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# BRCGS PACKAGING MATERIALS Issue 6

## P611: Issue 6 Transition Document for Basic Hygiene Sites

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### Document Scope

A guidance document for sites currently operating to the basic hygiene level of certification on how to prepare for audits against the new issue 6 of the Standard.

### Change log

Version no.	Date	Description
1	22/11/2019	Draft
2	5/12/2019	Final

## 1. Introduction

There are requirements that are completely new to the Standard in both existing high hygiene and basic hygiene sites which have been summarised in the ‘Welcome’ section of the Standard and the Key changes document P602. All sites are required to meet these new requirements as directed.

One of the key changes to the Standard is that hygiene levels have been removed from the Standard with sites now fully responsible for developing a risk-based hygiene program tailored to their needs.

Basic Hygiene sites represent a small, yet significant part of the sites certificated to the Standard. BRCGS aim to support these sites by further simplifying the process of becoming and remaining certificated against the new Issue 6. The reason for the move from two hygiene levels to a single approach base on risk include

Simplification of the process with the removal of the decision tree

Sites take ownership of the site and personnel hygiene requirements on the basis of risk, as with all activities included in the scope of their operations. This remains consistent with the essential requirements of the Standard for Product safety, legality and quality. This provides the opportunity for sites to identify the relevant hygiene requirements and justify why certain clauses are not implemented. Justification of these **risk-based deviations** (as defined in the Standard), is made by providing objective evidence in the form of a risk assessment.

Certain factors need to be taken into consideration by the HARA team when developing the risk assessment such as intended use, agreed customer expectations and local regulations for production or in the regions of intended sale.

The type of packaging material and its intended use, that is food contact, contact with other hygiene sensitive products such as cosmetics, nursery, personal hygiene, class I medical devices such as sterile plasters/band aid products.

Customers requiring additional modules such as Audit One typically specified high hygiene levels for all sites which created confusion and additional work where it may not have been required. Hygiene controls based on agreed customer expectations are still valid but will now be tailored to the relevant sites.

Table 1. contains a summary of the clauses that are new to current basic hygiene level sites with an indication as to which clauses can be deviated from based on risk. The rule for non-applicable clauses would also apply as with any site.

Some examples are given in section 2.1.

### Table 1. Clauses new to existing basic hygiene sites certificated to Issue 5

	Clause New to Basic Hygiene	Description	Potential Non applicable clause?	Can be deviated from on the basis of Risk?
<b>3 Product Safety and Quality Management – Internal audits</b>	3.5.5	Documented hygiene inspections for packaging materials to be in contact with food or hygiene sensitive products.  Frequency of these hygiene inspections is risk based	y	Y (frequency)
<b>4.2 Site Standards – Building fabrics and Interiors</b>	4.2.2	Suspended Ceilings	y	
	4.2.3	Internal drains protection		
	4.2.4	Windows and roof glazing - shall be protected from breakage		y
	4.2.5	Non-production glass breakage protection		y
	4.3	Utilities in production and storage areas, control of contamination		
<b>4.3 Site Standards – Utilities</b>	4.3.2	Water, air, other gases, monitoring		y
<b>4.5 Site Standards – Layout, product flow and segregation</b>	4.5	Layout, product flow, movement of personnel and segregation to prevent		

		contamination and comply with legislation		
	4.5.3	Sorting and direct handling of product shall take place in areas with same standard of hygiene as production areas		
	4.5.5	At risk activities that could result in contamination conducted in a designated, segregated area		
	4.5.7	Movement of personnel through simple logical routes		
	4.6.3	Wooden equipment, clean and not a contamination risk.	Y	Y
<b>4.6 Site Standards - Equipment</b>	4.6.4	Notices on equipment, cleanable and secure		
<b>4.7 Site Standards - Maintenance</b>	4.7.1	Maintenance programme critical for safety, quality and legality		
	4.7.2	Maintenance logs required		
	4.7.4	Documented clearance procedure		
	4.7.5	Tools and maintenance equipment shall be cleared away		

<b>4.8 Site Standards - Housekeeping and Cleaning</b>	4.8.2	Documented cleaning procedures, methods, frequency, cleaning materials as appropriate		Y
	4.8.4	Toilet cleaning materials segregated from other cleaning materials		
	4.8.5	Microbiological environmental monitoring programme in place		Y
<b>4.9 Site Standards – Product contamination control</b>	4.9.1.2	Control of potential product contamination of glass, brittle plastics, ceramics and similar materials - breakage register		
	4.9.2.4	Open notice board - contamination control		Y
<b>4.10 Site Standards – chemical and biological control</b>	4.10.6	Trademarked materials, use third party specialist for disposal		
	4.10.7	External Storage of refuse in designated maintained areas		
<b>4.11 Site Standards – Pest Management</b>	4.11	Pest management programme, effective and well resourced		

