

Global Standard Packaging Materials Issue 7 Draft for Industry Consultation (May 2024)

Document Scope:

Draft of Issue 7 of the Global Standard Packaging for industry consultation.

On conclusion of the consultation (refer to Part I Introduction) comments received will be reviewed by the BRCGS Technical Working Group and where applicable, the draft Standard updated prior to publication of the final text. This document shall therefore only be considered a draft document and not the final definitive text or normative version of the Standard.

Change log:

Version no.	Date	Description
1	10/05/2024	Final draft version of BRCGS Standard Packaging Issue 7 for industry consultation.

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¹ BRCGS is a trading name of BRC Trading Ltd.

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How this publication is organised

This publication sets out the draft requirements for auditing and certification of packaging manufacturers to achieve certification for the *Global Standard Packaging Materials Issue 7*.

The document consists of the following sections:

Part I - Introduction

Provides an introduction to this document and the consultation process.

Part II - Requirements

Details the proposed requirements of the Standard with which a company must comply to gain certification.

Part III - Summary of the Audit Protocol

Details the proposed protocol of the Standard describes the requirements for auditing options and activities associated with the certification processes for company's seeking to gain certification.

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Part I – Introduction

The information included in this consultation document has been developed and reviewed by a working group made up of international stakeholders representing food manufacturers, retailers, food service companies, certification bodies and independent technical experts.

An important next step in the development of the Global Standard Packaging Materials Issue 7 is an extensive consultation to understand stakeholders' requirements and views on the draft proposals.

This document therefore contains the proposals for Issue 7 and is structured as follows:

- Section II – full details of the proposed requirements for Issue 7
- Section III – full details of the proposed protocol for issue 7

Stakeholders are encouraged to consider the details within this document and provide feedback on both the proposed requirements and the audit protocol, by email, to BRCGS.enquiries@lgcgroup.com using the feedback form provided.

The closing date for submission of feedback is **12th June 2024**.

This draft is for the purposes of consultation only and the requirements and protocol are subject to change.

Effective Date of Issue 7

As with all revisions of the Global Standards, there must be a transition period between consultation, publication of the complete, finalised Standard and full implementation of the Standard. Therefore:

- Issue 7 will be published in October 2024
- Certification against Issue 7 will commence in audits from April 2025

All certificates issued against audits carried out prior to this date will be against Issue 6 and be valid for the period specified on the certificate.

Part II – Requirements

Each clause of the Standard begins with a statement of intent. This sets out the expected outcome of compliance with the requirements of that section. It forms part of the audit, and all sites must comply with the statements of intent in order to gain certification.

Below the statement of intent in the tables are more specific and detailed requirements (clauses) that, if applied appropriately, will help to achieve the stated objective of the requirement. All of the requirements shall form part of the audit.

Colour-coding of requirements

Manufacturing represents the key activities on site. The audit process therefore gives specific emphasis to the practical implementation of product safety procedures within the factory and general good manufacturing practices. Auditing these areas forms a significant proportion of the audit (this includes auditing manufacturing and site facilities, interviewing staff, observing manufacturing operations, and reviewing documentation in manufacturing areas with the relevant staff). All areas of the site, and off-site operations, within the scope of the certification will be audited. This will include staff facilities, storage, dispatch, engineering, on-site laboratory facilities, and external areas such as security.

As an aid to this process, the requirements within the Standard have been colour-coded. Colour-coding shows the activities that would usually be audited as part of the assessment of the production areas and facilities, and those that would form part of an audit of records, systems and documentation.

Key to colour-coding of requirements

Audit of site facilities and good manufacturing practice		
Audit of records, systems and documentation		
Requirements assessed in both		

Fundamental requirements

Within the Standard, certain statements of intent have been designated as 'fundamental'. These are marked with the word 'FUNDAMENTAL' and denoted with the following symbol ☆. The requirements that accompany these fundamental statements relate to the systems which are crucial to the establishment of an effective product quality and safety operation. They can be found in the following sections:

- Senior management commitment and continual improvement (1.1)
- Hazard analysis and risk assessment (2)
- Specifications (3.4)
- Internal audits (3.5)
- Traceability (3.10)

- Corrective and preventive actions (3.11)
- Housekeeping and cleaning (4.8)
- Manufacturing process control (5.4)
- Training and competence (6.1).

Failure to comply with the statement of intent of a fundamental requirement (i.e. a major non-conformity) leads to non-certification at an initial audit or withdrawal of certification at subsequent audits. This will require a further full audit to demonstrate evidence of compliance.

Additional Requirements

The requirements in section 1 – 6 shall be applied in **all** operations, except for 5.3 Print Control which only applies to sites that print or decorate packaging.

Where a site handles traded products (traded products are defined as products that would normally fall within the scope of the Standard and are stored at the site's facilities but that are not manufactured, , reworked or packed at the site being audited), the site can opt to include these products within the scope of their BRCGS audit. The requirements for traded products are detailed in section 7.

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1 Senior management commitment

1.1 Senior management commitment and continual improvement

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The site's senior management shall demonstrate that they are fully committed to the implementation of the Global Standard for Packaging Materials and to processes which facilitate continual improvement of packaging safety, quality management, and the sites product safety and quality culture.

