SLOVENSKI STANDARD
SIST EN 14065:2016

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Nadomešča:
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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 - Système de maîtrise de la biocontamination

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English Version

Textiles - Laundry processed textiles - Biocontamination control system

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

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European foreword

This document (EN 14065:2016) 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of an identical text or by endorsement, at the latest by November 2016, and conflicting national standards shall be withdrawn at the latest by November 2016.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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Introduction

The sensory cleanliness of processed textiles is important for the laundry industry and its 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. In addition, biocontamination control is important in many sectors, e.g. healthcare, food, pharmaceutical and medical device, but biocontamination of processed textiles is not easily verified in the laundry, and can have significant effects on people, products, materials and environments. Where laundries provide textile services in such cases, the processed textiles should be suitable for the intended use.

The purpose of this standard is to provide for a management system that can effectively and consistently ensure provision of processed textiles with a microbiological quality appropriate for the intended use. Regardless of variations between laundries, processes or products, all textiles returning to a laundry for processing are potentially contaminated. The objective of the laundering cycle is to achieve and then maintain the appropriate microbiological quality to the point of handover to customer control.

The approach used in this standard is to apply recognized risk and process management principles, and to provide for a Risk Analysis and Biocontamination Control (RABC) system. The first core RABC element is a general Prerequisite Programme (PRP) which includes the conditions and good manufacturing practices necessary to achieve and maintain the hygiene of the work environment, process and textiles. The second element is an operational PRP which includes the control measures that are most essential for protecting washed, dried textiles from re-contamination and cross-contamination until they are securely packed. The final RABC element is the seven RABC principles, which are applied to the most capable and crucial process steps, called Critical Control Points (CCPs) wherein textiles are thoroughly decontaminated. This can only be demonstrated through effective process validation. Where RABC implementation is complete and current, laundries can then assure all product released is suitable for its intended use through ongoing monitoring and verification that enables identification and remedial action for product from non-conforming processes.

The approach and the principles employed in RABC are similar to those used in the sectors named above, e.g. Infection Control, Hazard Analysis And Critical Control Points (HACCP), Good Manufacturing Practices (GMP). National and sector-specific guidance is available in many jurisdictions and can assist RABC implementation.

Implementing RABC effectively in a laundry requires a sound understanding of the laundering process, and of factors specific to the product/laundry/customer/sector/jurisdiction. The annexes to this standard therefore present examples and guidance to laundries. All annexes to this standard are informative only. They are neither intended nor suitable for specification or auditing. Annex A provides a description of the laundering process and an introduction to some of the key related issues. Annexes B to F relate in more detail to prerequisites, risk assessment, control measures, process parameters and validation approaches. Annex G provides cross references to EN ISO 9001 and to EN 14065:2016.

Implementing RABC is an iterative process. Review during implementation will identify different strategies for controlling re-contamination in terms of investment, plant design, construction and operation. Laundry operations and the market sector supplied will determine which is most appropriate. Review will also determine where further development is appropriate.

1 Scope

This European Standard describes a risk management approach, called Risk Analysis and Biocontamination Control (RABC), designed to enable laundries to continuously assure the microbiological quality of laundry processed textiles. The RABC approach applies for laundry market sectors where it is necessary to control biocontamination, e.g. pharmaceuticals, medical devices, food, healthcare and cosmetics. The RABC approach 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 document, the following terms and definitions apply.

3.1
acceptance criteria
required output from a process, specified quantitatively where possible, for particular product or process characteristics

Note 1 to entry: Meeting acceptance criteria is the minimum requirement for product release.

3.2
action level
established level of a CCP parameter set by the RABC team at which remedial procedures are activated to bring the laundry process back into control

3.3
alert level
established level of a CCP parameter set by the RABC team giving early warning of a change from normal conditions

3.4
biocontamination
contamination with viable microorganisms, where contamination is the presence of an unwanted constituent, foreign to the textile

3.5
control measure
action or activity used to prevent, contain, reduce or eliminate a biocontamination risk

3.6
control point (CP)
point or process step at which a control measure is applied

Note 1 to entry: Loss of control does not necessarily result in failure to meet acceptance criteria. Some control measures may not be applied at control points (e.g. cleaning, maintenance).

