

# Global Standard for Consumer Products

## CP434: ISO 22716 to Issue 4 upgrade tool

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### Document Scope

This checklist is intended to assist sites in understanding the key similarities between ISO 22716 and Issue 4 of the Global Standard for Consumer Products Personal Care and Household to align their systems to meet the requirements of both Standards.

### Change Log

Issue no.	Date	Description
1	April 2019	Draft for Consultation
	February 2020	Final

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## Welcome to the Upgrade Toolkit

If you are ISO 22716 certified, you are already part of the way to gaining BRCGS certification.

Increasingly, retailers and brand owners are looking beyond ISO 22716 to more specific and rigorous third-party certification offered by BRCGS. Developed in collaboration with technical experts from the Consumer Products industry and global retailers and brand owners, Global Standards are regarded as the gold standard in product safety and quality management systems.

This guide lists all the requirements of Global Standards for Consumer Products Issue 4 and the comparative ISO 22716 clause number along with commentary where detail within the clauses differs and requires more attention.

Additionally, there are differences in the audit scope and protocol, or operation, of the two Standards as summarised in Table 1.

### A note on terminology

For the purposes of this comparison, Global Standards regards 'products' as those finished products manufactured (or traded) by the site, and the "customer" as the organisations purchasing the finished product manufactured or traded by the site.

Global Standards refers to a self-contained manufacturer as a 'site'. Where that site is part of a group, those sites form a company. ISO terminology uses 'plant' which is broadly similar.

'Terms and definitions' are defined in the Glossary at the rear of the Global Standards for Consumer Products.

### 'Normative references' or other resources available to sites implementing Issue 4

A copy of the Global Standards for Consumer Products can be downloaded as a pdf. An interpretation guideline, plus additional guidance documents are also available. Locate these at: <https://www.brcgsbookshop.com/bookshop/consumer-products/c-24/c-69>

**Table 1 Comparison of Audit Scope and Protocol**

Area of Comparison	Global Standards for Consumer Products Issue 4 Personal Care & Household <b>Higher Level</b>	ISO 22716:2007 (E)
Audit Scope	<p>An accredited and internationally recognised 3<sup>rd</sup> party scheme that sets out the requirements for the production and supply of safe and legal consumer products of consistent quality covering hygiene sensitive products such as cosmetics.</p> <p>The Standard includes the quality management system and good manufacturing (GMP) principles of the ISO Standard but has been extended to provide a more prescriptive framework for product and process risk assessment, hygiene and process control.</p> <p>The audit report and certificate are site(factory) specific with sites classified via 21 product categories</p>	<p>The ISO standard provides guidelines covering the product quality aspects for the production, control, storage and shipment of cosmetic products, based on scientific judgements, documents and risk assessments.</p>
Consumer Product Category	A fuller range of products included within each Standard with 21 defined product categories	Cosmetics
Auditors Registration, Qualifications, Training & Competency requirements	Only registered BRCGS Auditors that have at least one of the 8 BRCGS product technologies can audit sites which fall within the audit scope of their product technical qualifications, training and experience.	Not specified
International Standards Reference	ISO 22716:2007 ISO 9001:2015	
Standards Requirements	<p>Consumer products Standard is split into two</p> <p>Aligned to buyer requirements</p> <p>1. Personal Care and Household Products</p> <p>Covers formulated and fabricated products which typically have higher hygiene requirements due to the nature and usage of products.</p> <p>Examples include cosmetics, medical devices, nappies, food wrap and household products</p>	

	<p>2. General Merchandise Where management of the production process to ensure safety and quality is the primary concern. These include apparel, toys, electrical/electronic and furniture</p>	
Site Certification Level	<p>There are two levels of certification Foundation and Higher. As a norm, sites manufacturing cosmetics are certificated to the higher level of personal care and household. Certificate issued to site only when all non-conformities identified at audit are corrected within agreed time period. Certification is underpinned by a robust compliance management process to maintain rigour of Standard.</p>	One level
Audit Frequency	Every 12 months	
Audit Options	Announced, Unannounced	Guidelines Not specified
Audit Grade	AA to D, Uncertificated(fail)	Guidelines Not specified

**Table 2. Summary Gap Analysis**

How ISO 22716 complies with requirements in the Global Standard for Consumer Products Issue 4 Personal Care & Household Products Higher level

