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| Self-Assessment Tool |
| BRCGS Standard for Consumer Products Issue 4 |
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**GLOBAL STANDARD FOR CONSUMER PRODUCTS 4 SELF-ASSESSMENT TOOL**

**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 Consumer Products Issue 4.

**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 BRC Training Academy has courses available to improve the understanding of the requirements for the BRCGS Standard for Consumer Products Issue 4 and may be useful for the person using the BRCGS Self-Assessment Tool. For further information on the courses available please visit [brcgstrainingacademy.com](http://www.brcgstrainingacademy.com)

**Further Information**

If you have any further questions about the BRCGS Self-Assessment Tool or the Global Standard for Issue 4 please do not hesitate to contact the BRCGS team.

Email – enquiries@brcgs.com

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**BRCGS Standard for Consumer Products Auditor Checklist General Merchandise Foundation**

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| **Clause** | **Requirements** |  |  |
| **1 Senior management commitment** |
| **1.1 Senior management commitment and continual improvement** |
| Fundamental Statement of Intent | The site’s senior management shall demonstrate they are fully committed to the implementation of the requirements of the Global Standard for Consumer Products and to processes which facilitate continual improvement of product safety and quality management. |  |  |
| 1.1.1 | The site shall have an implemented policy which demonstrates the site’s intention to meet its obligation to produce safe and legal products to the specified quality and its responsibility to its customers. This shall be:* authorised by the person with overall responsibility for the site
* communicated to all staff.
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| 1.1.2 | The site’s senior management shall ensure that clear objectives are defined to maintain safety and legality and improve the quality of products manufactured, in accordance with the site’s product safety and quality policy and commitment to implementing the requirements of this Standard. These objectives shall be clearly communicated to relevant staff and monitored, and results reported at least annually to site senior management. |  |  |
| 1.1.3 | The site shall have a programme of management meetings which enable product safety, legality or quality issues to be brought to the attention of senior management for resolution.Records of the minutes from these meetings shall be maintained. |  |  |
| 1.1.4 | The site’s senior management shall provide sufficient human and financial resources required to produce and improve products safely and in compliance with the requirements of this Standard. |  |  |
| 1.1.5 | Where the site is certificated to the Standard, it shall ensure that announced recertification audits occur on or before the audit due date indicated on the certificate. |  |  |
| 1.1.6 | The site shall have a genuine hard copy or electronic version of the current Standard available with a position statement and be aware of any changes to the Standard or protocol that are published on the BRC website. |  |  |
| 1.1.7 | Where required by legislation, the site shall be registered with or approved by the appropriate government agency and evidence of this shall be available. |  |  |
| 1.1.8 | A system shall be in place to close out non-conformities raised with consideration of the root cause. |  |  |
| **1.2 Organisational structure, responsibility and management authority** |
| Statement of Intent | The site shall have a clear organisational structure and lines of communication to enable effective management of product safety, legality and quality. |  |  |
| 1.2.1 | The responsibilities for the management of activities which ensure product safety, legality and quality shall be clearly allocated and understood by the managers responsible. |  |  |
| 1.2.2 | 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.A senior member of staff should be identified with responsibility and authority to stop production, if required. |  |  |
| **2 Product risk management** |
| Fundamental Statement of Intent | The site shall have a management process in place to ensure that a risk assessment is completed on each product group to ensure safety, legality and quality in the regions of intended sale, where known. |  |  |
| **2.1 Legislation and safety requirements** |
| 2.1.1 | The site shall have a system to demonstrate knowledge of all applicable legislation, product standards and product safety issues in the place of production and regions of intended sale of each product. This may be within the company or by use of external expertise. |  |  |
| **2.2 Product risk assessment** |
| 2.2.1 | A full assessment of the safety and legality of each product or product group shall be completed and be appropriate for the intended market. Records shall be available to demonstrate the safety and legality of each product.Where the assessment has been completed by a service provider or by the customer, confirmation of the safety and legality of the product shall be available. |  |  |
| 2.2.2 | The assessment shall be undertaken by suitably trained and competent internal or external resources. Evidence of this shall be available unless the assessment is provided by the customer. |  |  |
| 2.2.4 | The assessment shall be reviewed whenever changes occur to specification, legislative requirements or in response to significant changes in production methods, complaints or incidents with the product or similar products. |  |  |
| 2.2.5 | Where there is a legal requirement to do so or when it is necessary to confirm its safety or legality, a representative product should be submitted for testing to a suitably qualified and, where applicable, an accredited laboratory (internal or external). The results of the test should form part of the risk assessment. |  |  |
| 2.2.6 | Where legally required, the identity, competence, qualifications and/or licence of the person producing the safety review or risk assessment shall be documented and verified. |  |  |
| **2.3 Product labelling and claims** |
| 2.3.1 | The site shall verify that information shown on primary (consumer) package labels and outer cartons is correct and meets the regulatory and safety requirements of the region of intended sale. |  |  |
| 2.3.2 | The site shall have a process in place to ensure that any claims made about a product shall be fully validated to ensure that products meet the stated claim. |  |  |
| 2.3.3 | Where applicable, the site shall ensure that product-in-use evaluation (internal or external), reliability trials and shelf-life tests are validated. It shall be verified that the production of a safe and legal product is maintained, taking account of the category of consumers at risk. |  |  |
| **2.4 Packaging materials** |
| 2.4.1 | Packaging shall be assessed for fitness for purpose and found suitable with regard to:* protecting the product from damage
* maintaining product integrity
* protecting the consumer from injury
* preventing contamination.
