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Textiles — Laundry processed textiles — Biocontamination control system

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National foreword

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

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of an identical text or by endorsement, at the latest by November 2016, and conflicting national standards shall be withdrawn at the latest by November 2016.

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.

This document supersedes EN 14065:2002.

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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

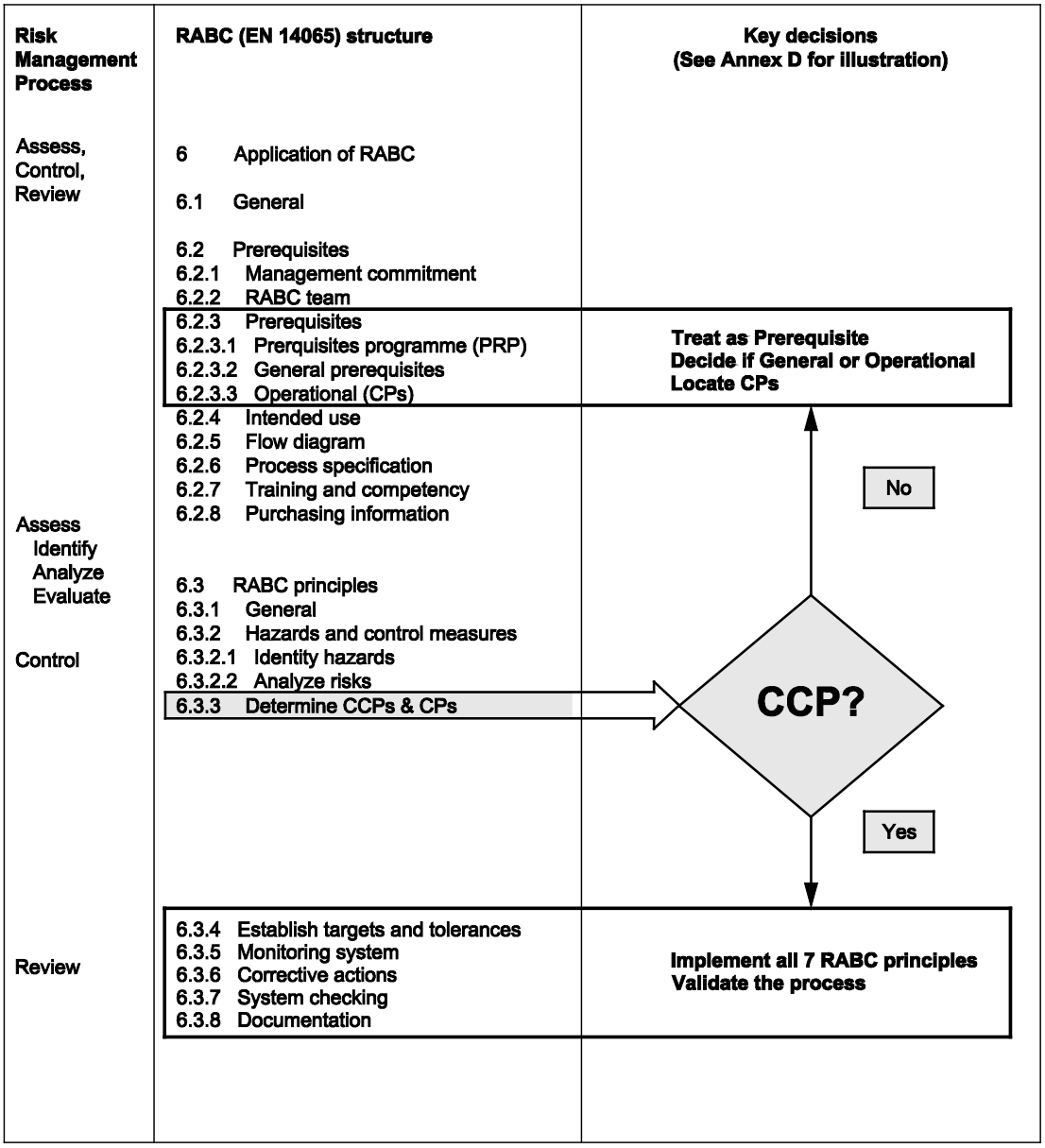
4 General principles and requirements

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;

— the quality team;

— microbiological expertise as appropriate.

6.2.3 Prerequisites programme (PRP)

6.2.3.1 General

The management shall provide and maintain the facilities and practices necessary to support the RABC system, including those which limit contamination from the work environment to the textile and cross-contamination and re-contamination after washing and drying. The RABC team shall implement and maintain the resulting PRP for general and operational considerations. Annex B (informative) provides examples of prerequisites.

6.2.3.2 General prerequisites

General prerequisites relate to the facility and facility-wide practices. The programme shall address at least the following elements, identifying the type of hazard to be controlled and the required conditions and/or control measures for each element:

— construction, layout and maintenance of premises, buildings and associated facilities – particularly production space and employee access facilities;

— cleaning/hygiene plans;

— water and steam systems – supply, storage, treatment and disposal;

— equipment suitability and control (e.g. cleaning, maintenance, calibration);

— control measures before decontamination and after packing, including handling, storage, packaging, transport and re-work (see 6.2.4 to 6.2.6);

— personnel competence, training and hygiene (see 6.2.7);

— purchased materials (see 6.2.8);

— pest control.

