SLOVENSKI STANDARD
oSIST prEN 14065:2026

01-april-2026

Tekstilije - Tekstilije, obdelane v pralnici - Sistem za nadzor biološke kontaminacije

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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ICS:

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

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN 14065

January 2026

ICS 07.100.99; 59.080.01

Will supersede EN 14065:2016

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

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European foreword

This document (prEN 14065:2026) has been prepared by Technical Committee CEN/TC 248 “Textiles and textile products”, the secretariat of which is held by BSI.

This document is currently submitted to the CEN Enquiry.

This document will supersede EN 14065:2016.

prEN 14065:2026 includes the following significant technical changes with respect to EN 14065:2016:

— An abbreviation list was added to the Clause 3, which was re-labelled “Terms, definitions and abbreviations”

— Several figures have been replaced by text to allow for being translated

— The original Annex G was deleted and replaced by a new one. The new informative Annex G

  — provides implementation guidance for users and auditors of the document

  — includes a Clause Examples of useful standards and references to assist the implementation, certification and auditing (G.3.4)

— The Bibliography has been updated

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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 critical in many sectors and contexts. Examples include pharmaceuticals, medical devices, cleanrooms, surgical textiles, healthcare linen, food sector workwear and during public health outbreaks. Biocontamination control is also important in sectors such as hospitality. Where laundries provide textile services in such cases, the processed textiles should be suitable for the intended use. Biocontamination of processed textiles is not easily verified in the laundry, and can have significant effects on people, products, materials and environments.

The purpose of this document is to provide an approach 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 document 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 ensure 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.

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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 and specifically Annex G present examples and guidance to laundries for implementing and auditing their RABC procedures. All annexes to this document are informative only. They are neither intended nor suitable for specification or auditing. Annex A (informative) 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.

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.

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1 Scope

This document describes a risk management approach, called Risk Analysis and Biocontamination Control (RABC), designed to enable laundries to continuously ensure the microbiological quality of laundry processed textiles. The RABC approach applies to 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

There are no normative references in this document.

3 Terms, definitions and abbreviations

3.1 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp/

— IEC Electropedia: available at https://www.electropedia.org/

3.1.1
microorganism
entity of microscopic size encompassing bacteria fungi protozoa and viruses

Note 1 to entry: Microbe is synonymous with microorganism.

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3.1.2
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.

3.1.3
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

3.1.4
alert level
established level of a CCP parameter set by the RABC team giving early warning of a change from normal conditions

3.1.5
biocontamination
contamination with viable microorganisms (3.1.30), where contamination is the presence of an unwanted constituent, foreign to the textile

3.1.6
control measure
action or activity used to prevent, contain, reduce or eliminate a biocontamination (3.1.5) risk

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3.1.7
control point (CP)
point or process step at which a control measure (3.1.6) is applied

Note 1 to entry: Loss of control does not necessarily result in failure to meet acceptance criteria (3.1.2). Some control measures (3.1.6) might not be applied at control points (e.g. cleaning, maintenance).

3.1.8
corrective action
action to be taken, when the results of monitoring indicate that alert or action levels (3.1.3) are exceeded, in order to restore control of the process

3.1.9
critical control point (CCP)
critical, higher level control point (3.1.7) at which all of the following apply:

— control is essential to eliminate or reduce biocontamination (3.1.5) risk,

— effective control is possible and is sufficient to achieve the acceptance criteria (3.1.2),

— no subsequent step can achieve the acceptance criteria (3.1.2)

3.1.10
cross-contamination
introduction of biocontamination (3.1.5) to decontaminated textiles, directly or indirectly from contaminated textiles

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3.1.11
decontamination
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process combining cleaning and sufficient microbial reduction for the intended purpose, e.g. disinfection

3.1.12
flow diagram
graphical representation of the sequence and interaction of steps in a process

3.1.13
hazard
in the context of this document, any element or factor that may adversely affect the achievement of the agreed microbiological quality of textiles

3.1.14
laundry
<noun>
facility where soiled/used textiles undergo a laundering cycle (3.1.15) such that processed textiles are fit for their intended use

3.1.15
laundering cycle
process steps that textiles undergo in a laundry (3.1.14), between receipt from and hand over to the customer, including all or a combination of the following: sorting, classifying, washing (3.1.31), extraction, drying, finishing, folding, packing

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3.1.16
microbiological quality
<textiles> number and if required types of microorganisms (3.1) present on textiles

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

3.1.17
monitoring programme
planned observations or measurements of control measures (3.1.6)

3.1.18
parameter
process or product characteristic which can be monitored and compared to an agreed range of values to indicate the current degree of control