	4.11.7	Catch analysis following infestation to identify problem areas		
<b>5 Product and Process control – Product inspection, testing and measuring</b>	5.6.6	In line testing equipment to identify and remove non-conforming product		
<b>5 Product and Process control – Storage of all materials and intermediate and finished products</b>	5.9.6	Documented procedures to segregate raw materials, intermediate and finished product to prevent contamination		
<b>5 Product and Process control –</b>	5.10.5	Documented hygiene and odour checking of all shipping containers and delivery vehicles		
<b>6 Personnel – Personal hygiene: raw materials handling, preparation, processing, packing and storage areas</b>	6.2.2	Handwashing at entry to production		Y
	6.2.4	Controlled use and storage of personal medicines		Y
	6.2.6	Cuts and grazes- apply appropriate covering		Y
<b>Personnel – Staff Facilities</b>	6.3.1	Locker rooms, no direct access to production		Y

	6.3.2	Lockers provided for personnel in production		Y
	6.3.3	Food stored in clean hygienic state, away from storage, processing production areas.		Y
	6.3.8	Protective clothing and personal clothing segregated within locker		Y
<b>Personnel – Medical Screening</b>	6.4	Health monitoring to prevent product contamination from staff, visitors and contractors		Y
<b>Personnel – Protective Clothing</b>	6.5.4	Protective clothing, appropriately designed, provides adequate coverage, frequently changed		Y
	6.5.5	Suitable footwear		Y
	6.5.6	Gloves, replaced regularly		Y
	6.5.7	Protective clothing kept clean		Y
	6.5.8	Home care laundry defined process		Y
	6.5.9	Clean and dirty clothing segregated		Y
	6.5.10	Disposable protective clothing, controlled		Y

## 2.1 Guidance risk-based deviations versus non-applicable clauses

### Risk Based Deviations

As summarised in the table below, a significant proportion of the clauses new to basic hygiene sites can be deviated from based on risk.

#### Example

Clause 4.9.2.4            Open notice board - contamination control

Where there is no contamination risk to the packaging materials and final product notice boards do not require to be covered by a protective plastic or glass.

This should be included in the documented risk assessment and provided to the auditor upon request.

Clause 6.2.2            Handwashing at entry to production

Where no food contact packaging materials are manufactured and/or no risk of contamination to the packaging material or final product, there is no requirement for a hygiene junction that requires staff and visitors to wash their hands before entry into production. Handwash facilities should still be provided in toilet facilities for general hygiene purposes.

This should be included in the documented risk assessment and provided to the auditor upon request.

### Non-applicable clauses

#### Example

Clause 4.2.2            Suspended Ceilings

Where a site building does not have suspended ceilings, this should be agreed with the CB prior to the audit and would be verified by the auditor. This would not be included in the documented risk assessment is not required.

### Risk based deviations and non-applicable clauses

#### Example

Clause 4.6.3            Wooden equipment, clean and not a contamination risk.

A site may use wooden equipment in the manufacturing of packaging materials. Where no food contact packaging materials are manufactured and/or no risk of



contamination to the packaging material or final product, a documented risk assessment must be in place.

Where the site does not use wooden equipment in the manufacturing, this should be agreed with the CB prior to the audit and would be verified by the auditor. This would not be included in the documented risk assessment.

## 2.2 Preparation for the Audit

Sites currently operating to the basic level of hygiene, are advised to use this document along with the self-assessment checklist and the Interpretation Guidelines as support to produce a gap analysis of the areas the site needs to concentrate efforts to bring them up to meet the requirements of the Standard.

The company seeking certification must conduct a hazard analysis and risk assessment which will establish a full description of the packaging material(s) and the intended use by the customer. Identifying potential hazards and establishing hygiene controls. This will enable the site to put in place the appropriate processes and procedures to meet the hygiene needs of the site that ensure product safety, legality and quality.

Deviations from some of the requirements may be permitted based on risk, however, in each case an up to date documented risk assessment must be in place.

For additional support in preparation for audits against the new Standard, sites should contact their preferred certification body.

For other enquiries and concerns, sites can contact the BRCGS at [enquiries@brcgs.com](mailto:enquiries@brcgs.com)