Implementation of

Risk Analysis and Biocontamination Control

(RABC) in Laundries

The TSA Guide to BS EN 14065

Published by:

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Introduction

Purpose of the guide

This guide is intended to assist laundry management to successfully implement a Risk Analysis & Biocontamination Control (RABC) Plan based on the standard BS EN 14065. The aim of any RABC Plan must be to assure the microbiological quality and thereby product safety of processed textiles.

RABC is simple shorthand for this approach. This guide sets out to provide the same for the standard, by developing, clarifying, detailing, interpreting and recommending key elements and options that face laundry management as the RABC plan takes shape.

Laundry management who intend to implement RABC should purchase a copy of BS EN 14065 and study it side by side with this document throughout the project. The standard "requires", the guide "recommends". Where the guide uses direct language, this serves simply to emphasize and simplify guidance.

Implementing RABC is an iterative process. Users cannot avoid this aspect, but the guide sets out to separate and develop the steps of the process. In particular…

- Sections 1-3 of both documents are for reference.
- During RABC implementation, users should focus on section 4 (with some attention to section 5) ***before*** addressing section 6 of both standard and guide. The guide makes this explicit and offers a path to implementation.
- The appendices to the guide include technical interpretations and detailed, proven recommendations for key aspects of a RABC Plan.

While primarily written for laundry management, this guide also serves as a platform for customer and market specific agreements and for 3rd party certification. The guide should thereby serve as a tool for process improvement, marketing and compliance. As a reference, it can stand with BS EN 14065 alone or in combination with other requirements/guidance (e.g. HTM-01-04 for services to Healthcare).

Context for the standard and the guide

The development of BS EN 14065 reflected an outstanding co-operative effort across the European laundry industry. Distinct and diverse models gave way to a common approach. The resulting standard gives the laundry industry an internationally recognised platform to develop and prove the capability to deliver laundered textiles with appropriate microbiological qualities, tailored to specific customers, sectors or jurisdictions.

Before microbiological quality is considered, other characteristics are central to successful laundering. Customers demand textiles to be visibly clean, free from stains and correctly dried or ironed; they must also be pleasant to the touch and fragrant or at least free from any unpleasant odours. In achieving these properties, laundering (particularly the wash stage) also disinfects, leading to low probability of survival for most micro-organisms.

The BS EN 14065 standard builds on this foundation, providing users with an approach (RABC) to assure consistently effective disinfection in the laundering process and reliable protection thereafter from recontamination. The standard fully describes the RABC approach, but it cannot provide for every laundry/market variable and leaves specification of process and product performance to local jurisdictions and/or industries.

The guide is more specific than the standard, and provides tools and techniques that will support achievement of a "Successful RABC Plan". Success in this context means that a laundry…

- has a fully documented and implemented plan
- can prove that the plan and facilities in place can consistently assure appropriate and/or agreed product safety
- is ready for certification to the standard BS EN 14065.

To this end the following themes receive particular attention throughout the guide:

- RABC as a plan
- Documenting RABC
- 3rd party certification
- RABC and other standards
- Alignment with other systems
- Meeting customer requirements
- Prerequisites
- Validation

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1 Scope of BS EN 14065

The standard particularly highlights the following market sectors as relying on assured levels of microbiological quality for processed textiles. The RABC approach may be applicable elsewhere, but this is not explicitly addressed in the standard.

- Healthcare providers
- Food processing, retailing
- Pharmaceuticals
- Medical Devices
- Cosmetics

Note that a RABC Plan must be specific – to a laundry site, to market/product categories and to achieve targeted, agreed levels of product safety.

2 References

Background

This guide is intended to assist laundry management teams to implement RABC. The reference standard for RABC throughout this guide is BS EN 14065:2002, Textiles – Laundry Processed Textiles – Biocontamination Control System.

Guidance

Users can implement RABC independently of other standards, but the RABC standard was written to be used with complementary structures and/or legal requirements that exist or are being developed throughout Europe.

Laundry management should establish what requirements, structures and factors apply in their unique circumstances. This should take place before and during Implementation. Accounting adequately for these factors is a prerequisite for a successful, effective RABC Plan. Often, going to original sources and directly to customers can be essential for fully identifying and developing those requirements. The requirements identified in this process should be included in the RABC plan (see sample documentation, Appendix A).

One factor to assess is the expectation that Customers and Auditors can and will look for the product and process standards that apply in their sector, or for strong supporting evidence justifying different standards where this is not the case.

Note: Different market sectors use specific labels for their approach to assuring product safety. Laundry management can introduce the idea of RABC by demonstrating its equivalence to these approaches:

- HACCP - Hazard Analysis, Critical Control Points, used in the Food industry.
- GMP – Good Manufacturing Practice, used in Pharmaceutical and Medical Device manufacturing sectors
- Infection Control – used by Healthcare providers.

Some familiarity with the above approaches is helpful for ensuring the final results are appropriate to a laundry's unique situation, and for communicating this to the customers and sectors involved.

The reference list below is intended as a starting point for the assessment noted above. It includes the most relevant reference resources for the UK, but is not all inclusive. As well as early research, these references may also be used to resolve specific issues, where interpretation or examples can direct development or clear up areas of doubt, e.g.:

- What constitutes a laundry prerequisite for us?
- What risk control measures might be appropriate in this situation?
- What process controls might achieve a given microbiological quality?
- What level of microbiological quality is appropriate for this product, when used as intended?

Reference (title, name, date of issue)	Comment (Relevance)
Food Hygiene Regulations Regulation (EC) 852/2004 (also regs 853, 854 of 2004)	EU regulations become national law in each member country, setting out the legal requirements for food processing and handling sectors, including the requirement to implement HACCP. This converts to customer pressure for laundries to implement HACCP or equivalent systems. Available online via: http://eur-lex.europa.eu/en/index.htm
BS EN ISO 9001:2000, Quality Management Systems – Requirements	Most quality management systems are based on this standard. RABC can be integrated into an existing Quality Management System. RABC documentation and redundancy can be minimised by this approach. Document control as required for ISO will also be required by 3rd parties for RABC certification.
BS EN ISO 22000:2005, Food Safety Management Systems – Requirements for any organisation in the food chain	The 7 principles of RABC system are the same as those used in ISO 22000 and other HACCP standards (Hazard Analysis & Critical Control Points). Food processors often apply this standard, and will therefore use its terminology when specifying requirements to laundry providers.
TSA Guidelines for the Provision of Workwear to the Food Industry FCRA monograph on "Laundering Workwear for the High Care Sector of the Food Industry"	These two documents were produced by the Laundry Industry, and develop the ideas of prerequisites and risk analysis beyond that given in EN 14065. Each step of the laundry process is considered, as are different categories of equipment. The FCRA document gives the most detailed examples, spells out the critical risk assessment issues and discusses useful "process and environmental control" solutions (e.g. Laundry design options, issues relevant to particular machine types or particular products).
Department of Health's Healthcare Technical Memorandum	This guidance document will deal with all aspects of the laundry arrangements for used and infective healthcare textiles. It will have legal status through its relationship with the Health Act (2007) and the enforcing authority will be the Health Care Commission. It will also be referenced in NHS linen service contracts.