3.1.19
prerequisites
facilities and practices relating to processing and hygiene that contribute significantly to effective implementation of a RABC system, including both enabling and control measures (3.1.6)

3.1.20
processed textiles
textiles which have undergone a laundering cycle (3.1.15)

3.1.21
process validation
providing objective evidence that a process operating within established parameters (3.1.18) consistently produces a result or product that meets its pre-determined specifications

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3.1.22
qualification
an individual study or process challenge conducted as part of a validation plan

3.1.22.1
design qualification
DQ
documented verification that the proposed design of the facilities, systems and equipment is suitable for the intended purpose

3.1.22.2
installation qualification
IQ
documented verification that the facilities, systems and equipment, as installed or modified, comply with the approved design and the manufacturer's recommendations

3.1.22.3
operational qualification
OQ
documented verification that the facilities, systems and equipment, as installed or modified, perform as intended throughout the anticipated operating ranges

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3.1.22.4
performance qualification
PQ
documented verification that the facilities, systems and equipment, as connected together, can perform effectively and reproducibly, based on the approved process method and product specification

3.1.23
re-contamination
introduction of biocontamination (3.1.5) to decontaminated textiles from sources other than contaminated textiles

3.1.24
re-validation
documented confirmation of an established validation, taking into account and documenting any interim variations capable of impacting on process performance

3.1.25
risk
probability of a hazard (3.1.13) occurring combined with the severity of the consequences

Note 1 to entry: For this document, consequences relate to the potential for adverse effects from processed textiles' (3.1.20) end use arising from biocontamination (3.1.5) of the textile.

3.1.26
risk analysis
investigation of available information to identify hazards (3.1.13) and to estimate the consequential risks (3.1.25)

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3.1.27
Risk Analysis and Biocontamination Control System
RABC system
industry recognised term for the management system for assuring processed textiles (3.1.20) of correct microbiological quality (3.1.16) according to their intended use

Note 1 to entry: The risk assessment is undertaken to define the control system.

3.1.28
target level
defined level for the parameters (3.1.18) which are monitored at the critical control points (CCPs) (3.1.7), generally established with action and alert levels (3.1.4)

3.1.29
verification
provision of objective evidence from operation of the monitoring programme (3.1.17) to confirm that specified requirements have been fulfilled

3.1.30
viable microorganisms
microorganisms (3.1.1) capable of multiplying to produce demonstrable growth

3.1.31
washing
operation taking place in a machine, in an aqueous medium containing washing supplies (3.1.32), for the purpose of cleaning, decontaminating and conditioning the textile

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3.1.32
washing supplies
materials used in the wash process, e.g. for one or more of the following functions; textile decontamination (3.1.11), suspension of soiling and staining from textiles, providing residual benefit to textile after washing (3.1.31)

3.2 List of abbreviations

Abbreviation	Full description
CCP	Critical Control Point
CP	Control Point
DQ	Design Qualification
ED	Experimental Design
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis and Critical Control Points
NHS	National Health Service (UK)
IQ	Installation Qualification
OQ	Operational Qualification
PQ	Performance Qualification
PRP	Prerequisite Programme
QMS	Quality Management System
RABC	Risk Analysis and Biocontamination Control (system)

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4 General principles and requirements

4.1 Principles and decision framework

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

These principles are developed specifically for RABC in laundries. The RABC implementation process identifies the clauses within this document addressing the elements of the RABC model in order of implementation, with a key decision point after completion of risk assessment. 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.

The RABC Implementation Process consists of the following stages:

a) Stages of Risk Management Process Assessment

   1) General Requirements for Application of RABC

   2) Define Prerequisites

   3) Establish Management commitment

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4) Structure the RABC Team

5) Determine Prerequisites programme and Operational CPs

6) Determine the intended use of the process

7) Establish a flow diagram to assist control communication

8) Define the process specification

9) Establish training procedures to achieve and verify competency

10) Define purchasing specifications and procurement controls

b) Stages of Risk Management Process Control

1) Implement the general principles

2) Identify the hazards

3) Analyse the risks

4) Determine the CCPs and the CPs and their impact on previous stages

c) Stages of Risk Management Process Review

1) Establish targets and tolerances

2) Address the monitoring system

3) Determine corrective actions

4) Review the process system

5) Address and review the process documentation

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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 5.

The RABC system shall include:

1) a prerequisites programme (PRP, see 5.1.3) providing for the work environment and good manufacturing practices necessary to support a successful RABC system, including those which limit contamination from the work environment to the textile and cross-contamination and re-contamination after washing and drying;

2) a RABC plan that applies the seven RABC principles (see 5.2) 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.

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