TSA GUIDANCE DOCUMENT

Implementing BS EN 14065:2016 Risk Analysis and Biocontamination Control (RABC) in Laundries

VERSION 2.0 | JANUARY 2021

INTRODUCTION

Purpose of RABC

RABC is shorthand for the approach called Risk Analysis & Bio-contamination Control. The aim of any RABC plan is to consistently assure the microbial quality of processed textiles through a laundry, so that they are clean and safe for their intended purpose, for their intended customer, and to objective standards. In other words, operating an RABC plan is how laundries ensure they produce safe-for-use textiles and prove this capability to their customers and markets, day after day and year after year.

The RABC approach can be employed in any market but is most widely used in technical and regulated markets, including Healthcare linen (in concert with HTM 01-04), Food Processing and Medical Devices (with Medical Device standards and regulations).

Laundries and other contexts vary, but all RABC plans set out to ensure good general practices, in an appropriate work environment, with capable, consistent equipment, processing and handling systems. The results should always include effective washing, disinfecting and drying through the laundry process, followed by protection from contamination through to the point of hand over to customers.

Purpose of This Guide

This guide will assist laundry management to successfully implement an RABC plan, in accordance with the standard BS EN 14065. The guide sets out to identify, clarify, recommend and explain good options for laundry management as they implement RABC in a laundry. The TSA issues operating guidelines for the deployment of RABC for particular applications.

The Language of Bio-Contamination Control

Different market sectors use specific labels for their approach to assure 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 Prevention** – used across the Healthcare Services.

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.

How To Use This Guide

Laundry management who intend to implement RABC should purchase a copy of BS EN 14065:2016 and study it alongside with this document throughout the project. The standard "requires and specifies", whereas the guide "recommends and suggests".

- **Sections 1-3** in both documents are for reference, providing definitions, links to external sources and other context, but not showing what to do or how to do it.
- **Section 4** shows an overview of an RABC plan and how to implement one. Useful for "big picture".
- **Section 5** is simply a signpost, highlighting that an RABC plan is intended to form part of a broader management system for a laundry.
- **Section 6** describes the RABC approach and how to develop an RABC plan. This is the core of the standard; the "RABC plan specification".
- **Appendices** These include technical interpretations and detailed examples for key aspects of an RABC Plan.

Caution on Scope

BS EN 14065 is the recognised basis for assuring microbiological quality of laundered textiles in 30 countries across Europe. It is however important to understand that this standard does not address presentation, feel, smell and other product characteristics that also require effective Quality Assurance measures. Also, BS EN 14065 is not a health and safety standard and therefore does not specify a safe system of work.

Certification

Certification is the means by which laundries secure and maintain objective, independent verification that an effective RABC plan is in place and is working effectively. BS EN 14065 was written to enable certification for a laundry for this purpose.

In the UK, UKAS (the United Kingdom Accreditation Service) accredits qualifying organisations to certify other organisations' capability and performance vs a range of standards. At the time of writing, the following UKAS accredited organisations offer certification to BS EN 14065: CFA, Intertek, NSAI, QMS, SGS. Others may be qualified and available to do so. This certification can be used in healthcare linen or food processing workwear and potentially in other markets. For Healthcare, certification to BS EN 14065 secures presumption of compliance to the Essential Quality Requirements of HTM 01-04.

Some certifications for other standards include an extra element. Where the demand is high enough, where there would be 1000s of certifications to a standard, then the authorities (UKAS for instance) develop a comprehensive, accredited, certification scheme. Owing to the small number of firms involved, such a scheme has not been developed to date for BS EN 14065. For this and other reasons, laundries cannot be accredited to BS EN 14065.

