BRCGS Standard for Packaging and Packaging Materials

P556: ISO 9001: 2015 to Issue 5 upgrade tool

Scope

This checklist is intended to assist sites in understanding the key similarities between ISO 9001:2015 and Issue 5 of the BRCGS Standard for Packaging in order to align their systems to meet the requirements of both Standards.

Change log

Version no.	Date	Description
1	August 2017	First issue
2	29/07/2019	New BRCGS logo and footer changed

Welcome to the toolkit.

If you're ISO 9001 certified, you're already over 60% of the way in gaining BRCGS certification. Much of the systems you'll have in place to meet ISO 9001:2015 stand you in good stead to add prestigious BRCGS certification to your company.

Increasingly, retailers and brand owners are looking beyond ISO 9001 to more specific and rigorous certification which includes that offered by BRCGS. Developed by technical experts in collaboration with the packaging industry and the retailers and brand owners themselves, BRCGS are regarded as the gold standard in product safety and quality management systems.

This guide lists all of the requirements of Issue 5 and the comparative ISO 9001 clause number along with commentary where detail within the clauses differs and requires more attention.

Additionally, there are differences in the scope and protocol, or operation, of the two Standards.

Overview

Complies	Partial	No match

1. Senior management commitment			2. Hazard and risk management system		
1.1	1.2	1.3	2.1	2.2	2.3
1.1.1	1.2.1	1.3.1	2.1.1	2.2.1	2.3.1
1.1.2	1.2.2	1.3.2	2.1.2	2.2.2	2.3.2
1.1.3	1.2.3	1.3.3	2.1.3	2.2.3	
1.1.4	1.2.4			2.2.4	
1.1.5				2.2.5	
1.1.6				2.2.6	
1.1.7				2.2.7	
1.1.8				2.2.8	
				2.2.9	
				2.2.10	
				2.2.11	

3. Product Safety and Quality Management					
3.1	3.4	3.6	3.7	3.9	3.11
3.1.1	3.4.1	3.6.1	3.7.1	3.9.1	3.11.1
3.1.2	3.4.2	3.6.2	3.7.2	3.9.2	3.11.2
	3.4.3	3.6.3	3.7.3	3.9.3	
3.2	3.4.4	3.6.4	3.7.4	3.9.4	3.12
3.2.1	3.4.5			3.9.5	3.12.1
3.2.2	3.4.6		3.8		3.12.2
			3.8.1	3.10	3.12.3
3.3	3.5		3.8.2	3.10.1	3.12.4
3.3.1	3.5.1			3.10.2	3.12.5
3.3.2	3.5.2			3.10.3	3.12.6
3.3.3	3.5.3				3.12.7
3.3.4	3.5.4				3.12.8

4. Site Standards					
4.1	4.3	4.6	4.8	4.10	4.11
4.1.1	4.3.1	4.6.1	4.8.1	4.10.1	4.11.1
4.1.2	4.3.2	4.6.2	4.8.2	4.10.2	4.11.2
4.1.3		4.6.3	4.8.3	4.10.3	4.11.3
4.1.4	4.4	4.6.4	4.8.4	4.10.4	4.11.4
4.1.5	4.4.1			4.10.5	4.11.5
	4.4.2	4.7	4.9	4.10.6	4.11.6
4.2	4.4.3	4.7.1	4.9.1.1		4.11.7
4.2.1		4.7.2	4.9.1.2		4.11.8
4.2.2	4.5	4.7.3	4.9.1.3		4.11.9
4.2.3	4.5.1	4.7.4	4.9.2.1		
4.2.4	4.5.2	4.7.5	4.9.2.2		
4.2.5	4.5.3	4.7.6	4.9.2.3		
4.2.6	4.5.4	4.7.7	4.9.2.4		
4.2.7	4.5.5		4.9.2.5		
	4.5.6		4.9.3.1		
	4.5.7		4.9.3.2		
5. Product and process control					
5.1	5.3	5.4	5.6	5.8	5.10
5.1.1	5.3.1	5.4.1	5.6.1	5.8.1	5.10.1
5.1.2	5.3.2	5.4.2	5.6.2	5.8.2	5.10.2
5.1.3	5.3.3	5.4.3	5.6.3		5.10.3
5.1.4	5.3.4	5.4.4	5.6.4	5.9	5.10.4
5.1.5	5.3.5	5.4.5	5.6.5	5.9.1	5.10.5
	5.3.6	5.4.6	5.6.6	5.9.2	5.10.6
5.2	5.3.7		5.6.7	5.9.3	
5.2.1	5.3.8	5.5	5.6.8	5.9.4	
5.2.2		5.5.1		5.9.5	
5.2.3		5.5.2	5.7		
5.2.4		5.5.3	5.7.1		
5.2.5			5.7.2		
5.2.6			5.7.3		
5.2.7					
6. Personnel					
6.1	6.2	6.3	6.4	6.5	
6.1.1	6.2.1	6.3.1	6.4.1	6.5.1	
6.1.2	6.2.2	6.3.2	6.4.2	6.5.2	
6.1.3	6.2.3	6.3.3		6.5.3	
6.1.4	6.2.4	6.3.4		6.5.4	
6.1.5	6.2.5	6.3.5		6.5.5	
	6.2.6	6.3.6		6.5.6	
		6.3.7		6.5.7	
		6.3.8		6.5.8	
		6.3.9		6.5.9	
		6.3.10		6.5.10	
		6.3.11		6.5.11	

Scope

ISO 9001 is a standard applicable to any type of organisation, and focuses on quality management systems. The BRCGS are a set of industry-specific standards, focusing on one industry sector, developed by industry for industry and focuses on product safety, and quality management systems.

This difference is most noticeable where ISO 9001: 2015 asks the site to determine the scope of the system (4.3). This scope must include all processes which the site has identified through a risk assessment based planning process that have an impact on the expectations and requirements of all key stakeholders in the business. In the BRCGS Standard for Packaging, this is pre-determined in the audit protocol (Part 3, 1.6), "The audit shall include all applicable requirements within the Standard and all production processes undertaken for the products included within the scope at the site seeking certification," and BRCGS rules state that all products must be included in the scope of the audit unless the rules around exclusions can be met.

This type of scope offers customers of certificated companies the assurance that their products are included within the certification.

Audit frequency

BRCGS audits are carried out on at least an annual basis. This is a GFSI requirement, but has been a BRCGS requirements for many years to ensure that certificated sites are regularly assessed. This continual assessment benefits the site in regular performance evaluations with constructive feedback, and reducing the audit burden where customers accept BRCGS certification. The ISO9001 standard requires a Stage 1 and Stage 2 Assessment and then a re-certification every 3 years with at least annual surveillance visits of a minimum of 1 day.

Auditor competence

BRCGS Standards are sector specific and BRCGS intent is that auditors challenge the site's operation armed with technical industry knowledge to test the sites processes and procedures. Auditors have often worked within industry for many years and are subject to training and competency requirements in each sector they will audit. This gives far greater integrity to the audit.

A note on the tool

Because ISO 9001 and Issue 5 are so very different in style, while it's possible to broadly align the requirements sites should take care to ensure that they review the detail in each clause to ensure they include what's relevant. For example, 1.2.2 in Issue 5 outlines the points required in the site's management review. This aligns well with 9.3.2 in ISO 9001 but the points differ from Issue 5. To be in compliance with both, the site should take note of the detail in each.

Hazard and risk analysis

The basis of an effective system for BRCGS Issue 5 is a robust hazard and risk analysis (2.2) and this is a key element of ISO 9001:2015. The ISO 9001:2015 is a generalised, non-industry specific standard and ISO certificated sites should check to see if they are meeting the more specific BRCGS Packaging industry approach.

A note on terminology

For the purposes of this comparison, BRCGS regards 'products' as those finished products manufactured (or traded) by the site, and the "customer" as the organisations purchasing the finished product manufactured or traded by the site.

BRCGS refers to a self-contained manufacturer as a 'site'. Where that site is part of a group, those sites form a company. ISO terminology uses 'organisation' which is broadly similar.

'Opportunities for improvement' is not terminology that is used in Issue 5, or any of the BRCGS Standards. However, you could interchange 'non-conformities' with 'opportunities for improvement' as the ideal handling of non-conformities includes use of root cause analysis to determine corrective and preventive action; ultimately, improving the system to prevent recurrence.

'External providers' in ISO is generally to be regarded as suppliers of raw materials and services, including contractors and subcontractors.

'Normative references' or other resources available to sites implementing Issue 5

An interpretation guideline, plus additional guidance documents are available for BRCGS Packaging Standard. Locate these at: https://www.brcgsbookshop.com/bookshop/packaging-and-packaging-materials/c-24/c-71

'Terms and definitions' are defined in the Glossary at the rear of the Standard, or using BRCGS Participate

Other resources

Should you have any questions about the Standards, please contact us using the contact us link on our webpage, or email enquiries@brcgs.com.