HTM 01-04 [in development to replace HSG(95)18]	
BS EN 13569:2001, Cabinet Towels – Performance Requirements and Processing	This standard refers to one product type only. The annexes include some useful guidance on laundry process controls and validation elements.
BS ISO 14644-1:1999 Cleanrooms… - Classification of air cleanliness	This standard distinguishes among controlled environments in terms of the maximum allowable levels of particulates of given sizes (i.e. More control = fewer and smaller particles allowed). Part 1 (quoted), lists the classes and sets the limits. Parts 2 – 8 detail other aspects of cleanrooms.
BS EN ISO 14698-1 Cleanrooms and associated controlled environments – biocontaminati on control	This standard sets out a RABC approach. BS EN 14065 is based on this approach. Appendix E also offers a technique for validating laundry processes.
EU Guide to GMP for medicinal products	Analogous to HACCP for food sector, often more detailed and prescriptive. Particularly relevant for guidance on validation (Annex 15 – Qualification and validation). Available online at: http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol4_en.htm
FDA Guideline on General Principles of Process Validation	Developed for the pharmaceutical and medicinal sectors as a model for greater assuring product safety. Predecessor to EU GMP guidance and prime reference for validation text in this document. Available online at: www.fda.gov/CDER/GUIDANCE/pv.htm

3. Definitions used in BS EN 14065

The terms and definitions from section 3 of the standard are reproduced here without alteration, but with the addition of several new items (identified with "*" in the table below).

Term	Description/Explanation
Action level	Established level of a CP monitoring variable set by the RABC team at which remedial procedures are activated to bring the laundry process back into control
Alert level	Established level of a CP monitoring variable set by the RABC team giving early warning of a change from normal conditions
*** Bioburden**	The assessed level of biocontamination on a given item or set of items.
Bio-contamination	Contamination with viable micro-organisms
***Calibration**	Demonstration that a particular instrument or device produces results within specific limits by comparison with those produced by a reference standard over a relevant range of measurement.
Control measure	the action or procedure required to control a bio-contamination risk
Control point (CP)	Any point or step in a process at which control is applied in order to contain, eliminate or reduce bio-contamination risk
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
*** Decontamination**	Reduction of bioburden by an appropriate degree.
*** Disinfection**	As for decontamination. The target for the purposes of this guide is 5 log reduction of bioburden for named organisms. This implies that the reduction will not be 100% because the process is not sterilisation; the preferred term is 'disinfecting process'
Flow diagram (or process map)	Graphical representation of all the steps in the process

Hazard	In the context of this standard, any element or factor that may adversely affect the achievement of the agreed microbiological quality of textiles
Laundry	Plant where soiled/used textiles are given an appropriate series of processes, e.g. washing, drying/finishing, ironing folding and packing, in order to deliver these articles fit for reuse
Laundering cycle	All or a combination of the following operations carried out firstly in a machine, in an aqueous medium; wetting out, preliminary washing, washing, bleaching, rinsing, neutralisation followed by extraction then drying, finishing, folding, packing
Microbiological quality of textiles	The number and if required types of micro-organisms present on textiles. NOTE: The intended end-use will determine the agreed level of microbiological quality
Monitoring programme	The identification of the variables to be monitored at the control points, together with the frequency of observation
*** Prerequisites**	Elements of good manufacturing practices for laundering as a prior condition for the implementation of the RABC Plan
Processed textiles	Textiles which have undergone a laundry cycle
*** Product safety**	Processed textiles must achieve the "agreed and appropriate microbiological quality" and other supporting characteristics: visible cleanliness, dryness to the touch. The process must protect these characteristics to the point of use or where control passes to another party by agreement.
RABC logbook	Chronicle of all monitoring data, observations and actions taken and their consequences
RABC manual	Record of all the administrative and implementation documentation for the RABC system

*** Recontamination**	Increase in the number of micro-organisms on a textile item; these may be original species or species introduced from the laundry environment. The level of recontamination might exceed the microbiological quality required by the user.
Risk	Likelihood of a harmful effect occurring as a consequence of a hazard
Risk analysis	Investigation of available information to identify hazards and to estimate the consequential risks
Risk Analysis and Bio-contamination Control System (RABC system)	Quality management system with an additional risk analysis for the control of risks of bio-contamination of laundry processed textiles
Target level	Defined level for the variables which shall be monitored at the control points
*** Validation (Re-)**	Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes.
Viable micro-organisms	Isolated, naturally occurring or accumulated micro-organisms capable of multiplying to produce demonstrable growth
Washing supplies	Products used in the machine during washing to assist the removal of soiling and stains and keep them in suspension in an aqueous medium. These include in particular soaps and surface-active agents, complexing agents, alkaline products and bleaching agents

4 Prerequisites and General Principles

Background

Section 4 of EN 14065 presents the RABC principles, without much elaboration. The importance of this section for implementation is simply that RABC team members must understand the principles and be competent to implement them.

Prerequisites are introduced and developed in the standard (see sections 4 and 6.1). Annex A of the standard also includes a sample set of prerequisites to address. The standard does not do the following:

- emphasise how important prerequisites are,
- instruct users to address prerequisites first.
- guide users in "how to" address prerequisites

The most basic error in RABC implementation is to rush prerequisites. This leads to poor or inadequate facilities, staff practices, product handling and process controls. In this case, no level of risk analysis will deliver the targeted level of product safety. The Laundry must maintain all of the characteristics of product safety either to the point of use or to the point of hand over to the user's responsibility. Prerequisites must be adequate to provide for this at every step of the process.

Guidance

Key guidelines follow for establishing a RABC plan. This is intended as a checklist to be used repeatedly during implementation:

- The full RABC team should undergo formal training in RABC or HACCP and/or bring in and retain this expertise throughout the implementation.
- Implementing RABC should be treated as a project. Produce the plan and manage progress against that plan, using standard RABC documents wherever possible. Sample documents are given in this guide's appendices.
- Fully investigate and document the prerequisites at the start of the project, before implementing the 7 RABC principles.
- This is the stage where the team needs to fully investigate the reference materials (see section 2 above) and bring to bear the available expertise (e.g. HACCP, microbiological, laundry technology). The facilities, equipment, process controls and practices must be adequate before RABC can be successfully implemented.
- Re-visit prerequisites after several months, when necessary changes to facilities and/or practices are complete. Significant changes may be required to enable consistent product safety.
- Map the full laundry/delivery cycle(s). The maps must be detailed and must take account of all significant process variations for relevant textiles.
- Address the 7 principles (see section 6 of the standard and this guide).
- Review the full RABC plan for effectiveness, document the review and revise the RABC plan as necessary. Repetition of the steps is essential to this process. With each iteration, the RABC system should become more useful and effective.
- For external certification, it is essential that document control is applied to the RABC system. ISO 9001 is a good resource and model for this consideration.
- For other items above, the laundry industry documents included in this guide's references are useful resources (particularly regarding prerequisites).

5 Alignment

Background

Implementation of EN 14065 need not result in duplicate management systems (e.g. 1 for Quality, 1 for RABC). Managing and documenting RABC should be effective and efficient for the organisation. The methods chosen and the final result should reflect a specific laundry's market, resources and existing systems.

Guidance

One useful way to view RABC is as a quality plan within a Quality Management System (QMS). The RABC plan should - in this view - document the requirements of BS EN 14065 fully, but often a reference in RABC documents to existing QMS documents or records is sufficient.

e.g. Some laundries have 10s, even 100s of wash processes. They may all be vital to the RABC plan, but duplication of the programmes may serve no purpose. Each one must be documented and controlled by management. Results of processing, and monitoring of processes, must also be recorded. These documents and records must be referenced in the RABC documentation, but can be held separately, without need for duplication.