Acknowledgements

The Textile Services Association gratefully acknowledges the following contributors to the development of this document:

- Eoin Flavin (also involved in the latest review)
- Mike Palin
- Paul Meads
- Richard Newton (also involved in the latest review)
- Simon Fry

VERSION HISTORY

VERSION	DATE	REVISION
Version 1.0	April 2009	Guide to Implementing BS EN 14065
Version 2.0	January 2021	Guidance made concise and easier to use

CONTENTS

SCOPE OF BS EN 14065

The standard highlights certain sectors where the RABC approach is most necessary, e.g. Pharmaceuticals, Medical Devices, Healthcare, Food Sectors. RABC can be used elsewhere, as deemed appropriate by laundry management and their customers/markets.

REFERENCES

Users can implement RABC independently of other standards or regulations, but BS EN 14065 was written to be used with complementary structures, whether existing or under development. Where legal requirements apply, laundry management has the clear responsibility to address these adequately as part of their RABC plan.

Laundry management should establish what requirements (e.g. regulations). models (e.g. HACCP) and authorities (e.g. a government agency) operate in their unique circumstances for their products and markets. This should take place before and during implementation, with the involvement of customers and market-specific sources. The identified requirements should be documented in the completed RABC plan.

The list below introduces key references for UK users of the standard. It is NOT all-inclusive. 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 microbial quality?
- What level of microbial quality is appropriate for this product, when used as intended?

REFERENCE (Title, Name, Issue Date)	**COMMENT** (Relevance)
HTM 01-04 2016 Department of Health	This series of Healthcare Technical Memorandums sets out the Essential Quality Requirements and Best Practice for the provision of textiles or “linen” services to healthcare services. This series also provides guidance for how linen processors can comply with HTM 01-04 by certifying to BS EN 14065. The HTMs are frequently referenced in healthcare procurement documentation (e.g. tender requests).
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 9001:2015, 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 9001 will also be required by 3rd parties for RABC certification.

DEFINITIONS USED IN BS EN 14065

The terms and definitions from section 3 of the standard are not reproduced here, but some additional guidance is provided below for some key terms.

TERM	COMMENT
Bio-contamination	Contamination from sources such as bacteria, fungi, protozoa and viruses
Control Measure **Control Point (CP)** **Critical Control Point (CCP)**	Action or activity used to prevent, contain, reduce or eliminate a biocontamination risk Point or process step at which a control measure is applied Any process where 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.
Decontamination	Achieving sufficient reduction in bio-contamination fur set purposes, such as disinfection.
Disinfection	This term is not defined in BS EN 14065, but is defined in many certification schemes, and is specified in HTM 01-04.
Microbiological (or microbial) quality of textiles	The amount and types of bio-contamination allowed on processed textiles is determined by the end use and by agreement with the end user or local authority.
Validation	In simple terms, validation is the accumulated efforts and evidence you need to put in place a capable disinfection process and to prove to independent parties that it consistently performs as it should.

GENERAL PRINCIPLES AND REQUIREMENTS

Summary

This section of the standard shows direction but not detail; it is helpful for getting a sense of the shape and scale of the project and for the realization that bio-contamination is a specific class of risk. RABC is therefore a “risk management application”.

Guidance

Identifying **Control Points** and **Critical Control Points** clearly and accurately is crucial. You can make the most of this as follows:

APPROACH	ELEMENTS
Start by producing a map of your process. Set out the pieces listed here → from BS EN 14065, side by side. The visuals and text reinforce each other.	Your Process Map Annex D (illustration) Section 3. Definitions (3.6 & 3.8) Section 4, Figure 1
Consider each step in your process using these elements as guidance.	**Is this step a CCP?** **Is this step a CP?** If NO to both, then treat provisionally as a prerequisite.

Prerequisites and the 7 RABC principles are EQUALLY important.

Start with a “cheap & cheerful” sketch or note set for each programme, then review at more depth to put together your project plan, your capital requirements (if any) and identify the critical path elements; the pieces that will hold the whole project up. e.g, physical plant changes, new processing equipment, controlling the wash process sufficiently to allow validation.

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.

APPLICATION OF THE RABC SYSTEM

Section 6 is the core of BS EN 14065. This is the checklist which assessors and customers alike will use to assess the performance and maturity of a RABC plan. Every paragraph in this section includes requirement.