Detailed comparison

	Issue 5	Equivalent ISO 9001:2015 clause	Commentary
1	**Senior Management Commitment and Continual Improvement**		
1.1	The company's senior management shall demonstrate that they are fully committed to the implementation of requirements of the BRCGS Standard for Packaging and Packaging Materials. This shall include provision of adequate resources, effective communication and systems of review to ensure continual improvement. Opportunities for improvement shall be identified, implemented and fully documented.	5.1.1. (a-j) 5.2.1 (a-d)	Complies
1.1.1	The site shall have a documented policy which states the site's intention to meet its obligation to produce safe and legally compliant products to the specified quality, and confirms its responsibility to its customers. This shall be: • signed by the person with overall responsibility for the site • communicated to all staff.	5.2.2	Both Standards require communication of the policy. BRCGS simply states that it should be communicated to all staff, whereas ISO requires the company to ensure it's understood and applied. It's worth noting that Section 3.2 – Documentation control has requirements around the control of all documentation related to the Standard. Also, Section 6 – Personnel of Issue 5 has specific clauses on training and competence of individuals within the organisation, and it's here that the understanding and use of the policy by employees is located.
1.1.2	The site's senior management shall establish clear objectives to maintain and improve the quality, safety and legality of products manufactured, in accordance with the product safety and quality policy and this Standard. These objectives shall be: • documented and include targets or clear measures of success • clearly communicated to relevant staff	6.2.1 10.1	Quality objectives are required for both standards but it should be noted that the scope of Issue 5 addresses product safety and hygiene as well as quality so any existing objectives may need to be reviewed for content and additional objectives included.

	• monitored, and the results reported at a suitable predetermined frequency to the site's senior management • reviewed at least annually.		Note that each Standard has differing detail requirements on the objectives although both align in the documentation and communication of the objectives.
1.1.3	The company's senior management shall provide the human and financial resources required to effectively implement the processes of the quality management system and product safety programme and maintain compliance with this Standard.	6.2.2 6.3 7.1 7.1.1 7.1.2	Complies
1.1.4	The company's senior management shall have a system in place to ensure that the site is kept informed of and reviews: • scientific and technical developments • industry codes of practice • all relevant legislation applicable in the country of manufacture and, where known, the country where the product will be used • any changes to the Standard or protocol published by the BRCGS.	4.1 5.1.1 7.1.6	Complies
1.1.5	The site shall have a genuine, current hard copy or electronic version of the Standard available.		
1.1.6	Where the site is certificated to the Standard, it shall ensure that recertification audits occur on or before the audit due date indicated on the certificate.		
1.1.7	The most senior production or operations manager on site shall participate in the opening and closing meetings of the audit for the BRCGS Standard for Packaging and Packaging Materials certification. Relevant departmental managers or their deputies shall be available as required during the audit.		
1.1.8	The site's senior management shall ensure that the root causes of non-conformities identified at the previous audit against the Standard have been effectively addressed to prevent recurrence. A system shall be in place to close out non-conformities raised in internal,	10.1 10.2.1	Complies

	second-party and third-party audits, with consideration of the root cause.		
1.2	**Management Review**		
1.2 SOI	The site's senior management shall ensure that a management review is undertaken to ensure that the product safety and quality system is both fully implemented and effective, and that opportunities for improvement are identified.	5.1.1	Complies
1.2.1	Management review meetings attended by the site's senior management shall be undertaken at appropriate planned intervals; as a minimum annually.	5.1.1	Complies
1.2.2	The review process shall include the evaluation of: • previous management review documents, action plans and timeframes • results of internal, second-party and third-party audits • customer performance indicators, complaints and feedback • review of the hazard and risk management (HARM) system • incidents, corrective actions, out-of-specification results and non-conforming materials • resource requirements • the site's performance against the Standard and the objectives set • the effectiveness of root cause analysis and corrective actions.	5.1.1 9.3.2 10.3	Complies
1.2.3	The meeting shall be documented and used to revise the objectives. The decisions and actions agreed within the review process shall be effectively communicated to appropriate staff, and actions implemented within agreed timescales.	9.3.3 9.3.3 10.2.2 10.3	Complies
1.2.4	The site shall have a demonstrable system in place which enables product safety, legality and quality issues to be brought to the attention of senior management and allows for the resolution of issues requiring immediate action.	5.1.1 (h)	Partial ISO 9001 talks of engaging and supporting persons to contribute to the effectiveness of the system. This should result in a good relationship between production staff and senior

			management, facilitating the timely transfer of information.
1.3	**Organisational Structure, Responsibilities and Management Authority**		
1.3 SOI	The company shall have a clear organisational structure and lines of communication to enable effective management of product safety, legality, regulatory compliance and quality.	5.1.1	Complies
1.3.1	The site shall have a current organisation chart demonstrating the management structure of the company. The responsibilities for the management of activities which ensure product safety, quality and legality shall be clearly allocated and understood by the managers responsible. It shall be clearly documented who deputises in the absence of the responsible person.	5.3	Complies
1.3.2	Clear communication and reporting channels shall be in place to report on and monitor compliance with the Standard.	5.1.1 7.4	ISO 5.1.1 is a broad requirement around the requirements on top management ('Senior management' for Issue 5), hence it appears multiple times across different Issue 5 requirements.
1.3.3	The site's senior management shall ensure that all employees are aware of their responsibilities. Where documented work instructions exist for activities undertaken, the relevant employees shall have access to these and be able to demonstrate that work is carried out in accordance with the instructions.	7.4	Complies
2.1	**Hazard and Risk Management Team**		
2.1 SOI	A multidisciplinary hazard and risk management team shall be in place to develop and manage the hazard and risk management system and ensure the system is fully implemented and evaluated for its effectiveness.		
2.1.1	The hazard and risk management system shall be developed, reviewed and managed by a multidisciplinary team that includes those responsible for quality, technical, engineering/maintenance,		

	production operations and other relevant functions. In the event that the site does not have the appropriate expertise in-house, external expertise may be used to analyse any hazards and the risk of them occurring, and/or develop and review the hazard and risk management system. However, the day-to-day management of the system shall remain the responsibility of the site.		
2.1.2	The multidisciplinary team shall have a designated team leader who shall be suitably trained and able to demonstrate competence and experience of hazard and risk analysis.		
2.1.3	The team shall be able to demonstrate competence in hazard and risk analysis principles and be kept up to date with factory changes and customer requirements as they occur.		
2.2	**Hazard and Risk Analysis**		
2.2 SOI	A documented hazard and risk management system shall be in place to ensure that all hazards to product safety, quality and legality are identified and appropriate controls established.	4.4.1	The basis of Issue 5 is the hazard and risk analysis which, in turn, is based on HACCP. The advantage of Issue 5 is that the assessment of the process and highlighting any hazards to product safety and quality (bearing in mind that ISO 9001 focuses only on quality) is laid out in a logical way, enabling the site to take a step-by-step approach to the hazard and risk analysis. The measures outlined in ISO 4.4.1 align in their intent, if not the assessment or the resultant system. Therefore, sites would be advised to carry out the hazard and risk analysis as it is set out in Issue 5 to ensure they capture each step and principle. BRCGS training is available on hazard and risk analysis (HARA).

2.2.1	The scope of the hazard and risk analysis shall be clearly defined and documented and shall cover all products and processes included within the intended scope of certification.	4.4.1	The basis of Issue 5 is the hazard and risk analysis which, in turn, is based on HACCP. The advantage of Issue 5 is that the assessment of the process and highlighting any hazards to product safety and quality is laid out in a logical way, enabling the site to take a step-by-step approach to the hazard and risk analysis. ISO9001:2015 with its much larger, generalised scope requires controls on all processes to meet interested parties (stakeholder) expectations and does not relate just to product quality but will relate to product quality, product safety, efficiency and potentially even efficiency and cost effectiveness if shareholders are considered as an interested party as they should be. The measures outlined in ISO 4.4.1 align in their intent, if not the assessment or the resultant system. Therefore, sites would be advised to carry out the hazard and risk analysis as it is set out in Issue 5 to ensure they capture each step and principle. BRCGS training is available on hazard and risk analysis (HARA).
2.2.2	The hazard and risk analysis team shall maintain awareness of and take into account: • historical and known hazards associated with specific processes, raw materials or intended use of the product (where known) • known likely product defects that affect safety or quality • relevant codes of practice or recognised guidelines • legislative requirements.	4.4.1	The measures outlined in ISO 4.4.1 align in their intent, if not the assessment or the resultant system. Therefore, sites would be advised to carry out the hazard and risk analysis as it is set out in Issue 5 to ensure they capture each step and principle.