Sample RABC documents for items with an asterisk (*) below are given in the appendices to this guide. RABC teams can use these as templates or models to produce a complete RABC plan:

1 RABC file with…

- Project Plan (introduction, timeline, resources etc.)
- Prerequisites Document *
- Process Maps *
- Risk Analyses *
- Risk control Plans *
- Validation records
- Records of regular "RABC Plan" reviews

All other documents and records required could remain as part of the QMS or other local systems.

It remains essential that the RABC team explain (in the RABC plan and the QMS) the relationships between the two systems, and how this is presented in the documentation.

6. Application of the RABC system

Background

Section 6 is the core of BS EN 14065, where the requirements are set out and developed. This is the checklist which assessors and customers alike will use to judge a RABC Plan. The RABC team must satisfy these requirements. The standard does not however prescribe performance levels, test methods, microbiological qualities. In most jurisdictions, these are specified through national and/or industry specific structures. Individual contracts or sector specific arrangements also commonly address these concerns.

As almost all of section 6 is "required" rather than "suggested" it can be difficult for a user to judge the relative importance of the RABC elements, and to choose among several paths to successful implementation (i.e. consistent microbiological quality, 3rd party certification, customer satisfaction as appropriate).

Guidance

As mentioned above, there can be doubt over what levels are acceptable, and often several options may be available for developing a RABC plan. The table and discussions below link each element of section 6 in BS EN 14065 to recommendations on priorities, appropriate levels, methods and qualities. The recommendations are developed in greater detail in the appendices to this guide. While these recommendations should be useful and sufficient in most cases, research by the RABC team and reference to individual customers or sectors may be necessary to support choices made in individual implementations.

EN 14065 Reference	Title	Recommendations
Prerequisites and preliminary actions This stage of the project should deliver an environment, equipment, process controls and other practices that are capable of delivering the targeted microbiological qualities, subject to further fine tuning, testing, proving etc. NB For each element below, consider the full laundry/delivery cycle.		
6.1.1	Management commitment	Reviews should be normally held at least annually, involving senior management.
6.1.2	RABC team	Expertise in microbiology and HACCP/RABC implementation should be available to the team throughout implementation and operation. This is most important for making product or process safety decisions - on risks, levels, test methods, microbiological qualities in particular.

6.1.3	Facilities etc.	As section 4 of this guide advises, this is a critical element, easy to under emphasize. Consider all examples given in Annex B of the standard and refer to laundry industry guidance. Document fully (see sample form given in Appendix A). Quarterly monitoring of environmental and processed textile bioburden is an appropriate schedule for assessing the adequacy of prerequisite measures. See sample given in Appendix A of this guide.
6.1.4	Intended use	Intended use determines what microbiological level is appropriate and can affect every other decision in RABC implementation. The uses should be agreed with customers and reflected in the service +/or sector agreements. The RABC team should record the uses within the RABC plan – at least for each category of goods and for each market sector. Intended use can be recorded on process maps or in the introduction to the plan.
6.1.5	Process Diagrams (or Maps)	Consider and map separately by product category/ market sector. Completed maps should account for each significant variation in processing. Details can be accounted for by reference to other QMS documents/records. See sample given in Appendix A of this guide. NB QMS = Quality Management System
6.1.6	Specification	Each process specification can be seen as consisting of the "map" + "QMS procedures" + "wash programme" + "other process parameters" specific to each category of goods. As section 5 of the guide outlines, the RABC plan can refer out to other documentation as appropriate.
6.1.7	Training	Laundry and distribution staff should be trained in Basic Hygiene and/or Good Manufacturing Practice. The level of training should reflect the type of work being done and the goods being handled.
6.1.8	Purchasing	This relates mainly to textiles, wash and packaging materials.

Application of the seven principles
When the project is in progress and the foundations are in place, the 7 RABC principles must be addressed to assure consistency and control is adequate and to prove this performance to customers and 3rd parties.
NB – for each element, consider the full laundry/delivery cycle.

6.2.1	List hazards and controls	The technique of Hazard & Risk analysis is central to RABC implementation. It is introduced in discussion (i) below, and expanded in appendix B. Individual RABC plans should follow this model as closely as practical. A sample document/form is given in Appendix A. A sample risk analysis is given in appendix C.
6.2.2	Control Points	It is essential to prioritize, and focus attention on the most important steps in the process. This guide recommends that CPs be named and Risk Control Plans be developed only for Critical Control Points. i.e. Where there is a capability to greatly reduce a significant risk and where subsequent processing cannot identify failures or reproduce the risk reduction. Other controls and measures will be required, but will be less critical. These can be included in the site QMS and referenced in the RABC Plan as necessary. See sample Risk Control Plan document given in Appendix A.
6.2.3	Target levels and limits	Intermediate process parameters can be set by laundry management. Final product and process quality levels should take account of customer/sectoral expectations. Some categories are subject to international standards (e.g. OR textiles, ref. EN 13795). This guide recommends a minimum performance level for disinfection capability (see section 3 – definition for disinfection. Also, section 2 – reference to ISO 14698).
6.2.4	Monitoring	The standard is very clear here. Competence in process control is necessary for effective monitoring. Alignment with an existing QMS is an effective option. Using a “traffic lights” colour code for results can simplify the process I.e. AOK Alert Action.
6.2.5	Corrective actions	Again, the standard is very clear here. Actions should be timely and should be assessed for effectiveness.
6.2.6	System checking	As with prerequisites, it is easy to under emphasize this element. It is critical for a successful RABC plan. For the review and audit requirements, alignment with a QMS is a sensible option. Validation should take account of discussion (ii) below and should follow the model presented in appendix D or some well established alternative.

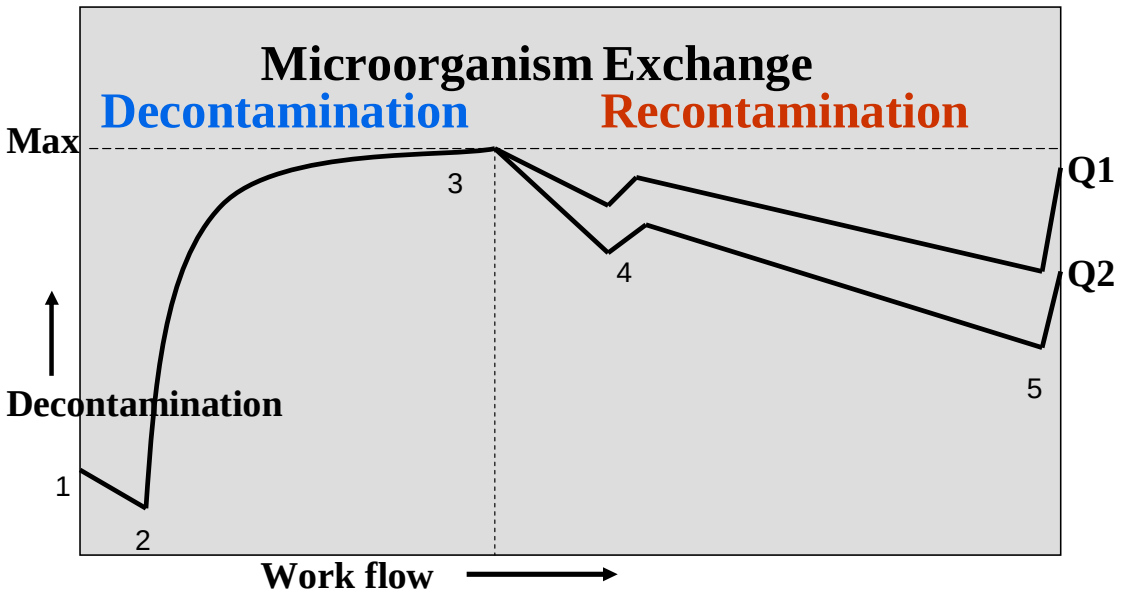
		Verification (e.g. product testing) is not sufficient for certification or to prove process capability.
6.2.7	Documentation	The phrasing of this paragraph can lead to confusion and redundancy in documentation. Sections 4 and 5 of this guide provide a path to ensuring the RABC plan is well documented. The RABC files should then include a section explaining how it deals with the requirements of 6.2.7. This is expanded on in discussion (iii) below.