Guidance on Documentation

BS EN 14065 does not advise on how to document a RABC plan. This guide provides a couple of simple recommendations to that end, and some templates in the appendices.

- Develop 1 document for prerequisites, addressing section 6.2 of the standard.
- Develop 1 document for risk analysis, addressing section 6.3 of the standard.

One useful way to view RABC is as a quality plan within a Quality Management System (QMS). When documented in this way, the RABC plan can include signposts to evidence or other required information kept as part of the QMS. This can avoid a lot of duplication.

Guidance on RABC projects

- Implementing RABC should be treated as a project. Produce the project plan and manage progress against that plan.
- Fully investigate and document the prerequisites at the start of the project.
- Depending on internal resources, external advice may be useful at this stage, particularly on microbiology, process validation and wash process control systems.
- Set up a programme of microbiological monitoring, to assess the performance of your control measures.
- Then develop your detailed plan following the 7 RABC principles.
- Re-visit prerequisites as a set after several months, when necessary changes to facilities and/or practices are complete, using data from microbiological monitoring and other sources.

GUIDANCE ON RABC DECISIONS

When developing a RABC plan, there may not always be an absolute standard to achieve, or there may be uncertainty about the best measures to employ to achieve the appropriate standards. Project uncertainty cannot be eliminated, but this section of the guide sets out to guide such decisions as possible.

The table below presents the key elements within section 6 of BS EN 14065, beside relevant recommendations, examples and links as available. This is not exhaustive, is not addressed at particular markets and does not specify performance targets. The TSA is developing a set of operating guidelines for particular sectors, for this purpose. These guidelines will reinforce and extend these recommendations, simplifying and clarifying implementation further for laundry management. Research by the RABC team and reference to individual customers or sectors may also be necessary or advisable to support choices made for individual RABC plans or projects.

Prerequisites and preliminary actions ("Ref" is to the paragraph numbers in BS EN 14065)		
Ref	**Title**	**Recommendations**
6.2.1	Management commitment	Reviews should be normally held at least annually, involving senior management.
6.2.2	RABC team	Expertise in microbiology and HACCP/RABC is crucial. The RABC team should undergo formal training in RABC or HACCP and/or bring in and retain this expertise throughout the implementation.
6.2.3	Prerequisites	Significant changes may be required to enable consistent product safety, e.g. to facilities, cleaning, packaging. Annex B of the standard includes a really useful list of considerations. Consider all of these for your laundry. Regular microbiological monitoring of the laundry, particularly for work and equipment surfaces after decontamination and before packaging is strongly recommended. Sampling staff hands and washed and textiles is also advisable.
6.2.4	Intended use	Intended use determines what microbial level is appropriate and can affect every other decision in RABC implementation. The uses should be agreed with customers and reflected in the customer agreement or in the minimum specification for a particular market. In the UK, HTM 01-04 is particularly relevant for Healthcare services. 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.
6.2.5	Laundry diagram (or Maps)	Consider and map separately by product category/ market sector. Completed maps should account for each significant variation in processing. Good, clear maps, specific to product and use and production line can greatly improve and simplify a RABC plan and its documentation. See examples in this guide's appendix.