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| **3.1 General documentation requirements** |
| **3.1 Product safety and quality management system** |
| Statement of Intent | The site’s processes and procedures to meet the requirements of this Standard shall allow consistent application, facilitate training, and support due diligence in the production of a safe and legal product to agreed quality. |  |  |
| 3.1.1 | The site shall have an established quality management system (QMS) in place which is appropriate to the size of business and risk associated with the products.The QMS shall be fully implemented, collated in a navigable and readily accessible way, and translated into appropriate languages if necessary. |  |  |
| **3.2 Documentation control** |
| Statement of Intent | The site shall operate an effective document control system to ensure that only the correct approved versions of documents, including recording forms, are available and in use. |  |  |
| 3.2.1 | The site shall be able to demonstrate that key documents which form part of the product safety and quality system are identified with a version number and issue date.This shall include a list of controlled documents indicating the last version number. |  |  |
| **3.3 Record completion and maintenance** |
| 3.3.1 | Records shall be maintained in good condition and retrievable. Any alterations to records shall be authorised and justification for alteration shall be recorded. Where records are in electronic form these shall be suitably backed up to prevent loss. |  |  |
| 3.3.2 | Records shall be retained for a defined minimum period with consideration given to:* legal requirements
* the shelf life of the product
* customer requirements.
 |  |  |
| **3.4 Internal audit** |
| Statement of Intent | The company shall be able to demonstrate that it verifies the effectiveness of the product safety and quality requirements implemented from the Global Standard for Consumer Products. |  |  |
| 3.4.1 | The internal audit shall consist of a scheduled programme of recorded inspections by trained staff to ensure that the factory environment and processing equipment is maintained in a suitable condition for production of safe and legal product against GMP guidelines. |  |  |
| 3.4.3 | The inspection programme shall be fully implemented, and the results shall be reported to a suitable person. Records of any non-conformities and corrective actions shall be available within agreed timescales and completion verified. |  |  |
| **3.5 Supplier approval and performance monitoring** |
| 3.5.1 Management of suppliers of raw materials, components and packaging |
| Statement of Intent | The site shall have an effective supplier approval and monitoring system to ensure that any potential risks from raw materials, components or packaging to the safety, legality and quality of the final product are understood and managed. |  |  |
| 3.5.1.1 | The site shall have a defined and implemented process for supplier approval, including a list of approved suppliers of raw materials, components and packaging impacting product safety, legality or quality.The approval of these suppliers shall be based on at least one or a combination of the following:* supplier questionnaire
* certificate of analysis
* supplier audits
* supplier certification with a scope covering the products supplied
* historical evidence of good supply.
 |  |  |
| 3.5.2 Control and acceptance of incoming raw materials, components and packaging materials |
| Fundamental Statement of Intent | The company shall have an effective process to ensure that incoming raw materials, components and packaging materials are suitable for use and do not adversely affect the safety, legality or quality of the finished product. |  |  |
| 3.5.2.1 | Raw materials, components and packaging shall be checked on arrival to ensure they conform to agreed specifications and any agreed acceptance criteria, e.g. certificates of analysis. |  |  |
| 3.5.2.2 | The company shall have a process to ensure that raw materials, components and packaging used by home workers (when used and if authorised by the customer) are approved. |  |  |
| 3.5.2.3 | The company shall have in place a process to ensure the authenticity of raw materials, components and packaging to prevent fraud. |  |  |
| **3.6 Specifications and technical files** |
| Statement of Intent | A system shall be in place to manage specifications and technical data for raw materials, components and packaging materials. |  |  |
| 3.6.1 | Suitably detailed and accurate specifications shall be held for all raw materials, components, packaging materials and finished products to ensure compliance with relevant safety, legislative, quality and customer requirements. The specifications shall be accessible to relevant staff and the company shall seek formal agreement of specifications with relevant parties. |  |  |
| 3.6.2 | A specification shall be available for each finished product and shall have been verified to ensure it is fit for purpose, meets customer requirements and is compliant with relevant safety and legislative requirements in the regions of intended sale.As a minimum, the specification may include the following, although this is not an exhaustive list:* product name and description
* composition
* physical and/or chemical parameters
* assembly diagrams
* packaging
* labelling
* intended shelf life
* warnings
* instructions for use.