2.2.3	A full description of the product shall be developed, which includes all relevant information on product safety, quality and integrity. As a guide this may include: • composition (e.g. raw materials, inks, varnishes, coatings and other print chemicals) • origin of raw materials, including use of recycled materials intended use of the packaging materials and defined restrictions on use; for example, direct contact with food or other hygiene-sensitive products, or the physical or chemical conditions.	4.4.1	The measures outlined in ISO 4.4.1 align in their intent, if not the assessment or the resultant system. Therefore, sites would be advised to carry out the hazard and risk analysis as it is set out in Issue 5 to ensure they capture each step and principle.
2.2.4	A flow diagram shall be prepared for each product, product group or process. This shall set out each process step from the receipt of raw materials to dispatch to the customer. As a guide this shall include, as relevant: • receipt and approval of artwork • receipt and preparation of raw materials such as additives, inks and adhesives • each manufacturing process step • in-line testing or measuring equipment • the use of rework and post-consumer recycled materials • any subcontracted processes • customer returns. The accuracy of the process flow shall be validated by the hazard and risk analysis team.	4.4.1	The measures outlined in ISO 4.4.1 align in their intent, if not the assessment or the resultant system. Therefore, sites would be advised to carry out the hazard and risk analysis as it is set out in Issue 5 to ensure they capture each step and principle.
2.2.5	The hazard and risk analysis team shall identify and record all potential hazards that are reasonably expected to occur at each step in relation to the product and process. The hazards considered shall include, where relevant: • microbiological • foreign objects • chemical contamination (e.g. taint, odour, allergen, component	4.4.1	The measures outlined in ISO 4.4.1 align in their intent, if not the assessment or the resultant system. Therefore, sites would be advised to carry out the hazard and risk analysis as it is set out in Issue 5 to ensure they capture each step and principle.

	transfer from inks, varnishes and glues) • potential problems arising from the use of recycled materials • legality • defects critical to consumer safety • hazards that may have an impact on the functional integrity and performance of the final product in use • potential for unintended migration of substances from the packaging material into food or other hygiene-sensitive product • potential for malicious intervention.		
2.2.6	The hazard and risk analysis team shall identify control measures necessary to prevent, eliminate or reduce each hazard to acceptable levels. Controls for identified hazards to product quality shall be appropriately managed through the prerequisite programme, as set out in section 5. Where control is through prerequisite programmes these shall be reviewed to ensure they adequately control the risk identified and, where necessary, improvements implemented.	4.4.1	The measures outlined in ISO 4.4.1 align in their intent, if not the assessment or the resultant system. Therefore, sites would be advised to carry out the hazard and risk analysis as it is set out in Issue 5 to ensure they capture each step and principle.
2.2.7	For each hazard that requires control, other than by an existing prerequisite programme (as set out in sections 4–6), the control points shall be reviewed to identify those that are critical. This process shall include an assessment of the risk level for each hazard based on the likelihood of the occurrence and the severity of the outcome. Critical control points shall be those control points that are required to prevent, eliminate or reduce a product safety or integrity hazard to acceptable levels. Where a control point is not classified as critical and control may be achieved through a prerequisite programme, a	4.4.1	The measures outlined in ISO 4.4.1 align in their intent, if not the assessment or the resultant system. Therefore, sites would be advised to carry out the hazard and risk analysis as it is set out in Issue 5 to ensure they capture each step and principle.

	programme shall be developed that is sufficiently specified to effectively control the identified hazard(s).		
2.2.8	For each critical control point, the appropriate critical limits shall be defined in order to identify clearly whether the process is in or out of control. Critical limits shall be measurable, where possible, and the rationale for their establishment clearly documented. Relevant legislation and codes of practice shall be taken into account when establishing the limits.	4.4.1	The measures outlined in ISO 4.4.1 align in their intent, if not the assessment or the resultant system. Therefore, sites would be advised to carry out the hazard and risk analysis as it is set out in Issue 5 to ensure they capture each step and principle.
2.2.9	For each critical control point, a monitoring system shall be defined in order to ensure compliance with critical limits. Records of the monitoring shall be maintained. Documented procedures relating to the monitoring of critical controls shall be included in internal audits against the Standard (see clause 3.3).	4.4.1	The measures outlined in ISO 4.4.1 align in their intent, if not the assessment or the resultant system. Therefore, sites would be advised to carry out the hazard and risk analysis as it is set out in Issue 5 to ensure they capture each step and principle.
2.2.10	The corrective action that shall be taken when monitored results indicate a failure to meet the control limit shall be established and documented. This shall include the procedures for quarantining and evaluating potentially out-of-specification products to ensure they are not released until their safety, quality and legality can be established.	4.4.1	The measures outlined in ISO 4.4.1 align in their intent, if not the assessment or the resultant system. Therefore, sites would be advised to carry out the hazard and risk analysis as it is set out in Issue 5 to ensure they capture each step and principle.
2.2.11	A review of the hazard and risk management system and prerequisite programmes shall be carried out at least once per year and following any significant incidents or when any process changes. The review shall include a verification that the hazard and risk analysis plan is effective and may include a review of: • process changes • product composition changes • complaints • product failures • finished product recalls from consumers (including system tests)	4.4.1	The measures outlined in ISO 4.4.1 align in their intent, if not the assessment or the resultant system. Therefore, sites would be advised to carry out the hazard and risk analysis as it is set out in Issue 5 to ensure they capture each step and principle.

	• product withdrawals • results of internal audits of prerequisite programmes • results from external and third-party auditors • new developments in industry associated with materials, process or product.		
2.3	**Exemption of Requirements based on Risk**		
2.3	The hazard and risk analysis study shall be fully supported by the implementation of the prerequisites set out in requirements clauses 4 to 6. However, the hazard and risk analysis may indicate that some of the requirements may be exempted.		
2.3.1	Exemptions shall be documented and regarded as proposed exemptions for review at audit. Acceptance or rejection of the proposed exemptions shall be recorded in the auditor's report.		
2.3.2	The site shall keep recorded exemptions to the Standard under review and provide documented evidence of this review at subsequent audit.		
3.1	**Product Safety and Quality Management**		
3.1 SOI	The site's processes and procedures to meet the requirements of this Standard shall be documented to allow consistent application, facilitate training, and support due diligence in the production of a safe and legal product.	1	Complies
3.1.1	The site's documented procedures, working methods and practices shall be collated in a navigable and readily accessible system, with consideration being given to translation into appropriate languages.	7.5.3.1 (a)	Complies
3.1.2	The system shall be fully implemented, reviewed at appropriate planned intervals and improved where necessary.	4.4.1 6.1.1 6.1.2 9.1.3	Complies

3.2	**Documentation Control**		
3.2 SOI	An effective document control system shall ensure that only the correct versions of documents, including recording forms, are available and in use.	4.4.2 7.5.1 7.5.3.2	Complies
3.2.1	The company shall have a documented procedure to manage documents which form part of the product safety and quality system. This shall include: • a list of all controlled documents indicating the latest version number • the method for the identification and authorisation of controlled documents • a record of the reason for any changes or amendments to documents • the system for the replacement of existing documents when these are updated.	4.4.2 7.5.1 7.5.3.2	Complies
3.2.2	Where documents and records are in electronic form these shall be suitably protected to prevent loss or malicious intervention.	7.1.3 (d) 7.5.3.1 (b)	Complies
3.3	**Record Keeping**		
3.3 SOI	The site shall maintain genuine records to demonstrate the effective control of product safety, legality and quality.	4.4.2 7.5.1	Complies Records can be deemend to be 'Documented Information' when Issue 5 is compared with ISO 9001.
3.3.1	Records shall be legible, appropriately authorised, retained in good condition, and retrievable. Where records are in electronic form these shall be suitably backed up to prevent loss.	4.4.2 7.5.3	Complies
3.3.2	Any alterations to records shall be authorised and justification for the alteration shall be recorded.	7.5.3.2	Complies
3.3.3	The company's senior management shall ensure that documented procedures are established and implemented for the organisation, review, maintenance, storage and retrieval of all records	4.4.2 7.5.3	Complies

	relating to product safety, legality, regulatory compliance and quality.		
3.3.4	The period of retention for records shall relate to the usable life of the packaging and products it is designed to contain and shall respect any customer requirements.	7.5.3.2	ISO 9001 is not specific to packaging materials, so while ISO expects retention to be addressed, this is not linked to the usable life of the materials.
3.4	**Specifications**		
3.4 SOI	Appropriate specifications shall exist for raw materials, intermediate and finished products, and for any product or service which could affect the quality of the finished product and customer requirements.	8.5.1	Complies
3.4.1	Specifications shall be suitably detailed and accurate, and shall ensure compliance with relevant product safety and legislative requirements.	8.5.1	Complies
3.4.2	The company shall seek formal agreement of specifications with relevant parties. Where specifications are not formally agreed then the company shall be able to demonstrate that they have taken steps to put an agreement in place.		
3.4.3	A declaration of compliance shall be maintained which enables users of the packaging materials to ensure compatibility between those materials and the product with which they may be in contact. The declaration of compliance shall contain as a minimum: • the nature of the materials used in the manufacture of the packaging • confirmation that the packaging materials meet relevant legal requirements • the inclusion of any post-consumer recycled materials. This shall identify any limitations of use of the product and the usable life of the packaging material (where relevant).		