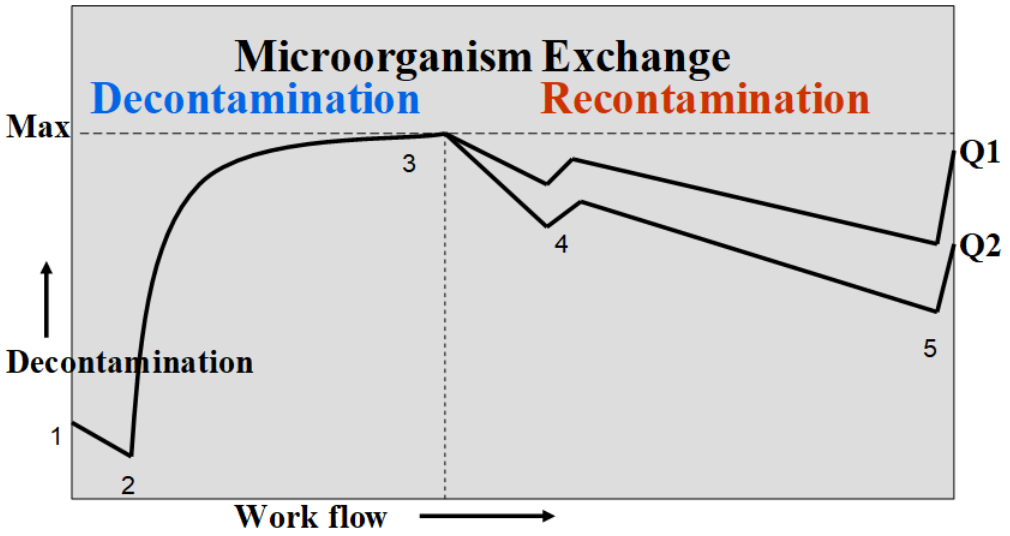
6.2.6	Specification	The laundry process (wash and dry steps in particular) should be chosen and designed based on how critical the use of the product is, not just what it is made of.
6.2.7	Training	Laundry and distribution staff should be trained in Basic Hygiene and/or Good Manufacturing Practice. The level of training should reflect the type of work being done and the goods being handled.
6.2.8	Purchasing	This relates mainly to textiles, washing supplies (detergents etc.) and packaging materials.

Application of the 7 RABC Principles
When the project is in progress and the prerequisites are being developed, the 7 RABC principles should be addressed. This provides for the tightest control and fail-safe measures required for the most critical steps in the process; the **Critical Control Points.**
NB –consider the full laundry/delivery cycle for each principle.

Principle	Title	Recommendation
1	List hazards and controls	Template documents are provided in the appendices to this guide. Annex C of the standard provides examples and guidance for risk assessment.
2	Determine Control Points (CPs) and Critical Control Points (CCPs)	It is essential to identify, prioritise, and plan in detail to maintain a much higher degree of control at the most important/critical steps in the laundry process. Refer to earlier in this guide (section 4) for help with the classification and identification of CCPs
3	Establish target levels and limits	For CCPs only. The RABC plan should be very clear on the criteria for accepting that a process has completed successfully and whether product from that load/batch should be released or re-processed. This requires clear pass/fail criteria for the process and for each load processed.
4	Establish monitoring	The RABC plan must be capable of identifying failures in processing, preventing release of the affected product and enabling investigation of the underlying issues. Using a “traffic lights” colour code for results can simplify the process I.e. AOK Alert Action.
5	Establish corrective actions	Actions should be timely and should be assessed for effectiveness.
6	System checking	This section is about process validation. Annex F of the standard provides excellent guidance on approaches. It is recommended as part of the validation programme to use bio-indicators at least annually to demonstrate the capability CCPs to reduce the bioburden to an acceptable degree and to the appropriate microbiological quality.
7	Documentation	In addition to the guidance earlier in this document, the standard requires records be retained from operating the prerequisites and RABC elements of the plan (e.g. microbiological monitoring data) and from regular reviews of the completed RABC plan. Reviews should annual, at a minimum.