Complies	Partial	No Match
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1. Senior management commitment		2. Product Risk Management			
1.1	1.2	2.1	2.2	2.3	2.4
1.1.1	1.2.1	2.1.1	2.2.1	2.3.1	2.4.1
1.1.2	1.2.2		2.2.2	2.3.2	
1.1.3			2.2.3	2.3.3	
1.1.4			2.2.4		
1.1.5			2.2.5		
1.1.6			2.2.6		
1.1.7					
1.1.8					
3. Product Safety and Quality Management					
3.1	3.4	3.5.2	3.7	3.9	3.11
3.1.1	3.4.1	3.5.2.1	3.7.1	3.9.1	3.11.1
	3.4.2	3.5.2.2	3.7.2	3.9.2	3.11.2
3.2	3.4.3	3.5.2.3	3.7.3	3.9.3	3.11.3
3.2.1			3.7.4	3.9.4	3.11.4
				3.9.5	3.11.5
3.3	3.5	3.6	3.8	3.9.6	3.11.6
3.3.1	3.5.1	3.6.1	3.8.1		3.11.7
3.3.2	3.5.1.1	3.6.2	3.10	3.10	3.11.8
	3.5.1.2	3.6.3		3.10.1	
	3.5.1.3			3.10.2	
				3.10.3	
4. Site Standards					
4.1	4.3	4.5	4.7	4.8	4.9
4.1.1	4.3.1	4.5.1	4.7.1	4.8.1	4.9.1
4.1.2	4.3.2	4.5.2	4.7.2	4.8.2	4.9.2
4.1.3	4.3.3	4.5.3	4.7.3	4.8.3	4.9.3
4.1.4	4.3.4	4.5.4	4.7.4	4.8.4	4.9.4
4.1.5	4.3.5	4.5.5			4.9.5
	4.3.6	4.5.6			4.9.6
	4.3.7	4.5.7			
4.2	4.4	4.6			
4.2.1	4.4.1	4.6.1			
4.2.2	4.4.2	4.6.2			
4.2.3	4.4.3	4.6.3			

4.2.4	4.4.4	4.6.4			
4.2.5		4.6.5			
4.2.6					
4.2.7					
5. Product Inspection and Testing			6. Control of Operations		
5.1	5.2	5.3	6.1	6.3	6.4
5.1.1	5.2.1	5.3.1	6.1.1.1	6.3.1	6.4.1
5.1.2	5.2.2	5.3.2	6.1.1.2	6.3.1.1	6.4.2
5.1.3		5.3.3	6.1.1.3	6.3.2	6.4.3
5.1.4		5.3.4	6.1.1.4	6.3.2.1	6.4.4
5.1.5			6.1.1.5	6.3.3.1	6.4.5
5.1.6			6.1.1.6	6.3.3.2	
			6.1.1.7		
			6.1.1.8		
			6.1.1.9		
			6.1.2	6.3.4	6.5
			6.1.2.1	6.3.4.1	6.5.1
				6.3.4.2	6.5.2
					6.5.3
			6.2	6.3.5.1	6.6
			6.2.1	6.3.5.1.1	6.6.1
			6.2.2	6.3.5.1.2	6.6.2
			6.2.3	6.3.5.2	6.6.3
			6.2.4	6.3.5.2.1	
			6.2.5	6.3.5.2.2	
			6.2.6	6.3.5.2.3	
				6.3.5.2.4	
				6.3.5.3.1	
				6.3.5.3.2	
7. Personnel					
7.1	7.2	7.3			
7.1.1	7.2.1	7.3.1			
7.1.2	7.2.2	7.3.2			
	7.2.3	7.3.3			
		7.3.4			
		7.3.5			
		7.3.6			
		7.3.7			
		7.3.8			

**Table 3. Comparison of Requirements**

BRCGS Clause	Requirements	ISO 22716 clause number  (if available)	
<b>1 Senior management commitment</b>			
<b>1.1 Senior management commitment and continual improvement</b>			
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.	3.3.1 3.3.1.1	
1.1.1	The site shall have a documented policy which states 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: <ul style="list-style-type: none"> <li>• authorised and signed by the person with overall responsibility for the site</li> <li>• communicated to all staff.</li> </ul>		
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.	3.3.2	
1.1.3	Management review meetings attended by the site's senior management shall be undertaken at appropriate planned intervals, at least annually, to review the site's performance against the Standard and objectives set in clause 1.1.2. The review process shall include the evaluation of:		



	<ul style="list-style-type: none"> <li>• previous management review action plans and timeframes</li> <li>• results of internal, second party and/or third-party audits (relevant to the scope of this Standard)</li> <li>• customer complaints and results of any customer feedback</li> <li>• product safety and quality incidents, corrective actions, out-of-specification results and non-conforming materials</li> <li>• output of review of the management of the systems for product risk assessment, changes in legal requirements and process performance</li> <li>• resource requirements.</li> </ul> <p>Records of the meeting shall be documented and used to revise the objectives. The decisions and actions agreed within the review process shall be effectively communicated to appropriate staff and actions implemented within agreed timescales.</p>		
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.	3.2.1.2	
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	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 at internal, second-party and third-party audits, with consideration of the root cause.		
<b>1.2 Organisational structure, responsibility and management authority</b>			
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.	3.2 3.2.1.3	
1.2.1	The site shall have an up-to-date organisation chart for key staff demonstrating the management structure of the company. The responsibilities for the management of activities which ensure product safety, legality and quality shall be clearly allocated and understood by the managers responsible. There shall be clear evidence of who deputises in the absence of the responsible person.	3.2.1.1	
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.	3.3.2 15	
<b>2 Product risk management</b>			
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.		
<b>2.1 Legislation and safety requirements</b>			
2.1.1	The site shall have a system to demonstrate knowledge of all applicable legislation, product standards and product safety issues in		
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	the place of production and regions of intended sale of each product. This may be within the company or by use of external expertise.		
2.1.2	If the site relies on information concerning product safety, quality and legality provided by their customer or a third party, it shall have a process in place to validate the credibility of the provider of the information and retain evidence of this validation.		
2.1.3	<p>The company's senior management shall have a system in place to ensure that the site is kept informed of and reviews:</p> <ul style="list-style-type: none"> <li>• changes in legislation</li> <li>• scientific and technical developments</li> <li>• industry codes of practice</li> <li>• new risks to raw materials, components, packaging and finished product.</li> </ul> <p>Any changes shall be implemented in a timely and controlled manner or as defined by legal requirements.</p>		
2.1.4	Copies of applicable legislation, standards, codes of practice and similar documents shall be available to relevant staff.		
<b>2.2 Product risk assessment</b>			
2.2.1	<p>The company shall ensure that a product hazard and risk assessment is undertaken for each product or product group. The assessment shall be documented and include:</p> <ul style="list-style-type: none"> <li>• a description of the product assessed (for example, approved samples or mock-ups, sample drawings, computer graphics, photographs, specification)</li> <li>• the intended use of the product and foreseeable abuse conditions</li> <li>• the hazards, the risk level for each hazard and whether the risk is acceptable</li> </ul>		

