**BRCGS GLOBAL MARKETS FOR PACKAGING**

**INTERMEDIATE LEVEL SELF-ASSESSMENT CHECKLIST**

**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 Global Markets for Packaging: Intermediate Level. This tool will be applicable for all BRCGS Global Markets for Packaging (Issue 5) audits for sites manufacturing food packaging.

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

This tool is designed to help you assess your operation against the requirements of the Global Markets programme and help prepare you for your audit.

The checklist covers each of the basic and intermediate level requirements of the Standard 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** |  |
| **1.1** | **Senior Management Commitment and Continual Improvement** |  |
| SOI | The company’s senior management shall demonstrate that they are fully committed to the implementation of requirements of the Global 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. |  |
| 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. |  |
| Notes |  | |
| **1.3** | **Organisational structure, responsibilities and management authority** |  |
| 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. |  |
| 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. |  |
| 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. |  |
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| **2** | **Hazard and risk management system** |  |
| **2.1** | **Hazard and risk management team** |  |
| 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. |  |
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| **2.2** | **Hazard and risk analysis** |  |
| 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. |  |
| 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. |  |
| 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. |  |
| 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. |  |
| 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. |  |
| 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 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. |  |
| 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 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. |  |
| 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). |  |
| 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. |  |
| 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) * 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. |  |
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| **2.3** | **Exemption of requirements based on risk analysis** |  |
| SOI | 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. |  |
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| **3** | **Product safety and quality management** |  |
| **3.1** | **Product Safety and Quality Management** |  |
| 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. |  |
| 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. |  |
| 3.1.2 | The system shall be fully implemented, reviewed at appropriate planned intervals and improved where necessary. |  |
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| **3.2** | **Documentation Control** |  |
| SOI | An effective document control system shall ensure that only the correct versions of documents, including recording forms, are available and in use. |  |
| 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. |  |
| Notes |  | |
| **3.3** | **Record keeping** |  |
| SOI | The site shall maintain genuine records to demonstrate the effective control of product safety, legality and quality. |  |
| 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 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. |  |
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| **3.4** | **Specifications** |  |
| 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. |  |
| 3.4.1 | Specifications shall be suitably detailed and accurate, and shall ensure compliance with relevant product safety and legislative requirements. |  |
| 3.4.5 | A specification review process shall be operated where product characteristics change or at an appropriate predetermined interval. |  |
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| **3.5** | **Internal Audits** |  |
| SOI | The company shall be able to demonstrate that it verifies the effective application of the requirements of the Global Standard for Packaging and Packaging Materials through internal audits. |  |
| 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. |  |
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| **3.6** | **Supplier approval and performance monitoring** |  |
| SOI | The company shall operate effective, documented procedures for approval and monitoring of its suppliers. |  |
| 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. |  |
| 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 BRC Global Standard, or other GFSI benchmarked scheme) * supplier questionnaires * supplier audits.   The site shall have an up-to-date list of approved suppliers. |  |
| 3.6.3 | Records of supplier assessment and necessary actions shall be maintained and reviewed. |  |
| Notes |  | |
| **3.7** | **Management of subcontracted processes** |  |
| 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. |  |
| 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. |  |
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| **3.9** | **Traceability** |  |
| 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. |  |
| 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. |  |
| 3.9.2 | Identification of raw materials, intermediate products, finished products, non-conforming product and quarantined goods shall be adequate to ensure traceability. |  |
| 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. |  |
| 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. |  |
| 3.9.5 | Where rework or any reworking operation is performed, traceability shall be maintained. |  |
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| **3.11** | **Complaint handling** |  |
| SOI | Customer complaints relating to product hygiene, safety or quality shall be handled effectively and the information used to reduce complaint levels. |  |
| 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. |  |
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| **3.12** | **Management of product withdrawals, and incidents and product recalls** |  |
| 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. |  |
| 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, 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. |  |
| 3.12.4 | 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. |  |
| 3.12.8 | 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. |  |
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| **4** | **Site Standards** |  |
| **4.1** | **External standards** |  |
| 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. |  |
| 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. |  |
| 4.1.4 | Where natural external drainage is inadequate, additional drainage shall be installed. Drains shall be properly protected to prevent entry of pests. |  |
| Notes |  | |
| **4.2** | **Building fabric and interiors** |  |
| SOI | 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. |  |
| 4.2.1 | Walls, floors, ceilings and pipework shall be maintained in good condition and shall facilitate cleaning. |  |
| 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. |  |