ILLUSTRATIONS – RABC IN ACTION

Figure 1. Decontamination During Laundering



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Notes on Figure 1

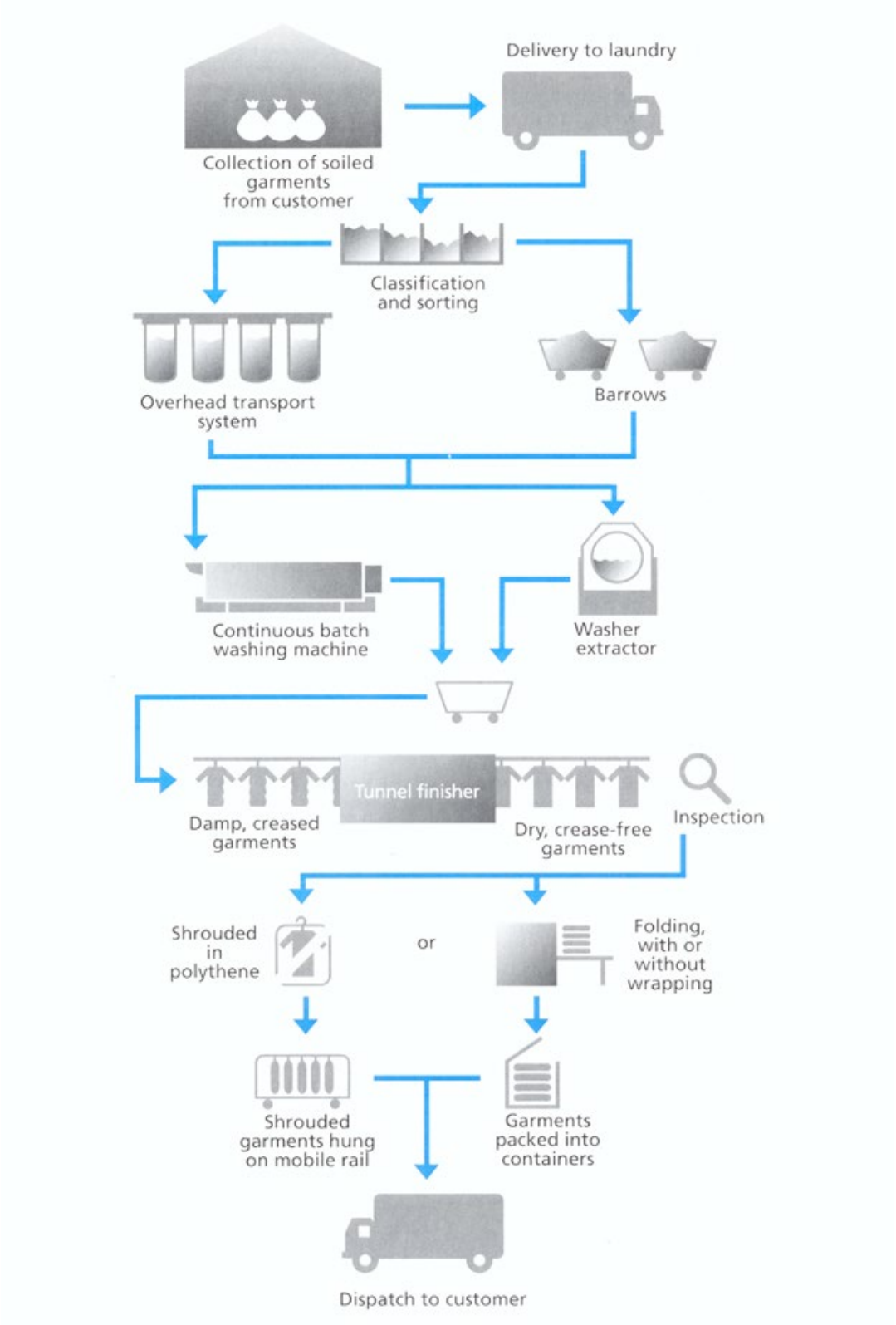
1. soiled receipt
2. delay before washing
3. end point of main wash process, before rinsing
4. end point of drying process
5. completion of packaging

Q1 and Q2 – different microbiological quality levels, from variation in process and product

Further Comments

- Rinsing can continue improvement or can re-contaminate 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 microbial quality is likely to improve over time to “Q” – the quality at time of use.