 |  |  |
| 3.6.3 | Companies shall maintain the data in a technical file that is accessible to relevant staff containing all relevant data (or details of where such data is located) to ensure that products meet the requirements of the specification and legislative and customer requirements.Relevant data may include:* bill of materials
* safety data sheets on all chemicals used where relevant to the safety, legality or quality of the product
* risk assessment(s)
* description of the conformity assessment procedure
* test reports
* inspection reports
* list of the legislation and product standards with which the products are manufactured to comply
* production control procedures and charts
* approvals by any government body (if applicable)
* declarations of conformity to legal requirements (if applicable)
* self-inspection reports

corrective actions. |  |  |
| **3.7 Corrective and preventive action**  |
| Fundamental Statement of Intent | The site shall be able to demonstrate that it uses the information from identified failures in the product safety and quality management system to make necessary corrections and prevent recurrence. |  |  |
| 3.7.1 | The company shall operate an effective system for the capture, recording and timely corrective actions of non-conformities or matters reported as possible non-conformities critical to product safety, legality or quality. |  |  |
| 3.7.3 | The company shall ensure that corrective actions prevent recurrence of the problem and shall monitor and record their completion. |  |  |
| **3.8 Control of non-conforming materials** |
| Statement of Intent | The company shall ensure that non-conforming raw materials, packaging, components and products are clearly identified, labelled, quarantined, investigated and documented. |  |  |
| 3.8.1 | Clear procedures for the control of non-conforming materials and products, including customer returns, shall be in place and understood by all relevant, authorised personnel. These shall include effective identification and quarantining before a decision has been made on the final disposition of the non-conforming product by rejection, acceptance by concession or regrading for an alternative use. |  |  |
| **3.9 Traceability** |
| Fundamental Statement of Intent | The site shall be able to trace all raw materials, components and packaging from its suppliers through all stages of processing and dispatch to its primary customers, and from the customer back to the supplier. |  |  |
| 3.9.1 | The site shall have a system in place to enable all raw materials, components and packaging materials critical to safety or where legally required to be traced to the supplier and the batch or order number. |  |  |
| 3.9.2 | Identification of lots/batches of raw materials, including packaging, processing aids, intermediate/semi-processed products, part-used materials, rework, finished products and materials pending investigation, shall be sufficient to ensure traceability. |  |  |
| 3.9.3 | Finished product shall be identified with a unique code such as a batch code applied to the product or packaging where legally required or specified by the customer.Systems must be in place to trace a finished product back to the batch of raw materials or packaging used. |  |  |
| 3.9.4 | Subcontracted manufacture of products or components shall have prior customer approval and shall be traceable to a level appropriate to the risk. |  |  |
| 3.9.5 | The company shall test the traceability system to ensure traceability can be determined from raw-material receipt to finished product. This shall occur at a predetermined frequency, at least annually, and results shall be retained. The time taken to complete the exercise shall be measured and recorded. |  |  |
| 3.9.6 | The need for extended traceability through the chain should be established on the basis of risk and any legal or specific customer requirements. Where required, extended traceability shall be implemented. |  |  |
| **3.10 Complaint handling** |
| Statement of Intent | The company shall operate an effective system for the capture, recording and investigation of product complaints at all levels of severity. |  |  |
| 3.10.1 | All complaints shall be recorded, investigated using root analysis and the results of the investigation recorded where sufficient information is provided. Actions appropriate to the seriousness and frequency of the problems identified shall be carried out to reduce the likelihood of recurrence. |  |  |
| 3.10.2 | The company shall have a process in place to respond in a timely manner to consumers and customers regarding complaints. |  |  |
| **3.11 Management of incidents, product withdrawal and product recall** |
| Statement of Intent | The company shall have a plan and system in place to manage incidents effectively and enable the withdrawal and recall of products should this be required. |  |  |
| 3.11.1 | The site shall have a system in place to monitor issues which could result in the need to withdraw or recall products including consumer complaints, product rejections and feedback from customers. There should be a process in place to notify senior management of an incident or emergency that may affect the legality, safety and quality of a product. |  |  |
| 3.11.2 | The site shall have a documented procedure in place to effectively manage product withdrawals and recalls. Procedures shall exist to ensure that customers are notified immediately on issues of significance to the customer or consumer in terms of product safety, quality or legality. |  |  |
| 3.11.3 | The documented product withdrawal and recall procedures shall include as a minimum:* identification of key staff constituting the incident management team and their key responsibilities
* an up-to-date list of key contacts, with details of agencies providing advice and support
* a list of persons who can initiate a recall.