3.7
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

3.8
critical control point (CCP)
any process step at which all of the following apply; control is essential to eliminate or reduce biocontamination risk, effective control is possible and is sufficient to achieve the acceptance criteria, no subsequent step can achieve the acceptance criteria

3.9
cross-contamination
introduction of biocontamination to decontaminated textiles, directly or indirectly from contaminated textiles

3.10
decontamination
process combining cleaning and sufficient microbial reduction for the intended purpose, e.g. disinfection

3.11
flow diagram
graphical representation of the sequence and interaction of steps in a process

3.12
hazard
in the context of this standard, any element or factor that may adversely affect the achievement of the agreed microbiological quality of textiles

3.13
laundry
plant where soiled/used textiles undergo a laundering cycle (see 3.14) such that processed textiles are fit for their intended use

3.14
laundering cycle
those process steps that textiles undergo in a laundry, between receipt from and hand over to the customer, including all or a combination of the following; sorting, classifying, washing, extraction, drying, finishing, folding, packing.

3.15
microbiological quality (of textiles)
number and if required types of microorganisms present on textiles

Note 1 to entry: The intended end-use will inform decisions on the agreed level of microbiological quality.

3.16
monitoring programme
planned observations or measurements of control measures

3.17
parameter
process or product characteristic which can be monitored and compared to an agreed range of values to indicate the current degree of control

3.18
prerequisites
those facilities and practices relating to processing and hygiene that contribute significantly to effective implementation of a RABC system, including both enabling and control measures

3.19
processed textiles
textiles which have undergone a laundering cycle

3.20
process validation
providing objective evidence that a process operating within established parameters consistently produces a result or product that meets its pre-determined specifications

3.21
re-contamination
introduction of biocontamination to decontaminated textiles from sources other than contaminated textiles

3.22
risk
probability of a hazard occurring combined with the severity of the consequences. For this standard, consequences relate to the potential for adverse effects from processed textiles' end use arising from biocontamination of the textile

3.23
risk analysis
investigation of available information to identify hazards and to estimate the consequential risks

3.24
Risk Analysis and Biocontamination Control System (RABC system)
management system for assuring processed textiles of appropriate microbiological quality according to their intended use

3.25
target level
defined level for the parameters which are monitored at the critical control points (CCPs), generally established with action and alert levels

3.26
verification
provision of objective evidence from operation of the monitoring programme to confirm that specified requirements have been fulfilled

3.27
viable microorganisms
microorganisms capable of multiplying to produce demonstrable growth

3.28
washing
operations taking place in a machine, in an aqueous medium, with the purpose of cleaning, decontaminating and conditioning the textile for further processing, e.g. wetting out, preliminary washing, washing, bleaching, decontaminating, neutralising, rinsing

3.29
washing supplies
materials used in the wash process, e.g. for one or more of the following functions; textile decontamination, suspension of soiling and staining from textiles, providing residual benefit to textile after washing