	Products shall meet at least minimum legal requirements in the country of manufacture, and use, where known.		
3.4.4	The presence of manufacturer's trademarks or logo on packaging materials shall, where appropriate, be formally agreed between relevant parties.		
3.4.5	A specification review process shall be operated where product characteristics change or at an appropriate predetermined interval.	8.2.3.1	Requirements around products and services are addressed by ISO somewhat differently, and it should be noted that the specification is often the primary source of information and agreement for requirements between supplier and customer.
3.4.6	Where specifications are in electronic form these shall be suitably protected to prevent loss or malicious intervention.	4.4.2 (a)	ISO uses the word 'maintain' which can imply digital integrity. Sites should ensure they have measures in place to maintain the integrity of digitally stored data.
3.5	**Internal audits**		
3.5 SOI	The company shall be able to demonstrate that it verifies the effective application of the requirements of the BRCGS Standard for Packaging and Packaging Materials through internal audits.	9.2.1	Complies
3.5.1	There shall be a scheduled programme of internal audits throughout the year with a scope which covers the hazard and risk management system, prerequisite programmes and all procedures that have been implemented to achieve this Standard. All activities shall be covered at least annually. The internal audit programme shall be fully implemented.	9.2.1	Complies
3.5.2	The scope and frequency of the audits shall be established in relation to the risks associated with the activity and previous audit performance.	9.2.2	Complies
3.5.3	Internal audits shall be carried out by appropriately trained, competent		

	auditors. Auditors shall be sufficiently independent from the process being audited to ensure impartiality (i.e. they must not audit their own work).		
3.5.4	Internal audit reports shall identify conformity as well as non-conformity. Results shall be notified to the personnel responsible for the process audited. Root cause analysis shall be used to determine appropriate corrective actions. Corrective actions and timescales for their implementation shall be agreed and completion of the actions verified.	9.2.2	Complies
3.6	**Supplier Approval and Performance Monitoring**		
3.6 SOI	The company shall operate effective, documented procedures for approval and monitoring of its suppliers.	8.4.1	Complies
3.6.1	The site shall have a documented supplier approval procedure and continual assessment programme in place, based upon risk analysis. These shall apply to suppliers of: • materials • subcontracted processes to the site and ensure that materials and services procured conform to defined requirements, where there is a potential impact to product safety, quality or legality.	8.4.1	Complies
3.6.2	The procedures shall include clear criteria for the assessment and approval of new suppliers. Assessment may take the form of: • supplier certification with a scope covering the products supplied (e.g. against the appropriate BRCGS Standard, or other GFSI benchmarked scheme) • supplier questionnaires • supplier audits. The site shall have an up-to-date list of approved suppliers.	8.4.1	Complies
3.6.3	Records of supplier assessment and necessary actions shall be maintained and reviewed.	8.4.1	Complies
3.6.4	The procedures shall define how exceptions are handled; for example, the		

	use of products or services where audit or monitoring has not been undertaken. Assessment (on a batch or delivery basis) may take the form of: • certificate of analysis • declaration of compliance.		
3.7	**Management of subcontracted processes**		
3.7 SOI	Where any process steps in the manufacture of the packaging material are subcontracted to a third party or undertaken at another site, this shall be managed to ensure it does not compromise the quality, safety or legality of the product.	8.4.2	Complies
3.7.1	The use of subcontractors and the status of the subcontractor with respect to the Standard shall be notified to the brand owner and/or customer.		
3.7.2	Where any processes are subcontracted, including artwork or pre-press activity, the risks to the quality and safety of the product shall form part of the hazard and risk analysis and the company's evaluation of the system shall be held on record.	8.4.2 8.4.3	Complies
3.7.3	Clear specifications shall be agreed for all work outsourced to a subcontractor.	8.2.3.1 (c) 8.4.3	As ISO 9001 is a general Standard its frame of reference is very generalised. ISO is concerned with, 'requirements specified by the organisation', i.e. the certificated site, and is broadly aligned with the requirements the site will have on its subcontractors.
3.7.4	Where any process steps in the manufacture of the packaging or packaging material are subcontracted, final release of the product shall remain the responsibility of the site. Controls shall be in place for checks on finished work to ensure product safety and quality meets specification prior to dispatch to the final customer.	8.4.3 (b) 8.6	Complies
3.8	**Management of Suppliers of Services**		

SOI	The company shall be able to demonstrate that where services are outsourced, the service is appropriate and any risks presented to product safety, quality or legality have been evaluated to ensure effective controls are in place	8.4.1	Complies
3.8.1	There shall be a documented procedure for the approval and monitoring of suppliers of services. Such services may include, but are not limited to: • pest control • laundry services • transport and distribution • storage and dispatch • sorting or rework • laboratory services • calibration services • waste management. Providers of utilities such as water, electricity or gas may be excluded on the basis of risk.	8.4.1	Complies
3.8.2	Documented agreements shall exist with the suppliers of services which clearly define service expectations and ensure potential risks associated with the service have been addressed.	8.4.1	Complies
3.9	**Traceability**		
3.9 SOI	The site shall be able to trace and follow all raw materials through processing to the distribution of the finished product (packaging material) to the customer and vice versa.	8.5.2	Complies
3.9.1	The site shall have a system which has the ability to trace and follow all raw materials from the supplier through all stages of processing and distribution of the finished product and vice versa. Where continuous processes are used or raw materials are in bulk silos, traceability shall be achieved to the best practical level of accuracy.	8.5.2	The traceability requirements in Issue 5 are specific to the manufacture of packaging materials.

3.9.2	Identification of raw materials, intermediate products, finished products, non-conforming product and quarantined goods shall be adequate to ensure traceability.	8.5.2	Complies
3.9.3	An appropriate system shall be in place to ensure the customer can identify a product or production lot number for the product, for the purposes of traceability.	8.5.2	Complies
3.9.4	The system shall be tested to ensure traceability can be determined from raw materials to the finished product and vice versa. Records shall be retrievable in a timely manner. This shall take place on a predetermined frequency, at least on an annual basis, and results retained for inspection.		
3.9.5	Where rework or any reworking operation is performed, traceability shall be maintained.		
3.10	**Customer Focus and Contract Review**		
3.10 SOI	The company's senior management shall ensure that processes are in place to determine customer needs and expectations with regard to quality, safety and legality, and ensure these are fulfilled.	4.2 8.2.1 8.3.2	Complies
3.10.1	The company shall clearly identify those job titles responsible for communication with customers and shall have an effective system for communication.	5.3 (d)	Complies
3.10.2	Customer needs and expectations shall be documented and reviewed on a suitable frequency. Any changes to existing agreements or contracts shall be agreed, documented and communicated to appropriate departments.	4.2 5.1.2 8.2.3.5 8.2.4 8.5.5 9.1.2	Complies
3.10.3	Where customers have set particular performance criteria or indicators for monitoring, these requirements shall be communicated to relevant staff, adhered to, and reviewed at appropriate intervals.	4.2 5.1.2	Complies

3.11	**Complaint Handling**		
3.11 SOI	Customer complaints relating to product hygiene, safety or quality shall be handled effectively and the information used to reduce complaint levels.	9.1.2	Customer satisfaction is addressed by ISO 9001 and within the context of product provision this might naturally fall to monitoring customer satisfaction and complaints. Sites should ensure any customer communication meets the requirements of Issue 5.
3.11.1	All complaints shall be recorded and investigated (including root cause analysis) and the results of the investigation documented. Actions appropriate to the seriousness and frequency of the problems identified shall be carried out promptly and effectively by appropriately trained staff.		
3.11.2	Complaint data shall be analysed to identify significant trends. Where there has been an increase or repetition of a complaint type, root cause analysis shall be used to implement ongoing improvements to product safety, legality and quality, and to avoid recurrence. This analysis shall be made available to relevant staff.		
3.12	**Management of Product Withdrawals, and Incidents and Product Recalls**		
3.12 SOI	The site shall have a plan and systems in place to effectively manage any product withdrawals or returns from customers, incidents and product recalls in order to ensure that all potential risks to the hygiene, quality, safety or legality of products and the final consumer are controlled.	8.7.1	ISO 9001 refers to detection of non-conforming product after delivery which addresses product withdrawals. However, this does not address any incidents, or product recalls initiated by customers of packaging manufacturers.
3.12.1	A product withdrawal procedure shall be documented and shall include as a minimum: • identification of the key personnel involved in assessing potential product withdrawals or returns,	8.7.2	ISO lists some records that are to be taken, but the Issue 5 list differs in including information about anyone who should be communicated with.

	with their responsibilities clearly defined • a communications plan including methods of informing customers • root cause analysis and corrective action to implement appropriate improvements as required.		
3.12.2	The withdrawal procedure shall be capable of being operated at any time and will take into account notification to the supply chain, stock return, logistics for recovery, storage of recovered product and disposal.		
3.12.3	The designated manager shall be responsible for ensuring that root cause analysis is used to determine and implement preventive action and improvements as necessary.		
3.12.4	The company shall provide written guidance and training for relevant staff regarding the type of event that would constitute an incident. A documented incident reporting procedure shall be in place.		
3.12.5	The company shall determine and document the activity required to effectively manage an incident to prevent release of product where hygiene, safety or quality may have been affected.		
3.12.6	A procedure to manage product recalls initiated by the brand owner or specifier shall be documented and shall include as a minimum: • identification of the key personnel involved in assessing potential recalls, together with clearly defined responsibilities • a communications plan that includes methods of informing customers and (where necessary) regulatory bodies in a timely manner • corrective action and business recovery		