 |  |  |
| 3.11.5 | In the event of a product recall, the certification body issuing the current certificate and the appropriate enforcement authorities shall be informed in a timely manner. The company shall be aware of and adhere to any legal reporting obligations in the regions of sale. |  |  |
| 3.11.6 | Products which are to be disposed of on safety grounds, as the result of a recall or withdrawal or as substandard trademarked materials, shall be disposed of securely. This may be delegated to a specialist in secure waste disposal. Records of such material destruction or disposal shall be maintained. |  |  |
| 3.11.7 | The product recall and withdrawal procedures shall be tested at least annually. |  |  |
| **4 Site standards** |
| **4.1 External standards** |
| Statement of Intent | Sites used for manufacturing, storage or distribution shall be of suitable size, location, construction and design to facilitate maintenance, prevent contamination and enable the production of safe and legal products. |  |  |
| 4.1.1 | The site to be included in the audit shall be clearly defined, and shall be located and maintained so as to allow the production of safe and legal products.The external areas and surroundings shall be maintained in good order. |  |  |
| **4.2 Security** |
| Statement of Intent | Security shall be maintained to prevent access of unauthorised persons to production and storage areas. |  |  |
| 4.2.1 | Access to the site by employees, contractors and visitors shall be controlled and a visitor-reporting system shall be in place. |  |  |
| 4.2.2 | Contractors involved in maintenance or repair shall be qualified or supervised and a member of staff shall oversee their activities. |  |  |
| **4.3 Layout, product flow and segregation** |
| Fundamental Statement of Intent | The factory layout, flow of processes and movement of personnel shall be adequate to prevent the risk of product contamination and mix-ups and to comply with relevant legislation. |  |  |
| 4.3.1 | The layout process flow of machinery and equipment shall be arranged to minimise the risk of product contamination and damage. |  |  |
| 4.3.2 | Premises shall allow sufficient working space and storage capacity to enable all operations to be carried out and, if necessary, in hygienic conditions. The necessary level of hygiene shall be maintained for each product. |  |  |
| 4.3.4 | When critical to product safety, legality, quality or customer requirements, controls shall be in place to ensure that raw materials, work in progress, rework, waste materials, packaging, components and finished products of different specifications are not inadvertently mixed and are effectively segregated. |  |  |
| 4.3.5 | Where materials or products require special handling procedures to be in place, these shall be maintained to ensure product safety, quality and legality are not compromised. |  |  |
| 4.3.7 | Materials and products requiring segregation (e.g. materials intended for different geographical regions) shall have control procedures in place to ensure that product integrity is maintained. |  |  |
| **4.4 Building interiors** |
| Statement of Intent | The interior of the site, buildings and facilities shall be suitable for the intended purpose. |  |  |
| 4.4.1 | The site shall be maintained to minimise potential for product contamination. The quality and finish of site buildings and facilities, including any pipework and drainage, shall be suitable for the intended purpose with due regard to the risk to product safety, legality and quality, and shall be maintained to an appropriate standard. This shall include, as defined by the risk assessment:* a clean, tidy and organised factory
* adequate lighting
* adequate ventilation
* walls, floors, windows, doors and ceilings maintained in a good condition to prevent foreign body risks
* suitable and sufficient removal of any by-products and contaminants.