	<ul style="list-style-type: none"> <li>the date performed, name of the person responsible and the evidence from which the assessment was derived.</li> </ul> <p>If the assessment indicates that a product may present an unacceptable risk to consumers, that product shall not be produced by the site. If the product requires modification, a new risk assessment shall be completed on the modified design.</p>		
2.2.2	<p>The risk assessment shall be produced by suitably trained and competent internal or external resources. Evidence of this shall be available unless the risk assessment is provided by the customer.</p> <p>Staff with responsibility for decision-making shall be trained to ensure they understand risk assessment procedures or outcomes necessary for their activity.</p>		
2.2.3	<p>The site shall determine and maintain up-to-date information about the legislation and mandatory standards applicable to each product and to the materials from which it is made, relevant in the regions of intended sale.</p>		
2.2.4	<p>The risk assessment shall be reviewed at least annually, and following any significant complaints or incidents, to ensure that the assessment remains up to date, and reflects any changes in specification, manufacturing process and legislation.</p>		
2.2.5	<p>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.</p>		
2.2.6	<p>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.</p>		

<b>2.3 Product labelling and claims</b>			
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.		
<b>2.4 Packaging materials</b>			
2.4.1	Packaging shall be assessed for fitness for purpose and found suitable with regard to: <ul style="list-style-type: none"> <li>• protecting the product from damage</li> <li>• maintaining product integrity</li> <li>• protecting the consumer from injury</li> <li>• preventing contamination.</li> </ul>		
<b>3.1 General documentation requirements</b>			
<b>3.1.1 Product safety and quality management system</b>			
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.	17.1	
3.2.1	<p>The site shall have a document control procedure to ensure that all key documents which form part of the product safety and quality system are effectively managed.</p> <p>This shall include:</p> <ul style="list-style-type: none"> <li>• a list of all controlled documents indicating the latest version number</li> <li>• the method for the identification and authorisation of controlled documents</li> <li>• a record of the reason for any changes or amendments to documents</li> <li>• the system for replacement of existing documents when these are updated.</li> </ul> <p>Documents which are in electronic form shall be suitably protected to prevent loss or malicious intervention.</p>	17.1 17.3	
3.3 Record completion and maintenance			
Statement of Intent	The site shall maintain original, accurate, timely and legible records to demonstrate the effective control of product safety, legality and quality.	17.4 17.5	
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.	17.4	
3.3.2	<p>Records shall be retained for a defined minimum period with consideration given to:</p> <ul style="list-style-type: none"> <li>• legal requirements</li> <li>• the shelf life of the product</li> </ul>	17.5	

	<ul style="list-style-type: none"> <li>customer requirements.</li> </ul>		
<b>3.4 Internal audit</b>			
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.	16	
3.4.1	There shall be a scheduled programme of internal audits throughout the year with a scope which covers the implementation of the process risk assessment, GMP and documented procedures to achieve this standard. The scope and frequency of the audits shall be established in relation to the risks associated with the activity and previous audit performance.	16.2	
3.4.2	Internal audits shall be carried out by appropriately trained, competent auditors. Auditors shall be independent (i.e. not audit their own work).	16.2.1	
3.4.3	The internal audit programme shall be fully implemented and tracked. Internal audit reports shall identify conformity as well as non-conformity and the results shall be reported to the personnel responsible for the activity audited. Corrective actions and timescales for their implementation shall be agreed and completion of the actions verified.	16.3	
<b>3.5 Supplier approval and performance monitoring</b>			
<b>3.5.1 Management of suppliers of raw materials, components and packaging</b>			
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.	6	
3.5.1.1	The site shall have a documented procedure for supplier approval, including a list of approved suppliers for products, materials and services	6.2 6.5.3	

