BRCGS Standard for Packaging and Packaging Materials

P555: Additional Interpretation

Document Scope

Additional interpretation for all users of the BRCGS Standard for Packaging and Packaging Materials, Issue 5.

Change log

Version No.	Date	Description
1	Feb-17	First issue
2	29/07/2019	New BRCGS logo and footer changed

1.1	**Senior management commitment and continual improvement**
1.1.6 Add interp	Withdrawal from the scheme While it is generally incompatible with the successful implementation of the scheme, it may be necessary for a site to withdraw from the scheme. Should this occur, then a minimum of 6 months shall pass before a site can begin the certification process. The site shall be required to undergo an initial audit and the date of certification shall not be related to any previous certification.
1.2	**Management review**
1.2.2 Add Interp	The Standard specifies that customer complaint data is to be included in the management review process, and that review meetings are undertaken at appropriate planned intervals. This should include review of complaint data, including the quantity of complaints and/or returns etc. compared to targets or objectives on a frequent enough basis to enable efficient response to emerging trends. The objective here is to ensure that sites don't focus solely on the financial impacts, but assess the detail and specific data associated with the complaints. Embedding this approach in the culture of senior management ensures that senior management fully understand the challenges and opportunities for their organisation.
1.3	**Organisational structure, responsibilities and management authority**
1.3 Add Interp	The site shall have an accountable person (or persons), with clearly defined responsibilities and a suitable level of independence and expertise for key decisions around product quality, such as product release, release from quarantine, etc. This person should be able to determine if product is suitable to be released to the customer based on the level of compliance the batch has with the agreed specification, without regard to the implications of not releasing product.
2	**Hazard and risk management system**
2.2	**Hazard and risk analysis**
2.2 Add Interp	It's vital that sites assess hazards to product quality, no matter how minor the potential quality issue might be perceived as. Any deviation from customer specification should be regarded as a potential quality issue. Assessing these potential quality issues at this point allows for any quality system pre-requisite programmes as set out in Section 5 to be validated, while establishing any special measures (which might be referred to as

	quality control points) which form part of the site's comprehensive product safety and quality management system.
3.5	**Internal audits**
3.5.1 Add Interp	The scope of internal audits need to be relevant to the site's aims and objectives, of which, achieving or maintaining certification to the Standard and any relevant additional voluntary modules (AVMs) should be one. Therefore, the site's internal audit programme should cover all of the aspects addressed by the Standard and its modules. Internal audits are a fundamental requirement within the Standard because an effectively implemented internal audit programme, with useful reports and functional non-conformity procedure is fundamental to the site's understanding of its level of compliance to the Standard. The importance of the internal audit programme cannot be underestimated. Reports from internal audits should be detailed enough that anyone who reads the report (and who is not related to the audit) can gain a good understanding of the condition of the aspect being audited. For example, an audit on the calibration of measuring devices finds that the calibration records of a vision system on a production line which is used to check print and detect physical contamination are not available. The responsible person should be notified and a corrective and preventive action plan developed to manage the issue, then the whole outcome of the report shared with senior management. Often, it's only senior management who are in a position to make any human or financial resources required as a result of a systems failure that may indicate a deeper root cause. The Standard requires that sites that use a risk-assessment to determine its internal audit programme, with every aspect audited at least annually (once a year). This includes the requirements of any additional modules. A risk-based approach should mean that certain aspects are audited on a more frequent basis which will result in non-conformities being raised that may need to be notified to senior management on a more frequent basis. There needs to be a mechanism to manage this where management review meetings are less frequent than the outputs of internal audits.
3.11 Add Interp	Ultimately the desired outcome of managing complaints from customers, conducting analysis and determining the root cause is to reduce the overall number of complaints received. Sites that work with their customers to identify complaints, and potential complaints or opportunities for process improvements, will see benefits through cost-savings, improved resource efficiency and demonstrating a commitment to continuous improvement.
3.11.2	The quality of complaint investigations should be considered, particularly where it's a key input to trending and analysis of complaints and their