 |  |  |
| 4.4.2 | Suitable and sufficient lighting shall be provided for correct operation of processes, inspection of products, and effective cleaning. |  |  |
| 4.4.3 | The site shall be assessed for any particular requirements relevant to the products being produced, such as temperature, humidity and electrostatic discharge. Any identified requirements shall be adopted, calibrated, documented, monitored and regularly reviewed. |  |  |
| 4.4.4 | Where water quality presents a risk to the final product it shall comply with the required specification (as defined in the region of intended product sale), suitably treated to prevent contamination and regularly monitored. |  |  |
| **4.5 Staff facilities** |
| Statement of Intent | 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. The facilities shall be maintained in a good and clean condition. |  |  |
| 4.5.1 | Staff facilities such as washrooms and break areas must be provided and maintained in a clean condition and segregated from production areas to prevent product contamination.Where a site provides food service the food preparation areas must be clean and fit for purpose and adequately segregated from production areas. |  |  |
| 4.5.2 | Where smoking or use of electronic cigarettes is allowed under national law, designated controlled smoking areas shall be provided and isolated from production and storage areas to an extent that ensures smoke cannot reach the product. Adequate arrangements for dealing with smokers’ waste shall also be provided at smoking facilities, both inside buildings and at external locations. |  |  |
| 4.5.3 | Storage facilities of sufficient size to accommodate all reasonable personal items shall be provided for all personnel who work in areas where they are unable to keep possessions with them. |  |  |
| 4.5.4 | Based on risk assessment, the site shall determine and provide workwear as required and make provisions for changing areas for all personnel: staff, visitors and contractors. |  |  |
| 4.5.5 | Suitable and sufficient hand-cleaning facilities shall be provided at access to production areas, and at other appropriate points within these areas, based on appropriate risk. |  |  |
| **4.6 Housekeeping and hygiene** |
| Fundamental Statement of Intent | Housekeeping and cleaning systems shall be in place which ensure appropriate standards of hygiene are maintained at all times and the risk of product contamination is minimised. |  |  |
| 4.6.1 | Equipment, production and storage areas shall be maintained in a state of cleanliness appropriate to the operations undertaken. Cleaning practices shall be completed so as to minimise risk of contamination and records kept. |  |  |
| 4.6.2 | Suitable cleaning chemicals shall be identified, clearly labelled and controlled to prevent the risk of product contamination. Chemicals shall not be decanted unless into properly labelled and identified containers. Adequate storage facilities shall be provided and sited so as not to compromise the safety, legality and quality of the product. |  |  |
| 4.6.3 | If cleaning services are outsourced, the service providers shall have signed a contract which identifies the scope and frequency of the work, and records shall be maintained. A defined company representative shall be responsible for ensuring that the work is carried out satisfactorily. |  |  |
| **4.7 Waste and waste disposal** |
| Statement of Intent | Waste disposal shall be managed in accordance with legal requirements and to prevent accumulation, mix-up, risk of contamination and the attraction of pests. |  |  |
| 4.7.1 | Waste disposal shall be managed in accordance with legal requirements and to prevent accumulation, mix-up, risk of contamination and the attraction of pests. |  |  |
| 4.7.2 | Where legally necessary, waste shall be removed by identified, licensed contractors, and records of disposal shall be maintained by the site. |  |  |
| **4.8 Pest control** |
| Statement of Intent | The whole site shall have an effective preventive pest control programme in place to minimise the risk of pests. Sufficient resources shall be available to respond rapidly to any issues that occur, in order to prevent risk to products. |  |  |
| 4.8.1 | The company shall be responsible for identifying and controlling the risk of pest infestation and shall operate pest control procedures. If no pest control is conducted the company shall have a full justification for its absence, including its customers’ acceptance. The justification shall be reviewed at least annually. (Note: If there is a justified absence of pest control then the other clauses in this section are not applicable.) |  |  |
| 4.8.2 | The company shall either have a clearly defined contract with external contractors which reflects the activities of the site, or have trained staff.During each visit activity/action reports shall be completed. These should include observations of pests or evidence of pest activity and recommendations for action by the site. |  |  |
| 4.8.3 | When necessary, materials or products shall be fumigated, and records of this process shall be kept. Fumigated goods may not be supplied to customers without full professional safety clearance and correct clearance documentation. All fumigation operations shall be controlled by staff with appropriate professional qualifications and/or training. |  |  |
| 4.8.4 | Full material safety data sheets for all chemical pest control agents used shall be controlled, available to relevant staff at all times and kept in a designated place. |  |  |
| **4.9 Product storage, dispatch and transport** |
| Statement of Intent | Facilities for the storage and transportation of products shall be suitable for purpose and minimise the risk of product contamination, damage and malicious intervention. |  |  |
| 4.9.1 | All materials, work in progress and product shall be properly identified and protected during storage by appropriate packaging to protect the product from contamination. |  |  |
| 4.9.2 | Where storage of raw materials, components, packaging, intermediate or finished product is necessary it shall be maintained in good condition and be securely protected from contamination, deterioration and damage.All handling operations during storage shall be managed to prevent product damage. |  |  |
| 4.9.3 | Vehicles or containers used for transportation and dispatch of product shall be inspected prior to loading to ensure that they are fit for purpose. Records of inspection shall be maintained. |  |  |
| 4.9.5 | Where product is vulnerable to weather damage, vehicles and containers for transportation shall be loaded and unloaded so as to protect the product. |  |  |
| 4.9.6 | Where a third-party haulage contractor is used, all the requirements shall be defined within a contract and effectively managed. |  |  |
| **5 Product inspection and testing** |
| **5.1 Product inspection and laboratory testing** |
| Fundamental Statement of Intent | The company shall have a programme for product inspection and testing to control products during and after production to ensure that products are safe, legal and meet the quality specification.. |  |  |
| 5.1.1 | There shall be a scheduled product-testing programme according to risk for each product or product group as defined in the specifications. This shall be based on information such as:* the outcome of the product and process risk assessments
* any legal requirements for testing in the regions(s) of intended sale
* the site’s requirements for demonstrating the production of safe products.