6.2.3.3 Operational prerequisites

Operational prerequisites concern control measures applied to protect decontaminated textiles from re-contamination and cross-contamination until they are packed. While individually these measures may not meet the criteria for CCPs (see 6.3 below), cumulatively they are equally important and shall be competent to maintain the microbiological quality of processed textiles. The operational prerequisites programme shall specify requirements for at least the following:

— microbiological hazard(s) to be controlled (see 6.3);

— control measure(s) and point(s) (CPs) for each microbiological hazard (particularly from direct contact surfaces such as packaging, equipment, hands);

— cleaning and decontamination as necessary for surfaces that directly contact processed textiles;

— monitoring programme and verifications sufficient to demonstrate all control measures are effective;

— corrections and corrective actions to be taken if monitoring shows that control has been compromised;

— responsibilities and authorities for recording monitoring and interpreting results;

— record(s) of monitoring.

6.2.4 Determination of the intended end use of the textile

The intended use of any given textile is one of the most important factors to consider when applying the RABC principles (see 6.3). Decisions affected include assessing risks, managing controls and agreeing final microbiological quality levels with the customer. The RABC team shall identify and document the intended end use of the textile taking into account requirements or specifications.

NOTE Requirements or specifications can originate with customers, sectors, National or European regulations, ISO and CEN Standards.

6.2.5 Preparation of laundry flow diagram(s)

The RABC team shall develop, document and check the laundry flow diagram(s) that identifies the key process steps and decisions and address the variations in processing related to product type, processing route and intended use.

6.2.6 Process specification

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

6.2.7 Training awareness and competency

The management shall:

a) identify awareness and competency needs for personnel performing activities affecting bio-contamination, e.g. hygiene, product and material handling;

b) develop and maintain those competences, through training and other appropriate activities;

c) evaluate the effectiveness of competence development;

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

6.2.8 Purchasing information

The RABC team shall identify materials that are bought in for use in the laundering cycle and that affect the microbiological quality of processed textiles through contact, whether direct (e.g. packaging) or indirect (e.g. surface disinfectants). Adverse effects can arise from the prior contamination of the material (e.g. new textiles, packaging) or from the performance of the material (e.g. washing supplies).The RABC team shall reference or include specifications for such materials in purchasing documentation and demonstrate that they are suitable for their intended use.

6.3 Application of the seven principles for implementing the RABC system

6.3.1 General

The RABC team shall establish and implement each of the RABC principles, as described here.

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

6.3.2.1 Identification of the hazard(s) associated with the environment, process or product

The RABC team shall list all the microbiological hazards that can impact the microbiological quality of textiles, addressing each step of the laundering cycle and other activities that are under the laundry's control.

6.3.2.2 Assessment of textile biocontamination risks

Risk assessment consists of analysis and evaluation of risks.

The RABC team shall carry out and document risk analysis for each hazard, deploying available evidence, expertise and experience. For each risk identified, the probability of occurrence for related hazards and the

severity of consequences where the hazard occurs shall be identified and assessed, discriminating on levels of risk. The consequence for end users from biocontamination of the processed textile shall be described for each risk.

The RABC team shall evaluate documented risks, to identify and prioritize where control measures are needed and to identify Critical Control Points (CCPs). When all RABC principles are addressed, the RABC team shall revise the risk assessment to account for the impact of control measures as implemented.

Completed risk assessments shall also be reviewed, and revised as necessary, during subsequent management review. More developed risk analysis techniques can be used where they incorporate the above elements. Annex C (informative) provides examples and guidance for risk assessment.

6.3.2.3 Identification of control measures

The RABC team shall identify the control measures and further control measure to be developed where necessary to achieve and maintain the appropriate microbiological quality. Control measures can be listed by the process steps (e.g. at CPs) at which they are applied.

Control measures shall be implemented for each listed hazard. The RABC team shall establish and document microbiological quality levels appropriate to the end-uses of the textiles. Annex D (informative) provides examples of control measures.

NOTE Control measures correspond to actions and activities required to prevent, eliminate or reduce biocontamination risks. More than one control measure can be required to control a given risk. Several risks can be controlled by the same control measure. Control measures can be general (e.g. plant-wide) or specific to a process step (i.e. CPs and CCPs).

6.3.3 Principle 2: Determine the Critical Control Points (CCPs) and Control Points (CPs)

The RABC team shall apply the definitions given in 3.5, 3.6, 3.8 of this standard to identify, document and treat each control measure as one of the following:

— Control measure – part of the general prerequisites programme (see 6.2.3.2);

— Control points (CPs) – part of the operational prerequisites programme (see 6.2.3.3);

— Critical Control Points (CCPs) – where all of the conditions explained in the definition (see 3.8) apply.

6.3.4 Principle 3: Establish the target levels and tolerance limits for each CCP

The RABC team shall determine and document tolerance limits for normal operating conditions at each CCP, including the rationale for the chosen limits, such that operation within these limits assures achievement of the agreed microbiological quality levels. Tolerance limits include measurable target, alert and action levels.

6.3.5 Principle 4: Establish a monitoring programme for each CCP

The RABC team shall develop and document a monitoring programme for the observation of the normal operating conditions of each CCP. The monitoring shall enable detection of any deviation from tolerance limits. The monitoring programme shall supply this information in sufficient time for corrective action to be taken to restore control of the laundry process and to deal with nonconforming textiles.

If deviations from normal operating conditions are detected (alert level), the monitoring programme shall be intensified. If the action level is exceeded, 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 (6.3.7.2), but shall provide for sufficient control of the CCP.

Most CCP monitoring should be capable of being performed in real time. 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 CCP monitoring shall be authorised by the person(s) performing the monitoring operations and by the designated person(s) responsible for interpreting the results.

6.3.6 Principle 5: Establish corrective actions

The RABC team shall develop and document the specific corrections and corrective actions which shall be implemented for each CCP 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 CCP have been met again. A decision shall also be required by the designated person on the disposition of affected textiles e.g. remedial treatment. The reasons for corrective action and the decision on the destination of textiles shall be documented.

