**BRCGS SELF-ASSESSMENT TOOL**

**High Hygiene Category**

**Welcome to the BRCGS Self-Assessment tool**

We hope that you will find this useful when preparing your site for an audit against the BRCGS Standard for Packaging and Packaging Materials Issue 5 and AuditOne requirements. This tool contains the requirements for the BRCGS AuditOne Module only, a checklist containing the requirements of Issue 5 high hygiene, plus the Module requirements is available (PAM9005) and any audit against Issue 5 and the Module will audit all requirements together.

**How to use the BRCGS Self-Assessment tool**

This tool is designed to help you assess your operation against the requirements of the Module and help prepare you for your certification audit.

The checklist covers each of the requirements of the Module and may be used to check your site’s compliance with each of these requirements. The checklist also allows you to add comments or identify areas of improvement in the empty boxes provided at the end of each section.

While we hope that this tool is useful in helping you prepare for your audit it should not be considered as evidence of an internal audit and will not be accepted by auditors during an audit.

**Training**

The BRCGS Training Academy has courses available to improve the understanding of the requirements for the BRCGS Standard for Packaging and Packaging Materials issue 5 and may be useful for the person using the BRCGS Self-Assessment Tool. For further information on the courses available please visit [brcgs.com/training/](https://www.brcgs.com/training/)

**Further Information**

If you have any further questions about this self-assessment tool or Issue 5 please do not hesitate to contact the BRCGS team.

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| **Ref.**  | **Clause** |  |
| **1** | **Senior Management Commitment** |  |
| **1.4** | **Business recovery plan**  |
| SOI  | The company’s senior management shall ensure that the continuing operation of the company is assured through a business recovery plan  |  |
| 9.1.4.1 | Electronic files, records, data and systems shall be suitably protected and backed up. A test of the system shall be carried out at least once per year, or when any significant changes are made to the system.  |  |
| Notes |  |
| **3** | **Product safety and quality management** |  |
| **3.1** | **Product safety and quality management system**  |  |
| 9.3.1.3 | The site shall define and document how new procedures, working methods and practices are communicated to relevant personnel.  |  |
| Notes |  |
| **3.3** | **Record keeping**  |  |
| 9.3.3.5 | A policy shall state that Production records and all other records associated with product safety, quality and legality shall be written indelibly. Any alterations to records shall be authorised and justification for the alteration shall be recorded.  |  |
| Notes |  |
| **3.11** | **Complaint handling**  |  |
| 9.3.11.3 | All complaints regarding raw material defects identified by the site shall be recorded and investigated (including root cause analysis) and the results of the investigation documented. |  |
| Notes |  |
| **4** | **Site Standards**  |  |
| **4.1** | **External standards**  |  |
| 9.4.1.6 | Where production and storage areas are surrounded by grassed or planted areas, there shall be a vegetation free zone around the buildings.  |  |
| Notes |  |
| **4.6** | **Equipment**  |  |
| 9.4.6.5 | Lubrication points and application methods of any lubricant shall not be able to contaminate the product. |  |
| Notes |  |
| **4.8** | **Housekeeping and cleaning**  |  |
| 9.4.8.5 | The conditions required in production and storage areas shall be specified. There shall be a regular documented check that conditions match those required, and activity undertaken where required.  |  |
| 9.4.8.6 | The site shall ensure that equipment, in-process and finished articles are subject to sufficient segregation to reduce the risk of mixing. |  |
| Notes |  |
| **4.11** | **Pest control**  |  |
| 9.4.11.10 | The site shall assess the suitability of its pest control programme to address variation in pest activity through different seasons, and consider any additional preventative activity required. The site shall document and implement this additional activity. |  |
| 9.4.11.11 | Risk assessment and ongoing data should be used to determine whether lighting type or positioning is adversely attracting insects and/or highlighting any mitigation where required. Internal and external lighting for production and storage buildings shall be designed and constructed to avoid attracting insects through windows or other openings.  |  |
| 9.4.11.12 | The site shall use a documented risk and ongoing assessment to determine if double door sets are required when moving from external to internal areas. The site shall conduct ongoing assessment to determine if the closing systems are effective, where implemented.  |  |
| Notes |  |
| **9.4.12** | **Ambient Environment**  |
| SOI  | The site shall ensure that local environmental factors such as temperature and humidity do not affect product quality from raw materials to finished products.  |  |
| 9.4.12.1 | The site shall evaluate the typical local environmental conditions such as temperature and humidity on the quality and process characteristics (e.g. machine settings). Evaluation of hazards identified shall be documented, and measures established to manage this impact shall be documented and validated. |  |
| **5** | **Product and process control** |  |
| **5.1** | **Product development** |  |
| 9.5.1.6 | A documented procedure shall be place to address the transfer of customer specification to the site’s own systems. This shall include (but is not limited to): * validation of accuracy of data transferred
* how changes to customer specifications are updated and communicated
* how customer testing method requirements are met
* evaluation of how changes made to customer specification affect the technical product specification (5.1.1)
 |  |
| 9.5.1.7 | New products or product changes shall be subject to suitable testing to ensure that required quality parameters can be achieved. |  |
| 9.5.1.8 | The site shall determine the outputs and success criteria required from a production trial, changes and/or additions made to materials, processing characteristics or equipment.  |  |
| 9.5.1.9 | Settings derived from successfully qualified production trials or equipment installations shall be transferred accurately to process control documentation.  |  |
| 9.5.1.10 | The site’s test methods used in both on-line and off-line testing shall be validated to ensure their validity, sensitivity, reproducibility and range, in addition to any other relevant criteria.  |  |
| Notes |  |
| **5.4** | **Process control**  |  |
| 9.5.4.7 | The documented line clearance procedure shall include:* the roles of persons involved in line clearance
* areas where materials can become trapped
* validation of the line clearance
* sign-off for continuing production