| Notes |  | |
| **4.3** | **Utilities** |  |
| 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. |  |
| 4.3.1 | All water used in the processing of the products or equipment cleaning shall be potable or suitably treated to prevent contamination. |  |
| 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. |  |
| Notes |  | |
| **4.4** | **Security** |  |
| SOI | Security arrangements shall be assessed to ensure the integrity of products and processes. |  |
| 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. |  |
| Notes |  | |
| **4.5** | **Layout and product flow** |  |
| 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. |  |
| 4.5.2 | The process flow from intake to dispatch shall be arranged to minimise the risk of contamination or damage to the product. |  |
| Notes |  | |
| **4.6** | **Equipment** |  |
| SOI | 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. |  |
| 4.6.1 | Equipment shall be designed for the intended purpose and shall minimise the risk of contamination to the product. |  |
| Notes |  | |
| **4.7** |  |  |
| SOI | An effective maintenance programme shall be in operation for plant and equipment to prevent contamination and reduce the potential for breakdowns. |  |
| 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. |  |
| 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. |  |
| 4.7.4 | 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. |  |
| Notes |  | |
| **4.8** | **Housekeeping and cleaning** |  |
| 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. |  |
| 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. |  |
| Notes |  | |
| **4.9** | **Product contamination control** |  |
| SOI | All practicable steps shall be taken to identify, eliminate, avoid or minimise the risk of foreign body or chemical contamination. |  |
| **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. |  |
| 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. |  |
| Notes |  | |
| **4.10** | **Waste and waste disposal** |  |
| SOI | Suitable facilities shall be provided for the storage and disposal of process and other waste. |  |
| 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. |  |
| Notes |  | |
| **4.11** | **Pest control** |  |
| 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. |  |
| 4.11.7 | 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. |  |
| 4.11.9 | Employees shall understand the signs of pest activity and be aware of the need to report any evidence to a designated manager. |  |
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| **5** | **Product and process control** |  |
| **5.1** | **Product development** |  |
| SOI | Documented product development or modification procedures shall be in place to ensure the production of safe and legal products to defined quality parameters. |  |
| 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. |  |
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| **5.2** | **Graphic design and artwork control** |  |
| 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. |  |
| 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. |  |
| 5.2.5 | 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. |  |
| Notes |  | |
| **5.3** | **Packaging print control** |  |
| 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. |  |
| 5.3.3 | 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. |  |
| 5.3.7 | Any unused printed product shall be accounted for and either disposed of or identified and appropriately stored. |  |
| Notes |  | |
| **5.4** | **Process Control** |  |
| SOI | Documented procedures shall be in place to ensure effective quality assurance of operations throughout the process. |  |
| 5.4.2 | For each manufacturing process control point, machine settings or process limits shall be established and documented – the process specification. |  |
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| **5.5** | **Calibration and control of measuring and monitoring devices** |  |
| SOI | The site shall be able to demonstrate that measuring and monitoring equipment is sufficiently accurate and reliable to provide confidence in measurement results. |  |
| 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. |  |
| 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 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. |  |
| Notes |  | |
| **5.6** | **Product inspection, testing and measuring** |  |
| SOI | The company shall use appropriate documented procedures and facilities when undertaking or subcontracting inspection and analyses critical to product safety, legality and quality. |  |
| 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. |  |
| 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. |  |
| Notes |  | |
| **5.7** | **Control of non-conforming product** |  |
| SOI | The site shall ensure that out-of-specification product is clearly identified and quarantined. |  |
| 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. |  |
| 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. |  |
| Notes |  | |
| **5.9** | **Storage of all materials and intermediate and finished products** |  |
| SOI | The storage of all materials and products shall minimise the risk of contamination or malicious intervention, and protect product safety, quality and legality. |  |
| 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. |  |
| 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. |  |
| Notes |  | |
| **5.10** | **Dispatch and transport** |  |
| SOI | 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. |  |
| 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. |  |
| 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. |  |
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| **6** | **Personnel** |  |
| **6.1** | **Training and competence**  raw materials handling, preparation, processing, packing and storage areas |  |
| 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. |  |
| 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. |  |
| 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. |  |
| 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, and 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. |  |
| 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.   The site shall put in place documented programmes covering the training needs of relevant personnel. |  |
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| **6.2** | **Personal hygiene**  **raw materials handling, preparation, processing, packing and storage areas** |  |
| 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. |  |
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| **6.3** | **Staff facilities** |  |
| 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. |  |
| 6.3.2 | 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. |  |
| 6.3.5 | 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. |  |
| 6.3.8 | 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. |  |
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| **6.4** | **Medical screening** |  |
| 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. |  |
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| **6.5** | **Protective clothing** |  |
| SOI | Appropriate protective clothing shall be worn in production and storage areas to minimise the risk of product contamination. |  |
| 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). |  |
| Notes |  | |