Clause	Requirements
1.1.1	<p>The site shall have-maintain a documented policy which states the site's intention to meet its obligation to produce safe and legally compliant products to the specified quality and confirms its responsibility to its customers. This shall be:</p> <ul style="list-style-type: none"> • signed by the person with overall responsibility for the site • <u>communicated to all staff</u> • <u>include commitment to continuously improve the site's product safety and quality culture.</u>
1.1.2	<p>The site's senior management shall define and maintain a clear and effective plan for the development and continual continuing improvement of a product safety and quality culture. <u>The plan shall include measures needed to achieve a positive culture change.</u></p> <p>This shall include:</p> <ul style="list-style-type: none"> • <u>defined activities involving all sections of the site that have an impact on product safety and quality</u> <p><u>As a minimum, these activities shall be designed around:</u></p> <ul style="list-style-type: none"> • <u>clear and open communication of product safety</u> • <u>training</u> • <u>feedback from employees</u> • <u>the behaviours required to maintain and improve product safety processes</u> • <u>performance measurement of activities related to the safety, legality and quality of products</u> <ul style="list-style-type: none"> • <u>an action plan indicating description of how the activities will be undertaken and measured, and the intended timescales</u> • <u>a review of the effectiveness of completed and ongoing activities.</u> <p><u>Clause effective from 1 February 2021. The plan shall be reviewed and updated, at a minimum, annually.</u></p>
1.1.3	<p><u>The company shall have a confidential reporting system to enable staff to report concerns relating to product safety, legality and quality.</u></p> <p><u>The mechanism (e.g. the relevant telephone number) for reporting concerns shall be clearly communicated to staff.</u></p> <p><u>The company's senior management shall have a process for assessing any concerns raised. Records of the assessment and, where appropriate, actions taken, shall be documented.</u></p>

1.1.4	<p>The site's senior management shall establish clear objectives to maintain and improve the quality, safety and <u>legality and quality</u> of products manufactured, in accordance with the site's product safety and quality policy and this Standard. These objectives shall be:</p> <ul style="list-style-type: none"> • documented and include targets or clear measures of success • clearly communicated to relevant staff • monitored, and the results reported at a suitable predetermined frequency to the site's senior management.
1.1.5	<p>The company's senior management shall provide the human and financial resources required for the production of safe packaging material and legal products, to the required quality, and in compliance with the requirements of this Standard.</p>
1.1.6	<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"> • scientific and technical developments • industry codes of practice • all relevant legislation applicable in the country of manufacture and, where known, the country where the product will be used. <p>Products shall meet the minimum legal requirements in the country of manufacture and of use where known.</p>
1.1.7	<p>The site shall have a genuine, original hard copy or electronic version of the current Standard and be aware of any changes to the Standard or protocol that are published on the BRCGS website.</p>
1.1.8	<p>Where the site is certificated to the Standard, it shall ensure that <u>announced or blended announced</u> re-certification audits occur on or before the audit due date indicated on the certificate.</p> <p><u>It is the site's responsibility to ensure that all requirements are met, to ensure the unannounced audit can be undertaken in accordance with the audit protocol (part III, section 4.7.1) of the Standard.</u></p>
1.1.9	<p>The most senior production or operations manager on site shall participate in the opening and closing meetings of the audit for certification to the Standard.</p> <p>Relevant departmental managers or their deputies shall be available as required during the audit.</p> <p><u>A member of the senior management team on site shall be available during the audit for a discussion on effective implementation of the product safety and quality culture plan.</u></p>
1.1.10	<p>The site's senior management shall ensure that the root causes of any non-conformities identified at the previous audit against the Standard have been effectively addressed to prevent recurrence.</p>
1.1.11	<p>The BRCGS logo and references to certification status shall be used only in accordance with the conditions of use detailed in the audit protocol section (Part III, section 5.6-6.7 <u>of the Standard</u>).</p>

1.2 Management review

The site's senior management shall ~~ensure that undertake~~ a management review ~~is undertaken~~ to ensure that the product safety and quality management system is both fully implemented and effective, and that opportunities for improvement are identified.

Clause	Requirements
1.2.1	Management review meetings attended by the site's senior management shall be undertaken at appropriate scheduled intervals (at a minimum annually) to review the site's performance against the Standard and the objectives set out in clause 1.1.4.
1.2.2	The review process shall include the evaluation of: <ul style="list-style-type: none"> • previous management review documents, action plans and timeframescales. • the results of internal, second-party and third-party audits • any customer performance indicators, complaints and feedback • the effectiveness of the hazard <u>analysis</u> and risk management <u>(HARM) systemassessment</u> • the impact of any applicable legislative and certification scheme changes • any incidents, corrective actions, out-of-specification results and non-conforming materials • resource requirements • any objectives that have not been met, to understand the underlying reasons. This information shall be used when setting future objectives and to facilitate continual improvement • the effectiveness of the product defence, and product fraud prevention plans, <u>and product safety and quality culture plans.</u>
1.2.3	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.
1.2.4	Staff shall be aware of the need to report any risks or any evidence of unsafe or out of specification product, equipment or raw materials, to a designated manager to enable the resolution of issues requiring immediate action. The site shall have a demonstrable system in place which enables product safety, legality, integrity and quality issues to be brought to the attention of a designated manager. The system shall allow for the resolution of issues requiring immediate action.

1.3 Organisational structure, responsibilities and management authority

The company shall have a clear organisational structure and lines of communication to enable effective management of product safety, legality, ~~regulatory compliance~~ and quality.

Clause	Requirements
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1.3.1	<p>The site shall have re shall be a current organisation chart demonstrating the management structure and reporting channels of the company.</p> <p>The responsibilities for the management of activities which ensure product safety, quality and legality <u>legality and quality</u> shall be clearly allocated and understood by the managers responsible. It shall be clearly documented who deputises in the absence of the responsible person.</p>
1.3.2	<p>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.</p>
1.3.3	<p><u>If the site does not have the appropriate in-house knowledge of product safety, legality and quality, external expertise (e.g. consultants, technical experts) may be used, however the day-to-day management of the product safety and quality management systems shall remain the responsibility of the company.</u></p>

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2 Hazard analysis and risk management assessment

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A hazard analysis and risk assessment (HARA) shall be implemented and maintained to ensure that all hazards to product safety and legality are identified, and appropriate controls established.