	• review of any recalls in order to conduct root cause analysis and implement appropriate improvements as required.		
3.12.7	Where a site's products are involved in a product recall, the site shall assist with provision of information (such as traceability) as required.		
3.12.8	The product withdrawal procedure shall be tested, at least annually, in a way that ensures its effective operation. Results of the test shall be retained and shall include timings of key activities. The results of the test, and of any actual withdrawals, shall be used to review the procedure and implement improvements as necessary.		
4	**SITE STANDARDS**		
4.1	**External Standards**		
4.1 SOI	The site shall be of suitable size and construction, in a suitable location, and maintained to an appropriate standard to reduce the risk of contamination and facilitate the production of safe and legal products.	7.1.3 (a)	Complies
4.1.1	Consideration shall be given to local activities and the site environment, which may have an adverse impact on the safety or quality of the finished product or raw materials, and measures shall be taken to prevent contamination. Where measures have been put in place to protect the site, they shall be regularly reviewed to ensure they continue to be effective (e.g. flood controls).	7.1.3	Complies
4.1.2	The external areas shall be maintained in good order. Any grassed or planted areas surrounding buildings shall be regularly tended and well maintained. External traffic routes under site control shall be suitably surfaced to avoid contamination of the product.	7.1.3	Complies
4.1.3	The building fabric shall be maintained to minimise potential for pest entry, ingress of	7.1.3	Complies

	water and other contaminants. External silos, pipework or other access points for the product and/or raw materials shall be appropriately sealed and secured. Where possible, a clean and unobstructed area shall be provided along the external walls of the buildings used for production and/or storage.		
4.1.4	Where natural external drainage is inadequate, additional drainage shall be installed. Drains shall be properly protected to prevent entry of pests.		
4.1.5	Where external storage of raw materials is necessary, these shall be protected in order to minimise the risk of contamination.		
4.2	**Building Fabric and Raw Materials**		
4.2	The internal site, buildings and facilities shall be suitable for the intended purpose and shall be designed, constructed, maintained and monitored to effectively control the risk of product contamination.	7.1.4	Complies
4.2.1	Walls, floors, ceilings and pipework shall be maintained in good condition and shall facilitate cleaning.	7.1.4	Complies
4.2.2	Where suspended ceilings exist they shall be constructed, finished and maintained to prevent the risk of product contamination, and accessible for cleaning and inspection for pests unless the void is fully sealed.	7.1.4	Although not specifically mentioned in ISO 9001, to ensure the environment for processes is sound, these specific topics should be included in any maintenance in order to comply with Issue 5.
4.2.3	All internal drain openings shall be suitably protected against the entry of pests and designed to minimise odour.	7.1.4	Although not specifically mentioned in ISO 9001, to ensure the environment for processes is sound, these specific topics should be included in any maintenance in order to comply with Issue 5.
4.2.4	Where they constitute a risk to product, and based on the likelihood and risk of contamination, windows and roof glazing shall be protected against breakage.		

4.2.5	Where they constitute a risk to product, and based on the likelihood and risk of non-production glass contamination, all bulbs and strip lights, including those on flying-insect control devices, shall be adequately protected.		
4.2.6	Suitable and sufficient lighting shall be provided to ensure a safe working environment, correct operation of processes, effective inspection of the product and cleaning.	7.1.4 (c)	Complies
4.2.7	Suitable and sufficient ventilation shall be provided.	7.1.4 (c)	Complies
4.3	**Utilities**		
4.3 SOI	All utilities to and within the production and storage areas shall be designed, constructed, maintained and monitored to effectively control the risk of product contamination.	7.1.3 (a)	Complies
4.3.1	All water used in the processing of the products or equipment cleaning shall be potable or suitably treated to prevent contamination.	7.1.3	Complies
4.3.2	Based on risk assessment, the microbiological and chemical quality of water, steam, ice, air, compressed air or other gases which come into direct contact with packaging shall be regularly monitored. These shall present no risk to product safety or quality and shall comply with relevant legal regulations.	7.1.3	Complies
4.4	**Security**		
4.4 SOI	Security arrangements shall be assessed to ensure the integrity of products and processes.		
4.4.1	The company shall undertake a documented risk assessment of the security arrangements and potential risks to the products from any deliberate attempt to inflict contamination or damage. Areas shall be assessed according to risk; sensitive or restricted		

	areas shall be defined, clearly marked, monitored and controlled. Identified security arrangements to reduce risks shall be documented, implemented and reviewed at least annually.		
4.4.2	Measures shall be in place to ensure only authorised personnel have access to production and storage areas, and access to the site by employees, contractors and visitors shall be controlled. A visitor reporting system shall be in place. Staff shall be trained in site security procedures and encouraged to report unidentified or unknown visitors.		
4.4.3	External storage tanks, silos and any intake pipes with an external opening shall be sufficiently secure to prevent unauthorised access.		
4.5	**Layout and Product Flow**		
4.5 SOI	The factory layout, flow of processes and movement of personnel shall be sufficient to prevent the risk of product contamination and to comply with all relevant legislation.		
4.5.1	There shall be a plan of the site which defines: • access points for personnel • travel routes • staff facilities • process flow • storage areas.		
4.5.2	The process flow from intake to dispatch shall be arranged to minimise the risk of contamination or damage to the product.		
4.5.3	Premises shall allow sufficient working space and storage capacity to enable all operations to be carried out properly under safe and hygienic conditions.		

4.5.4	Sorting or other activities involving the direct handling of the product shall take place in areas that have, as a minimum, the same standards as production areas.		
4.5.5	Activities that could produce a contamination risk, such as the removal of outer packaging, shall be carried out in a designated, segregated area.		
4.5.6	If it is necessary to allow access through production areas, designated walkways shall be provided that ensure there is adequate segregation from materials.		
4.5.7	Where possible, all facilities shall be designed and positioned so that movement of personnel is by simple, logical routes.		
4.6	**Equipment**		
4.6	Equipment shall be suitably designed for the intended purpose and shall be maintained and used so as to minimise the risk to product safety, legality and quality.	7.1.3 (b)	Complies
4.6.1	Equipment shall be designed for the intended purpose and shall minimise the risk of contamination to the product. Equipment shall be constructed of suitable materials and be designed to ensure it can be effectively cleaned and maintained.	7.1.3 (b)	Complies
4.6.2	Newly installed equipment shall be properly specified before purchase. New equipment shall be tested and commissioned prior to use and a maintenance and cleaning programme established.		
4.6.3	Wooden equipment including desks, chairs, tables, etc. shall be properly sealed to enable effective cleaning. This equipment shall be kept clean, in good condition and free from splinters or other sources of physical contamination.		

4.6.4	Notices on equipment shall be cleanable and secure.		
4.7	**Maintenance**		
4.7 SOI	An effective maintenance programme shall be in operation for plant and equipment to prevent contamination and reduce the potential for breakdowns.	7.1.5.1	Complies
4.7.1	A documented programme of maintenance shall be operated, covering all items of production equipment and plant, to prevent contamination and reduce the risk of breakdown.	7.1.5.1	Complies
4.7.2	A condition-based or preventive maintenance programme shall be in place, covering all items of equipment and plant that are critical to product safety, legality and quality.		
4.7.3	In addition to any planned maintenance programme, where there is a risk of product contamination by foreign bodies arising from equipment failure or damage, the equipment shall be inspected at predetermined intervals, inspection results documented and appropriate action taken.		
4.7.4	Maintenance work shall not place product safety, quality or legality at risk. Maintenance work shall be followed by a documented clearance procedure which records that contamination hazards have been removed and equipment cleared to resume production.		
4.7.5	Tools and other maintenance equipment shall be cleared away after use and appropriately stored.		
4.7.6	Temporary repairs/modifications using tape, cardboard, etc., shall only be permitted in emergencies and where product contamination is not at risk. Such modifications shall be subject to a time limit and shall be recorded and scheduled for correction.		

4.7.7	Engineering workshops shall be controlled to prevent transfer of engineering debris to production or storage areas (e.g. by provision of swarf mats).		
4.7.8	Contractors involved in maintenance or repair shall be suitably monitored by a staff member who shall be responsible for their activities.		
4.8	**Housekeeping and Cleaning**		
4.8 SOI	Housekeeping and cleaning systems shall be in place which ensure that appropriate standards of hygiene are maintained and that risk of contamination to the product is minimised.	7.1.4 (c)	ISO 9001 requirements are around the environment for processes, including hygiene, so sites should ensure that their hygiene procedures are reviewed in light of the extra Issue 5 requirements.
4.8.1	Good standards of housekeeping shall be maintained, which shall include a 'clean as you go' policy.	7.1.4 (c)	ISO 9001 requirements are around the environment for processes, including hygiene, so sites should ensure that their hygiene procedures are reviewed in light of the extra Issue 5 requirements.
4.8.2	Documented cleaning procedures shall be in place and maintained for buildings, equipment and vehicles. The frequency and methods of cleaning shall be based on risk. Cleaning schedules and procedures shall include the following information: • responsibility for cleaning • item/area to be cleaned • frequency of cleaning • method of cleaning • cleaning materials to be used • cleaning record and responsibility for verification.		
4.8.3	Cleaning chemicals shall be fit for purpose, suitably labelled, and used in accordance with manufacturers' instructions. They shall be stored in a secured, designated location, in closed containers. Chemicals that are strongly		

	scented or could give rise to taint and odour contamination shall not be used. Cleaning equipment shall be kept in a suitable designated location.		
4.8.4	Materials and equipment used for cleaning toilets shall be segregated from those used elsewhere.		
4.9	**Product Contamination Control**		
4.9 SOI	All practicable steps shall be taken to identify, eliminate, avoid or minimise the risk of foreign body or chemical contamination.		
4.9.1	**Glass, Brittle Plastics, Ceramics and Similar Materials Control**		
4.9.1.1	There shall be no unnecessary non-production glass, ceramics or brittle plastic, which may pose a risk of contamination.		
4.9.1.2	All glass or brittle plastics other than the product shall be controlled and recorded on a register which shall include as a minimum: • a list of items detailing location, number, type and condition • recorded checks of condition of items, carried out at a specified frequency that is based on the level of risk to the product • details on cleaning or replacing items to minimise potential for product contamination. Glass or brittle plastics not in the production or storage areas shall be included in the register on the basis of risk.		
4.9.1.3	Where non-production glass or brittle plastic breakage occurs, a responsible person shall be placed in charge of the clean-up operation and shall ensure that no other area is allowed to become contaminated due to the breakage. Any product that has become contaminated shall be segregated and disposed of.		