Discussions

(i) Hazards & Risk Analysis

Soiled items must be considered contaminated. Laundering must decontaminate and thereafter protect the goods from recontamination. At each stage of the process the RABC team must effectively control for the hazards and risks of failure in either regard. Figure 1 below is a schematic of this scenario, which is useful for considering the levels and types of risk for consideration.

Figure 1. Decontamination during laundering



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Notes on Figure 1
1 – soiled receipt
2 – delay before washing
3 – end point of main wash process, before rinsing
4 – end point of drying process
5 – completion of packaging
Q1 and Q2 – different quality (microbial) levels, from variation in process and product

Further comments:

- Rinsing can continue improvement or can recontaminate the laundry (e.g. quality of water)
- Packaged goods can continue to support some microbial growth if not sufficiently dry.
- In the absence of moisture at this stage, overall microbiological quality is likely to improve over time to "Q" – the quality at time of use.

The RABC team must ensure that all steps of the process and all potential risks are addressed in the plan. Figure 2 below is intended as a visual aide to assist the team in this process.

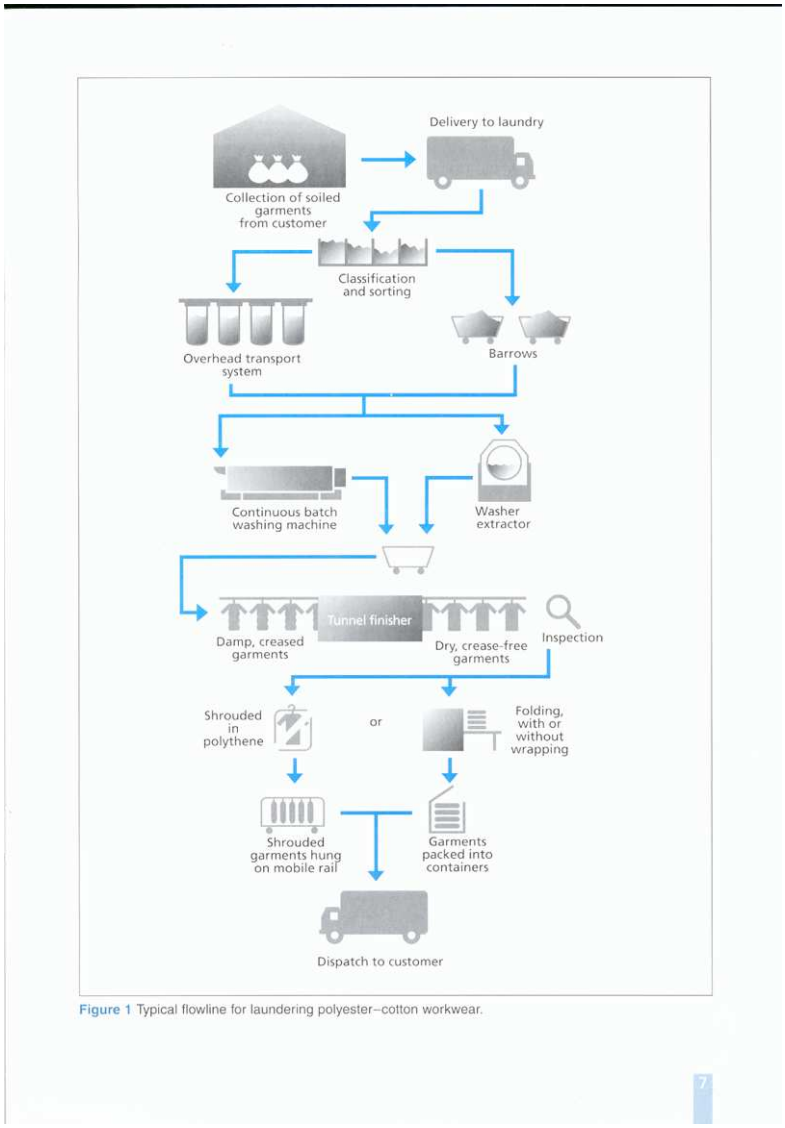

Figure 1 Typical flowline for laundering polyester–cotton workwear.

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The technique used by the RABC team when considering and documenting these issues is called "Hazard & Risk Analysis". In the standard, this is broken down to 3 steps:

1. Identify (and list) the hazards
2. Classify (and record) the risks
3. Identify (and record) the control measures

Appendix B of this guide gives a fully developed method for this step in the process.
The key is to be detailed and thorough, and to establish decisions based on data and well founded experience. To achieve certification, or to consistently achieve targeted microbiological qualities, these decisions must be sound.

(ii) Validation

The primary purpose of validation in a RABC plan is to produce and document evidence that the current local processes can consistently reproduce the intended result. The proof should be sufficient to satisfy customers, sectors and 3rd party certifiers. The intended result should be "processed textiles that are safe for their intended use". Well designed validations can go on to identify and rank factors that affect the intended result, thereby enabling the RABC team to confirm a monitoring programme and set action and alert levels..

The RABC team should plan the local "process validations" in a simple, effective manner.
Providing for such an approach is a challenge, as BS EN 14065 provides no guidance in this matter. Most European jurisdictions address this gap through local arrangements such as national standards or codes of practice. This is not the case in the UK.

This guide therefore sets out to bridge the gap, with a definition of validation given in section 3 above, some background notes for "process validation as part of a RABC Plan" below and a detailed recommendation in appendix D. The approach here is to adapt the model most acceptable to customers/sectors served by laundries and to the 3rd party certifying the RABC plan. The validation model presented here comes from the Pharmaceutical and Medical Device sectors. It is called the "life cycle" model. These sectors, and the 3rd party certifiers, base their understanding of validation on guidance from the EU and from the U.S. Federal Drug Administration (FDA) on "Good Manufacturing Practice for Pharmaceuticals and Cosmetics sectors". Full references for this guidance are given in section 2 of this guide.

The RABC team should review the available guidance and then put together a "validation master plan" covering the key laundry processes. The plan should set out to capture evidence that those processes are built and used effectively. The individual "captures" of evidence are called qualifications. This leads to the phrase "**I**Q, **O**Q, **P**Q" for capturing the evidence at key life cycle steps - **I**nstallation (of individual machines and/or programmes), 1st **O**peration and ongoing use (**P**erformance). The techniques for capturing the evidence are generally simple and already in use by laundry management (eg. checklists, testpieces, calibration), but they must be assembled and presented carefully, so that there are no significant gaps in the evidence trail. The RABC Team may find that specialist expertise is required– for training the RABC team, for initial documentation or for designing particular qualifications.