6.3.7 Principle 6: Establish the RABC system checking procedures

6.3.7.1 Validation and re-validation of CCPs

6.3.7.1.1 Introduction

Where a CCP has been established, the RABC team shall validate the related process.

6.3.7.1.2 General

Process validations shall establish and document at least the following:

— identify the processes to be validated;

— define the acceptance criteria for review and approval of such processes;

— directly verify process performance during validation. Retain and approve records of validation methods and test results.

Annex F (informative) provides examples of approaches to process validation for laundries.

6.3.7.1.3 Microbial reduction

As verification of decontamination in the washing process in the available time is not possible, the washing process shall be validated. For wash validations, the RABC team shall establish and document the following:

— Identify the process parameters, targets and tolerances necessary for achieving decontamination [see Annex E (informative)].

— Establish the acceptance criteria for successful completion of decontamination, in terms of process capability for microbiologic reduction and of the microbiological quality of the processed textile.

— Confirm that the process operates within the identified process parameters.

— Verify that the control measures are sufficient to enable routine release of the product subsequent to validation. E.g. equipment, detergent dosing and software.

— Using recognised microbiological test methods, demonstrate the capability of the process to consistently achieve the established acceptance criteria.

NOTE See Bibliography for examples of microbiological methods. Microbial reduction can include removal and/or inactivation of biocontamination. In some jurisdictions or applications, inactivation may be specified as a requirement (e.g. medical devices).

— Re-validate at least every 12 months, or earlier where significant changes in process or product are planned or as indicated by monitoring results as described in 6.3.7.2.

6.3.7.2 Review of the RABC system

The RABC team shall develop, implement and document regular reviews of the RABC system.

RABC reviews shall assess the currency, suitability and effectiveness of the RABC system, including at least the following considerations:

— the RABC documentation, including policy and objectives;

— whether changes in facility, layout, equipment, procedures or laundry practice are necessary;

— whether changes as above shall require validation;

— the intended uses and flow diagrams for textiles;

— the alert and action levels and the related monitoring programme;

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

— customer complaints or other market feedback concerning the microbiological quality of processed textiles.

Agreed actions from the reviews shall be included in review records.

6.3.7.3 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.

6.3.8 Principle 7: Establish a documentation system

Effective documentation is essential for the proper implementation of the RABC system.

The documentation system shall comprise at least the following:

— Documentation of the Pre-requisites Programme (PRP), addressing 6.2 of this standard;

— Documentation of the implementation of all RABC principles, addressing 6.3 of this standard;

— Records arising from operation of the PRP and RABC plans, including from system reviews.

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

— size and type of the laundry;

— complexity of the processes;

— competence of personnel.

Annex A
(informative)

Rationale for application of RABC in laundries

A.1 Introduction

The Introduction to this standard speaks of applying biocontamination control to laundries in general. This annex focuses attention on the laundering cycle itself, and on considerations that affect implementation of biocontamination control. Such issues include the role of laundering cycle stages in RABC terms, variations in product intended use and variations within and between market sectors. Establishing the capability of process stages, then capturing these variations and using subsequent risk analysis to decide rationally on the appropriate level of control is the core of the RABC method. This approach allows for great flexibility in the choice of solutions – in facility, processes and control measures. Subsequent annexes develop issues raised here in further detail.

A.2 The process

As textiles are generally re-used, most laundering is part of a service involving collection of used items, return to the laundry for laundering, then delivery to the customer. Laundries should operate sound hygiene and good working practices throughout, but most effort in RABC implementation will be in the plant. Related terms (e.g. laundering cycle) are defined in Clause 3 of the standard. For RABC purposes, three stages are recognised:

General: The laundry should implement a plant-wide prerequisites programme, particularly for activities and facilities before decontamination and after processed textiles are packed. The main focus is on good practices, and prevention of cross-contamination and re-contamination. The prerequisites should also support CP and CCP implementation (e.g. maintenance of process equipment). In this standard, 6.2 (particularly 6.2.3.2) and Annexes, B, D and E are the key references

Decontamination: This is where the highest levels of performance and control are required, to be achieved by applying the seven RABC principles. In this standard, 6.3 and Annexes C, D, E and F are the key references. The key to maximum effect from minimum cost & disruption is to prepare well with effective prerequisite (PRP) implementation, i.e. Identify the intended use clearly, map the process simply to help show where control measures are most critical, ensure effective process and equipment control measures are in place.

Re-contamination and Cross-contamination: Once textiles have been decontaminated, the laundry should ensure that RE and CROSS contamination does not occur, particularly up to the point where textiles are packed. This is where the operational prerequisite programme applies, with control points that may individually not be critical but which shall work together to protect textiles effectively. In this standard, 6.2 (particularly 6.2.3.3) and Annexes B, C and D are the key references

Notes on process capability: A well-engineered and operated wash process benefits from a well-established interaction of time, temperature, mechanical and chemical factors, and is the only process capable of achieving the appropriate microbiological quality for most textiles. The dry process can further decontaminate but less so than washing. Before washing, used textiles may increase in biocontamination, so isolation is key.

A.3 Variations in intended use

This is the most important source of variation affecting laundries' implementation of RABC. Where processed textiles are intended for use in critical environments, with acknowledged potential for impact on the final consumer/patient, the risk profile for the textiles can be high and this should be reflected in the risk analysis and subsequent control measures. By the same reasoning, where textiles' uses are not identified as high risk, risk analysis and subsequent control measures can reduce in scope and degree. The range of

variation is broad and applies in most market sectors where RABC applies. Laundries should carefully identify the intended use of the textiles they process and plan RABC implementation accordingly.