2.1 The Hazard analysis and risk management assessment team

~~A multidisciplinary hazard and risk management team shall be in place to develop and manage the hazard and risk management system and to ensure that the system is fully implemented and evaluated for its effectiveness.~~

Clause	Requirements
2.1.1	<p>The hazard analysis and risk assessment (<u>HARA</u>) shall be developed, reviewed and managed by a multi-disciplinary team that includes those responsible for quality, technical, engineering/maintenance, production manufacturing operations and other relevant functions <u>(e.g. engineering, product development)</u>.</p> <p><u>The multi-disciplinary team shall have a designated team leader who shall be suitably trained and able to demonstrate competence and experience of hazard analysis and risk assessment.</u></p> <p><u>The team shall be able to demonstrate competence in hazard analysis and risk assessment principles.</u></p> <p><u>The team shall ensure that the appropriate knowledge and expertise are available for the development of an effective HARA, including being kept up to date with factory changes and customer requirements as they occur.</u></p> <p>In the event that the site does not have the appropriate expertise in-house, external expertise may be used to analyse any hazards and the risk of them occurring, and/or develop and review the hazard and risk management system. However, the day-to-day management of the system shall remain the responsibility of the site.</p>
2.1.2	<p>The multidisciplinary team shall have a designated team leader who shall be suitably trained and able to demonstrate competence and experience of hazard and risk analysis.</p>
2.1.3	<p>The team shall be able to demonstrate competence in hazard and risk analysis principles and be kept up to date with factory changes and customer requirements as they occur.</p>

2.2 ~~Prerequisite programmes~~ **Hazard analysis and risk assessment**

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~~A documented hazard analysis and risk assessment (HARA) shall be in place to ensure that all hazards to product safety and legality are identified and appropriate controls established.~~

Clause	Requirements
2.2.1	<p>The team shall establish and maintain environmental and operational programmes necessary to create an environment suitable to produce safe and legal products (prerequisite programmes). As a guide these may include the following, although this is not an exhaustive list:</p> <ul style="list-style-type: none"> • supplier approval and purchasing (Section 3.6) • maintenance programmes for equipment and buildings (Section 4.7) • cleaning and housekeeping (Section 4.8) • Product Contamination Control (section 4.9) <ul style="list-style-type: none"> • pest management (Section 4.11) • product development (Section 5.1) • print control (Section 5.3) • dispatch and transport (Section 5.9) • staff training and competence (Section 6.1) • personal hygiene requirements (Section 6.2) <p>The control measures and monitoring procedures for the prerequisite programmes shall be clearly documented and shall be included within the development and reviews of the hazard analysis and risk assessment.</p> <p>The scope of the hazard analysis and risk assessment shall be clearly defined and documented and shall cover all products and processes included within the intended scope of certification.</p>
2.2.2	<p>The HARA team shall maintain awareness of and take into account:</p> <ul style="list-style-type: none"> • historical, known and foreseeable product safety hazards associated with specific processes and raw materials • intended use of the product (where known) • known likely product defects that affect safety • relevant codes of practice or recognised guidelines • legislative requirements.
2.2.3	<p>A full description of the product, product group and process shall be developed, which includes all relevant information on product safety and integrity. As a guide this shall include:</p> <ul style="list-style-type: none"> • composition (e.g. raw materials, inks, varnishes, coatings and other print chemicals) • origin of raw materials, including use of recycled materials • intended use of the packaging materials and defined restrictions on use; for example, direct contact with food or other hygiene-sensitive products, or the physical or chemical conditions.
2.2.4	<p>The process flow diagram prepared for each product, product group and process shall set out each process step from the receipt of raw</p>

	<p>materials, through manufacture and storage, to dispatch to the customer. As a guide this shall include, where applicable:</p> <ul style="list-style-type: none"> • receipt and approval of artwork and specification • receipt and preparation of raw materials such as additives, inks and adhesives • each manufacturing process step • in line testing or measuring equipment • the use of rework and post-consumer recycled materials • any subcontracted processes • customer returns.
2.2.5	<p>The accuracy of the process flow diagram shall be verified by the HARA team at least once per year and following any significant incidents or process changes.</p>
2.2.6	<p>The HARA team shall identify and record all potential product safety hazards that are reasonably expected to occur at each step in relation to the product and process. The hazards considered shall include, where relevant:</p> <ul style="list-style-type: none"> • microbiological hazards • chemical contamination (e.g. taint, odour, allergen, component transfer from inks, varnishes and glues) • potential for unintended migration of substances from the packaging material into food or other hygiene sensitive products • foreign objects • potential problems arising from the use of recycled materials • foreseeable misuse by the consumer • defects critical to consumer safety • hazards that may have an impact on the functional integrity and performance of the final product in use • potential for malicious intervention • potential for raw material fraud.
2.2.7	<p>The HARA team shall identify control measures necessary to prevent, eliminate or reduce each product safety hazard to acceptable levels.</p> <p>Where control is through prerequisite programmes as set out in sections 3, 4 and 6, these shall be reviewed to ensure they adequately control the risk identified and, where necessary, improvements implemented.</p>
2.2.8	<p>For each hazard that requires control, other than by an existing prerequisite programme, the control points shall be reviewed to identify those that are critical. This process shall include an assessment of the risk level for each hazard based on the likelihood of the occurrence and the severity of the outcome.</p> <p>Critical control points (CCPs) shall be those control points that are required to prevent, eliminate or reduce a product safety hazard to acceptable levels. Where a control point is not classified as critical and control may be achieved through a prerequisite programme, a programme shall be developed that is sufficiently specified to effectively control the identified hazard(s).</p>

2.2.9	For each CCP, the appropriate critical limits shall be defined in order to identify clearly whether the process is in or out of control. Critical limits shall be measurable, where possible, and the rationale for their establishment clearly documented. Relevant legislation and codes of practice shall be taken into account when establishing the limits.
2.2.10	For each CCP, a monitoring system shall be defined in order to ensure compliance with critical limits. Records of the monitoring shall be maintained. Documented procedures relating to the monitoring of critical controls shall be included in internal audits against the Standard (see clause 3.5).
2.2.11	The corrective action that shall be taken when monitored results indicate a failure to meet the control limit for CCPs shall be established and documented. This shall include the procedures for quarantining and evaluating potentially out-of-specification products to ensure they are not released until their safety, quality and legality can be established.
2.2.12	<p>A review of the hazard and risk management system and prerequisite programmes shall be carried out at least once per year and following any significant incidents or when any process changes.</p> <p>The review shall include a verification that the hazard analysis and risk assessment plan is effective. It shall also include any:</p> <ul style="list-style-type: none"> • process changes • product composition changes • complaints • product failures and finished product recalls from consumers (including system tests) • product withdrawals • results of internal audits of prerequisite programmes • results from external and third party audits • new developments in the industry associated with materials, process or product.