	<p>impacting product safety, legality or quality.</p> <p>The approval of these suppliers shall be based on at least one or a combination of the following:</p> <ul style="list-style-type: none"> <li>• supplier questionnaire</li> <li>• certificate of analysis</li> <li>• supplier audits</li> <li>• supplier certification with a scope covering the products supplied.</li> </ul>		
3.5.1.2	<p>Documented procedures shall be established which include clear criteria for ongoing assessment of the standards of performance required. Ongoing assessment may employ one or more of the following or other acceptable methods:</p> <ul style="list-style-type: none"> <li>• in-house checks</li> <li>• certificate of conformity</li> <li>• supplier audits</li> <li>• traceability checks.</li> </ul> <p>Records of this monitoring shall be retained with consideration given to legal requirements, product shelf life and customer requirements.</p>		
3.5.1.3	<p>Documented procedures shall define how exceptions are handled; for example, the use of products where audit or monitoring has not been undertaken.</p> <p>Based on a batch or delivery basis, the procedure may involve the assessment of certificates of analysis.</p>		
<b>3.5.2 Control and acceptance of incoming raw materials, components and packaging materials</b>			
Fundamental Statement of Intent	<p>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.</p>	6.1	



3.5.2.1	<p>Raw materials, components and packaging shall have documented approval procedures to ensure they conform to agreed specifications and requirements and documented positive batch release.</p> <p>Incoming goods, including materials returned to site from subcontractors (and home workers), shall be subject to a documented positive batch release procedure.</p>	6.3.2	
3.5.2.2	The company shall have a documented procedure 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 documented procedure to ensure the authenticity of raw materials, components, packaging and documentation to prevent fraud.	6.4	
<b>3.6 Specifications and technical files</b>			
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.	6.1	
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.	8.1	

	<p>As a minimum, the specification may include the following, although this is not an exhaustive list:</p> <ul style="list-style-type: none"> <li>• product name and description</li> <li>• composition</li> <li>• physical and/or chemical parameters</li> <li>• assembly diagrams</li> <li>• packaging</li> <li>• labelling</li> <li>• intended shelf life</li> <li>• warnings</li> <li>• instructions for use.</li> </ul>		
3.6.3	<p>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.</p> <p>Relevant data may include:</p> <ul style="list-style-type: none"> <li>• bill of materials</li> <li>• safety data sheets on all chemicals used where relevant to the safety, legality or quality of the product</li> <li>• risk assessment(s)</li> <li>• description of the conformity assessment procedure</li> <li>• test reports</li> <li>• inspection reports</li> <li>• list of the legislation and product standards with which the products are manufactured to comply</li> <li>• production control procedures and charts</li> <li>• approvals by any government body (if applicable)</li> <li>• declarations of conformity to legal requirements (if applicable)</li> <li>• self-inspection reports</li> <li>• corrective actions.</li> </ul>		
<b>3.7 Corrective and preventive action</b>			
Fundamental Statement of Intent	The company shall operate an effective system for the capture, recording and timely corrective actions of non-conformities or matters reported as	13	

	possible non-conformities critical to product safety, legality or quality.		
3.7.1	The company shall operate an effective documented process for the capture, recording and timely investigation of non-conformities or matters reported as possible non-conformities critical to product safety, legality or quality.	13.1	
3.7.2	An appropriate staff member shall be identified and assigned the responsibility and accountability for each corrective action. This shall be documented.		
3.7.3	The company shall ensure that effective corrective actions are taken to prevent recurrence of the problem and shall monitor and record their completion within an appropriate timescale.	13.2	
3.7.4	The company shall review its processes at least annually and adopt preventive measures as they become available.		
<b>3.8 Control of non-conforming materials</b>			
Statement of Intent	The company shall ensure that non-conforming raw materials, packaging, components and products are clearly identified, labelled, quarantined, investigated and documented.	6.4 6.4.3	
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.	6.4.2 8.5	
<b>3.9 Traceability</b>			
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 which has the ability to trace and follow all raw materials, components and		

	packaging materials from the supplier through all stages of processing and distribution of the finished product, and vice versa, in a timely manner.		
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.	6.5 7.2.3 7.3.8	
3.9.3	Finished product shall be identified with a unique code such as a batch code applied to the product or packaging.  Documented procedures must be in place to trace a finished product back to the batch of raw materials or packaging used.	8.3.4	
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 system shall be tested to ensure traceability can be determined from raw-material receipt to finished product and vice versa. 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.		
<b>3.10 Complaint handling</b>			
Statement of Intent	The company shall operate an effective system for the capture, recording and investigation of product complaints at all levels of severity.	14	
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	14.1.1 14.2	

	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.		
3.10.3	Complaint data shall be analysed for significant trends. This analysis shall be made available to relevant staff.	14.2.5	
<b>3.11 Management of incidents, product withdrawal and product recall</b>			
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.	14.3	
3.11.1	The site shall determine and provide written or other guidance to relevant staff regarding the type of event that would constitute an incident or emergency situation that impacts product safety, legality or quality, and a documented reporting procedure shall be in place which shall include informing their customers in a timely manner.		
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.	14.3.2	
3.11.3	The documented product withdrawal and recall procedures shall include as a minimum: <ul style="list-style-type: none"> <li>• identification of key staff constituting the incident management team and their key responsibilities</li> <li>• an up-to-date list of key contacts, with details of agencies providing advice and support</li> <li>• a list of persons who can initiate a recall.</li> </ul>	14.3.1 14.3.3	
3.11.4	The site shall have written technical and quality agreements in place with agents		