A.4 Variations in market sector

A.4.1 General

Different jurisdictions and market sectors apply varying rules. A laundry implementing RABC should review the requirements and expectations applying locally and incorporate the relevant elements in their RABC system.

A.4.2 Food sector

RABC is highly consistent with the food sector's HACCP model, allowing for a broad range of intended uses and RABC implementation. The main textile product type is workwear, where operators in food processing and retailing wear laundered garments. Cabinet towels can also be used in this sector, for drying staff hands. On return to the laundry, such textiles can be heavily soiled. The cleaning efficiency of the wash process is a significant factor in final decontamination performance. Processed textiles should have a low total bioburden as well as being substantially free from food-related pathogens and spoiling species. Rinse water bioburden is a frequent focus of food sector customers. Operator hand hygiene and dryness of finished garments also frequently receive attention.

A.4.3 Healthcare

As hospitals are particularly concerned with the spread of pathogens from patient to patient and beyond the hospital, laundries should pay particular attention to isolating used from in-process and processed textiles. The focus should be to avoid cross-contamination, directly or indirectly from un-decontaminated textile. This care should extend to surface cleaning and operator hygiene, for plant and transport activities, Specific measures may be required for equipment that is re-used (such as cages). Re-contamination derived from non-healthcare environments should be controlled, but is less significant.

A.4.4 Cleanrooms

Laundries supply textiles for use in operating theatres, manufacturers of medical devices/pharmaceuticals/IT products and to laboratories and other controlled environments. In some instances, the textile can be provided sterile, but in all such cases the processed textiles shall have very low bioburden. RABC is appropriate, and the laundry should consider market or sector specific regulations and ISO/CEN Standards. As the textiles returning to the laundry are generally only lightly soiled, decontamination may not be difficult to achieve, but the rinse water quality is critical, and is often tightly specified for the particular sector involved. Processing after washing usually occurs within a cleanroom or controlled environment to prevent subsequent contamination. Typical control measures include regular hand hygiene, the use of gloves, hermetically sealed packaging. Microbial monitoring of the clean area should be carried out frequently to monitor the effectiveness of clean area contamination controls.

Annex B
(informative)

Examples of prerequisites

B.1 General

This annex provides examples, for considerations when developing a prerequisites programme (PRP). The relevance of individual items, and the standards to which they will require development, follow from the intended use of the textiles, external requirements and from the strategy of the laundry. Requirements and controls are often less strict for General and stricter for Operational prerequisites. Annex D provides an illustration of how and where to apply these considerations in a laundry.

B.2 Premises and structures

— suitability & sufficiency of design, layouts and materials, particularly those in contact with processed textiles;

— segregation, zoning and access facilities;

— staff and plant hygiene facilities;

— water supply, treatment, storage and disposal;

— ventilation system and air flow;

— storage.

B.3 Cleaning

— clearing, cleaning and if necessary disinfecting for key surfaces, using recognised disinfectants;

— order of cleaning (e.g. critical areas 1st, high to low and back to front of surface, back of area to exit);

— standardizing methods (equipment, materials, techniques, schedule, criteria);

— verifying effectiveness.

B.4 Personnel

— hand hygiene, personal hygiene and adornment such as jewellery;

— protective clothing, staff access rules;

— food and drink practices;

— product handling rules;

— staff training and competence;

— medical care and screening.

B.5 Equipment

— processing, transport and cleaning equipment;

— utility equipment;

— measuring and monitoring equipment;

— preventative maintenance, servicing, repair, calibration and cleaning of equipment;

— suitability of equipment and work surfaces for contact with processed textiles (impermeable, washable);

— capability to work within tolerances;

— capability to prevent release or alarm when tolerances are exceeded;

— process all stages of the process, including re-work and transport;

— prevention, limit, reduction, elimination of biocontamination, including re-contamination and cross-contamination;

— parametric controls, failsafes, monitoring, verification, inspection, testing, checklists.

B.6 Foreign bodies and inappropriate materials

— pest control;

— inappropriate materials in contact with processed textiles (eg. rust, uncovered wood);

— unprotected glass and hard plastics.

B.7 Supplies

— suitability of bought in materials and equipment for direct contact with in-process or processed textiles;

— specifications;

— handling and storage measures.

B.8 Monitoring of PRP effectiveness

Possible measures include inspections, regular checklists, good practice audits, system audits, microbiological monitoring, work records, trending and analysis of data etc.

Annex C
(informative)

Examples and guidance for risk assessment

Risk assessment includes analysis and evaluation elements. A RABC team should employ the best expertise available and simple-to-use techniques to enable judgements on the level and the priority for risks related to biocontamination control. Completed risk assessments can then be reviewed for accuracy and sufficiency. Examples shown here are indicative only. Alternatives are available.

Analysis examples

Rate each hazard for **Probability** and for **Severity factors**, using evidence and experience.
Levels – e.g. **a** 4 point scale is used below, **Describe** points on the scale in concrete terms, as below.
Scale **Weighting** – using higher numbers for a factor (as for Severity below) shows the importance ascribed by the risk assessment team.

Probability	**Severity** (at the point of textile end use)
1 – unlikely, rare, < 1/year or < 1 in the life of the textile **2 –** can happen, not frequent, < 1/month **3 –** likely to happen during a week **4 –** likely, frequent, happens most weeks	**1 –** no health impact envisaged **2 –** health impact unlikely/minor, skin irritation **4 –** health impact possible/significant, eg. short illness **8 –** major health impact possible, e.g. permanent health damage

Where it is difficult to assign a value to the rating, **experience and expertise** are most valuable.
Remember, values help to think about **priority**, but a risk score of 2 is **not** exactly ½ of the risk Vs a score of 4.
When risk assessment takes place before a RABC plan is implemented, the result is a "prior" or original risk rating.
When this is done after RABC implementation, the assessment shows "residual" risk rating.