2.3 Describe the product

<u>Clause</u>	<u>Requirements</u>
2.3.1	The scope of the HARA shall be defined including products and manufacturing operations covered.
2.3.2	<p>A full description of the products or groups of products shall be developed, which includes all relevant information. As a guide, this may include the following, although this is not an exhaustive list:</p> <ul style="list-style-type: none"> • composition (e.g. raw materials, additives, inks, varnishes, coatings and other print chemicals) • origin of raw materials, including use of recycled materials • treatments and processes undertaken • intended use of the finished products and defined restrictions on use, e.g. direct contact with food or other hygiene-sensitive products, • functional properties •

	<u>storage conditions and expected usable life of the finished product.</u>
2.3.3	<p>All relevant information needed to conduct the HARA shall be collected, maintained, documented and updated. As a guide, this may include the following, although this is not an exhaustive list:</p> <ul style="list-style-type: none"> • <u>historical and known hazards associated with specific processes, raw materials and finished products</u> • <u>relevant codes of practice or recognised guidelines</u> • <u>legislation relevant to the manufacturing and sale of finished products</u> • <u>customer requirements</u> • <u>a copy of any existing site HARA plans (e.g., for products already in manufacture at the site)</u> • <u>a map of the premises and equipment layout</u> • <u>intended use of the product (where known)</u> • <u>known likely product defects that affect safety</u> • <u>allergen-containing raw materials</u> • <u>conditions for storage, method of transport and distribution</u> • <u>packing materials used for the protection of the finished product.</u>

2.4 Construct and verify process flow diagram

<u>Clause</u>	<u>Requirement</u>
2.4.1	<p>A flow diagram shall be prepared to cover each product, group of products or manufacturing process. This shall set out the sequence and interaction of the steps in the operation. As a guide, this may include the following, although this is not an exhaustive list:</p> <ul style="list-style-type: none"> • <u>receipt and approval of artwork and specification</u> • <u>receipt and preparation of raw materials such as additives, inks and adhesives</u> • <u>each step of the manufacturing process or work in progress retention stage</u> • <u>introduction of utilities and other contact materials (e.g., air, water and packing materials)</u> • <u>outsourced processes</u> • <u>in-line testing or measuring equipment</u> • <u>the use of rework and recycled materials</u> • <u>waste</u> • <u>finished product storage and dispatch</u> • <u>customer returns or materials to be returned to the supplier.</u>
2.4.2	<p>The HARA team shall verify the accuracy of the flow diagrams by on-site audit at least, annually to confirm that they effectively reflect operations undertaken on site, and whenever there are changes, to ensure these have been considered as a part of the HARA.</p> <p>Records of verified flow diagrams shall be maintained.</p>

2.5 List all potential hazards associated with each manufacturing step, conduct a hazard analysis and consider any measures to control identified hazards

<u>Clause</u>	<u>Requirement</u>
2.5.1	<p>The HARA team shall identify and record all the potential hazards that are reasonably expected to occur at each manufacturing process step, and consideration of the following types of hazard:</p> <ul style="list-style-type: none"> • <u>microbiological</u> • <u>physical</u> • <u>chemical</u> <p>The HARA shall take into account, potential for:</p> <ul style="list-style-type: none"> • <u>migration of substances</u> • <u>issues arising from the use of recycled materials</u> • <u>limitations of use of the product</u> • <u>foreseeable unintended use by the customer or consumer</u> • <u>defects critical to consumer safety</u> • <u>hazards that may have an impact on the functional integrity and performance of the final product in use</u> • <u>malicious intervention</u> • <u>raw material fraud (e.g., substitution, adulteration or misrepresentation)</u> • <u>allergen contamination risks.</u>
2.5.2	<p>The HARA team shall conduct a hazard analysis to identify the significant hazards (i.e., those hazards that are reasonably likely to occur at an unacceptable level), which need to be prevented, eliminated or reduced to acceptable levels.</p> <p>Consideration shall be given to at least the following:</p> <ul style="list-style-type: none"> • <u>likelihood of occurrence, considering prerequisite programs in the absence of additional control</u> • <u>severity of the outcome.</u>
2.5.3	<p>The HARA team shall consider the control measures necessary to prevent or eliminate each product safety hazard or reduce it to an acceptable level.</p> <p>Consideration may be given to using more than one control measure.</p> <p>Where elimination of the hazard is not practical, justification for acceptable levels of the hazard in the finished product shall be determined and documented.</p>
2.5.4	<p>Where the control of a specific product safety hazard is achieved through prerequisite programmes (see requirement 2.2), or control measure other than critical control measure (see requirement 2.6), this shall be stated and the adequacy of the programme to control the specific hazard validated.</p>

2.6 Determine the critical control measures

<u>Clause</u>	<u>Requirement</u>
2.6.1	<p>For each hazard that requires control, control measures shall be reviewed to identify those that are critical. This requires a logical approach and may be facilitated by use of a decision tree.</p> <p>Critical control measures shall be those controls which are required in order to prevent or eliminate a product safety hazard or reduce it to an acceptable level.</p> <p>If a hazard is identified at a step where control is necessary for safety, but the control does not exist, the product or manufacturing operation shall be modified at that step, or at an earlier step, to provide a control measure.</p>