The methods, frequency and specified limits of testing shall be clearly defined. |  |  |
| 5.1.2 | The testing programme shall be implemented and records kept of all test results. Results which are outside the defined specification shall be reviewed promptly by an authorised competent person. The need for corrective action shall be assessed and documented, and any action carried out as necessary. |  |  |
| 5.1.3 | Where the company undertakes or subcontracts analyses which are 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/IEC 17025.Documented justification shall be available where accredited methods are not undertaken. |  |  |
| 5.1.4 | Procedures shall be in place to ensure reliability of test results, other than those critical to safety and legality. These shall include:* use of recognised test methods and reference standards, where available
* documented testing procedures
* ensuring staff are suitably qualified and/or trained and competent to carry out the analysis required
* use of a system to verify the accuracy of test results (e.g. ring or proficiency testing)
* use of appropriately calibrated and maintained equipment.
 |  |  |
| 5.1.5 | Test and inspection results shall be reviewed regularly to identify trends. The significance of external laboratory results must be understood and acted upon accordingly.Appropriate actions shall be implemented promptly to address any unsatisfactory trends. |  |  |
| **5.2 Quantity control** |
| Statement of Intent | The company shall operate a quantity control system which conforms to the legal requirements in the country where the product is sold and any additional customer requirements. |  |  |
| 5.2.1 | Where necessary the company shall operate a quantity control system which conforms to legal requirements and/or specified customer requirements in the region where the product is available for sale.Documentary evidence shall be available on site to substantiate claims. |  |  |
| 5.2.2 | Where quantity checking is required, the frequency and methodology used based on valid sampling plans shall meet the minimum requirements of any legislation governing quantity verification. |  |  |
| **5.3 Product sample control** |
| Statement of Intent | The site shall ensure that procedures are in place for the selection, handling, storage, approval and use of reference samples taken from pre-production, subcontracted and finished production in accordance with customer requirements. |  |  |
| 5.3.1 | Where legally required or specified by a customer, a reference sample of the product which has been approved by the customer or a representative of the agreed specification shall be retained. |  |  |
| 5.3.2 | Reference samples shall be stored and recorded in suitable environmental conditions to maintain their original status for a specified period. |  |  |
| 5.3.3 | A secure and tamper-evident system shall be in place for the storage of samples. A sample-tracking process shall be in place and temporary removal of samples shall be managed. |  |  |
| **6. Process control** |
| **6.1 Control of operations** |
| Fundamental Statement of Intent | The site’s programme of process and quality controls to ensure the production of safe and legal products of consistent quality shall be based on a risk assessment of the production process and the potential for product contamination. |  |  |
| 6.1.1.1 | There shall be a suitably experienced designated manager with overall responsibility for the assessment of process controls to ensure the safety and quality of products. |  |  |
| 6.1.1.4 | The site shall consider the potential product safety and quality issues which could occur at each process stage.Each potential issue shall be assessed to determine the level of risk and suitable controls established to reduce or eliminate the risk. |  |  |
| 6.1.1.5 | A record shall be maintained of in-process checks and of any actions taken where checks identify any failure to meet the control limits. |  |  |
| 6.1.1.6 | In circumstances where process parameters are controlled by in-line monitoring devices, these shall be linked to a suitable failure alert system and routinely tested. |  |  |
| 6.1.1.9 | The programme of controls for product safety and quality shall be reviewed whenever new product types are manufactured or significant changes are made to production methods. |  |  |
| 6.1.2 Line clearance and in-process checks |
| 6.1.2.1 | Before the start of any manufacturing operation and following changes of product, checks shall be made to ensure that the production line has been cleared and made ready for use.All work instructions, raw materials, components and packaging with the necessary equipment shall be available for use. |  |  |
| **6.2 Equipment and equipment maintenance** |
| Statement of Intent | Equipment shall be suitable for the intended purpose and shall be used in such a way as to minimise the risk of contamination of product. |  |  |
| 6.2.1 | All equipment shall be fit for purpose and constructed of appropriate materials. The design and placement of equipment shall ensure it can be effectively cleaned and maintained. |  |  |