Figure 2. The Laundry Service Cycle



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APPENDIX

Documentation Templates

Document Structure

As suits the local context. Minimum recommendation (consistent with main text of this guide):

A. Prerequisite documentation
B. RABC Principles documentation
C. Records of operating the plan and of regular reviews

Recommended set of sub-headings to include in RABC plan documentation:

- Purpose (of the site specific RABC Plan)
- Scope (of operations of the site and of the RABC plan)
- Intended Uses (for each category of laundered textiles)
- References (specific to this RABC Plan, particular to local and legal requirements)
- Team members & responsibilities
- Alignment with Quality Management System (if applicable)

Templates provided on the following pages:

1. Prerequisites Program form
2. Process Maps (flow diagrams)
3. Risk Analysis form
4. Risk Control form

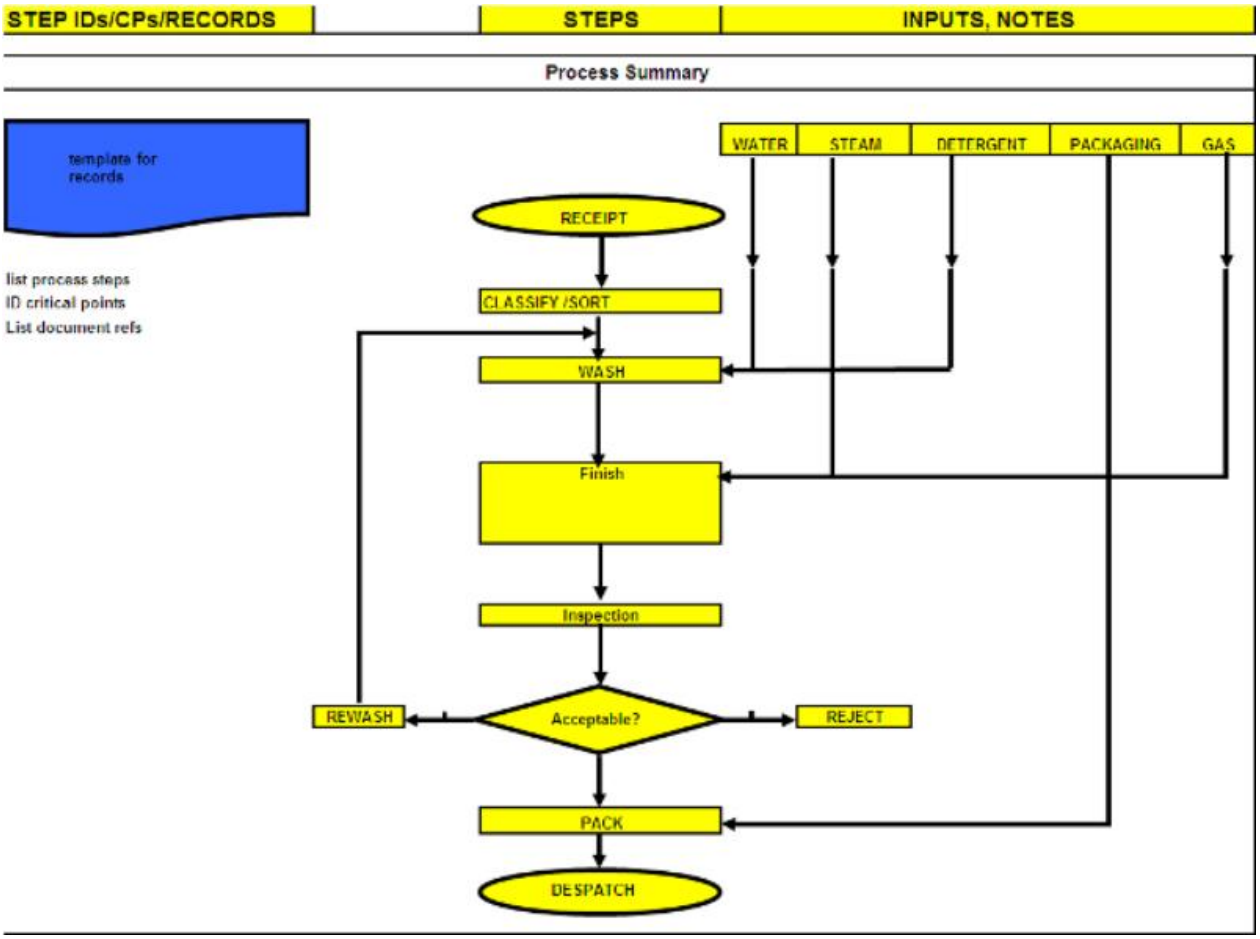
1. Pre-requisites Program (PRP)