	and distributors and other parties in the supply chain where these are necessary to ensure effective withdrawal/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.	14.3.4	
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.	14.3.4	
3.11.7	The product recall and withdrawal procedures shall be regularly tested, at least annually, in a way that ensures their effective operation. Results of the test shall include timings of key activities and shall be retained.  The company's senior management shall ensure that results of this test shall be used to implement improvements as necessary.	14.3.5	
3.11.8	The company shall develop contingency planning for business continuity in the event of major incidents such as: <ul style="list-style-type: none"> <li>• disruption to key services (e.g. water, energy, staff availability)</li> <li>• events such as flood, fire and natural disaster</li> <li>• malicious contamination or sabotage.</li> </ul>		
<b>4 Site standards</b>			
<b>4.1 External standards</b>			
Statement of Intent	Sites used for manufacturing, storage or distribution shall be of suitable size, location, construction and design to facilitate maintenance, prevent	4.3	

	contamination and enable the production of safe and legal products.		
4.1.1	<p>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.</p> <p>The external areas and surroundings shall be maintained in good order.</p> <p>A site plan shall be retained and readily available.</p>	4.11	
4.4.2	<p>Consideration shall be given to local activities and the site environment and measures shall be taken to prevent contamination.</p> <p>Where measures have been put into place to protect the site (from potential contaminants, flooding, etc.), they shall be regularly reviewed in response to any changes.</p>		
<b>4.2 Security</b>			
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.	3.6	
4.2.2	Contractors involved in maintenance or repair shall be qualified or supervised, and a nominated staff member shall be responsible for their activities with regard to potential effects on the safety, legality or quality of products.		
<b>4.3 Layout, product flow and segregation</b>			
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.	4.4	
4.3.1	The layout process flow of machinery and equipment shall be arranged to	4.4	

	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.	5.2	
4.3.3	The location of facilities and services, including toilets, cleaning and catering facilities, shall be segregated and separated from production areas and shall not jeopardise the integrity of the product.	4.2 4.6	
4.3.4	There shall be effective segregation to minimise the risk of product cross-contamination taking into account the flow of product, nature of materials, equipment, personnel, waste, airflow, air quality and utilities.  Documented control procedures shall be in place.	4.4	
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.		
4.3.6	The company shall determine whether allergenic or sensitising materials are used and, if so, documented policies shall exist for the handling of such materials including: <ul style="list-style-type: none"> <li>• physical or time segregation from other products</li> <li>• use of identified, dedicated equipment if necessary</li> <li>• adequate labelling of final products.</li> </ul>		
4.3.7	Materials and products requiring segregation (e.g. materials intended for different geographical regions) shall have documented 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	
4.4.1	<p>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:</p> <ul style="list-style-type: none"> <li>• a clean, tidy and organised factory</li> <li>• adequate lighting</li> <li>• adequate ventilation</li> <li>• walls, floors, windows, doors and ceilings maintained in a good condition to prevent foreign body risks</li> <li>• suitable and sufficient removal of any by-products and contaminants.</li> </ul>	4.1 4.5 4.8 4.9	
4.4.2	Suitable and sufficient lighting shall be provided for correct operation of processes, inspection of products, and effective cleaning.	4.7	
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.	6.8	
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.	4.6	
4.5.2	Where smoking or use of electronic cigarettes is allowed under national law, it shall only be permitted in designated controlled smoking areas which shall be isolated from production and storage areas and fitted with air extraction to the exterior of the building. Adequate arrangements for dealing with smokers' waste shall also be provided at smoking facilities, both inside buildings and at external locations.	3.5.1.4	
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	The site shall use risk assessment to determine where a change to workwear in different areas is required. Any required changing facilities shall be provided for all personnel: staff, visitors and contractors. Changing areas should be sited to allow direct access to the production, packing or storage areas without exposure to any external area. Where this is not possible, the site shall use the risk assessment to help determine the activities required to mitigate any risk. This procedure shall be documented.	3.5.1.1	
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	

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.	4.10	
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.	5.5.1	
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.	5.5.2	
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.		
4.6.4	<p>Documented cleaning procedures shall be in place, validated and maintained for the building, utilities, plant and all equipment. Where more than basic cleaning is required, cleaning procedures shall include the following information as a minimum:</p> <ul style="list-style-type: none"> <li>• responsibility for cleaning</li> <li>• item/area to be cleaned</li> <li>• frequency of cleaning</li> <li>• method of cleaning</li> <li>• cleaning materials to be used</li> <li>• cleaning records and responsibility for verification.</li> </ul> <p>Cleaning and housekeeping shall be carried out by trained personnel in accordance with documented</p>	4.10.4	

	procedures, and records shall be maintained.		
4.6.5	<p>The standard of cleaning shall be appropriate to the product being manufactured and shall be verified and documented and, where relevant, agreed with the customer. Corrective actions shall be documented.</p> <p>Cleaning procedures shall be revalidated following building work, maintenance, changes to equipment or new product introduction.</p>	4.10.2	
<b>4.7 Waste and waste disposal</b>			
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.	4.4	
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.	11.1 11.2	
4.7.2	Where legally necessary, waste shall be removed by identified, licensed contractors, and records of disposal shall be maintained by the site.		
4.7.3	Waste materials shall be controlled, clearly labelled and where necessary quarantined to ensure that they are not reintroduced into non-waste production flows.	11.3	
4.7.4	External waste collection containers and compactors shall be managed in such a manner as to minimise risk to the product if necessary.	11.4	
<b>4.8 Pest control</b>			
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.	4.13.2	