2.7 Establish validated critical limits for each critical control measure

<u>Clause</u>	<u>Requirements</u>
2.7.1	For each critical control measure, the appropriate critical limits shall be defined in order to identify clearly whether the manufacturing process is in or out of control. Critical limits shall be: <ul style="list-style-type: none"> measurable wherever possible supported by clear guidance or examples where measures are subjective (e.g. photographs).
2.7.2	The HARA team shall validate each critical control measure including critical limits. Documented evidence shall show that the control measures selected, and critical limits identified are capable of consistently controlling the hazard to the specified acceptable level.
2.7.3	Where equipment settings are critical to the safety or legality of the product, changes to the equipment settings shall only be completed by trained and authorised staff. Where applicable, controls shall be password-protected or otherwise restricted.

2.8 Establish a monitoring system for each Critical control measure

<u>Clause</u>	<u>Requirements</u>
2.8.1	A monitoring procedure shall be established for each critical control measure to ensure compliance with critical limits. The monitoring system shall be able to detect loss of control of the measures and, wherever possible, provide information in time for corrective action to be taken. As a guide, consideration may be given to the following, although this is not an exhaustive list: <ul style="list-style-type: none"> online measurement offline measurement at predetermined intervals continuous measurement.
2.8.2	Records associated with the monitoring of each critical control measure shall include the date, time and result of measurement, and shall be signed by, or be electronically traceable to the person responsible for the monitoring.

2.9 Establish a corrective action plan

<u>Clause</u>	<u>Requirements</u>
2.9.1	The HARA team shall specify and document the corrective action to be taken when monitored results indicate a failure to meet a control limit, or results indicate a trend towards loss of control. This shall include the action to be taken by nominated personnel regarding: <ul style="list-style-type: none"> any products that have been manufactured during the period when the activity was out of control how control was regained how potential recurrence is minimised.

2.10 Validate the hazard analysis and risk assessment plan and establish verification procedures

<u>Clause</u>	<u>Requirements</u>

2.10.1	<p>HARA plans shall be validated prior to any changes which may affect product safety, to ensure that the plan will effectively control the identified hazards before implementation.</p> <p>For existing HARA plans, this may be achieved using the established processes detailed in requirements 2.10.2 and 2.10.3.</p>
2.10.2	<p>Procedures of verification shall be established to confirm that the HARA plan, including controls managed by prerequisite programmes, continues to be effective. Examples of verification activities include:</p> <ul style="list-style-type: none"> • internal audits • review of records where acceptable limits have been exceeded • review of complaints or feedback • review of incidents of product withdrawal or recall. <p>Results of verification shall be recorded and communicated to the HARA team.</p>
2.10.3	<p>The HARA team shall review the plan, prerequisites and flow diagrams at least annually and prior to any change that impacts the potential hazards and/or the control measures which may affect product safety. As a guide, these may include the following, although this is not an exhaustive list:</p> <ul style="list-style-type: none"> • change in raw materials or supplier of raw materials • change in product composition • change in manufacturing conditions, process flow, manufacturing environment, or equipment • change in packing material, storage or distribution conditions • change in customer use • trends in root cause and/or testing/analysis results • emergence of a new risk • results from verification activities as defined in requirement 2.10.2 • internal and external audits • review following incidents of product withdrawal or recall • new legislation or developments associated with raw materials, manufacturing, or product. <p>Appropriate changes resulting from the review shall be incorporated into the HARA and/or prerequisite programmes.</p> <p>Changes shall be fully documented, and the validation shall be recorded.</p> <p>Where appropriate, the changes shall also be reflected in the company's policy (requirement 1.1.1) and objectives (requirement 1.1.4).</p>

2.11 Hazard analysis and risk assessment documentation and record-keeping

Clause	Requirements
2.11.1	<p>Documentation and record-keeping shall be sufficient to enable the site to verify that the HARA and product safety controls, including controls managed by prerequisite programmes, are in place and maintained.</p>

3 Product safety and quality management

3.1 Product safety and quality management system

The ~~site's company's~~ processes and procedures to meet the requirements of this Standard shall be documented to allow consistent application, facilitate training, and support due diligence in the production of a safe and legal product.

Clause	Requirements
3.1.1	<p>The site's documented policies, procedures, working methods and practices shall be collated in a navigable and readily accessible system, with Cconsideration shall being given to translation into appropriate languages, <u>including the use of photographs, diagrams or other pictorial instructions where written communication alone is not sufficient (e.g., there are issues of literacy or foreign language).</u></p> <p>Where the site is part of a company governed by a head office, the interaction between the site's system and that of other sites and the head office should be documented.</p> <p>All policies and procedures necessary for the operation of the site being assessed must shall be available at the site.</p>
3.1.2	The system shall be fully implemented, reviewed at appropriate planned intervals and improved, where necessary.

3.2 Document control

An effective document control system shall ensure that only the correct versions of documents, including record~~ing~~ forms, are available and in use.

Clause	Requirements
3.2.1	<p>The company shall have a documented procedure to manage documents which form part of the product safety and quality management system. This shall include:</p> <ul style="list-style-type: none"> • a register /list of all controlled documents indicating the latest version number • the method for the identification and authorisation of controlled documents • a record of the reason for any changes, or amendments to the documents • the system for the replacement of existing documents when these are updated, <u>including communicating changes to relevant personnel.</u>
3.2.2	<p>Where documents and records are in electronic form these shall be:</p> <ul style="list-style-type: none"> • stored securely (e.g. with authorised access, control of amendments, or password-protected) • backed up to prevent loss or malicious intervention.

3.3 Record-keeping

The site shall maintain genuine records to demonstrate the effective control of product safety, legality and quality.