Appendix D expands on the brief description above, with practical advice on how to put together a validation plan and how to qualify individual processes. Before being immersed in the topic, one example may be useful. The most important, most familiar process in the laundry is the wash process. Qualifying a wash process means (at least!)…establishing that the machinery (e.g. extractors, water pumps) and inputs (e.g. water, detergent) are installed (**I**Q), then commissioned (**O**Q) so that wash programmes will run as designed (e.g. time, temperature within defined tolerances).Then the wash programme should be challenged (**P**Q) to show that the results (e.g. disinfection) are reliably as intended.

Note: The RABC team may also have an opportunity (or may need) to aim higher with qualifications. Carefully designed qualifications can aid in designing a process, or allow for subsequent variations in some inputs (e.g. to reduce cost or to improve stain removal). This prospect is also developed to a degree in appendix D.

(iii) RABC Manual

BS EN 14065 calls for a RABC manual, but also specifically allows for alignment with an existing Quality Management System (QMS), wherein the details required by a "RABC Manual" should be well represented. This arrangement may also be subject to audit as part of an ISO 9001 certification.

In this situation, different documentation arrangements are likely to suit individual laundries, and this should be allowed for by the RABC team and by 3rd party assessors.

Section 5 of this guide outlines one established method of documenting a RABC plan.
Appendix A presents examples of such documents.
The following notes support this option by suggesting how to align this arrangement with section 6.2.7 of the standard:

- The RABC files, as indicated in section 5 of this guide, form the "RABC manual".
- Each requirement detailed in section 6 of the standard for documents +/or records should be reflected in this file, in one or more of the standard RABC documents.
- The "introduction" or "project plan" document should outline how the team interprets "manual", "logbook", "review minutes" (i.e. where, when and why the RABC files refer out to other QMS documents).
- The methods used by a RABC team to address sections 6.1.1 to 6.1.8 should be recorded in one or more of the following:
    - Introduction/project plan
    - Prerequisites schedule
    - Process maps
- The elements called for by sections 6.2.1 to 6.2.7 in the standard should be listed in the Risk Analysis and Risk control Plan documents, but the records may be held as part of the QMS (e.g. Documentation of corrective actions, validation protocols and reports, logsheets, audit reports).

Appendix A Documentation - Samples

Document samples for a RABC Plan include:

A1. Introduction
A2. Prerequisites
A3. Process Maps
A4. Risk Analysis
A5. Risk control Plan

Notes

The RABC team should authorise and issue each document

A1. RABC Plan – Introduction

Note: This document has no set format, but should address…

- **Purpose (of the site specific RABC Plan)**
- **Scope (of operations of the site and of the RABC plan)**
- **Intended Uses (for laundered textiles)**
- **References (specific to this RABC Plan)**
- **Project plan (time line, resources etc.)**
- **Team Members & responsibilities**
- **Managing the RABC Plan**
- **Alignment with the Quality Management System**
- **RABC plan – contents (refer to other documents, records in the plan)**

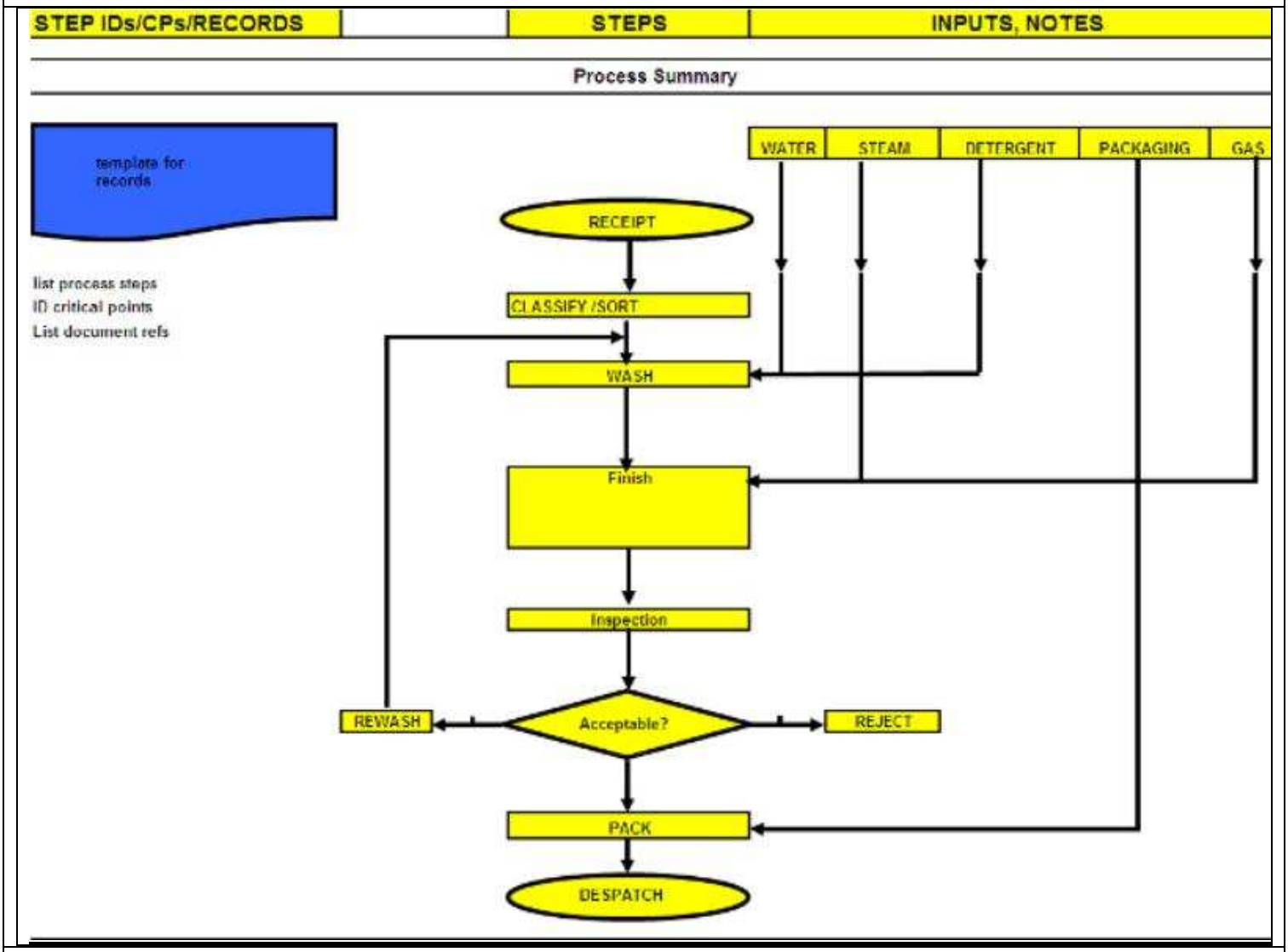
A2. Prerequisite Programme (PRP)

Note "references" – detail where in the quality or other site systems this control is documented

Requirements	Controls In Place	References:	Actions Outstanding
1. **Premises and Structures**			
2. **Cleaning**			
3. **Control and Reprocessing**			
4. **Equipment & Plant**			
5. **Foreign Body**			
6. **Garments**			
7. **Personnel Hygiene**			
8. **Storage, Transport**			
9. **Supplies**			
10. **Training**			
11. **Packing**			