4.8.1	<p>The pest control programme shall be based on a documented risk assessment which should include the product, the material included, the location and type of premises, the possible types of pest, and the process.</p> <p>The pest control provider shall be a specialist or a trained employee.</p> <p>The pest control programme shall include a documented inspection schedule.</p>		
4.8.2	<p>The company shall either have a clearly defined contract with external contractors which reflects the activities of the site or have trained staff.</p> <p>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.</p>		
4.8.3	<p>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.</p>		
4.8.4	<p>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.</p>		

## 4.9 Product storage, dispatch and transport

Statement of Intent	<p>Facilities for the storage and transportation of products shall be suitable for purpose and minimise the risk of product contamination, damage and malicious intervention</p>	8.3.1	
4.9.1	<p>All materials, work in progress and product shall be properly identified and protected during storage by appropriate</p>	7.2.6	

	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	6.6.1 6.6.2 8.3.3	
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.		
4.9.4	Documented procedures to maintain product safety and quality during loading and transportation shall be developed and implemented.		
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.	9.1.2	
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: <ul style="list-style-type: none"> <li>the outcome of the product and process risk assessments</li> </ul>	9.2.1	

	<ul style="list-style-type: none"> <li>any legal requirements for testing in the regions(s) of intended sale</li> <li>the site's requirements for demonstrating the production of safe products.</li> </ul> <p>The methods, frequency and specified limits of testing shall be clearly defined.</p>		
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.	9.5	
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: <ul style="list-style-type: none"> <li>use of recognised test methods and reference standards, where available</li> <li>documented testing procedures</li> <li>ensuring staff are suitably qualified and/or trained and competent to carry out the analysis required</li> <li>use of a system to verify the accuracy of test results (e.g. ring or proficiency testing)</li> <li>use of appropriately calibrated and maintained equipment.</li> </ul>	9.2 9.3 9.6	
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.	9.4	

	Appropriate actions shall be implemented promptly to address any unsatisfactory trends.		
5.1.6	<p>Where testing is submitted to third parties, the required testing shall be clearly defined, including reference to the number, date and version of the test standard or method to be used.</p> <p>In cases where the company relies on the expertise of third-party testing organisations to determine appropriate test requirements, the company shall ensure that the third party receives a clear written briefing on the purpose of the test and that the testing programme is formally agreed and documented.</p>		
<b>5.2 Quantity control</b>			
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	<p>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.</p> <p>Documentary evidence shall be available on site to substantiate claims.</p>		
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.		
<b>5.3 Product sample control</b>			
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 sample of the product	9.7	



	<p>which has been approved by the customer or a representative of the agreed specification shall be retained.</p> <p>The company shall document a process to identify, select and categorise reference samples. If customers have a defined system of sealed samples referring to different stages of sample approval, the customer's procedure shall be documented and followed.</p>		
5.3.2	Reference samples shall be stored and recorded in suitable environmental conditions to maintain their original status for a specified period.	9.8.1 9.8.2	
5.3.3	<p>A secure and tamper-evident system shall be in place for the storage and tracking of samples, with access by authorised personnel.</p> <p>The removal and return of samples to storage shall be documented and authorised by a designated responsible person.</p>		
5.3.4	Documented procedures shall be in place to determine the retention time for samples. This should normally be the foreseeable lifetime of the product unless otherwise justified.		
<b>6. Process control</b>			
<b>6.1 Control of operations</b>			
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.	7.1	
6.1.1.1	A hazard and risk analysis shall be carried out by a multi-disciplinary team including representatives who are experienced in the particular activities undertaken by the site. The team members shall have knowledge of the hazard and risk analysis principles.		

6.1.1.2	<p>The person responsible for leading the hazard analysis shall receive sufficient training to be able to demonstrate competence in the understanding of hazard and risk management principles and their application.</p> <p>In the event of the site not having appropriate in-house knowledge, external expertise may be sought but the day-to-day management of the system shall remain the responsibility of the site.</p>		
6.1.1.3	<p>Where the hazard and risk analysis study has been undertaken centrally by the head office, accurate flow diagrams shall be available on site.</p> <p>It must be possible to demonstrate that a central hazard and risk analysis has been verified to meet the specific activities of the local operation. Verification activities include internal audits and complaints analysis.</p>		
6.1.1.4	<p>The scope of the hazard and risk analysis shall be defined in terms of the products and processes that are covered.</p> <p>The site shall establish precise process flow diagrams identifying each step in the production of the products.</p>		
6.1.1.5	<p>The site shall consider the potential product safety and quality issues which could occur at each process stage. This should include:</p> <ul style="list-style-type: none"> <li>• physical or chemical product contamination</li> <li>• microbiological contamination</li> <li>• product quality or safety issues as appropriate to the products manufactured.</li> </ul> <p>The results of this assessment shall be documented.</p>		
6.1.1.6	<p>An analysis of any identified issues shall be undertaken in order to decide which need to be controlled. The following should be considered:</p> <ul style="list-style-type: none"> <li>• the likely occurrence of the issue</li> </ul>	7.2.5.1	