The line clearance procedure shall be fully implemented for each production run. |  |
| Notes |  |
| **5.6** | **Product inspection, testing and measuring** |  |
| 9.5.6.9 | Samples for checking in-process quality shall be selected according to customer requirements or by industry standard testing protocols.  |  |
| 9.5.6.10 | The site shall define how samples used for checking in-process quality are disposed of. This may be by returning to stock, re-grind/recycling, or segregation and disposal.  |  |
| 9.5.6.11 | Test methods, analytical methods and customer approved reference samples shall be available, kept up to date in the laboratory or where off-line testing is conducted, and shall be suitably stored to avoid degradation.  |  |
| 9.5.6.12 | Traceability of test data and samples to production lots shall be maintained.  |  |
| 9.5.6.13 | Where testing shows out of specification results, there shall be a documented procedure on how these results are investigated to determine if the cause of the out of specification results is non-conforming product or a testing failure. (Re-testing of an out of specification sample shall be done to demonstrate analytical error, not to reverse a previous result.) |  |
| 9.5.6.14 | Maintenance logs shall be maintained for all off-line testing equipment. This shall include as a minimum: * adjustments
* re-calibration
* date of any interventions.
 |  |
| Notes |  |
| **5.8** | **Incoming goods** |  |
| 9.5.8.3 | All incoming raw materials shall be appropriately validated or tested prior to use. All raw materials awaiting results of in-house testing or validation of data shall be held until released for use.  |  |
| Notes |  |
| **5.9** | **Storage of all materials and intermediate and finished products** |  |
| 9.5.9.6 | All raw materials shall have an expiration date defined and documented and a procedure defining how they should be handled where they exceed this date. Where raw materials have no reasonable expiration date, e.g. cullet for glass manufacture, this shall be documented.  |  |
| 9.5.9.7 | Warehousing equipment shall be kept in a good state of repair and cleanliness.  |  |
| 9.5.9.8 | Materials shall be stored away from walls to aid cleaning and inspection of production and storage areas.  |  |
| 9.5.9.9 | To minimise the risk of mix-ups and cross contamination, different materials shall not be stored on the same pallet unless physically segregated.  |  |
| Notes |  |
| **5.11** | **Product handling** |
| SOI  | The handling and management of intermediate and finished products shall ensure their quality is maintained.  |  |
| 9.5.11.1 | Packaging used for storage or despatch of intermediate or finished products, such as pallets, shall be appropriately covered if stored outside and inspected for signs of damage or contamination prior to use.  |  |
| 9.5.11.2 | Finished products shall not be stored outside.  |  |
| 9.5.11.3 | The site shall have a system in place to validate all raw materials and intermediate products prior to introduction to the process.  |  |
| 9.5.11.4 | Unloading areas for bulk deliveries shall be clearly identified and designed to prevent product mix-ups. |  |
| 9.5.11.5 | Finished product storage shall meet customer requirements (with regards to first-in-first-out, or FIFO, where applicable), with dispatch after quality release. |  |
| Notes |  |
| **5.12** | **Product release** |
| SOI  | The final product release to the customer shall be determined by a suitably trained and competent person.  |  |
| 9.5.12.1 | The site shall have a procedure that defines how the release of products shall be approved by an authorised person.This procedure shall ensure that only product meeting specification is shipped.  |  |
| Notes |  |
| **5.13** | **Validation and change control**  |
| SOI  | The labelling of intermediate and finished product shall facilitate identification throughout the supply chain.  |  |
| 9.5.13.1 | All coding applied to intermediate or finished products shall be checked for legibility and accuracy against production records.  |  |
| 9.5.13.2 | Labelling or any other type of identification shall be applied at the line of manufacture upon completion. |  |
| 9.5.13.3 | The site shall have documented procedure in place controlling label reprints and pallet labelling. |  |
| Notes |  |
| **6** | **Personnel**  |  |
| **6.1** | **Training and competence** **raw materials handling, preparation, processing, packing and storage areas** |  |
| 9.6.1.6 | The effectiveness of trainers shall be monitored and verified.  |  |
| 9.6.1.7 | The site shall ensure that the competency of personnel responsible for laboratory testing and assessment is maintained and developed.  |  |