Principle 6 : Establish the RABC system checking procedures

6.2.6.1 Validation and revalidation of the laundry process

The process shall be designed to achieve an agreed level of microbiological quality and shall be validated. This shall be carried out according to the process specification and using specific microbiological test methods.

The validation is carried out to assure that the process complies with the required performance and to establish the limits of identified process parameters to allow product release without routine testing of textiles.

Revalidation shall be carried out at least every twelve months or at any shorter interval indicated by the monitoring results described in clause 6.2.6.2.

6.2.6.2 Review of the RABC system

The RABC team shall define and implement procedures to monitor that the RABC system operates correctly. These shall be documented in the RABC manual.

Regular review meetings shall be held and include :

— the updating of the RABC manual ;

— whether changes in equipment, procedures or laundry practice shall require revalidation ;

— review of the purpose for which the textiles are required taking particular note of customer requirements, specifications and depending on the intended end-use ;

— the monitoring programme ;

— incidents leading to deviations from target levels or tolerance limits or loss of control of the laundry process ;

— customer complaints concerning the microbiological quality of processed textiles.

Actions from the reviews shall be recorded in the minutes of review meetings and kept with the RABC manual.

6.2.6.3 Internal audit

The management shall conduct periodic internal audits to determine whether the RABC system conforms to the requirements of this European standard and has been effectively implemented and maintained.

6.2.7 Principle 7 : Establish a documentation system

Efficient and accurate collation of all appropriate documentation is essential for the proper implementation of the RABC system. The documentation system shall comprise at least, the RABC manual, the logbook and the minutes of the review meetings. The complete content of the documentation system shall be listed in the RABC manual. The RABC team shall be responsible for documenting each of the steps in the laundry flow line. In addition other written requirements specified in 6.2.1 to 6.2.7 shall be included in the RABC manual.

The extent of the documentation system shall be dependent on the following:

a) size and type of the laundry ;

b) complexity and interaction of the processes ;

c) competence of personnel.

The RABC manual can include elements listed in annex A.

Annex A
(informative)

Examples of good manufacturing prerequisites for biocontamination control

A.1 General

The following are examples of topics and activities of good manufacturing practices, which will be present to a greater or lesser extent in every laundry operations. Whether they are adequate will be determined during the implementation of the RABC system.

A.2 Documentation of legal requirements

A.3 Responsibilities

The responsibilities of each function should be clearly established including the management commitment and the delegation of responsibility within the organisation.

A.4 Architectural and technical hygiene requirements with respect to

— Buildings;

— sanitary facilities;

— water supply and disposal;

— ventilation system and air flow;

— processing machinery.

A.5 Staff hygiene requirements with respect to

— Hand hygiene;

— care of the body and staff clothing;

— medical care.

A.6 Textiles, supplies and production hygiene requirements with respect to

— Specifications;

— supplier assessment and selection;

— purchasing control;

— water inspection;

— storage;

— production;

— waste disposal;

— transport;

— canteen;

— control of measuring and monitoring devices.

A.7 Cleaning and disinfecting plan

— Cleaning and disinfecting products;

— maintenance of cleaning machines;

— cleaning and disinfecting procedures;

— rooms and areas;

— devices and equipment;

— microbiological effectiveness control.

A.8 Pest control

A.9 Staff hygiene training

A.10 Summary of hygiene controls

A.11 Check of hygiene control effectiveness

Annex B
(informative)

Examples of microbiological hazards

Reception, storage and sorting of soiled textiles	Washing	Drying, finishing, folding, packaging	Transport - Delivery of processed textiles
• Staff movement between different areas of the laundry	• Staff movement between different areas of the laundry	• Staff movement between different areas of the laundry	• Staff movement between different areas of the laundry
		• Hand transmitted recontamination	• Hand transmitted recontamination;
• Biocontamination of air, surfaces, transport equipment	• Biocontamination of feed water for washers	• Recontamination of clean textiles from air, surfaces, equipment and pests (e.g flatwork ironing machines, tunnel finishers and finishing cabinets).	• Recontamination of clean textiles by contact with soiled textiles, from the vehicle interior and pests
	• Biocontamination from supplies		
• Increased biocontamination through excessive storage time	• Build up of biocontamination in washers and ancillary equipment	• Methods of handling (risk of microbiological proliferation associated with the dampness of textiles).	• Air contamination
	• Inadequate processing of textiles leading to non-conformity		

Annex C
(informative)

Examples of control measures

Reception, storage and sorting of soiled textiles	Washing	Drying,finishing,folding packaging	Transport - Delivery of processed textiles
• Cleaning, disinfecting of rooms, equipment and surfaces : specify the cleaning plan	• Cleaning, disinfecting of rooms, equipment and surfaces : specify the cleaning plan	• Cleaning, disinfecting of equipment and surfaces : specify the cleaning plan	• Cleaning, disinfecting of vehicles, equipment (including bags, containers and insides of vehicles) and surfaces : specify the cleaning plan
• Restriction of staff movement	• Restriction of staff movement	• Restriction of staff movement	• Restriction of staff movement
• Personnel hygiene (e.g. dress, hand hygiene)	• Personnel hygiene (e.g. dress, hand hygiene)	• Personnel hygiene (e.g. dress, hand hygiene).	• Personnel hygiene (e.g. dress, hand hygiene)
• Training of personnel		• Training of personnel (e.g see annex H of prEN ISO 14698-1:2002).	• Training of personnel
	• Regular inspection of machine settings and monitoring of washing cycles ;	• Regular inspection of machine settings and monitoring of drying cycles ;	
	• Functional separation of clean and soiled textiles to avoid recontamination	• Functional separation from other areas	
		• Protection of textiles appropriate to their use;	• Protection of textiles appropriate to their use;
• Avoid microbiological development by controlling the length of storage	• Quality of supplies : use suppliers with an auditable quality system. Implement a controlled storage and use system	• Control of the length of storage of washed and damp textiles	
		• Textiles should be adequately dried before packing	

• Specific rooms of sufficient surface area, easy to clean surfaces and equipment, control of the air circulation	• Water quality treatment (e.g. filtration, softening, chlorination, etc.)	• After repairs, reprocessing of textiles depending on their use	• If a single vehicle is used : protection of processed textiles by a functional separation (e.g. partition, container bag) in order to avoid recontamination
		• Procedures for the identification, isolation and reprocessing of non-conforming textiles.	

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