The **risk table** below shows a sample risk assessment.

Evaluation examples

Values are only shortcuts. Use experience. Consider if the results of analysis match the team's judgement.
Identify if controls are required, and if controls qualify as control points (CP) or critical control points (CCP).
Consider if risks are detectable, can they be addressed before product release, should several risks be aggregated.
These considerations can affect decisions on treatment priority. It is sensible to band risks for treatment, e.g.:

Risk band	1 - 4 Low	6 - 12 Medium	16 - 24 High	32 Very High
Risk tolerance:	Tolerate	"ALARP"	Reduce	Do not tolerate

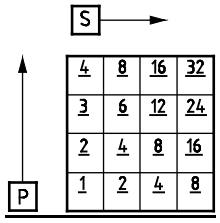
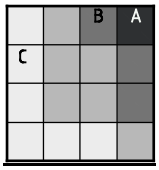
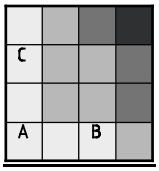
ALARP means "as low as reasonably practical". Reduce means reduce at least by a risk band.

The **risk graph** or "heat map" below shows how a RABC team might visualise the status of individual risks and the overall RABC plan

Risk table examples

Description			Analysis P x S = R			Evaluation	
Step	**Hazard**	**Consequence**	**Probability P**	**Severity S**	**Risk R**	**Control Point Identity**	**Priority**
Wash	**A. Temperature failure**	**failure to decontaminate**	**4**	**8**	**32**	**CCP**	**Very High**
Dry	**B. Not dry**	**Possible biocontaminatio n growth**	**4**	**4**	**16**	**CP**	**High**
Pack	**C. Outside of packaging not cleaned**	**Slight chance of minor contamination**	**3**	**1**	**3**	**N/A**	**Low**

Risk Graph examples – showing sample risk scores and bands for risks A, B and C in above table

Risk scores	Initial risk bands (before control measures)	Residual risk bands (after control measures)
		

Review

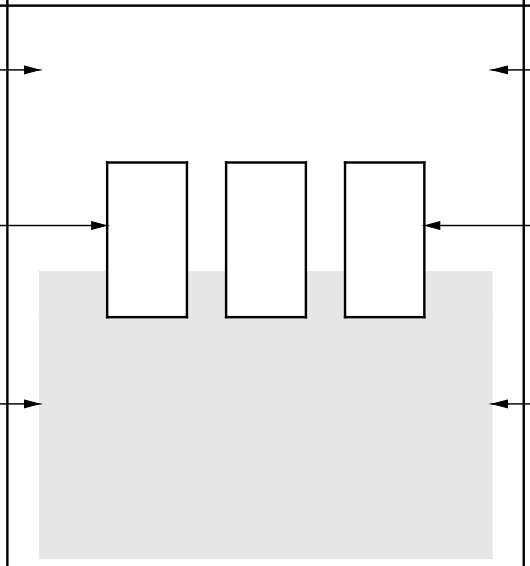
Control measures reduce biocontamination risk to the appropriate level, either singly or in combination. Once they are in place, risk assessment review can assess effectiveness of controls and residual risk, i.e. the treatment priority should reduce, e.g. from “high” to “low”.

Examples of hazards			
Before washing	**Washing**	**Drying through packing**	**Transport**
High contamination levels on incoming textiles Increasing contamination during delay to processing Cross-contamination from other textiles, people, surfaces	Water volumes inadequate Water quality inadequate Detergent delivery failure Temperature not reached Batch not weighed	Cross-contamination of textiles from people/surfaces/other processed textiles Increased contamination from moisture and warmth Air-borne contamination	Product packaging breaks Cross-contamination from people, surfaces Cross-contamination from used textiles Air-borne contamination

Annex D
(informative)

Control concepts illustration

NOTE See Annex B for specific examples.

Process Stages	Plant/Process Illustration	Control Classification	Broad Examples
Isolation, prior to decontamination		**Control Measures** (see Annex B for more examples)	Facility design Transport Staff access Plant cleaning Maintenance
Decontamination (in decontaminating equipment)		**CCPs** (see definition 3.8) **Essential** ✓+ **Effective, sufficient** ✓+ **Final opportunity** ✓	Installation & commissioning Calibration & maintenance Wash programmes Process parameters (see Annex E) Failsafes Process verification
Protection (of decontaminated textiles from re-contamination and cross-contamination, before packing)		**Operational Prerequisite Control Measures including CPs** (see definition, 3.6)	Process parameter controls (e.g. for drying) Inspection (e.g. for dryness) Product-contact surface cleaning & disinfecting Staff hand hygiene Packaging material controls
Protection (of packed textiles for transport & delivery)		**Prerequisite Control Measures**	Packaging materials and cleanliness + as prior to decontamination

Annex E
(informative)

Examples of wash process aspects

The list below is non-exclusive, but identifies parameters and process controls that may deserve attention from laundries when designing monitoring programmes and identifying targets and tolerances for achieving decontamination. This list can be used as a reference for risk analysis and risk control plans and for validation and verification methods.

Tunnel wash equipment	**Batch wash equipment**
Equipment Identity, description	
Programme Identification	
Goods and soiling classification	
Load weight	
Temperature, by stage	
Liquor ratio, by stage/zone	
Water quality – hardness, bioburden	
Identity, nature and volume/mass of dosed wash supplies	
Liquor alkalinity	
Failsafe controls, e.g. temperature, dosage, water, weight	
Cycle time	Time, by stage
	Dip level
Water flow rates, by zone	Water volumes, by stage

Annex F
(informative)

Examples of approaches to process validation for laundries

F.1 General

This annex presents examples of process validation approaches which may be useful to laundries implementing RABC. RABC teams should choose the approach most suitable for the sector they work in and to the intended use of processed textiles (e.g. life cycle model for medical devices, simpler models for lower risk products). Annex A further develops sector-specific concerns and implications of the "intended use".