	All breakages shall be recorded in an incident report.		
4.9.2	**Sharps Control**		
4.9.2.1	There shall be a documented policy for the control of the use of sharps.		
4.9.2.2	Sharp blades, equipment and tools shall not be left in a position that allows them to contaminate the product.		
4.9.2.3	Sharp cutting instruments used in the manufacture of packaging materials shall be controlled to prevent product contamination. This shall include control into and out of the factory.		
4.9.2.4	Snap-off blade knives shall not be used.		
4.9.2.5	Where open noticeboards are present in production, packing and storage areas, loose fastenings, such as drawing pins and staples, shall not be used.		
4.9.3	**Chemical and Biological Control**		
4.9.3.1	Processes shall be in place to manage the use, storage and handling of non-production chemicals, to prevent chemical contamination. These shall include as a minimum: • a list of approved chemicals for purchase • availability of material safety data sheets and specifications • avoidance of strongly scented products • the labelling and/or identification of containers of chemicals at all times • designated storage area with access restricted to authorised personnel • use by trained personnel only.		
4.9.3.2	Hazard and risk analysis shall be used to identify, control and manage any potential risks from microbiological		

	contamination and any potential allergens.		
4.10	**Waste and Waste Disposal**		
4.10 SOI	Suitable facilities shall be provided for the storage and disposal of process and other waste.		
4.10.1	Where licensing is required by law for the removal of waste, it shall be removed by licensed contractors and records of removal shall be maintained and available for audit.		
4.10.2	Suitable and sufficient refuse and waste containers shall be provided, which shall be emptied at appropriate frequencies and maintained in an adequately clean condition.		
4.10.3	Where appropriate, waste shall be categorised according to legislative requirements based on the intended means of disposal (such as recycling), and sorted, segregated and collected in appropriate designated waste containers.		
4.10.4	Substandard trademarked materials shall be rendered unusable through a destructive process. All materials disposed of shall be recorded.	8.7.1	ISO 9001 refers to control of non-conforming product, and sites should note that Issue 5 requires an assessment of how the substandard material is disposed of.
4.10.5	If substandard trademarked materials are transferred to a third party for destruction or disposal, that third party shall be a specialist in appropriate waste disposal and shall provide records of material destruction.		
4.10.6	External storage of refuse shall be in designated areas and designed or maintained to minimise the risk of pest harbourage.		
4.11	Pest Control		
4.11 SOI	In order to minimise the risk of infestation and prevent risk to products, the whole site shall have an effective preventive pest control programme in place and the		

	resources available to respond immediately to any issues which occur.		
4.11.1	A preventive pest control programme shall be maintained, covering all areas of the site under the site's control.		
4.11.2	The site shall either contract the services of a competent pest control organisation or shall have appropriately trained staff for the regular inspection and treatment of the site in order to deter and eradicate infestation. The frequency of inspections shall be determined by risk assessment and shall be documented. Where the services of a pest control contractor are employed, the service contract shall be clearly defined and reflect the activities of the site.		
4.11.3	Where a site undertakes its own pest control, it shall be able to demonstrate that: • pest control operations are undertaken by trained and competent staff with sufficient knowledge to select appropriate pest control chemicals and proofing methods and understand the limitations of use, relevant to the biology of the pests associated with the site • staff undertaking pest control activities meet any legal requirements for training or registration • sufficient resources are available to respond to any infestation issues • there is ready access to specialist technical knowledge when required • legislation governing the use of pest control products is understood • dedicated locked facilities are used for the storage of pesticides.		
4.11.4	Pest control equipment such as bait stations, traps or electric fly-killing devices		

	shall be appropriately located and operational.		
4.11.5	Effective precautions shall be in place to prevent pests entering the premises. The building shall be suitably proofed against the entry of all pests via doors, windows, ducts and cable entry points.		
4.11.6	In the event of infestation, immediate action shall be taken to eliminate the hazard. Action shall be taken to identify, evaluate the potential for contamination or damage, and authorise the release of any product potentially affected.		
4.11.7	In the event of an infestation, and at appropriate intervals, the site shall request a catch analysis from flying-insect control devices to help identify problem areas. In the event of increase in activity, the site shall use risk assessment to determine the activity required to eliminate the hazard.		
4.11.8	Documented procedures and detailed records of pest activity, pest control inspections and recommendations shall be maintained. These shall include as a minimum: • an up-to-date, signed and authorised site plan identifying numbered pest control device locations • identification of the baits and/or monitoring devices on site • clearly defined responsibilities for site management and the contractor • details of pest control products used and instructions for their effective use • detailed records of pest control inspections, recommendations and of any pest infestation. It shall be the responsibility of the site to ensure that all the relevant recommendations made by the contractor or in-house expert are		

	implemented in a timely manner and monitored for efficacy.		
4.11.9	Employees shall understand the signs of pest activity and be aware of the need to report any evidence to a designated manager.		
5	**PRODUCT AND PROCESS CONTROL**		
5.1	**Product Development**		
5.1 SOI	Documented product development or modification procedures shall be in place to ensure the production of safe and legal products to defined quality parameters.	8.1 8.2.2 8.3.1 8.3.2 8.5.6	Complies
5.1.1	Customer requirements relating to the design, development, specification, manufacture and distribution of the product shall be documented and agreed with the customer. This shall take into consideration process requirements and end use, where possible. Any critical-use parameters shall be identified and defined; for example, barrier requirements, max/min use temperature, machine running, use of recycled materials, and testing requirements (including migration, where relevant). Special attention shall be paid to any materials that are required or requested to be manufactured from recycled materials, to ensure that they are both appropriate and legal.	8.3.3 8.3.6 8.5.1	Complies
5.1.2	The site shall clearly define and document when a production trial is required. Where appropriate, production trials shall be carried out and testing shall validate that manufacturing processes are capable of producing a safe and legal product to the required quality.	8.2.3.1 8.3.4	Complies
5.1.3	The company shall ensure that production is carried out using defined operating	8.3.3	Complies

	conditions that result in safe and legal products of the prescribed quality.		
5.1.4	A technical product specification shall be prepared and, where possible, agreed with the customer or brand owner before the production process begins.	8.3.5	Complies
5.1.5	Samples as agreed with the specifier shall be retained for future reference.		
5.2	**Graphic Design and Artwork Control**		
5.2 SOI	Artwork and all pre-press processes conducted by the site shall be managed to ensure loss of information and variation from customer specification is eliminated.	8.3.2 8.5.3	Graphic design can be deemed a concern of product development processes when comparing ISO 9001 and Issue 5. For Issue 5, any artwork supplied to the company from a customer can be regarded as property belonging to them.
5.2.1	The site shall have a documented artwork management procedure covering the activities for which the site has responsibility. This may include, but is not limited to: • collation of information to be included into artwork • receipt of artwork files from the customer • verification of completed artwork and approval by the customer.		
5.2.2	A process shall be in place to seek formal acceptance and approval of final product concepts and artworks by the specifier. The outcome shall be documented.		
5.2.3	Where appropriate, print trials shall be carried out and testing shall validate that the agreed product quality and print standards can be consistently achieved.		
5.2.4	Printing equipment such as plates, silk screens, anilox rollers, cylinders and blankets shall be verified as being correct to specification and artwork version or agreed master prior to use, and fully		

	traceable to the customer's approved origination material.		
5.2.5	Customer-approved reference material, including artwork masters and colour standards used during print runs, shall be controlled to ensure minimisation of degradation and shall be returned to appropriate storage after use. The site shall have a policy to address requirements for renewal of approved masters, as necessary.		
5.2.6	The site shall have a documented procedure for managing changes to artwork and print specifications to manage obsolete artwork and printing materials.	8.5.6	Complies
5.2.7	Where artwork files and approved masters are in electronic form, these shall be suitably protected to prevent loss or malicious intervention.	8.5.3	Complies
5.3	**Packaging Print Control**		
5.3 SOI	Where packaging materials are printed or decorated, procedures shall be in place to ensure that the information is fully legible and correctly reproduced to customer specification and any applicable legal requirements.		
5.3.1	An assessment shall be carried out of the pre-press activity, print process and handling of printed packaging (product) to identify: • risks of loss of essential information • mixing of printed product. Controls shall be established and implemented to reduce the risks identified.		
5.3.2	Printing plates, cylinders, cutting dies, print blankets and any other printing equipment shall be appropriately stored to minimise damage.		