Clause	Requirements
3.3.1	Records shall be legible, appropriately authorised, retained in good condition, and retrievable.
3.3.2	Any alterations to records shall be authorised and justification for the alteration shall be recorded.
3.3.3	The company's senior management shall ensure that documented procedures are established and implemented for the organisation, review, maintenance, storage and retrieval of all records relating to product safety, legality, regulatory compliance and quality.
3.3.4	The site shall document its period of retention for records which relate to the usable life of the packaging and the products, it is designed to contain, and shall <u>the intended use, and</u> respecting any customer <u>or legal</u> requirements.

3.4 Specifications

☆ FUNDAMENTAL

Appropriate specifications shall exist for raw materials, ~~intermediate work in progress~~ and finished products, and for any product or service which could affect the safety, ~~quality or legality~~ legality and quality of the finished product and customer requirements.

Clause	Requirements
3.4.1	Specifications shall be suitably detailed, accurate and compliant with relevant product safety and legislative requirements. They may be in the form of a printed or electronic document, or part of an online specification system. <u>Where the packaging material imparts or provides a functional effect on the safety of the final product, the specification shall contain reference to documented evidence to demonstrate effectiveness, or proof of effect claimed by the packaging material such as shelf-life extension, freshness, and temperature monitoring.</u>
3.4.2	The company shall seek formal agreement of specifications with relevant parties where required by the customer. Where specifications are not formally agreed, then the company shall be able to demonstrate that it has taken steps to put an agreement in place.
3.4.3	Where packaging for food or other hygiene-sensitive products is produced, a statement of compliance shall be maintained which enables users of the packaging to ensure compatibility between the packaging and the <u>final</u> product with which it may be in contact.

	<p>The statement of compliance shall be compiled and authorised by a suitably competent person. It shall contain as a minimum:</p> <ul style="list-style-type: none"> the nature of the materials used in the manufacture of the packaging product confirmation that the packaging product meets relevant legal requirements in the country of manufacture and where known, the country of use the inclusion of any post-consumer recycled materials. <p>The statement shall identify:</p> <ul style="list-style-type: none"> its date of issue and, where appropriate, its expiry date any limitations of use of the product, and the usable life of the packaging durability (where relevant). <p>The site shall review the statements of compliance at a risk-based frequency.</p>
3.4.4	<p>The presence of a manufacturer's trademarks or logo on packaging materials products shall, where appropriate, be formally agreed between the relevant parties.</p>
3.4.5	<p>A specification review process procedure shall be operated in place, where the product composition or characteristics change, or at an appropriate predetermined interval. Reviews and changes shall be documented and communicated to the customer, where required.</p> <p>Any changes to existing agreements or contracts shall be agreed, documented and communicated to appropriate departments.</p>

3.5 Internal audits

☆ **FUNDAMENTAL**

The company shall be able to demonstrate that it verifies the effective application of the HARA and the implementation of the requirements of the Standard and the site's product safety and quality management system and any applicable module through internal audits.

Clause	Requirements
3.5.1	<p>There shall be a scheduled programme of internal audits, <u>spread throughout the year and shall be fully implemented and effective.</u></p> <p>The frequency at which each activity is audited shall be established in relation to the risks associated with the activity and previous audit performance. All processes activities shall be audited at least annually.</p> <p>The internal audit programme shall be fully implemented and effective.</p>
3.5.2	<p>As a minimum, the scope of the internal audit programme shall include the:</p> <ul style="list-style-type: none"> HARA product safety and quality <u>plan management system</u>, including the activities to implement it (e.g. supplier approval, corrective actions and verification)

	<ul style="list-style-type: none"> prerequisite programmes (e.g. hygienehousekeeping, pest control, maintenance) product defence and product fraud prevention plans procedures implemented to achieve the Standard and modules. <p>Each internal audit within the programme shall have a defined scope and consider a specific activity or section of the HARA or product safety and quality management system plan.</p>
3.5.3	Internal audits shall be carried out by appropriately trained and competent auditors. Auditors shall be independent from the process or activity being audited to ensure impartiality (i.e.e.g. they must not audit their own work).
3.5.4	<p>Internal audit reports shall identify conformity, as well as non-conformity and include objective evidence of the findings.</p> <p>The rResults shall be notified-reported to the personnel responsible for the process/activity audited.</p> <p>Corrective and preventive actions, and timescales for their implementation, shall be agreed and their completion verified. All non-conformities shall be handled as detailed in section 3.11.</p> <p>A summary of the results shall be reviewed in the management review meetings, (requirement 1.2.2).</p> <p>Root cause analysis shall be used to determine appropriate corrective actions and a designated manager shall be responsible for the implementation.</p>
3.5.5	<p>For sites manufacturing materials intended to be in contact with food or other hygiene-sensitive products, in addition to the internal audit programme, there shall be a separate programme of documented inspections to ensure that the factory environment and processing manufacturing equipment are maintained in a suitable condition. At a minimum, these shall include:</p> <ul style="list-style-type: none"> hygiene inspections to assess cleaning and housekeeping performance inspections to identify risks to the product from the building or equipment. <p>The frequency of these inspections shall be based on risk.</p> <p>The results shall be reported to the personnel responsible for the activity or area audited. Corrective actions, and timescales for their implementation, shall be agreed.</p>

3.6 Supplier approval and performance monitoring

The company shall operate effective procedures for the approval and ~~performance~~ monitoring of its suppliers.

