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NSAI Standards

Irish Standard
I.S. EN 14065:2016

Textiles - Laundry processed textiles - Biocontamination control system

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I.S. EN 14065:2016

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NSAI	T +353 1 807 3800	Sales:
1 Swift Square,	F +353 1 807 3838	T +353 1 857 6730
Northwood, Santry	E standards@nsai.ie	F +353 1 857 6729
Dublin 9	W NSAI.ie	W standards.ie

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National Foreword

I.S. EN 14065:2016 is the adopted Irish version of the European Document EN 14065:2016, Textiles - Laundry processed textiles - Biocontamination control system

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 14065

May 2016

ICS 07.100.99; 59.080.01

Supersedes EN 14065:2002

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 22 February 2016.

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CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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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of an identical text or by endorsement, at the latest by November 2016, and conflicting national standards shall be withdrawn at the latest by November 2016.

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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.

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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

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