F.2 Introduction to Process Validation

F.2.1 Overview

This standard describes a risk management system for the assured delivery of textiles that are suitable for their intended use. Process validation is essential to RABC. It is part of principle 6 "system checking procedures" and is implemented during installation of a RABC system, following risk analysis and identification of CCPs. It provides confidence/assurance that the process will produce the intended result time after time. Re-validation at regular intervals ensures that change and variation, whether planned or from natural drift, do not undermine process performance and validation.

F.2.2 Key to terms

In addition to terms and definitions of the standard, the following additional definitions apply to Annex F:

Qualification

An individual study or process challenge conducted as part of a validation plan

Design Qualification (DQ)

The documented verification that the proposed design of the facilities, systems and equipment is suitable for the intended purpose.

Installation Qualification (IQ)

The documented verification that the facilities, systems and equipment, as installed or modified, comply with the approved design and the manufacturer's recommendations.

Operational Qualification (OQ)

The documented verification that the facilities, systems and equipment, as installed or modified, perform as intended throughout the anticipated operating ranges.

Performance Qualification (PQ)

The 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.

Re-validation

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

F.2.3 Process Validation Model for Laundries

A common approach to process validation uses a model (sometimes called the 'life cycle' model, see Figure F.1 below and see Bibliography for references). The model provides a cumulative approach for obtaining proofs of process capability at every stage of process development and at regular intervals during laundry

operation and it illustrates different levels of necessary input of information into the validation step for its assurance. The model also allows laundries to use the results of their risk assessment to control the scope and methods of validation in line with the intended use of the textile being processed and their local circumstances. Laundries can then determine which elements of the validation model to apply in their validation plan. F.3 below presents examples of how laundries might apply this model.

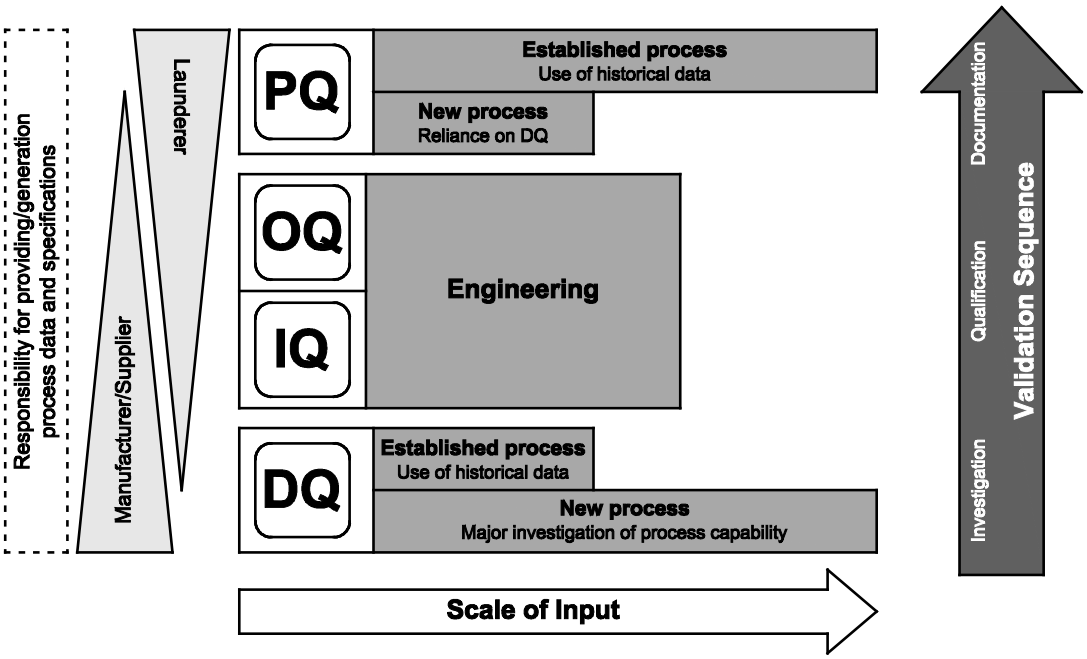


Figure F.1 — Validation model

F.3Considerations for developing validation plans

F.3.1 Prior to validation

The results of risk assessment provide laundries with the basis for determining the scope and stringency of validation to be planned. Consideration of extremes and potential changes is also sensible at this stage, e.g.:

- does the sector or intended use dictate the extent of validation (e.g. The full life cycle model is expected for medical device textiles but not in food or hospitality sectors)?
- what textile or classification presents the toughest challenge to the process?
- which process variation (e.g. wash programme) has the least capability to perform as intended?
- is it possible to vary process parameters but NOT require immediate re-validation?
- what changes to the facility, equipment or process recipes are envisaged in the short to medium term?

For all laundries implementing RABC, the RABC team should identify the processes to be validated and then plan and execute PQ for those processes, demonstrating that they are effective, consistent and robust. This should include regular microbiological process challenges, e.g. to the wash process. The examples below demonstrate some of the variations that can be expected.

F.3.2 Examples

Example 1 – Established and stable process, equipment, facility

Case A – Process and equipment control is well established and documented. Historical data for process and product performance is abundant and clear in demonstrating the current system performs consistently as

intended. **Impact on validation plan** – Data should be included or referenced in risk assessment. Design and execute PQs.

Case B – As in Case A, but where one or more of the elements above is lacking or inadequate

Impact on validation plan – Address weaknesses by implementing the RABC principles and by inclusion in PQs.