Clause	Requirements
3.6.1	The site shall have an initial approval and ongoing assessment procedure for suppliers of raw materials, including finished product

	<p>packing materials, based upon risk analysis and defined performance criteria, a documented supplier approval procedure and continual assessment programme in place, based upon risk analysis and defined performance criteria. These shall apply to the suppliers of:</p> <ul style="list-style-type: none"> • materials • outsourced (subcontracted) production. <p>The procedure shall ensure that these are procured according to defined requirements where there is a potential impact to product safety, legality and quality, the materials and services procured conform to defined requirements where there is a potential impact to product safety, quality or legality.</p>
3.6.2	<p>The initial approval procedure of manufacturing sites of raw materials that influence product safety, legality and quality shall be based on risk and include either one or a combination of:</p> <ul style="list-style-type: none"> • a valid certification to a globally-recognised product safety management system e.g., certification to the applicable Global Standard or GFSI-benchmarked standard. Or certification to a globally-recognised quality management system that incorporates an assessment of traceability and confirmation that products supplied are safe and legal, e.g. declaration of compliance. The scope of the certification shall include the raw materials purchased. and the site shall validate any BRCGS certificates using the BRCGS Directory. • supplier audits, with a scope to include a review of the product safety system, traceability, HARA review and good manufacturing practices prerequisite controls, undertaken by an experienced and demonstrably competent product safety auditor. A full audit report shall be available. Where the supplier audit is completed by a second or third party, the company shall be able to: <ul style="list-style-type: none"> • demonstrate the competency of the auditor • confirm that the scope of the audit includes a review of the product safety system, traceability, HARA review and good manufacturing practices and prerequisite controls • obtain, and review and approve a copy of the full audit report. or • supplier self-audit questionnaire or supplier-provided information may be used for approval, where a valid risk-based justification is provided, a satisfactorily completed supplier questionnaire may be used for initial approval. The questionnaire shall have a scope that includes the product safety system for the product supplied, verification of the traceability system, HARA review and good manufacturing practices and prerequisite controls, and it shall have been reviewed and verified approved by a demonstrably competent person. <p>Where approval cannot be based on the above, then the site shall be able to demonstrate their criteria for approval and evaluation of the supplier to ensure that all supplied raw materials do not pose a risk to product safety, legality and quality and meet the specified requirements or specifications.</p>

3.6.3	There shall be a procedure for ongoing supplier approval and performance review, based on risk and defined performance criteria. The process shall be fully implemented.
3.6.4	<p>There shall be a documented process for ongoing supplier performance review, based on risk and defined performance criteria. The process shall be fully implemented.</p> <p>Where <u>ongoing supplier</u> approval is based on questionnaires, <u>or supplier-provided information</u>, these shall be reissued at repeated, and traceability systems verified, at agreed intervals based on risk, and suppliers shall be required to notify the site of any significant changes in the interim, including any change in certification status.</p> <p>Records of ongoing supplier <u>assessment approval</u>, and any <u>changes or necessary corrective or preventative</u> actions shall be <u>reviewed and approved by a demonstrably competent person</u>, maintained and reviewed.</p>
3.6.5	<p>The site shall have an up-to-date list, or database of approved suppliers. This may be on paper (hard copy), or it may be controlled on an electronic system.</p> <p>The list or relevant components of the databases <u>supplier information</u> shall be readily available to the relevant <u>appropriate</u> staff.</p>
3.7.5	<p>The company shall ensure that its suppliers of raw materials have an effective traceability system. Where a supplier has been approved based on a questionnaire instead of certification or audit, verification of the supplier's traceability system shall be carried out on first approval and then at least every 3 years. This may be achieved by a traceability test.</p>
3.6.6	<p>Where raw materials are purchased from companies that are not the manufacturer or packer (e.g. purchased from an agent, broker or wholesaler), the site shall know the identity of the last manufacturer or packer.</p> <p>Information to enable the approval of the manufacturer or packer shall be obtained from the agent, /broker or <u>wholesaler, directly from the supplier</u>, unless they are agent/broker is certified to the relevant Global Standard (e.g. Global Standard for Agents and Brokers/<u>Storage and Distribution with Wholesaler module</u>) or a relevant standard benchmarked by GFSI.</p>
3.6.7	<p>The supplier approval procedure shall address procurement in emergency situations, to ensure the materials still conform to the specified requirements and specifications and the supplier has been evaluated. In these circumstances, an assessment of incoming materials may include certificates of analysis, statement of compliance, or through testing.</p>
3.6.8	<p>The company shall define how exceptions are handled, for example, the use of products where an audit or monitoring has not been undertaken. Assessment (on a batch or delivery basis) may take the form of certificate of analysis statement of compliance</p>

3.7 Product authenticity, claims and chain of custody

Systems shall be in place to minimise the risk of purchasing or use of fraudulent raw materials ~~for packaging~~ and to ensure that all product descriptions and claims are legal, accurate and verified.

Clause	Requirements
3.7.1	<p>The company shall have processes in place to access information on historical and developing threats to the supply chain which may present a risk of substitution, <u>adulteration, or misrepresentation</u> of raw materials (i.e. fraudulent raw materials). Such information may, for example, come from:</p> <ul style="list-style-type: none"> • trade associations • government sources • private resource centres.
3.7.2	<p>A documented vulnerability assessment shall be carried out on all raw materials or groups of raw materials <u>or finished product packing materials</u> to assess the potential risk of substitution, <u>adulteration, or misrepresentation</u>. This shall take into account:</p> <ul style="list-style-type: none"> • historical evidence of substitution, <u>adulteration, or misrepresentation</u> • economic factors which may make <u>fraudulent activity</u> substitution more attractive • ease of access to raw materials through the supply chain • <u>sophistication of routine and upstream testing to identify substitution</u> • <u>physical form</u> • <u>supplier relationships</u> • <u>nature of the raw material, adverse impact on the user of the final product.</u> <p><u>Personnel involved in the vulnerability assessments shall understand potential fraud risks.</u></p> <p>The output from this assessment shall be a documented vulnerability assessment plan.</p> <p>This plan shall be kept under review to reflect changing economic circumstances and market intelligence which may alter the potential risks. It shall be formally reviewed annually.</p>
3.7.3	<p>Where raw materials <u>and finished product packing materials</u> are identified as being at particular risk of <u>substitution, fraudulent activity, or where claims are made, including the provenance, chain of custody or assured status.</u> The vulnerability assessment plan shall include appropriate assurance and/or testing processes to mitigate the identified risk(s). <u>This may include supporting information from the supplier to verify the claim.</u></p>

3.8 Management of ~~subcontracted activities and~~ outsourced processes

Outsourced processing (also referred to as 'subcontracted processing') is defined as where intermediate manufacturing steps, or storage in the manufacture of a product is completed at another site.