5.3.3	Each print run shall be approved against the agreed standard (or master sample). This shall be recorded.		
5.3.4	A system shall be in place to detect and identify printing errors during the run and to sort these errors from the acceptable printed material.		
5.3.5	Where composite print is used (a mixture of different designs printed together), a process shall be in place to ensure effective segregation of differing print variants.		
5.3.6	Samples of printed packaging shall be retained together with production records for a period of time to be agreed with the customer/specifier/brand owner.		
5.3.7	Any unused printed product shall be accounted for and either disposed of or identified and appropriately stored.	8.5.3	Complies
5.3.8	Lighting in print inspection cabinets and other means of print/colour checking shall be agreed with the customer or conform to accepted industry standards.		
5.4	**Process Control**		
5.4	Documented procedures shall be in place to ensure effective quality assurance of operations throughout the process.	4.4.1 5.1.2 (b) 8.1 8.5.4	Complies
5.4.1	A review of the manufacturing and, where applicable, printing process shall identify manufacturing process control points that could significantly affect the quality of the products produced.	4.4.1 5.1.2 (b) 8.1 8.5.4	Complies
5.4.2	For each manufacturing process control point, machine settings or process limits shall be established and documented – the process specification.		
5.4.3	A bill of materials and process specification (including manufacturing		

	process control points) shall be available for each batch or lot during production.		
5.4.4	Documented process checks shall be undertaken at start-up, following adjustments to equipment and periodically during production, to ensure products are consistently produced to the agreed quality specification.		
5.4.5	A documented clearance procedure shall be in place to ensure that at start-up the line is clear of all previous work and production documents.		
5.4.6	In the event of changes to product composition, processing methods or equipment, the site shall, where appropriate, re-establish process characteristics and validate product data to ensure product safety, legality and quality are achieved.	8.5.1 (f)	Complies
5.5	**Calibration and control of measuring and monitoring devices**		
5.5	The site shall be able to demonstrate that measuring and monitoring equipment is sufficiently accurate and reliable to provide confidence in measurement results.	7.1.5.2	Complies
5.5.1	The site shall identify and control in-line and off-line measuring equipment used to monitor critical control points (where applicable) and product safety, quality and legality. This shall include as a minimum: • a documented list of equipment and its location • an identification code and calibration due date • prevention from adjustment by unauthorised staff • protection from damage, deterioration and misuse.	7.1.5.2	Complies
5.5.2	All identified measuring equipment shall be checked and adjusted at a predetermined frequency, based on risk analysis. This shall be carried out by trained staff to a defined method to	7.1.5.2	Complies

	ensure accuracy within defined parameters. All results shall be documented. Where possible, calibration shall be traceable to a recognised national or international standard. Where a traceable calibration is not possible, the site shall demonstrate the basis by which standardisation is carried out.		
5.5.3	Corrective action and reporting procedures shall be established and documented in the event of the monitoring and testing procedure identifying any failure of product inspection, testing or measuring equipment. Any such failures shall be subject to an assessment of potential risk; subsequent action may include a combination of isolation, quarantine and re-inspection of products produced since the last acceptance test of the equipment. The site shall conduct a root cause analysis into the equipment failure and implement the appropriate corrective action.	8.7.2	Complies
5.6	**Product inspection, testing and measuring**		
5.6	The company shall use appropriate documented procedures and facilities when undertaking or subcontracting inspection and analyses critical to product safety, legality and quality.	7.1.5 8.6 9.1	Complies
5.6.1	Quality checks shall be carried out to demonstrate that the finished product is within the tolerances laid down in the agreed product specification and conforms to any critical technical/legal requirements. The frequency of checks shall be in accordance with industry-accepted practice or customer requirements and based on risk analysis.	7.1.5 8.6 9.1	Complies
5.6.2	Hazard and risk analysis principles shall be used to determine the need for in-line product testing equipment to ensure product safety, quality and legality.		

5.6.3	The accuracy of in-line equipment shall be specified (with permitted tolerances), having due regard to the product parameter being controlled.		
5.6.4	5.6.4 The company shall establish, document and implement procedures for the operation, routine monitoring and testing of all equipment used in product inspection, testing and measurement. This shall include: • frequency and sensitivity of checks • authorisation of trained personnel to carry out specified tasks • documentation of test results.	9.1.3	Complies
5.6.5	Routine off-line quality checks shall be carried out at appropriate stages in production to demonstrate that the product is within the tolerances laid down in the agreed product specification. A system, which includes off-line or randomised quality checks, shall be in place to identify and remove non-conforming product from the production lot and ensure that any appropriate action is taken in consideration of the root cause.		
5.6.6	In-line testing equipment critical to product quality or safety shall incorporate a system to identify non-conforming product for removal or divert it out of the product flow.		
5.6.7	5.6.7 Procedures shall be in place to ensure the reliability of test results.	9.1.3	Complies
5.6.8	Where the company undertakes or subcontracts analyses critical to product safety or legality, the laboratory or subcontractors shall have gained recognised laboratory accreditation or operate in accordance with the requirements and principles of ISO 17025 for the test undertaken (General requirements for the competence of testing and calibration laboratories). Documented justification shall be available where accredited methods are not undertaken.		

5.7	**Control of non-conforming product**		
5.7 SOI	The site shall ensure that out-of-specification product is clearly identified and quarantined.	8.5.3 8.7.1	Complies
5.7.1	5.7.1 Clear procedures for the control of out-of-specification or non-conforming materials shall be in place, documented and understood by all personnel. These shall include the effective identification and quarantining of materials before a decision has been made on their final disposition.	8.5.3 8.7.1	Complies
5.7.2	5.7.2 Non-conforming materials shall be assessed and a decision taken to reject, accept by concession, rework or put to alternative use. The decision and reasons shall be documented.	8.7.1	Complies
5.7.3	5.7.3 Corrective actions, root cause analysis and preventive actions shall be implemented to avoid recurrence of the non-conformity. Actions taken shall be documented.	8.7.2	Complies
5.8	**Incoming Goods**		
5.8 SOI	Incoming goods shall be appropriately checked for contents, packaging integrity and potential contamination.		
5.8.1	The site shall document a raw materials and intermediate product intake procedure to ensure that incoming goods match purchase or product specifications. This may take the form of: • purchase orders • delivery notes.		
5.8.2	Receipt documents and/or product identification shall facilitate correct stock rotation of goods in storage and, where appropriate, ensure materials are used in the correct order and within the prescribed shelf life.		
5.9	**Storage of all Materials and Intermediate and Finished Products**		

5.9	The storage of all materials and products shall minimise the risk of contamination or malicious intervention, and protect product safety, quality and legality.	8.5.4	Complies
5.9.1	All materials, work in progress and product shall be properly identified and protected during storage by appropriate packaging to protect the product from contamination.	8.5.4	Complies
5.9.2	Storage, including off-site storage, shall be controlled to protect the product from contamination, including taint or odour and malicious intervention. Where off-site storage is used, the same site standards requirements apply as for on-site storage.	8.5.4	Complies
5.9.3	In order to prevent contamination, documented procedures shall be in place to appropriately segregate raw materials, intermediate products and finished products.		
5.9.4	The site shall ensure that hazardous chemicals are handled in such a way that risk to product safety, quality and legality is minimised.		
5.9.5	Material intended for recycling shall be appropriately protected against contamination hazards.		
5.10	**Dispatch and transport**		
5.10 SOI	5.10 The dispatch and transport of raw materials and finished products shall be undertaken in a manner that minimises the risk of contamination or malicious intervention and maintains product safety, legality and quality.	7.1.3 (c) 8.5.4	Complies
5.10.1	All products and materials shall be identified and either protected during distribution by appropriate external packaging or transported under conditions to protect the product from contamination. This shall include the risk of taint or odour and of malicious intervention.	7.1.3 (c) 8.5.4	Complies

5.10.2	All pallets shall be checked. Damaged, contaminated or unacceptable pallets shall be discarded. Wooden pallets that come into direct contact with finished products or raw materials shall not be allowed to contaminate the product. Wooden pallets, if used, shall be sound, dry, clean and free from damage and contamination.		
5.10.3	All company-owned vehicles used for deliveries shall be included in the documented cleaning schedules and kept clean and in a condition to minimise the risk of product contamination.		
5.10.4	All delivery vehicles and shipping containers shall be subject to a documented hygiene-checking procedure before loading.		
5.10.5	Where the company employs third-party contractors there shall be a contract or agreed terms and conditions. All the requirements specified in this section shall be clearly defined in the contract or the company shall be certificated to the BRCGS Standard for Storage and Distribution. Where this is not possible, with general carriers, the packaging shall be adequate to protect the product against damage, contamination hazards, taint and odour.		
5.10.6	Vehicle drivers shall comply with the site rules relevant to this Standard. Access to the site for third-party transport personnel shall be controlled and, where possible, facilities provided to negate the need to enter storage or production areas.		
6	**PERSONNEL**		
6.1	**Training and Competence**		
6.1 SOI	The company shall ensure that all personnel are adequately trained, instructed and supervised commensurate with their activity and that they are competent to undertake their job role.	7.2	Complies

