**BRCGS SELF-ASSESSMENT TOOL**

**Basic 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. This tool will be applicable for all BRCGS Standard for Packaging and Packaging Materials Issue 5 audits in the Basic Hygiene Category.

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

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

The checklist covers each of the 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.** |  | **Comment** |
| **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 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. |  |
| 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. |  |
| 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 * monitored, and the results reported at a suitable predetermined frequency to the site’s senior management * reviewed at least annually. |  |
| 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 program and maintain compliance with this Standard. |  |
| 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 . |  |
| 1.1.5 | The site shall have a genuine, current hard copy, or electronic version of the 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, second-party, and third-party audits, with consideration of the root cause. |  |
| Notes |  | |
| **1.2** | **Management Review** |  |
| 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. |  |
| 1.2.1 | Management review meetings attended by the site’s senior management shall be undertaken at appropriate planned intervals; as a minimum annually. |  |
| 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. |  |
| 1.2.3 | Records of management reviews and action plans shall be documented. |  |
| 1.2.4 | Product safety, legality, and quality issues shall be brought to the attention of senior management, allowing for the resolution of issues requiring immediate action. |  |
| Notes |  | |
| **1.3** | **Organisational structure, responsibilities and management authority** |  |
| SOI | The organizational structure shall be clear, with defined responsibilities, and key staff shall be aware of their responsibilities with regard to packaging safety and quality. |  |
| 1.3.1 | The site shall have a current organization 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 deputizes in the absence of the responsible person. |  |
| 1.3.2 | 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. |  |
| Notes |  | |
| **2** | **Hazard and risk management system** |  |
| **2.1** | **Hazard and risk management team** |  |
| SOI | The hazard and risk management system shall be managed by a multidisciplinary team competent in hazard and risk analysis. |  |
| 2.1.1 | There shall be a multidisciplinary team with a designated team leader who shall be suitably trained and able to demonstrate competence and experience of hazard and risk analysis.  In the event that the site does not have the appropriate expertise in-house, external expertise may be used to analyze 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. |  |
| Notes |  | |
| **2.2** | **Hazard and risk analysis** |  |
| SOI | A documented hazard and risk management system shall establish the effectiveness of the site’s prerequisite programs and identify any further risks to the safety, quality, and legality of products. |  |
| 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 recognized 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:   * foreign objects * legality * chemical contamination (e.g. taint, odor, allergen, component transfer from inks, varnishes, and glues) * 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. |  |
| 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 programs, as set out in section 5. |  |
| 2.2.7 | For each hazard that requires control, the control points shall be reviewed to evaluate whether existing prerequisites are effective in providing control.  Where greater controls are required to the prerequisite programs, improvements shall be implemented to ensure control is achieved. |  |
| 2.2.8 | For any critical control points, 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 any critical control points, 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 programs shall be carried out at least once per year and following any significant incidents or when any process changes.  The review shall include 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 programs * results from external and third-party auditors * new developments in the market or industry associated with materials, process or product. |  |
| Notes |  | |
| **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. |  |
| Notes |  | |
| **3** | **Product safety and quality management** |  |
| **3.1** | **Product safety and quality management system** |  |
| 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. |  |
| Notes |  | |
| **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 controlled documents indicating the latest version number * the method for the identification and authorization 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. |  |
| 3.2.2 | Where documents and records are in electronic form these shall be suitably protected to prevent loss or malicious intervention. |  |
| Notes |  | |
| **3.3** | **Record keeping** |  |
| SOI | The site shall maintain genuine records to demonstrate the effective control of product safety, legality, and quality. |  |
| 3.3.1 | Records shall be legible, appropriately authorized, retained in good condition, and retrievable. Where records are in electronic form these shall be suitably backed up to prevent loss. |  |
| 3.3.2 | Any alteration to records shall be authorized and justification for the alteration shall be recorded. |  |
| 3.3.3 | The company’s senior management shall ensure that documented procedures are established and implemented for the organization, 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. |  |
| Notes |  | |
| **3.4** | **Specifications** |  |
| SOI | Appropriate specifications shall exist for raw materials, intermediate and finished products, and 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. |  |
| 3.4.2 | 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 | Where packaging for food or other hygiene-sensitive products is produced, 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. |  |
| 3.4.6 | Where specifications are in electronic form these shall be suitably protected to prevent loss or malicious intervention. |  |
| Notes |  | |
| **3.5** | **Internal audits** |  |