	<ul style="list-style-type: none"> <li>the severity of the hazard (e.g. injurious to health, potential to cause, rejection or a product recall)</li> <li>existing activities that effectively prevent or reduce the issue to acceptable limits.</li> </ul>		
6.1.1.7	For each issue which requires control, control points shall be reviewed to identify those that are critical to prevent, eliminate or reduce a significant issue to acceptable limits.	7.2.5.2	
6.1.1.8	<p>If there are identified critical control points (CCPs) where product safety and legality require control measures to be in place, then for each CCP the site shall:</p> <ul style="list-style-type: none"> <li>establish and validate critical limits</li> <li>establish a system to monitor control of the CCPs</li> <li>establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control</li> <li>establish procedures of validation and verification to confirm that the system is working effectively, including auditing of the system</li> <li>establish appropriate documentation concerning all procedures and records.</li> </ul>		
6.1.1.9	Corrective action shall be taken in the event of deviation of the process from specification. This shall be recorded.	13.1 13.2	
6.1.1.10	The hazard and risk analysis shall be reviewed whenever new product types are manufactured or significant changes are made to production methods.		
6.1.1.11	The hazard and risk analysis shall also be formally reviewed at least annually, and this review shall be documented.		
<b>6.1.2 Line clearance and in-process checks</b>			
6.1.2.1	Before the start of any manufacturing operation, documented checks shall be carried out to ensure that the production line and the relevant areas around it have been cleared and, where	7.2.2	

	<p>necessary, cleaned, to avoid mixing with materials from the previous operations.</p> <p>All documentation, raw materials, components and packaging with the necessary equipment shall be available for use.</p> <p>It shall be possible to identify the production line with its name or identifying code as determined by the risk assessment.</p>		
<b>6.2 Equipment and equipment maintenance</b>			
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.	5.6	
6.2.1	<p>All equipment shall be fit for purpose and constructed of appropriate materials.</p> <p>The design and placement of equipment shall ensure it can be effectively cleaned and maintained.</p>	5.2 5.3	
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.	5.6.3	
6.2.3	A documented planned preventive maintenance programme based on risk assessment and 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.	5.7	
6.2.5	Repairs or servicing of equipment shall be completed by competent maintenance personnel.	3.4.1	

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.	5.3.3	
<b>6.3 Product contamination control</b>			
Statement of Intent	Appropriate facilities and procedures shall be in place to control the risk of foreign body, chemical or biological contamination.		
<b>6.3.1 Identification and prevention of risk of product contamination</b>			
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.		
<b>6.3.2 Chemical and biological control</b>			
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: <ul style="list-style-type: none"> <li>a list of approved chemicals for purchase</li> <li>availability of material safety data sheets</li> <li>the labelling and/or identification of containers of chemicals and biological materials at all times</li> <li>a designated storage area with access restricted to authorised personnel.</li> </ul>		
<b>6.3.3 Metal control</b>			
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: <ul style="list-style-type: none"> <li>tools permanently attached to equipment to prevent loss</li> </ul>		

	<ul style="list-style-type: none"> <li>• items controlled by an issue listing and registration procedure</li> <li>• recovery of all parts of broken needles before the issue of a replacement needle.</li> </ul> <p>Snap-off-blade knives shall be prohibited.</p>		
6.3.3.2	<p>Staples, paper clips and drawing pins shall not be used in open product areas.</p> <p>Where staples or other items are present as packaging materials or closures, appropriate precautions shall be taken to minimise the risk of product contamination.</p>		
<b>6.3.4 Glass, brittle plastic, ceramics, wood and similar materials control</b>			
6.3.4.1	<p>Glass or other brittle materials shall be excluded or protected against breakage in areas where there is a risk of product contamination.</p>		
6.3.4.2	<p>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:</p> <ul style="list-style-type: none"> <li>• regular checks of the condition of these materials carried out at specified intervals and recorded</li> <li>• recording of all breakages in an incident report</li> <li>• segregation of contaminated product</li> <li>• recording details of cleaning or replacement to minimise potential for product contamination.</li> </ul>		
<b>6.3.5 Foreign body detection and removal equipment</b>			
Statement of Intent	<p>The risk assessment shall identify the potential use of equipment to detect or remove foreign body contamination.</p>		

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	<p>Filters and sieves shall be regularly inspected and tested for damage at a documented frequency determined by the risk assessment.</p> <p>Defective sieves and filters shall be segregated, and appropriate action taken to replace them.</p> <p>Records shall be maintained.</p>		
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	<p>The metal detector or X-ray equipment shall incorporate one of the following:</p> <ul style="list-style-type: none"> <li>• an automatic rejection device</li> <li>• a belt stop system with an alarm where the product cannot be automatically rejected (e.g. for very large packs)</li> <li>• in-line detectors which identify the location of the contaminant to allow effective segregation of the affected product.</li> </ul>		
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	There shall be a documented procedure to examine product rejected by the metal detector and to retain any metal contaminant.		