6.1.1	All personnel, including temporary personnel and contractors, shall be appropriately trained prior to commencing work and adequately supervised throughout the working period. Induction training shall include the company hygiene rules.	7.3	Complies
6.1.2	Where personnel are engaged in activities relating to product safety, quality and legality, relevant training and competency assessment shall be in place. This may include, but is not limited to: • product inspection, testing and measuring • calibration • printed packaging controls • operatives at manufacturing process control points.	7.2	Complies
6.1.3	The company shall routinely review and document the competencies of all staff and provide relevant training as appropriate. This may be in the form of training, refresher training, coaching, mentoring, or on-the-job experience.		
6.1.4	Records of training shall be available. These shall include: • the name of the trainee and confirmation of attendance • the date and duration of the training • the title or course contents, as appropriate • the training provider (external or internal provider). Where training is undertaken by agencies on behalf of the company, records of the training shall be available.	7.2	Complies
6.1.5	The site shall put in place documented programmes covering the training needs of relevant personnel. These shall include as a minimum: • identifying the necessary competencies for specific roles		

	• providing training or other action to ensure staff have the necessary competencies • reviewing the effectiveness of training • the delivery of training in the appropriate language of trainees.		
6.2	**Personal Hygiene**		
6.2 SOI	The site's personal hygiene standards shall be developed to minimise the risk of product contamination from personnel. These standards shall be appropriate to the products produced and be adopted by all personnel, including agency-supplied staff, contractors and visitors to the production facility.		
6.2.1	The requirements for personal hygiene shall be documented and communicated to all personnel. These shall include, as a minimum, the following instructions: • watches shall not be worn • jewellery shall not be worn on exposed parts of the body, with the exception of a plain wedding ring or wedding wristband and sleeper earrings (continuous loop). • perfume or aftershave shall not be worn. Compliance with the requirements shall be checked routinely.		
6.2.2	Hand washing shall be performed on entry to the production areas and at a frequency that is appropriate to minimise the risk of product contamination.		
6.2.3	Personal items and belongings, including personal mobile phones, shall not be taken into production areas without the permission of the management.		
6.2.4	Procedures and written instructions shall be in place to control the use and storage of personal medicines, to minimise the risk of product contamination.		

6.2.5	Fingernails shall be kept short and clean. False fingernails, nail varnish/polish or nail art shall not be permitted. Where visitors cannot comply, suitable control procedures shall be in place (e.g. non-handling of product, use of gloves).		
6.2.6	All cuts and grazes on exposed skin shall be covered by an appropriately coloured plaster that is different from the product colour (preferably blue). These shall be site issued and monitored when involved in work with materials intended to come into direct contact with food or other hygiene-sensitive products. Where appropriate, in addition to the plaster, a finger stall or glove shall be worn.		
6.3	**Staff Facilities**		
6.3 SOI	Staff facilities shall be sufficient to accommodate the required number of personnel and shall be designed and operated to minimise the risk of product contamination. Such facilities shall be kept in a good and clean condition.		
6.3.1	Locker rooms shall be accessed without the need to enter production areas unless appropriately segregated walkways are in place.		
6.3.2	Lockers shall be provided for all personnel who work in raw material handling, processing, preparation, packing and storage areas. Lockers shall be of sufficient size to accommodate all reasonable personal items and any protective clothing required.		
6.3.3	Site-issued protective clothing and personal clothing shall not be stored in the same locker or shall be effectively segregated within the locker.		
6.3.4	Eating (including the eating of confectionery and chewing of gum or tobacco), drinking and smoking shall not be allowed in locker and changing rooms.		

6.3.5	Suitable and sufficient hand-washing facilities shall be available to enable cleaning of hands before commencing work, after breaks, and as necessary during the course of work. Such hand-washing facilities shall provide, as a minimum: • sufficient quantity of water at a suitable temperature to encourage hand washing • unscented liquid soap or foam • adequate hand-drying facilities • advisory signs to prompt use (including signs in appropriate languages). Where materials are handled that will be in direct contact with food or other hygiene-sensitive products, hand-washing facilities shall be sited at the entrance to the production area.		
6.3.6	Toilets shall not open directly into storage, processing or production areas in order to prevent the risk of contamination to product. Toilets shall be provided with suitable and sufficient hand-washing facilities.		
6.3.7	Facilities for visitors and contractors shall enable compliance with the site's hygiene policy.		
6.3.8	All food brought into manufacturing premises shall be stored in a clean and hygienic state. No food shall be taken into storage, processing or production areas.		
6.3.9	Eating (including the eating of confectionery and chewing of gum or tobacco), drinking and smoking shall not be allowed in the production or storage areas. If it is impractical for personnel to leave their work area, local controlled facilities (such as a fully walled area with hand-washing facilities) shall be provided.		
6.3.10	Drinking of water from purpose-made dispensers and/or by using disposable conical cups or spill-proof lidded containers may be allowed, provided it is		

	confined to a designated area away from equipment.		
6.3.11	Where smoking is allowed under national law, it shall only be permitted in designated controlled smoking areas which shall be isolated from production and storage areas and fitted with extraction to the exterior of the building. Adequate arrangements for dealing with smokers' waste shall also be provided at smoking facilities, both inside buildings and at external locations. The use of electronic cigarettes and associated materials shall not be permitted in locker rooms, or in production or storage areas, and shall only be permitted in designated smoking areas.		
6.4	**Medical Screening**		
6.4 SOI	The company shall ensure that documented procedures are in place to ensure health conditions likely to adversely affect product safety are monitored and controlled.		
6.4.1	Where there is handling of materials intended for direct contact with food or other hygiene-sensitive products, the site shall make employees aware of the symptoms of infection, disease or condition which would prevent a person working. The site shall have a procedure for the notification by personnel, including temporary personnel, of any relevant infections, diseases or conditions with which they may have been in contact or be suffering from. Employees, contractors and visitors suffering from any of the above shall be excluded from work involving the handling of direct-food contact or other hygiene-sensitive product packaging for as long as the symptoms persist.		
6.4.2	Where permitted by law, visitors and contractors shall be required to fill in a health questionnaire or otherwise confirm that they are not suffering from any symptoms which may put product safety		

	at risk, prior to being allowed into production, packing or storage areas.		
6.5	**Protective Clothing**		
6.5 SOI	Appropriate protective clothing shall be worn in production and storage areas to minimise the risk of product contamination.		
6.5.1	Hazard and risk principles shall be used to determine the need for protective clothing, including garments and footwear in raw materials handling, preparation, production and storage areas. Where no need for protective clothing has been established by risk assessment in a particular area, it shall be fully justified and shall not pose a contamination risk to the product.		
6.5.2	The company shall use risk assessment to determine, document and communicate to all employees, including temporary personnel and contractors, the rules regarding: • the wearing of protective clothing on the journey to work • the wearing of protective clothing in raw materials handling, preparation, production and storage areas • the wearing of protective clothing away from the production environment (e.g. removal before entering toilets, canteen or smoking areas).		
6.5.3	Where the need for protective clothing has been determined, appropriate clean protective clothing that cannot contaminate the product shall be worn. Sufficient sets of clothing appropriate to the activities carried out shall be provided.		
6.5.4	Protective clothing worn in production areas shall provide adequate coverage of the upper torso.		

	Where there is handling of materials intended for direct contact with food or other hygiene-sensitive products, the clothing shall have no external pockets on the upper body garments or sewn-on buttons. Changes of such clothing shall be available at all times as required.		
6.5.5	Based on the assessment of risk to the product, suitable footwear shall be worn within the factory environment.		
6.5.6	In production and packing areas, hazard and risk analysis shall be used to determine the need for: • snoods for beards and moustaches • scalp hair coverings.		
6.5.7	If gloves are used they shall be replaced regularly, be distinctive, intact and not cause a contamination risk to the product.		
6.5.8	Protective clothing shall be kept clean and laundered. Laundering shall be carried out by one of the following methods: • professional laundry service • in-house • controlled laundering facilities • self-care.		
6.5.9	Where self-care laundry is permitted, it shall be ensured that: • employees have received written instructions regarding the laundering process to be used and these shall be reinforced as part of an induction or other in-house training programme • employees shall be provided with suitable means to safely transport washed garments from home to the workplace • there shall be a defined process within the site for monitoring the effectiveness of the system		

	• there shall be a procedure and system for dealing with any case where employees are unable to perform self-laundry effectively, through lack of either diligence or facilities.		
6.5.10	Clean and dirty clothing shall be segregated and controlled to prevent cross-contamination.		
6.5.11	Disposable protective clothing, if used, shall be subject to adequate control to avoid product contamination.		