| SOI | The company shall be able to demonstrate it verifies the effective application of the requirements of the BRCGS Standard for Packaging and Packaging Materials through internal audits. |  |
| 3.5.1 | There shall be a scheduled program of internal audits throughout the year with a scope which covers the hazard and risk management system, prerequisite programs, and all procedures that have been implemented to achieve this Standard. All activities shall be covered at least annually.  The internal audit program shall be fully implemented. |  |
| 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. |  |
| 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 action. Corrective actions and timescales for their implementation shall be agreed and completion of the actions verified. |  |
| Notes |  | |
| **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 program 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 BRCGS 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. |  |
| 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. |  |
| Notes |  | |
| **3.7** | **Management of subcontracted processes** |  |
| SOI | Subcontractors shall be managed effectively to prevent any risk of contamination or damage and ensure that product is produced to specification. |  |
| 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 be assessed. Any risks shall be communicated to relevant personnel and effectively managed. |  |
| 3.7.3 | Clear specifications shall be agreed for all work outsourced to a subcontractor. |  |
| 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. |  |
| Notes |  | |
| **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. |  |
| 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 * transport and distribution * storage and dispatch * calibration services * waste management.   Providers of utilities such as water, electricity, or gas may be excluded on the basis of risk. |  |
| 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. |  |
| Notes |  | |
| **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 products, 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. This test shall take place at least annually. |  |
| 3.9.5 | Where rework or any reworking operation is performed, traceability shall be maintained. |  |
| Notes |  | |
| **3.10** | **Customer Focus and Contract Review** |  |
| 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. |  |
| 3.10.1 | The company shall identify those job titles responsible for communication with customers and shall have an effective system for communication. |  |
| 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. |  |
| 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. |  |
| Notes |  | |
| **3.11** | **Complaint handling** |  |
| SOI | Customer complaints relating to product safety or quality shall be effectively handled and information used to reduce complaint levels. |  |
| 3.11.1 | Actions appropriate to the seriousness and frequency of identified problems shall be carried out promptly and effectively by appropriately trained staff. |  |
| 3.11.2 | Complaint data shall be analyzed to identify significant trends. Where there has been a significant 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. |  |
| Notes |  | |
| **3.12** | **Management of product withdrawals, and incidents and product recalls** |  |
| SOI | The site shall have systems in place to effectively manage any product withdrawals or returns from customers, incidents, and product recalls to ensure that all potential risks to the quality and legality of products 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. |  |
| 3.12.3 | 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 effectively manage an incident to prevent release of product where 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 any information (such as traceability) as required. |  |
| 3.12.8 | The product withdrawal procedure shall be tested at least annually to ensure its effective operation.  The results of the test, and of any actual withdrawals, shall be used to review the procedure and implement improvements as necessary. |  |
| Notes |  | |
| **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. |  |
| 4.1.1 | Consideration shall be given to local activities and the site environment, which may have an adverse impact on the quality of the finished product. Measures shall be taken to prevent contamination. |  |
| 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. |  |
| 4.1.3 | The building fabric shall be maintained to minimize potential for pest entry, ingress of 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 minimize the risk of contamination. |  |
| Notes |  | |
| **4.2** | **Building fabric and interiors**  raw materials handling, preparation, processing, packing and storage areas |  |
| SOI | The internal site, buildings and facilities shall be suitable for the intended purpose. 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. |  |
| 4.2.1 | Walls, floors, ceilings (including suspended ceilings), and pipework shall be maintained in good condition and shall facilitate cleaning. |  |
| 4.2.2 | 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. |  |
| 4.2.3 | 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. |  |
| 4.2.4 | Suitable and sufficient lighting shall be provided to ensure a safe working environment, correct operation of processes, effective inspection of the product and cleaning. |  |
| 4.2.5 | Suitable and sufficient ventilation shall be provided. |  |
| Notes |  | |
| **4.3** | **Utilities** |  |
| SOI | Product quality shall not be compromised by the location, construction, and delivery of the utilities to and within the production and storage areas. |  |
| 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 | Air, compressed air or other gasses that come into direct contact with the packaging shall present no risk to product safety or quality and shall comply with any relevant legal regulations. |  |
| Notes |  | |
| **4.4** | **Security** |  |
| SOI | Product and process integrity shall be assured through appropriate site security provision. |  |
| 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 authorized 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 unauthorized access. |  |
| Notes |  | |
| **4.5** | **Layout and product flow** |  |
| SOI | Premises and plant shall be logically designed, constructed, and maintained. |  |
| 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 minimize 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. |  |
| 4.5.4 | If it is necessary to allow access through production areas, designated walkways shall be provided that ensure there is adequate segregation from materials. |  |