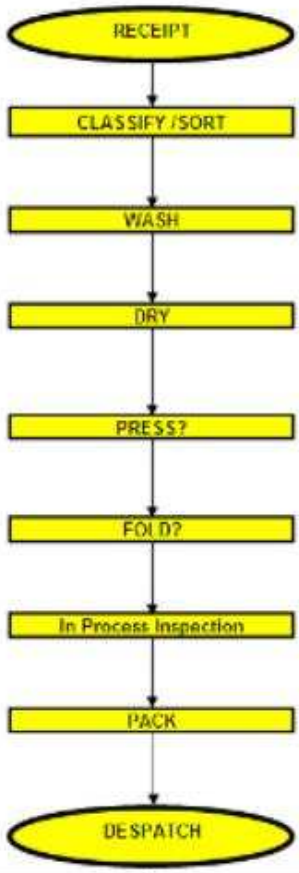
A3 Process Map

Notes This example is a high level "summary" map. Extend to each key product category and each significant "process line" on the site

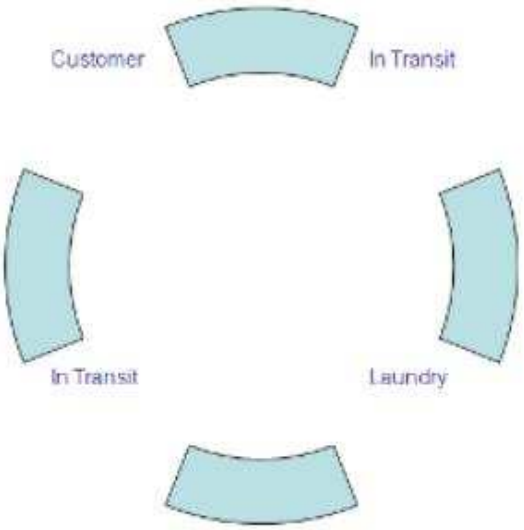


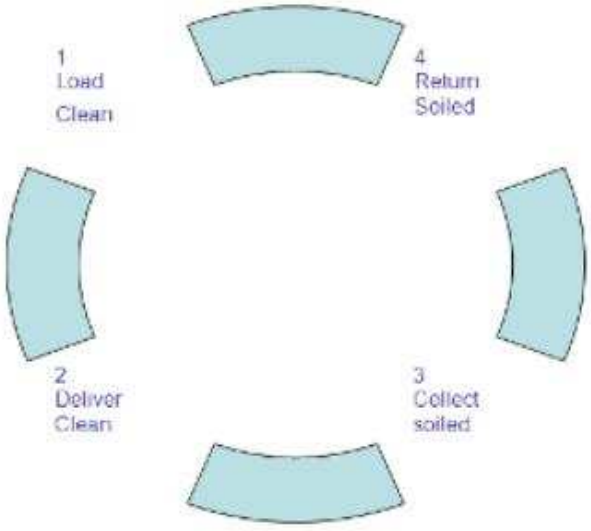
STEP IDs/CPs/RECORDS		Steps	Equipment ID, Equipment transfers,	Zone

Category specific maps - Name the product category/market sector, intended uses



Service Cycle	Delivery/Collection





A4. Risk Analysis

Note For how to use this form, review "Appendix B" for technique and "Appendix C" for a worked example. "CP" refers to "Critical Points". Choice of format - The format below allows for 1 risk analysis. The format in appendix C later in this guide uses the same technique, but shows subsequent analysis on the same report.

By process step						
STEP	**RISK**	**CONTROL MEASURE**	**Rating P**	**S**	**R**	**CP (Y/N)**
Sort/Classify						
Wash						
Press						
Drying						
Inspection						
Folding						
Packing.						
Despatch						
Delivery/collection						
By process input						
Water						
Energy						
Detergent						

A5. Risk Control Plan

Note **Report a separate Risk Control Plan for each named CP**
For detail on "Control measures", expand here or refer out, as in A2 above.
As in sample A4 above, refer to the other appendices for guidance on how to use this form.

Risk	Control Measure	Limits	Monitoring			Corrective Action	Doc. Ref.	Verification
			Ref	By	Frequency			
Biological Survival								
Biological Growth								
Biological Contamination								

Appendix B Risk Analysis - Technique

B1. Hazards and risks

Most people in the working environment these days are familiar with hazard and risk, and the difference between them, because they have been involved in their identification and assessment in Health and Safety (H&S). This document deals with bio-contamination in the laundry, either its removal from used textiles or the prevention of recontamination of cleaned work. The approach used for hazard and risk analysis can be used for bio-contamination control.

Most people, however, have only a very general appreciation of micro-organisms and what their characteristics are; what they look like, how numerous they are (and how to sample and count them, at least in theory), how many are needed to cause illness and even death, where and how they prosper, what kills them and, very importantly, how they move around and contaminate.

Thus it is very important that staff, engaged in the implementation of BS EN 14065, are given an appreciation of these characteristics and that expert advice is obtained, either through a microbiologist on the staff or as a consultant.

B2. Assessing hazards and risk

BS EN 14065 describes a very simple method of classifying the risk associated with a particular hazard based on four categories, i.e. very high, high, moderate and low (or non-significant). Drawing on experience in H&S this classification can be greatly improved upon.

More recent assessments schemes also include some allowance for the consequences of a hazard occurring. For example if the hazard is low and the risk is high as in catching “flu” through travelling on the Tube every day throughout winter, what might the consequences be? They may be relatively small to the individual, perhaps a couple of days in bed, but to the operation of a company, if most of the staff goes off sick, the effect could be considerable. Contrast this with the high level of hazard associated with an incident at a nuclear power plant and the low risk of it occurring. The consequences for local inhabitants and even those far afield could be very severe.

The analysis method proposed here follows a common H&S model, which first identifies a hazard, then attributes a probability, P of it occurring and associates that with the consequences as a severity term, S. The ‘quantified’ risk, R is then the simple product of these terms viz.

Equation 1. $P \times S = R$

However, before applying this model BS EN 14065 requires a more systematic approach to be taken with regard to inspection of the plant and understanding it from the Biocontamination perspective.

B3. Preparation of flow charts and checking the laundry layout

This document assumes that the implementation of BS EN 14065 is taking place in an existing laundry. The first task of the constituted and trained-up RABC team is to examine the most recent process maps and equipment specifications for the laundry and then to check these against the actual layout of the plant. The plans and equipment descriptions must be brought up to date to include any changes and/or modifications.

Secondly, the staff list, job descriptions, training and health records must be similarly examined and updated, especially where there have been staff changes.

The RABC team is now ready to carry out its hazard and risk assessment. Where possible, group members ought not to be assessing their own departments. They will get an opportunity to comment when the team convenes to discuss the assessments.

The primary objective of each group will be to identify and list, with a good description, all the microbiological hazards which could prejudice the hygienic quality in their allotted department(s). It will probably be necessary to consult the microbiologist to check this activity. The microbiologist will then be required to confirm if the hazard truly exists by means of suitable microbiological testing.