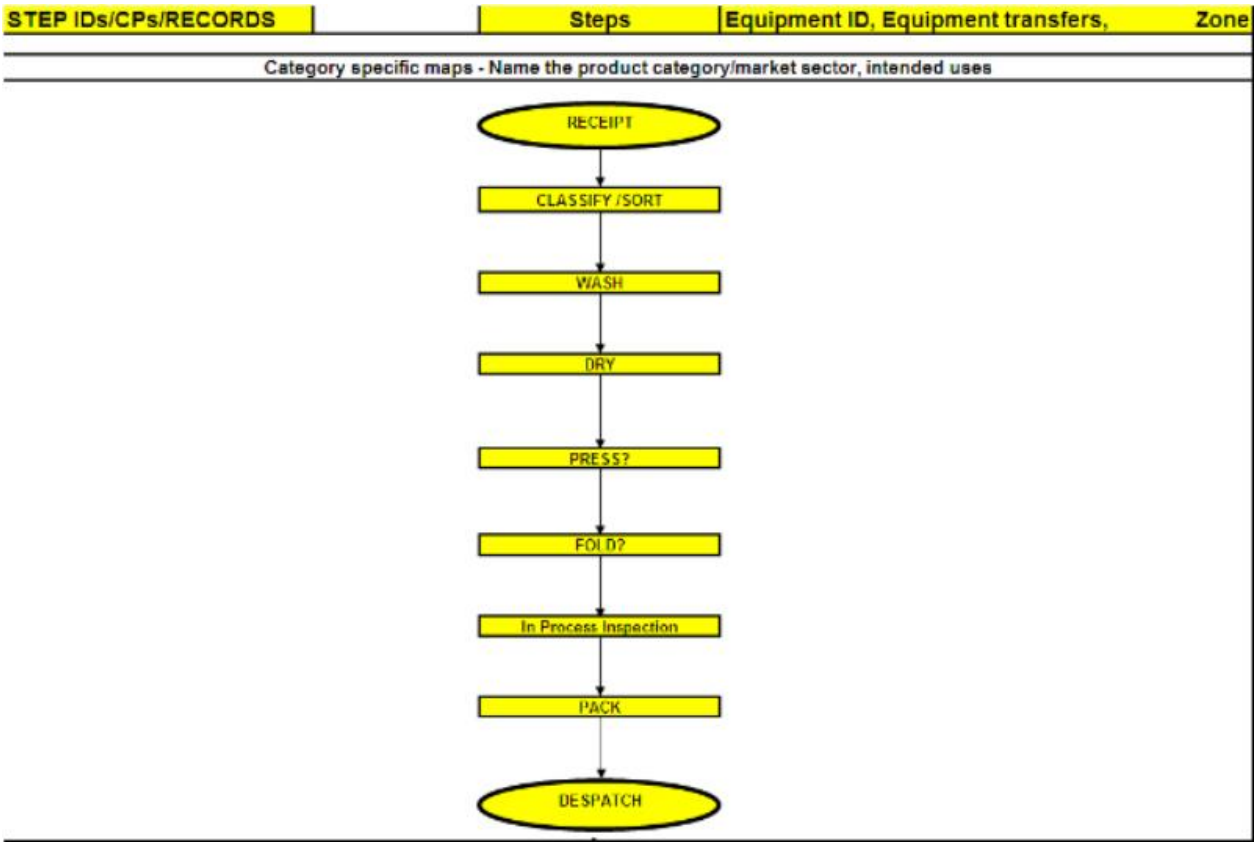
Note: “references” – link to where in the quality or other site systems this control is documented