Add interp	root causes. Sites might consider the use of tools such as ishikawa (fishbone), or 5 whys to facilitate an effective root cause analysis.
4.1.2 Add Interp	External areas should be generally tidy with storage of excess waste or other debris avoided. External areas should not be a dumping ground for old equipment, and unwanted materials and become potential harbourage for pests.
4.1.3 Add interp	Where damaged to the building is identified, it should be recorded and scheduled for correction. Risk assessment can be used to prioritise corrective actions, and damage that can cause immediate potential hazards to the product corrected promptly. Site personnel should be vigilant to the appearance of damage over time. This is often difficult as people become accustomed to their surroundings, but many non-conformities arise on the site tour part of the audit through the presence of gaps around doors, or where walls or floors are found to be in poor condition. This doesn't mean the site is required to undertake an extensive renovation projects in order to meet the Standard, unless it's found that the site requires this in order to meet some of the specific requirements in the Standard.
4.2	**Building fabric and interiors**
4.2 Add interp	In order to maintain a good level of tidiness and cleanliness in production areas, sites may choose to pursue a 5S approach. This method describes how to organize working spaces for efficiency and effectiveness by identifying and storing the items used, maintaining the area and items, and sustaining the new order. The 5 S are: **Sort** remove unnecessary materials and sort those that are required to aid the working process **Set in Order** arrange materials required in order to smooth the workflow **Shine** clean the work area and maintain cleanliness to keep it safe and easy to work in **Standardise** implement standardised practices to facilitate consistency **Sustain** maintain the system and use internal audits to monitor effectiveness of the system.
4.7	**Maintenance**
4.7.2 Add Interp	The Standard requires that the site implement an effective maintenance programme addressing all items of production, equipment and plant, in addition to a condition-based preventive maintenance programme. Both factors should direct the site to a point where compliance to

	customer product safety, quality and regulatory requirements are facilitated rather than hindered by the condition of equipment. The auditor will expect to see a risk-based ongoing maintenance programme for all equipment on site, with evidence of maintenance and activities undertaken in logs and potentially a demonstrable benefit through reduced breakdowns or equipment failures, which may be reflected in the site's objectives. Tracking planned and preventive maintenance and breakdowns also allows the site to identify recurrence of breakdowns or required unplanned maintenance and opportunities for equipment replacement.
4.7.4 Add Interp	On occasions where equipment is subject to maintenance interventions, it may be necessary to re-validate specified machine settings, particularly those that have been determined to be quality control points. Sites should consider this in their maintenance and change management procedures, and assess under which circumstances re-validation may be required, allowing time and resources to be allocated to conduct the activity.
4.8 Add. Interp	The site should also determine the cleaning frequency for structures at a high level. This may be building structures, framework for production equipment, brackets and struts. All of which are potential sources of physical contamination.
4.11.9 Add. Interp	The Standard requires that employees understand the signs of pest activity and be aware that should they identify evidence of pests then they should notify someone who is able to act on the information. Note that in addition to signs of pest activity, personnel should also be aware of potential points of pest ingress, such as gaps or holes in doors or open doors, and where materials or grassy areas next to buildings might camouflage these. It's vital that everyone on site is involved in pest control, and other measures, to maintain the required hygiene level.
5.4.1 Add. Interp	The purpose of assessing the whole manufacturing process through the hazard and risk analysis, and validation and verification of the implementation and use of the pre-requisite programmes, is to ensure that if at any point any aspect might go out of control, the site is aware of the potential for an out of control result and have mitigating measures in place. It's tempting to think only about significant issues, such as those that might cause harm to human health. However, this requirement can and should be applied more broadly and more in-depth to ensure that any parameter that might produce an out of specification result is controlled; no matter how slight the impact, and no matter how infrequent the occurrence. This will ensure appropriate quality is maintained.

	Consideration shall be given to use of raw materials. Are they sufficiently controlled and validated to ensure the quality required using them can be achieved? This may be through the provision of certificates of analysis (CofA), or in-house/contracted testing of raw materials. Similarly, the site should ensure that the process been validated with consideration of the parameters of raw materials, such as relative humidity, or temperature. The site might take a risk-assessed approach to this. Considering those factors that are critical to product safety and quality, then penetrating to the less frequent issues.
5.4.4 Add. Interp	The site is required to have documented the validated settings for use in processes, then record the actual key critical process settings. The site should ensure that they have physical records of critical quality parameters, which not only allow control adjustment to previously validated tolerances/settings, but allows for trends to be seen and also offers clear records for root cause analysis when quality issues are detected.
5.6.4 Add. Interp	Where automated vision systems are in use, they should be challenged tested with appropriate samples to ensure correct function. The site should have a programme of testing, but the auditor should view a challenge test and assess the outcome. The rationale for the testing methods developed by the site should be relative to the parameters being examined, ensure the system is capable of identifying the required level of contaminant or deviation from specification.
5.7 Add Interp	All rejected or non-conforming product must be physically segregated from fit-for-purpose product. The procedure should cover how non-conforming product will be labelled or identified, with what information, how it should be held in any electronic inventory system and who has the authority to release it. Periodic testing of any electronic inventory control system of quarantined product should be in place and documented. The intent here is that anything that is quarantined cannot be inadvertently shipped to the customer.
6.1.2 Add Interp	Specific skill training should cover all tasks related to all control points including all quality parameters that may or may not create a safety issue. This is about broadening focus solely from CCPs that injure people to quality control points that creates non-conforming products that do not meet customer specification and expectation.