Example 2 – Novel process or significant change to process

Where new processes or technology are being introduced, the RABC team can consider all model stages (DQ, IQ, OQ, PQ), securing evidence (e.g. from testing, from suppliers) that the novel element is competent for its intended purpose and is validatable in a laundry environment.

Case A – Where process design remains unchanged, e.g. where equipment is bought in or moved.

Impact on validation plan - Installation (IQ) and commissioning (OQ) should be completed and documented and should demonstrate that the installed system performs as planned.

Case B – Where a novel design, technology or approach is introduced.

Impact on validation plan - DQ should also be completed. The originator or commissioner of the novel element is responsible for delivering the DQ.

F.4Guidance on basic validation elements

F.4.1 General

This section introduces and expands on ideas mentioned above. More developed guidance for these and for other validation options is available (see Bibliography for references).

F.4.2 Use of historical data

Different jurisdictions and/or market sectors have their own guidance and/or regulations with respect to microbiological decontamination processes, indicating the degree and nature of supporting evidence to be supplied. This evidence includes results from process challenges and other (microbiological testing data) collected over a period of time to demonstrate the stability of the process. In the sense of this standard, these results are referred to as historical data.

Where substantial historical data is available (e.g. microbiological testing data and data from process monitoring), the RABC team may determine if the process design and system currently used is adequate, based on review of the available evidence. The review should demonstrate that the key process parameters (e.g. in washing) correlate well with the microbiological quality of the product and should ensure that the alert and action limits which have been set to control the process will function as intended. The need for qualifications can thereby be much reduced.

This approach is well established, for example, with the time-temperature relationship during the thermal disinfection and the activity of real time monitoring of both variables to enable product release - provided key process parameters have been controlled effectively (e.g. load weights, water levels. See Annex E). Insufficient or unavailable historical date may be compensated for by the process microbiological challenge

F.4.3 Performance Qualification (PQ)

This is the element of validation that most laundries will focus on, particularly where historical data is abundant and sufficient. The PQ study challenges the performance of the system as is, demonstrating its current performance, robustness and capability to perform consistently. Data can come from process challenge devices, parametric verification, product testing and other sources. Cumulatively, effective PQs rest on demonstrating that the process as currently specified, including tolerances for key variables, consistently deliver the required performance. See Annex E for examples. Where product testing data is used, a statistically valid sampling plan, adapted to the laundry activity, would be expected, along with evidence of the correlation between biocontamination for textiles before and after decontamination for a given batch.

The scope, method and frequency of PQ is determined by the RABC team, on the basis of the completed risk assessment. Options chosen depend on consideration of the issues developed in this annex. For competent process challenge based PQs, annual re-validation (by repetition of the PQ) is often sufficient. As variation in process, textile and biocontamination level are considerable, the scope and frequency of testing are likely to be significantly increased where data from product testing data is applied.

F.4.4 Operational Qualification (OQ)

Where a system or system element has been installed, an OQ demonstrates that it works as intended, particularly with regard to controls, monitoring and failsafes. See Annex E for examples. It is important to ensure performance across the normal operation range for each parameter, e.g. accuracy of water volumes, weigh scales, temperature gauges.

F.4.5 Installation Qualification (IQ)

Where a system or system element is being introduced, an IQ demonstrates that the correct element is in place and that it has been correctly integrated into the laundry. See Annex E for examples. It is important to ensure that specification and functions are present, connected and operating as intended, e.g. temperature gauges, switches, supplies.

F.4.6 Design Qualification (DQ)

The originator or commissioner is responsible for DQ. In most laundry contexts, this relates to the provider of the novel element(s) of the proposed processing system. The resulting DQ should comprise a technically disciplined investigation identifying key process variables, using scientifically justifiable methods and providing tolerances (and evidence in support of these) within which the process is to be operated. Operation with those tolerances should assure release of product suitable for its intended use (see also experimental design approach in F.5.2). Laboratory investigations and laundry field trials contribute largely to the DQ. The DQ should generate and present to the laundry enough data to enable a simple PQ.

F.5Guidance on more developed validation elements

F.5.1 Worst case challenge

The worst case challenge is an approach for planning a qualification at any stage in the validation process (i.e. from DQ to PQ). The intent is to look at the limits of how the laundry plant/line operates and to identify a performance window. The laundry then tests process performance at the limits of that window. Where testing proves that the system performs as intended at the limits then laundries can vary process operation within the window without triggering re-validation. With methodical and systematic planning, a cost effective and practical validation plan can be developed, e.g. one study to qualify all wash processes on a machine.

It is particularly useful where historical data is clearly inadequate and, implicitly, for innovative processes. It combines local experience, equipment and methods with the detailed knowledge gained by suppliers whilst conducting the process DQ. If the process is stable and reliable, the tolerances will be large enough for the laundry to carry out worst case trials within the tolerances and so avoid producing non-compliant textiles or lose production time. The process parameters should be identified and given as prerequisites by the RABC team.

For example a wash process PQ could be designed with reduced time, temperature, liquor ratio and increased load weight. Process performance could be challenged by use of bio-indicators including inoculated textiles.

Worst case challenge tests may need to be replicated in order to increase confidence that the process delivers the desired results in a repeatable way.

F.5.2 Experimental Design

In certain cases, statistical experimental design (ED) techniques may be used to conduct DQ investigations where process validation is essential.

It offers an approach for the development of innovative processes and has, by providing a high standard of evidence, the considerable advantage of leading directly to a compliant process validation.

The ED approach identifies the statistically significant key process variables, quantifies their contribution to the required decontamination capability, reveals otherwise undetected process variable interactions, provides guidance for future process development and allows confident calculation of safety margins (tolerances) for key variables in order to sustain the intended result.