	<p>The source of the contamination shall be investigated, and appropriate corrective action taken to minimise the risk of further contamination.</p> <p>Records shall be maintained.</p>		
<b>6.3.5.3 Magnets</b>			
6.3.5.3.1	<p>The type, location and strength of magnets shall be recorded in a register.</p> <p>Documented procedures shall be in place for inspection, cleaning, strength testing and integrity checks. Records of all checks shall be maintained.</p>		
6.3.5.3.2	<p>Optical sorting equipment shall be checked on the basis of the manufacturer's instructions or recommendations.</p> <p>Records of all checks shall be maintained.</p>		
<b>6.4 Calibration and control of measuring and monitoring devices</b>			
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 identify 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).	5.4.1 7.3.5	
6.4.3	The calibration of identified equipment shall be traceable to a recognised national standard. Where such a standard does not exist, the basis by which calibration is declared shall be verified.		
6.4.4	Records of the results of calibration and verification shall be maintained for a suitable period, taking account of the life of the products being produced.		



6.4.5	<p>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.</p> <p>Procedures shall be in place for actions to be taken if equipment is found not to be operating within specified tolerances and/or limits.</p>	5.8	
<b>6.5 Final product packing and control</b>			
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.	7.3	
6.5.1	<p>Before the start of the packaging operation, documented checks shall be carried out to ensure that the packing line and the relevant areas around it have been cleared, and where necessary cleaned, to avoid mixing with materials from the previous operations.</p> <p>All documentation and packaging materials shall be available for use.</p> <p>The packing line shall be identifiable by its name or identifying code as determined by the risk assessment.</p>	7.3.2	
6.5.2	<p>The company shall have a validated, documented procedure for the packing of products taking particular account of customer requirements.</p> <p>This shall include methods of ensuring that the correct product(s) and components are correctly packaged and placed in the correct outer packaging.</p>	7.3.1.2	
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	8.2	
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.	8.3.5	
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	<p>A documented procedure shall be in place to ensure that only products conforming to specification are released for dispatch. Procedures may include, but are not limited to:</p> <ul style="list-style-type: none"> <li>• positive final release by authorised staff</li> <li>• online test methods</li> <li>• automatic rejection process (which shall be validated and monitored).</li> </ul> <p>If a risk assessment determines that no such control is required, the company shall have a full justification for its absence, which is documented in the customer agreement and shall be reviewed at least annually.</p>		
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	3.4.1	
7.1.1	<p>The company shall ensure that all employees are able to demonstrate competence with regard to their activity.</p> <p>The company shall:</p>	3.4.1	

	<ul style="list-style-type: none"> <li>• identify the need for training</li> <li>• document training procedures and records to demonstrate that training is effective and regularly reviewed</li> <li>• ensure that training includes both general information on the company and specific job training</li> <li>• retain all training records.</li> </ul>		
7.1.2	Training records shall be stored in such a way as to ensure privacy of personnel is protected and legal compliance with data protection laws in the country of operation are respected, while also allowing auditors access to necessary information. Training shall be traceable to an individual employee.		
<b>7.2 Protective clothing</b>			
Statement of Intent	The company's standards shall be documented and adopted by all personnel, including contractors and visitors to the production facility.	3.5.1.1	
7.2.1	<p>The company shall use risk assessment to determine the need for protective clothing.</p> <p>Where a need for protective clothing has been identified by the risk assessment, this shall not pose a contamination risk to the product.</p>	3.5.1.3	
7.2.2	Based on the assessment of risk to the product integrity, suitable footwear shall be worn within the factory environment.	3.5.1.3	
7.2.3	<p>Protective clothing, where provided, shall be effectively laundered at an appropriate frequency.</p> <p>Disposable protective clothing, if used, shall be subject to adequate control to avoid product contamination.</p>		
<b>7.3 Hygiene practices</b>			
Statement of Intent	Standards of hygiene shall be applied with due regard to the risk of product contamination.	3.5.2 3.6	

7.3.1	The company shall have a policy to control the wearing of jewellery so that it poses no risk of product contamination.	3.5.1.4	
7.3.2	All cuts and grazes on exposed skin shall be covered by a contrasting coloured plaster that is issued and monitored by the site, to avoid contamination of product.	3.5.2	
7.3.3	Where metal foreign body detection is in place, detectable plasters shall be used and shall be regularly tested through the detector.		
7.3.4	Hand-cleaning shall be performed at a suitable frequency to maintain hygienic conditions.	3.5.1.2	
7.3.5	Eating, drinking or smoking shall only be permitted within designated areas and where there is no risk of contamination of products.	3.5.1.4	
7.3.6	The company shall use risk assessment to determine the need for all head and facial hair to be covered and fully contained to prevent product contamination.		
7.3.7	Where there is a risk to product safety and quality, fingernails shall be kept short, clean and unvarnished.  False fingernails shall not be permitted.		
7.3.8	The site shall have a documented procedure for the notification by personnel, including temporary personnel, visitors and contractors, of any relevant infections, diseases or conditions which they may have been in contact with or be suffering from.	3.5.2	