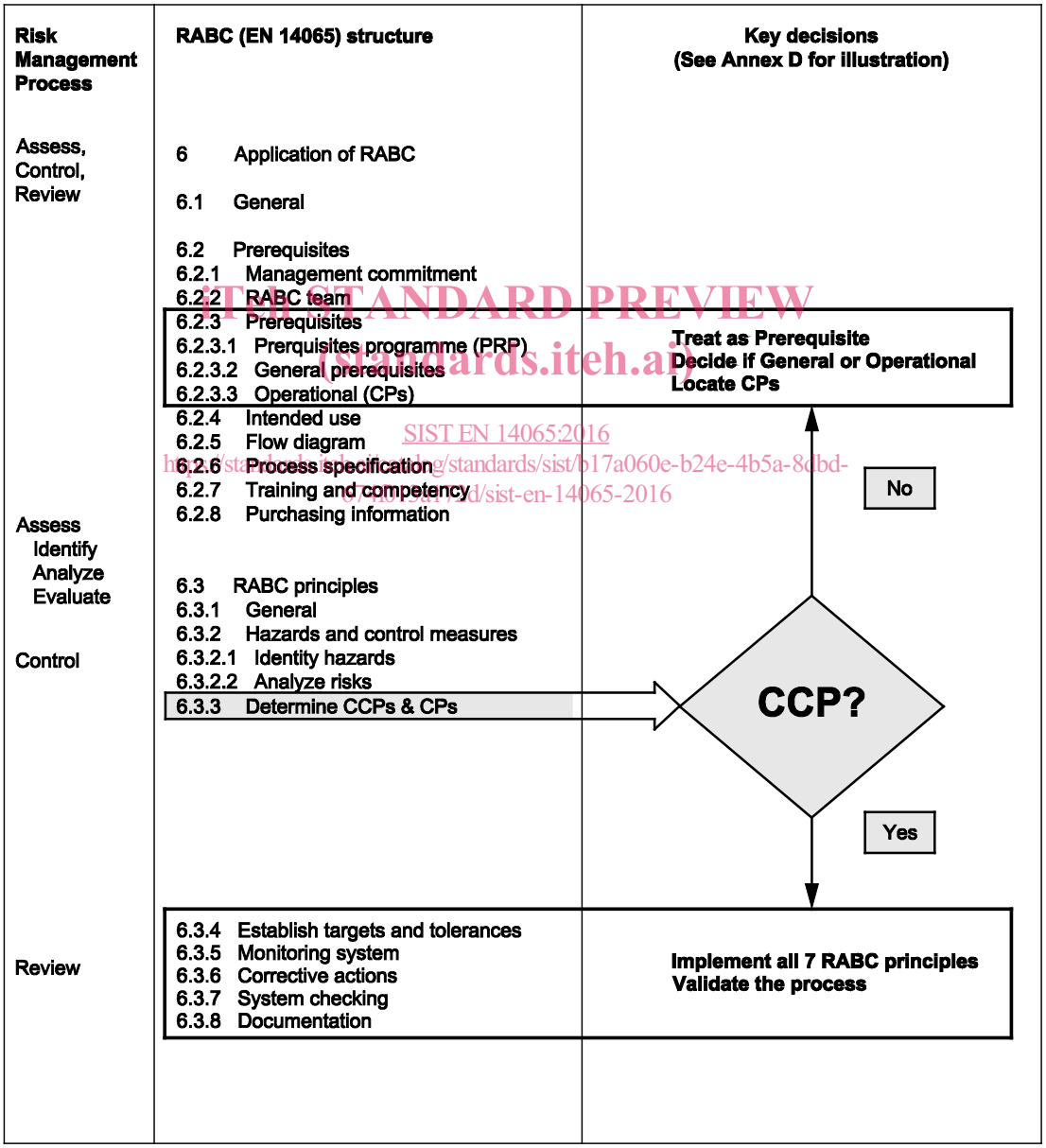
4 General principles and requirements

4.1 Principles and framework

The general principles of risk management provide an approach that is integral to business operation, addresses uncertainty, and is systematic and iterative and responsive to change.

These principles are developed specifically for RABC in laundries as represented in Figure 1 below. Figure 1 identifies the clauses within this standard addressing the elements of the RABC model in order of implementation, with a key decision point after completion of risk assessment. The figure also shows how the RABC model aligns with generally accepted risk management practices.

Implementation is unlikely to be achieved in one attempt; it is a progressive, iterative process, which may be broken down into smaller groups of activities which can be pursued concurrently or sequentially.



Key

CP Control Point

CCP Critical control point

Figure 1 — Risk management and RABC

4.2 General requirements

The management shall establish, document, implement and maintain a RABC system to eliminate or reduce the risks of textile biocontamination to the extent and type appropriate, according to the intended use of the textiles. The required principles, methods and detailed controls are developed in Clause 6.

The RABC system shall include:

— first, a prerequisites programme (PRP, see 6.2) focused on the work environment and good manufacturing practices

— followed by a RABC plan, applying the seven RABC principles (see 6.3) to each critical process step or "critical control point (CCP)".

A PRP is less formal than the RABC plan, but is an essential foundation and requirement for implementation of a RABC system. The RABC system shall be regularly reviewed for currency and effectiveness.

Annex A (informative) introduces a rationale and key issues for developing a RABC system in laundries.

Annex B (informative) provides examples of prerequisites.

5 Alignment with a quality management system

A RABC system, including the required documentation, can be integrated with a quality management system.

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

6.1 General

The Risk Analysis and Biocontamination Control (RABC) system shall be implemented throughout the laundering cycle and for other activities where the textiles remain under the laundry's control; potentially from collection through to delivery. Besides increasing the microbiological quality of textiles delivered to the users, its benefit is to improve process management.

6.2 Prerequisites and preliminary actions for establishing a RABC system

6.2.1 Management commitment

The management shall provide evidence of its commitment to the development and the improvement of the RABC system by establishing and documenting the scope of the RABC system and a RABC policy, setting RABC objectives, conducting and recording management reviews and ensuring the availability of necessary resources, particularly with respect to corrective actions.

6.2.2 Constitution of the RABC team

The management shall constitute a RABC team. The RABC team shall implement and maintain the RABC system. This team shall be multidisciplinary with specific knowledge and experience appropriate to the process considered and end product requirements. External resources may be employed, e.g. to provide sufficient expertise.

NOTE A multidisciplinary team (depending on the organisation of the laundry) could be drawn from:

— different experience and seniority levels (e.g. manager, supervisor, operator);

— production, engineering and distribution resources;

— a representative of each section of the laundry;

— a representative of the hygiene/cleaning team;