| 6.2.2 | In the case of equipment failure, procedures shall be in place to establish the safety and legal status of the product prior to release. |  |  |
| 6.2.3 | An implemented maintenance programme covering all items of equipment and plant which are critical to product safety, legality and quality shall be in place. |  |  |
| 6.2.4 | Materials (e.g. chemical lubricating oils and paints) used for equipment and plant maintenance shall be assessed to establish whether they pose a risk by direct or indirect contact with raw materials, intermediates, components, packaging and finished products. If necessary, they shall be suitably identified for the intended use and controlled. |  |  |
| 6.2.5 | Repairs or servicing of equipment shall be completed by competent maintenance personnel. |  |  |
| 6.2.6 | When possible, equipment shall be positioned so as to give access beneath, inside and around it for ease of cleaning and servicing. |  |  |
| **6.3 Product contamination control** |
| Statement of Intent | Appropriate facilities and procedures shall be in place to control the risk of foreign body, chemical or biological contamination. |  |  |
| 6.3.1 Identification and prevention of risk of product contamination |
| 6.3.1.1 | The site shall ensure that all necessary steps are taken to identify and prevent the risks of foreign body, chemical and biological contamination as identified by risk assessment. This shall include any contamination potentially introduced by raw materials, components or packaging. |  |  |
| 6.3.2 Chemical and biological control |
| 6.3.2.1 | Processes shall be in place to manage the use, storage and handling of non-production chemicals and biological materials to prevent contamination. These shall include as a minimum:* a list of approved chemicals for purchase
* availability of material safety data sheets
* the labelling and/or identification of containers of chemicals and biological materials at all times
* a designated storage area with access restricted to authorised personnel.
 |  |  |
| 6.3.3 Metal control |
| 6.3.3.1 | Tools and other sharp metal implements including knives, cutting blades, needles, perforation blades and wires used in production shall be controlled where there is a risk of product contamination. Methods such as, but not limited to, the following may be used:* tools permanently attached to equipment to prevent loss
* items controlled by an issue listing and registration procedure
* recovery of all parts of broken needles before the issue of a replacement needle.

Snap-off-blade knives shall be prohibited. |  |  |
| 6.3.3.2 | Staples, paper clips and drawing pins shall not be used in open product areas.Where staples or other items are present as packaging materials or closures, appropriate precautions shall be taken to minimise the risk of product contamination. |  |  |
| 6.3.4 Glass, brittle plastic, ceramics, wood and similar materials control |
| 6.3.4.1 | Glass or other brittle materials shall be excluded or protected against breakage in areas where there is a risk of product contamination. |  |  |
| 6.3.4.2 | Where there is a potential risk to product all glass, ceramic, wood and brittle-plastic items in production areas (except where the item is part of the product) shall be included in the risk assessment and listed in a register. Documented procedures for handling these materials shall include:* regular checks of the condition of these materials carried out at specified intervals and recorded
* recording of all breakages in an incident report
* segregation of contaminated product
* recording details of cleaning or replacement to minimise potential for product contamination.
 |  |  |
| 6.3.5 Foreign body detection and removal equipment |
| Statement of Intent | The risk assessment shall identify the potential use of equipment to detect or remove foreign body contamination. |  |  |
| 6.3.5.1 Filters and sieves |
| 6.3.5.1.1 | Filters and sieves used for foreign body control shall be of a specified mesh size or gauge and designed to provide the maximum protection that is practical for the product. Material retained or removed by the system shall be examined and recorded to identify risks. |  |  |
| 6.3.5.1.2 | Filters and sieves shall be regularly inspected and tested for damage.Defective sieves and filters shall be segregated and appropriate action taken to replace them.Records shall be maintained. |  |  |
| **6.3.5.2 Metal Detectors and X-ray equipment** |
| 6.3.5.2.1 | Where a metal or other foreign body detector is required based on risk assessment, the company shall establish documented procedures specifying the methods and frequency of testing, critical limits for detection, and recording of test results. |  |  |
| 6.3.5.2.2 | The metal detector or X-ray equipment shall incorporate one of the following:* an automatic rejection device
* a belt stop system with an alarm where the product cannot be automatically rejected (e.g. for very large packs)
* in-line detectors which identify the location of the contaminant to allow effective segregation of the affected product.