F.6Parametric release

In order to release a product from a specified process, the laundry needs assurance that the product was processed within the tolerances established for the PQ.

For processes where a parametric release specification is agreed, it may be possible to programme equipment to automatically prevent product release until or unless agreed process parameters have been achieved. Other release regimes, such as positive release based on batch data may also be possible. In these circumstances the effectiveness of automatic controls should be confirmed as part of the validation.

Where this is verified by the laundry for each batch, and/or is automated by equipment/software, laundries can demonstrate ongoing process control and can release product on this basis. This practice is known as parametric release.

Annex G
(informative)

Synopsis of EN ISO 9001:2008 and EN 14065:2016

This synopsis provides information about linkages/cross-references between EN ISO 9001:2008 and EN 14065:2016, where a RABC system is intended to be integrated into / aligned with a quality management system. As the scope and purpose of the two standards is different, the links illustrated here are approximate and are not exhaustive.

Even though EN ISO 9001:2015 was published in September 2015, EN ISO 9001:2008 will remain the reference standard for certified quality management systems for some time to come. Auditing to EN ISO 9001:2008 will remain possible through a certificate validity period which may individually run for up to 3 years (i.e. up to September 2018). CEN/TC 248/WG 17 therefore judged EN ISO 9001:2008 to be the more useful comparator for EN 14065:2016.

Paragraph	Title	EN ISO 9001:2008 (Reference Standard)	EN 14065:2016
0	Introduction	0.1 General 0.2 Process approach 0.3 Relationship with EN ISO 9004:2009 0.4 Compatibility with other management systems	dto
1	Scope	1 Scope 1.1 General 1.2 Application	dto.
2	Normative references	dto.	dto.
3	Terms & definitions	dto.	dto.
4	Quality management system	4 Quality management system 4.1 General requirements	4 General Principles and requirements 4.1 Principles and framework

		4.2 Documentation requirements 4.2.1 General 4.2.2 Quality manual 4.2.3 Control of documents 4.2.4 Control of records	4.2 General requirements 5 Alignment with a quality management system
5	Management responsibility	5 Management responsibility 5.1 Management commitment 5.2 Customer focus 5.3 Quality policy 5.4 Planning 5.4.1 Quality objectives 5.4.2 Quality management system planning 5.5 Responsibility, authority and communication 5.5.1 Responsibility and authority 5.5.2 Management representative 5.5.3 Internal communication 5.6 Management review 5.6.1 General 5.6.2 Review input 5.6.3 Review output	6 Application of the Risk Analysis and Biocontamination Control system to laundries 6.2 Prerequisites and preliminary actions for establishing an RABC system 6.2.1 Management commitment
6	Resource management	6 Resource management 6.1 Provision of resources 6.2 Human resources 6.2.1 General 6.2.2 Competence, training and awareness 6.3 Infrastructure 6.4 Work environment	6.2.2 Constitution of the RABC team
7	Product	7 Product realization	6.2.3 Prerequisites programme (PRP)

	realization	7.1 Planning of product realization 7.2 Customer-related processes 7.2.1 Determination of requirements related to the product 7.2.2 Review of requirements related to the product 7.2.3 Customer communication 7.3 Design and development 7.3.1 Design and development planning 7.3.2 Design and development inputs 7.3.3 Design and development outputs 7.3.4 Design and development review 7.3.5 Design and development verification 7.3.6 Design and development validation 7.3.7 Control of design and development changes 7.4 Purchasing 7.4.1 Purchasing process 7.4.2 Purchasing information 7.4.3 Verification of purchased product 7.5 Production and service provision 7.5.1 Control of production and service provision 7.5.2 Validation of processes for production and service provision 7.5.3 Identification and traceability 7.5.4 Customer property 7.5.5 Preservation of product 7.6 Control of monitoring and measuring equipment	6.2.3.2 General prerequisites 6.2.3.3 Operational prerequisites 6.2.4 Determination of the intended end use of the textile 6.2.5 Preparation of laundry flow diagram(s) 6.2.6 Process specification 6.2.7 Training awareness and competency 6.2.8 Purchasing information 6.3 Application of the seven principles for implementing the RABC system 6.3.2 Principle 1: List of microbiological hazards and list of control measures 6.3.2.1 Identification of the hazard(s) associated with the environment, process or product 6.3.2.2 Assessment of textile biocontamination risks 6.3.2.3 Identification of control measures 6.3.3 Principle 2: Determine the Critical Control Points (CCPs) and Control Points (CPs) 6.3.4 Principle 3: Establish the target levels and tolerance limits for each CCP 6.3.5 Principle 4: Establish a monitoring programme for each CCP 6.3.6 Principle 5: Establish corrective actions 6.3.7 Principle 6: Establish the RABC system checking procedures 6.3.7.1 Validation and revalidation of the laundry process 6.3.7.1.2 General 6.3.7.1.3 Microbial reduction
8	Measurement, analysis and improvement	8 Measurement, analysis and improvement 8.1 General 8.2 Monitoring and measurement 8.2.1 Customer satisfaction 8.2.2 Internal audit 8.2.3 Monitoring and measurement of processes	6.3.7.2 Review of the RABC system 6.3.7.3 Internal audit 6.3.8 Principle 7: Establish a documentation system

		8.2.4 Monitoring and measurement of product 8.3 Control of nonconforming product 8.4 Analysis of data 8.5 Improvement 8.5.1 Continual improvement 8.5.2 Corrective action 8.5.3 Preventive action	
	Annexes	-	Informative Annexes A to G – these annexes have no direct counterparts in EN ISO 9001

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BSI Group Headquarters

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