The groups then need to assess the probability of each hazard occurring using Equation 1 above in the following way

Figure 3. Quantification of risk

Probability of risk occurrence, P		Severity if risk occurs, S		Possible combinations of 'Quantified' risk, R
Negligible/low	= 1	Negligible/low	= 1	1, 2, 2, 3, 3, 4, 4, 4, 6, 6, 8, 8, 9, 12, 12, 16
Medium	= 2	Medium	= 2	
High	= 3	High	= 3	
Very high	= 4	Very high	= 4	

The P, S and R outcomes can be recorded in a table as per the example below

Figure 4. Risk analysis (1ST assessment)

Task	Microbial hazard – what's at risk?	Classification of risk			Existing control measures	
		P	S	R		
Reception - Storage	**Limitation of microbial growth** *Soiled work will be microbially contaminated and bacteria will multiply in storage making disinfection less certain.*	*2*	*4*	*8*		

When risks have been quantified as above, the team must consider whether they are sufficiently controlled. Obviously, the higher the final "R" number, the less adequate the control may be. High numbers should lead the team to consider improved controls. Numbers under 4 probably will not receive early attention for improved controls.

The team also needs to consider detectability. This should be part of a sense check on the completed risk analysis. If faults are not consistently detectable, this should be reflected in the final risk analysis by adjusting the P or S elements.

Figure 5. Risk analysis (2nd assessment)

Task	**Microbial hazard** – what's at risk?	Classification of risk			Existing control measures	Measures required to control risk	Re-classification of risk		
		P	S	R			P	S	R
Reception - Storage	**Limitation of microbial growth** *Soiled work will be microbially contaminat-ed and bacteria will multiply in storage making disinfection less certain.*	*2*	*4*	***8***	Storage area dry & adequately ventilated	Planned random inspection by supervisor	*2*	*2*	*4*

By following this process, it is simple to identify the local Control Points. One way to formalise this is to state that - for the purposes of the RABC plan - a CP is any point with a "R" number over "x" (e.g. 4 x 3 = 12).

The RABC implementation then proceeds by implementing the remaining RABC principles (see section 6 of the standard and the guide). This in turn leads to subsequent risk assessment (Figure 5) and to progressively improved ability to achieve and preserve the appropriate product safety.

Appendix C Risk Analysis - Example

Background

This appendix takes a typical but imaginary laundry process. The sample shown here presents a "worked example" of a risk analysis, focusing on microbiological contamination or re-contamination, step by step through the process. The assessment below uses "Probability" (P), "Severity" (S) and "Risk" (R) as defined in Appendix B. The assessment assumes a laundry with limited control measures in place. The resulting risk (R) has been colour coded in bands as follows:

1 - 4	Low
5 - 8	Moderate
9 - 12	High
13 -16	Very high

Note - every laundry will be different depending on the type of work being processed, the systems and machinery used, and the physical construction of buildings. Each RABC team must conduct a unique risk analysis. The analysis must be repeated after controls are in place, and should be reviewed regularly thereafter.

This sample simply draws attention to some issues that may arise, and to show how such issues might be represented. This in turn may direct a RABC team to more specific assessments. This further investigation by the RABC team will identify which items will require control and will lead to the identification of specific control points. A more in-depth discussion on microbiological risks in the laundry process can be found in the FCRA monograph on "Laundering Workwear for the High Care Sector of the Food Industry".

Sample

Storage of Soiled Textiles

Risk	P	S	R
Damp storage conditions will allow rapid microbial growth. This will provide a greater microbiological challenge to the disinfection process.	**3**	3	9
Cross contamination from "potentially infective" textiles to other items	**3**	4	12

Sorting Classification and Weighing

Risk	P	S	R
Incorrect use of a wash program for a particular classification of work could result in disinfection not being correctly achieved. Efficacy of the classification process and the correct tracking of the assigned classification to the washing machine.	**2**	4	8
Incorrectly weighed loads. Over or under loaded machines will not perform to the operational specification of the wash process.	**3**	2	6

Washing

Risk	P	S	R
Insufficient temperature or time (if thermal disinfection is being used).	**2**	4	8
Insufficient chemical concentration (if thermal disinfection is being used) can result in poor physical removal of contamination from fabrics.	**2**	2	4
Insufficient chemical concentration (if chemical disinfection is being used).	**2**	4	8
Incorrect water levels can effect the efficacy of chemical or thermal disinfection.	**2**	3	6
Recontamination by water or chemicals used after the disinfection stage of the process. This may be a particular problem with warm recycled water.	**4**	3	12
Parts of the washing machine that are in contact with water (or stored water itself) that are not disinfected by the wash process. This is particularly a problem with pipes and tanks on Continuous Tunnel Washing machines (CTWs).	**4**	3	12
Water contraflow in the rinse sections of CTWs can support rapid micro-biological growth.	**4**	4	16

Work storage prior to drying

Risk	P	S	R
Textiles left in a damp / wet condition after washing will support microbiological growth.	**3**	4	12
Microbiological build up on surfaces in contact with textiles particularly if the surfaces are damp or wet.	**3**	3	9

Drying

Risk	P	S	R
Recontamination from airflows in tunnel finishers or tumble driers	**3**	2	6
Insufficient temperature and time if the drying process is being relied on for thermal disinfection. Some parts of the textile item will dry slower than other parts (for example around pockets) and may not be disinfected.	**3**	4	12
Textiles that are not sufficiently dried will be damp and can support subsequent microbiological growth.	**3**	3	9

Post Disinfection Environment

Risk	P	S	R
Recontamination from operator's hands	**4**	4	16
Recontamination from operator's clothing	**2**	4	8
Recontamination from airborne contamination	**3**	4	12
Recontamination from surfaces (lint accumulation may be a particular problem in laundries)	**2**	4	8

Packaging & Despatch

Risk	P	S	R
Contamination on surface of packaging in contact with textile.	**2**	3	6
Damp garments if packaged will remain damp and support microbiolgical growth.	**3**	4	12

Delivery & Collection

Risk (recontamination)	P	S	R
Contamination on outer surface of packaging during delivery.	**2**	1	2
Contamination transfer to textile during handling at delivery	**3**	3	9
Contamination from failure of packaging (e.g. rip, hole) during storage and transport.	**2**	3	6

Appendix D Validation

Introduction

Validation is defined in section 3 of this guide. A discussion in section 6 develops the concept in the context of a RABC plan.

This appendix recommends an approach based on EU GMP Guidance for Pharmaceutical and Cosmetics Manufacturers (annex 15 – qualification and validation). This is similar to FDA guidance (see section 2 of this guide for references). Any RABC team planning to validate processes should consult these references, and/or source training or coaching in the approach.
This approach is proven worldwide and allows the laundry management to control the scope and methods of validation, in line with the market requirements, the risk profile of the goods being processed and the capability of the processes being used.

The EU/FDA validation model, often referred to as "life cycle" or "IQ/OQ/PQ" uses the term validation globally, i.e. proof of process capability at every stage of its life cycle, and at regular intervals while in use. Figure D1 below shows how the pieces of this model fit together. The recommendation for laundries is to adopt those elements of the model appropriate to their local situation. Guidance on how to use the model is detailed in paragraphs D1 to D3 below.

<table>
<tr><th>Location</th><th colspan="3">Validation "life cycle" stages</th><th>Primary Responsibility</th></tr>
<tr><td>Sub contractors</td><td colspan="3">Design Qualification (DQ)</td><td rowspan="2">Manufacturer/supplier</td></tr>
<tr><td rowspan="4">Laundry</td><td rowspan="2">Process Qualifications</td><td rowspan="2">New set up Equipment +/or Programmes</td><td>Installation (IQ)</td></tr>
<tr><td>Operational (OQ)</td></tr>
<tr><td colspan="2">Established set up - Performance (PQ)</td><td rowspan="3">RABC Team</td></tr>
<tr><td colspan="3">Routine monitoring (verification that supports validation)</td></tr>
<tr><td colspan="3">Re-validation (PQ), annual and as indicated by results, change dependant</td></tr>
</table>

Figure D1 Diagram of the 'Life Cycle' Model for Validation

Key terms

DQ Sub contractors (e.g. Of wash equipment, detergents) should establish and document intended performance levels and physical requirements to achieve these levels.