| Notes |  | |
| **4.6** | **Equipment** |  |
| SOI | Equipment shall be suitably designed for the intended purpose and shall be maintained and used so as to minimize the risk to product safety, legality, and quality. |  |
| 4.6.1 | Equipment shall be constructed of suitable materials and be designed to ensure it can be effectively cleaned and maintained. |  |
| 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 program established. |  |
| Notes |  | |
| **4.7** | **Maintenance** |  |
| SOI | An effective maintenance program shall be in operation for plant and equipment to prevent contamination and reduce the potential for breakdowns. |  |
| 4.7.1 | A documented program 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 | Maintenance work shall not place product quality or legality at risk. Maintenance work shall be followed by a documented clearance procedure which records that equipment is cleared to resume production. |  |
| 4.7.3 | Tools and other maintenance equipment shall be cleared away after use and appropriately stored. |  |
| 4.7.4 | 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. |  |
| 4.7.5 | Engineering workshops shall be controlled to prevent transfer of engineering debris to production or storage areas (e.g. by provision of swarf mats). |  |
| 4.7.6 | Contractors involved in maintenance or repair shall be suitably monitored by a staff member who shall be responsible for their activities. |  |
| 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 minimized. |  |
| 4.8.1 | Good standards of housekeeping shall be maintained, which shall include a ‘clean as you go’ policy. |  |
| 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:   * item/area to be cleaned * frequency of cleaning * method of cleaning * cleaning materials to be used. |  |
| 4.8.3 | Cleaning chemicals shall be fit for purpose, suitably labeled, secured in closed containers, and used in accordance with manufacturers’ instructions. Materials and equipment used for cleaning toilets shall be segregated from those used elsewhere. |  |
| Notes |  | |
| **4.9** | **Product contamination control** |  |
| SOI | All practicable steps shall be taken to identify, eliminate, avoid, or minimize the risk of foreign body or chemical contamination. |  |
| **4.9.1** | **Glass, brittle plastics, ceramics and similar materials control** |  |
| 4.9.1.1 | The company shall use risk assessment to determine whether glass or brittle plastics (other than the product in the production and storage areas) pose a risk to product safety or integrity.  Where a potential hazard is identified, the glass or brittle plastic shall be controlled and recorded on a register which shall include:   * recorded checks of condition of items, carried out at a suitable predetermined frequency * details on cleaning or replacing items to minimize potential for product contamination. |  |
| 4.9.1.2 | 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. |  |
| Notes |  | |
| **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 | Snap-off blade knives shall not be used. |  |
| Notes |  | |
| **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 * avoidance of strongly scented products * the labeling and/or identification of containers of chemicals at all times. |  |
| Notes |  | |
| **4.10** | **Waste and waste disposal** |  |
| SOI | Suitable facilities shall be provided for the storage and disposal of process and other waste. |  |
| 4.10.1 | 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 | Where appropriate, waste shall be categorized according to legislative requirements based on the intended means of disposal (such as recycling), segregated, and collected in appropriate designated waste containers. |  |
| 4.10.3 | Substandard trademarked materials shall be rendered unusable through a destructive process. All materials disposed of shall be recorded. |  |
| Notes |  | |
| **4.11** | **Pest control** |  |
| SOI | The company shall be responsible for minimizing the risk of pest infestation on the site. |  |
| 4.11.1 | A preventive pest control program 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 organization or shall have appropriately trained staff for the regular inspection and treatment of the site in order to deter and eradicate infestation. |  |
| 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 | In the event of infestation, immediate action shall be taken to eliminate the hazard. Action shall be taken to evaluate the potential for contamination or damage to packaging and checks instigated before release. |  |
| 4.11.6 | A pest control manual shall be maintained which shall include:   * an up-to-date site plan identifying numbered pest control device locations * identification of the baits and/or monitoring devices on site * details of pest control products used and instructions for their effective use * detailed records of pest control inspections and of any pest infestation. |  |
| 4.11.7 | Employees shall understand the signs of pest activity and be aware of the need to report any evidence to a designated manager. |  |
| Notes |  | |
| **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. |  |
| 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. |  |
| 5.1.3 | The company shall ensure that production is carried out using defined operating 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. |  |
| 5.1.5 | Samples as agreed with the specifier shall be retained for future reference. |  |
| Notes |  | |
| **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. |  |
| 5.2.2 | 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 color standards used during print runs, shall be controlled to ensure minimization 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. |  |
| 5.2.7 | Where artwork files and approved masters are in electronic form, these shall be suitably protected to prevent loss or malicious intervention. |  |
| 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 the customer’s specification and 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 minimize 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. |  |
| 5.3.8 | Lighting in print inspection cabinets and other means of print/color checking shall be agreed with the customer or conform to accepted industry standards. |  |
| Notes |  | |
| **5.4** | **Process control** |  |
| SOI | Documented procedures shall be in place to ensure effective quality assurance of operations throughout the process. |  |