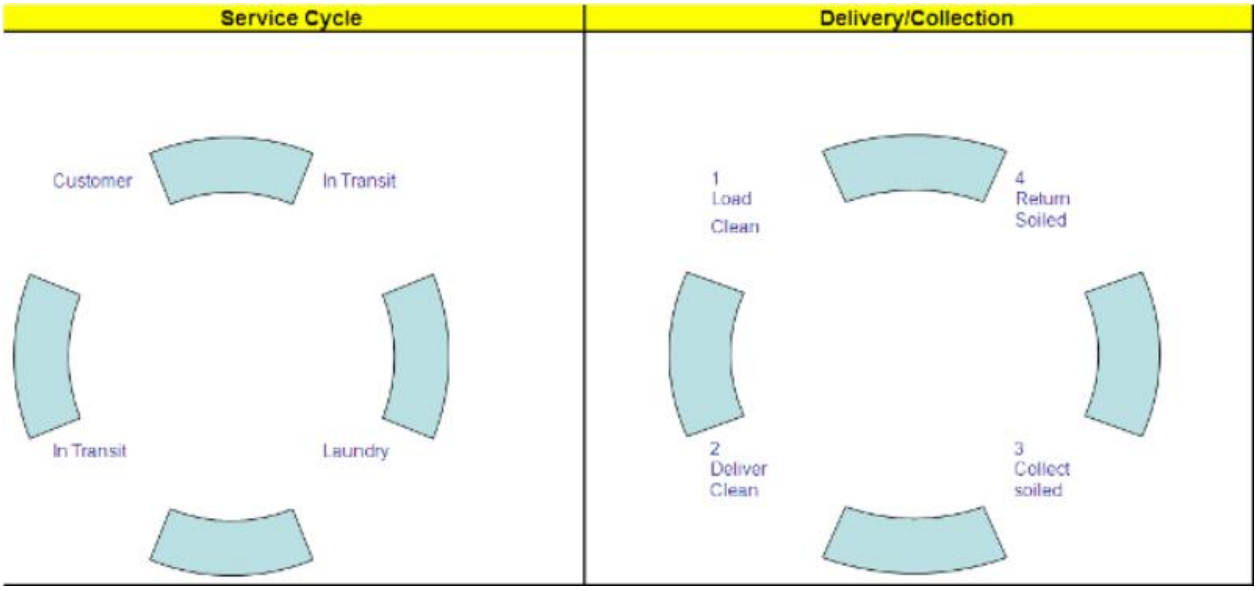
REQUIREMENTS	CONTROLS IN PLACE	REFERENCES	ACTIONS OUTSTANDING
1. **Premises and Structures**			
2. **Cleaning**			
3. Control and Reprocessing			
4. Equipment and Plant			
5. Foreign Body			
6. Garments			
7. Personnel Hygiene			
8. Storage and Transport			
9. Supplies			
10. Training			
11. Packing			

2. Process Maps

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
RECEIPT
CLASSIFY /SORT
WASH
DRY
PRESS?
FOLD?
In Process Inspection
PACK
DESPATCH


Service Cycle
Delivery/Collection
Customer
In Transit
In Transit
Laundry
1
Load
Clean
4
Return
Soiled
2
Deliver
Clean
3
Collect
soiled

3. Risk Analysis

Notes: **P** = Probability. **S** = Severity. **R** = P x S. Use a simple scale. 0 to 3 perhaps. Declare a value or range for each point on the scale. Analyse and document before and after controls are put in place and review annually.

STEP	RISK	CONTROL MEASURE	RATING			CCP (Y/N)
			P	S	R	
BY PROCESS STEP						
Sort and Classify						
Wash						
Press						
Drying						
Inspection						
Folding						
Packing						
Despatch						
Delivery/Collection						
BY PROCESS INPUT						
Water						
Energy						
Detergent						

4. Risk Controls

Notes: Document a set of Risk Controls for each named CCP

RISK	CONTROL MEASURE	LIMITS	MONITORING			CORRECTIVE ACTION	DOC. REF.	VERIFICATION
			Ref.	By	Freq.			
Biological Survival								
Biological Growth								
Biological Contamination								

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