IQ/OQ The sub contractors and the laundry should ensure that all equipment and related systems are assembled, installed and operated as intended, e.g. motors , utilities, indicators and controls function as intended.

PQ The RABC team should design and execute challenges designed to establish that existing processes are effective and reproducible.

Re-validation This step normally consists of a repeat of the PQ, perhaps with some simplification, taking into account and documenting any interim variation in the process.

D1 Validations in laundries

D1.1 The RABC team's risk analysis identifies where qualifications are required and the targets for those qualifications. Feedback from the market and other parties (e.g. validation specialists or certifiers) may also assist in the identification process.

The risk analysis should identify, rate and document the capability of each process to produce the intended results. The results should be specified clearly for each process in quantitative terms and with clear tolerances, e.g. processed textiles should be disinfected (i.e. 5 log bioburden reduction), final bioburden to be <50 colony forming units (cfu) per dm^2 of textile and with no pathogens identified. Other intended results could include cleanliness, dryness and lack of damage.

Some results can be verified before product release to the satisfaction of customers or certifiers. Verification in this context is practical, frequent and immediate (e.g. product inspection, daily temperature checks). Where verification is not satisfactory and the risk of process failure is unacceptable (e.g. microbiological quality), qualifications are required. This is most likely to be the case for the core laundry processes – washing and drying.

When considering what qualifications are appropriate, it is worth noting that most RABC plans start with an established facility, including equipment and processes. Laundry products also have a much lower risk profile than typical Pharmaceuticals or Medical Devices. When combined with industry experience, this foundation suggests that RABC teams should focus on the PQ element of validation. D2 below advises on how to design a PQ.

D1.2 The RABC team should document a plan for carrying out (or executing) the necessary qualifications (PQs at least). This plan should consist of a "Validations Procedure" and a "Validation Master Plan (VMP)". These can also be combined into one document.

The validation procedure should detail how PQs are to be undertaken, including responsibilities, documentation, review criteria, responses to variances and the conditions for re-validation. The procedure should call for "protocols" to be documented and authorised in advance of each qualification and "reports" afterwards (these are detailed further below).

The VMP should be specific to the site, listing the RABC team's schedule of PQs.

D1.3 Each PQ should be carried out (or "executed") in stages, as follows:

Protocol – the plan for each PQ is documented and authorised in advance of being executed.
Log – the records of the PQ as it is executed.
Results – as logged and from other sources, e.g. Lab assessment of bioburden on textiles
Report –the success of each PQ is reported and authorised, accompanied by the log & results.

When a process passes planned PQs, it can be deemed "qualified". Note that qualifications are specific, e.g. programme 4, machine 2, soiling type X, soiling level Y and material Z. The same process on a different machine should be qualified separately. Significant deviations should result in investigation, corrective actions and perhaps re-validation. Re-design of the process may be required in some cases.

D1.4 Qualified processes should be maintained as qualified, with sufficient monitoring to assure no variation sufficient to affect product safety takes place until subsequent re-validation.

D1.5 Re-validation is normally annual but can be more frequent where process changes are made or where results from validations, process monitoring or other data indicate such a need.

D1.6 Significant process changes should be considered in advance, and decisions on re-validation should be documented by the RABC team. Once validation has been identified as necessary, no relevant goods should be released until they have undergone a PQ.

D2 Designing a Performance Qualification (PQ) for a laundry process.

There are many ways to design qualifications. Different processes call for different approaches. For laundries, the wash process has the most direct and significant effect on the bioburden of textiles. Paragraphs 2.1 to 2.3 below provide a "least burdensome" approach to qualifying this process.

D2.1 Baseline The RABC team should first establish that the process is operating correctly, e.g. equipment should be proven to work, processes should operate within agreed tolerances, indicators and instruments should be calibrated. The PQ should proceed only when this been adequately documented. Prior execution of IQ/OQs explicitly addresses these concerns.

D2.2 Bio burden assay Measuring the bioburden on laundered textiles and in rinse water provides supporting evidence of final product safety, and can be included in a PQ, but this does not adequately assess process capability, even when done "before and after". Such testing suffers from low sensitivity and limited control over test conditions.

D2.3 Inoculated test pieces A PQ should comprehensively test or challenge the current process, under controlled conditions. The challenge should distinguish the effects of the process Vs other factors (e.g. the laundry environment). One well established technique is to inoculate textile test pieces, put some through the laundry and compare the bioburden of processed to unprocessed samples. The target is to demonstrate 5 log reduction of named species.

While the above 3 elements form the core of a useful PQ protocol or plan, there is no allowance for change, such as loss of control over a process input, or the potential for varying detergent amounts or types for different soiling. Building in such considerations on top of the core elements above can increase safety margins for processing, assist in designing a new process or even allow for new laundry technology to be introduced. Using over-simplified qualifications can actually increase costs, where unforeseen changes lead to frequent re-validations. Where laundries have many equipment/programme/product combinations to validate, this is particularly true. Paragraphs 2.4 & 2.5 below present some techniques for developing more capable, flexible qualifications.

D2.4 Worst case challenge This idea is developed clearly in the EU & FDA guidance. Based on local experience and perhaps input from specialists or subcontractors, the PQ is planned with extra constraints to present a scenario that is as tough a challenge as could be expected. For example a wash process PQ could dictate that wash parameters should be reduced, load weight or soiling could be artificially increased or test pieces could be inoculated with sporing organisms that are very hard to inactivate.

D2.5 Statistical experimental design approach In some cases, the worst case model can be inefficient or even inadequate. Where new, innovative processes are intended, or where little historical data is available this may be particularly true. Another case to consider is where a laundry has a significant range of equipment, wash processes and textile categories. Separate qualifications for each distinct combination can then be prohibitive in time, complexity and cost.

Such cases may call for a further level of discipline in design. In the "experimental design" approach all the process elements which experience indicates contribute to the intended result are varied according to a statistically based experimental plan. This approach is potentially the most powerful available, identifying and ranking the significance of factors, deriving process interactions, providing guidance for future process development and allowing confident calculation of safety margins for key variables to sustain the intended result.

Further references for PQ Design

Both the EU & FDA guidance documents are short, readable references.
The bioburden and inoculation techniques above are detailed in ISO 14698-1 (particularly appendices D, E and F).
EN 13569 presents a checklist of process parameters to consider with respect to qualifications.
Specialist expertise in validations is not always required, but where more capable, flexible qualifications are envisages, this may become a valuable resource.

D3 The Life Cycle model

This appendix recommends a limited implementation of the life cycle model, focusing on PQs. On the other hand, customers and certifiers are often familiar with the full life cycle or "IQ/OQ/PQ" model. Some laundries may therefore find the full model is more appropriate for their needs. This may be particularly true for new laundries or processing lines, or where the prime market sector is pharmaceuticals.

In such cases, the EU GMP guide should be the prime validation reference for the RABC team. While it is demanding and sometimes expensive to implement in full, this "life cycle" approach is a valuable tool for assuring product safety. Over 20 years of global experience with a broad range of products and processes has also produced an extensive learning set for our industry, along with a terminology and style of presentation that is now the norm for many laundry market sectors and for 3rd party certifiers.