 |  |  |
| 6.3.5.2.3 | Systems shall be in place to segregate product rejected by the metal detector to prevent accidental reintroduction and allow investigation of the source of the metal contaminant. |  |  |
| 6.3.5.2.4 | The company shall examine product rejected by the metal detector and retain any metal contaminant.The source of the contamination shall be investigated and appropriate corrective action taken to minimise the risk of further contamination.Records shall be maintained. |  |  |
| 6.3.5.3 Magnets |
| 6.3.5.3.1 | The type, location and strength of magnets shall be recorded in a register.Documented procedures shall be in place for inspection, cleaning, strength testing and integrity checks. Records of all checks shall be maintained. |  |  |
| **6.4 Calibration and control of measuring and monitoring devices** |
| Statement of Intent | Measuring equipment used to monitor product safety, quality and legality shall be calibrated and of suitable accuracy for its intended purpose. |  |  |
| 6.4.1 | The site shall have a list of equipment used to make measurements relevant to product safety, legality and quality. |  |  |
| 6.4.2 | The equipment used to accept or reject a product shall be calibrated to a specified accuracy and precision at a defined frequency (or before use). |  |  |
| 6.4.5 | Adjustment of identified equipment by unauthorised staff shall be prevented and the equipment shall be marked to show its calibration status and period of validity.A process shall be in place for actions to be taken if equipment is found not to be operating within specified tolerances and/or limits. |  |  |
| **6.5 Final product packing and control** |
| Statement of Intent | The company shall ensure that products are packed in accordance with customer-specified requirements and any relevant safety criteria, quality and legal requirements. |  |  |
| 6.5.1 | Before the start of the packaging operation and following changes of product, checks shall be carried out to ensure that the packing line has been cleared and made ready for packing.All work instructions and packaging materials shall be available for use. |  |  |
| 6.5.2 | The company shall ensure that product packing is effectively managed to ensure that it meets customer-specified packing requirements for the product.This shall include methods of ensuring that the correct product(s) and components are correctly packaged and placed in the correct outer packaging. |  |  |
| 6.5.3 | The quantity of product should match the quantity markings, which should be accurate, verified and in accordance with the legal requirements in the country of sale. |  |  |
| **6.6 Stock control and product release** |
| Statement of Intent | The company shall ensure that stock and finished product are not released unless all agreed procedures have been followed and the release is suitably controlled |  |  |
| 6.6.1 | Controls shall be in place to ensure correct stock rotation and that materials and products are used in the correct order and within the allocated shelf or usage life as applicable. |  |  |
| 6.6.2 | The company shall ensure that product brought in from off-site subcontractors shall be included in the product release procedure. |  |  |
| 6.6.3 | Only products conforming to specification and agreed quality requirements are to be released for dispatch.If no such control is conducted, the company shall have a full justification for its absence documented in the customer agreement, which shall be reviewed at least annually. |  |  |
| **7 Personnel** |
| **7.1 Training and competency** |
| Fundamental Statement of Intent | The company shall ensure that personnel performing work that affects product safety, legality and quality are demonstrably competent to carry out their activity, through training, work experience or qualification |  |  |
| 7.1.1 | The company shall ensure that all employees are able to demonstrate competence with regard to their activity. |  |  |
| 7.1.2 | Records shall be available of the training provided to employees, including:* general training provided at induction
* training provided relevant to the job role.
 |  |  |
| **7.2 Protective clothing** |
| Statement of Intent | The company's standards shall be documented and adopted by all personnel, including contractors and visitors to the production facility. |  |  |
| 7.2.1 | The company shall use risk assessment to determine the need for protective clothing.Where a need for protective clothing has been identified by the risk assessment, this shall not pose a contamination risk to the product. |  |  |
| **7.3 Hygiene practices** |
| Statement of Intent | Standards of hygiene shall be applied with due regard to the risk of product contamination. |  |  |
| 7.3.1 | Where the risk has been identified, the company shall have a policy to control the wearing of jewellery so that it poses no risk of product contamination. |  |  |
| 7.3.4 | Hand-cleaning shall be performed at a suitable frequency to maintain hygienic conditions. |  |  |
| 7.3.5 | Eating, drinking or smoking shall only be permitted within designated areas and where there is no risk of contamination of products. |  |  |