| 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. |  |
| 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 that product safety, legality, and quality are achieved. |  |
| Notes |  | |
| **5.5** | **Calibration and control of measuring and monitoring devices** |  |
| SOI | Measuring equipment used to monitor manufacturing process control points, product quality, and legality shall be calibrated. |  |
| 5.5.1 | The site shall identify and control in-line and off-line measuring equipment used to monitor product safety and quality. |  |
| 5.5.2 | Where possible, calibration shall be traceable to a recognized national or international standard. Where a traceable calibration is not possible, the site shall demonstrate the basis by which standardization is carried out. |  |
| 5.5.3 | Results and any actions taken when measuring equipment is found to be operating outside the specified limits shall be documented. |  |
| 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 legal requirements.  The frequency of checks shall be in accordance with industry-accepted practice or customer requirements and based on risk analysis. |  |
| 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 | 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. |  |
| 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. |  |
| 5.6.6 | Procedures shall be in place to ensure the reliability of test results. |  |
| 5.6.7 | Where the company undertakes or subcontracts analyses critical to product safety or legality, the laboratory or subcontractors shall have gained recognized 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. |  |
| 5.7.2 | 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. |  |
| 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 |  | |
| **5.8** | **Incoming goods** |  |
| 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. |  |
| Notes |  | |
| **5.9** | **Storage of all materials and intermediate and finished products** |  |
| SOI | The risk of contamination of raw materials and finished products shall be minimized while in storage. |  |
| 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. |  |
| 5.9.3 | The site shall ensure that hazardous chemicals are handled in such a way that risk to product quality and legality is minimized. |  |
| 5.9.4 | Material intended for recycling shall be appropriately protected against contamination hazards. |  |
| Notes |  | |
| **5.10** | **Dispatch and transport** |  |
| SOI | The dispatch and transport of finished products shall be undertaken in a manner that minimizes the risk of contamination or malicious intervention and maintains product quality and legality. |  |
| 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. |  |
| 5.10.2 | All pallets shall be checked. Damaged, contaminated or unacceptable pallets shall be discarded. 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 visually checked for cleanliness before loading. Unsatisfactory trucks shall not be loaded. |  |
| 5.10.4 | Where the company employs third-party contractors there shall be a contract or agreed terms and conditions.  Where this is not possible, with general carriers, the packaging shall be adequate to protect the product against damage, contamination hazards, taint and odor. |  |
| 5.10.5 | 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. |  |
| Notes |  | |
| **6** | **Personnel** |  |
| **6.1** | **Training and competence**  raw materials handling, preparation, processing, packing and storage areas |  |
| SOI | The company shall ensure that all employees 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, shall be appropriately trained prior to commencing work and adequately supervised throughout the working period. |  |
| 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 staff and provide relevant training as appropriate. Records of this review shall be maintained. |  |
| 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 programs covering the training needs of relevant personnel. |  |
| Notes |  | |
| **6.2** | **Personal hygiene**  raw materials handling, preparation, processing, packing and storage areas |  |
| SOI | The company’s personal hygiene standards shall be developed to minimize 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 determined on the basis of risk, documented and communicated to all personnel. This shall address:   * hand washing * wearing of jewelry, including wristwatches. |  |
| 6.2.2 | Personal items and belongings, including personal mobile phones, shall not be taken into production areas without the permission of the management. |  |
| Notes |  | |
| **6.3** | **Staff facilities** |  |
| SOI | Staff facilities shall be sufficient to accommodate the required number of personnel and shall be designed and operated to minimize the risk of product contamination. Such facilities shall be kept in a good and clean condition. |  |
| 6.3.1 | Eating (including the eating of confectionery and chewing of gum or tobacco), drinking, and smoking shall not be allowed in locker and changing rooms. |  |
| 6.3.2 | Suitable and sufficient hand-washing facilities shall be available to enable cleaning of hands before commencing work 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). |  |
| 6.3.3 | 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. |  |
| 6.3.4 | Facilities for visitors and contractors shall enable compliance with the site’s hygiene policy. |  |
| 6.3.5 | Eating (including the eating of confectionery and chewing of gum or tobacco), drinking, and smoking shall not be allowed in production or storage areas. |  |
| 6.3.6 | 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. |  |
| Notes |  | |
| **6.4** | **Protective clothing** |  |
| SOI | Appropriate protective clothing shall be worn in production and storage areas to minimize the risk of product contamination.  The risk of product contamination from clothing, hair, or personal items shall be minimized. |  |
| 6.4.1 | 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, it shall be fully justified and shall not pose a contamination risk to the product. |  |
| 6.4.2 | 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). |  |
| 6.4.3 | Where protective clothing is used it shall be kept adequately clean. Changes of clothing shall be available as required. |  |
| 6.4.4 | Where protective clothing is used, clean and dirty clothing shall be segregated and controlled to prevent cross-contamination. |  |
| 6.4.5 | Disposable protective clothing, if used, shall be subject to adequate control to avoid product contamination. |  |
| Notes |  | |