It should be noted that outsourced processing refers to an intermediate step – therefore during outsourced processing the product, or partly processed product leaves the site being audited for the completion of the outsourced manufacturing operation, before returning to the site.

Where there is additional storage or processing of raw materials prior to their initial arrival on site, this is not considered as outsourced, but should be managed by the site using supplier approval, raw material risk assessments and raw material specifications.

Where a product undergoes further manufacturing operations off-site and the product does not return to site, this is not considered an intermediate step or outsourced processing. This is outside the scope of the audit.

Where any intermediate process steps (including manufacturing or storage) in the manufacturing operation is of the packaging material are outsourced to a third party, or ~~the process is wholly subcontracted to undertaken at~~ another site, and subsequently returned to the site, this shall be managed to ensure it does not compromise the quality, product safety, or legality or quality of the product.

Clause	Requirements
3.8.1	The company shall be able to demonstrate that, where any part of the production <u>intermediate manufacturing operations</u> are outsourced and undertaken off-site, this has been declared to the customer or brand owner and, where required, approval granted <u>agreed</u> .
3.8.2	Where any <u>intermediate manufacturing steps/processes</u> are subcontracted or outsourced, including artwork or pre-press activity, the risks to the <u>quality and safety, legality and quality</u> of the product shall form part of the hazard <u>analysis</u> and risk analysis <u>assessment</u> and the company's evaluation of the <u>outsourced manufacturing operations/system</u> shall be held on <u>recorded</u> .
3.8.3	<u>Requirements for outsourced operations shall be agreed and documented in a service specification, which includes an effective traceability system. This shall include any specific handling requirements for the products. Clear specifications shall be agreed for all work outsourced or subcontracted.</u>
3.8.4	Where any process steps in the manufacturing step <u>of the packaging materials</u> are subcontracted or outsourced, final release of the product shall remain the responsibility of the site. Controls on completed, shall be in place for checks on finished work <u>outsourced manufacturing steps shall be undertaken</u> to ensure product safety, <u>legality</u> , and quality meets specification prior to dispatch to the final customer.

3.9.5	The company shall ensure that any subcontracted or outsourced processors have an effective traceability system. Where a supplier has been approved based on a questionnaire instead of certification or audit, verification of the supplier's traceability system shall be carried out on first approval and then at least once every 3 years. This may be achieved by a traceability test.
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3.9 Management of suppliers of services

The company shall be able to demonstrate that, where services are outsourced, ~~any~~ risks presented to product safety, ~~quality or~~ legality or quality have been evaluated to ensure effective controls are in place.

Clause	Requirements
3.9.1	<p>There shall be a documented procedure for the approval and monitoring of suppliers of services. Such services shall include, but are not limited to:</p> <ul style="list-style-type: none"> • <u>outsourced operations</u> <ul style="list-style-type: none"> • pest control • laundry services • transport and distribution • storage and dispatch • sorting or rework • laboratory services • calibration services • waste management • product safety and quality <u>external expertise e.g. consultants, training providers to the site</u> • <u>servicing and maintenance of equipment.-</u> <p>Providers of utilities such as water, electricity or gas may be excluded on the basis of risk.</p> <p>The frequency of <u>is</u> approval and monitoring process shall be risk-based, <u>or whenever significant changes occur</u> and take into consideration:</p> <ul style="list-style-type: none"> • risk to the safety and quality of products • compliance with any specific legal requirements • potential risks to the security of the product (i.e. risks identified in the vulnerability and product defence assessments).
3.9.2	Contracts or formal agreements shall exist with the suppliers of services which clearly define service expectations and ensure potential risks associated with the service have been addressed.

3.10 Traceability

☆ **FUNDAMENTAL**

The site shall be able to trace ~~and follow~~ all raw materials through ~~processing manufacturing~~ (including ~~subcontracted processes~~ outsourced operations) to the distribution of the finished product ~~(packaging material)~~ to the customer and from

finished product supplied to the customer through manufacturing, back to the raw materials, and vice versa.

Clause	Requirements
3.10.1	<p>The site shall have a documented traceability procedure <u>designed to maintain traceability throughout the site's operations. At a minimum, this shall include:</u></p> <ul style="list-style-type: none"> • <u>how the traceability system works</u> • <u>the product identification systems (such as labelling and coding of raw materials, work in progress, finished products), and records required, and system that can trace and follow all raw materials from the supplier through all stages of processing (including subcontracted processes) and distribution of the finished product, and vice versa.</u> <p>Where continuous processes are used, or raw materials are in bulk silos, traceability shall be achieved to the best practical level of accuracy.</p>
3.10.2	<p>Identification of raw materials, intermediate products <u>work in progress</u>, finished products, non-conforming products and quarantined goods shall be adequate to ensure traceability.</p>
3.10.3	<p>For traceability, a <u>An appropriate system shall be in place to ensure that the customer can identify a product or production lot number for the product.</u></p> <p>Where coding is applied, this shall be checked for legibility and accuracy against production records.</p>
3.10.4	<p><u>The site shall test the traceability system across the range of product groups, to ensure traceability can be determined from raw materials through manufacturing, including outsourced operations, to the distribution of the finished product to the customer and from finished product supplied to the customer through manufacturing to the raw materials.</u></p> <p><u>The traceability test shall include a summary of the documents referenced during the test, and clearly show the links between them.</u></p> <p>The traceability procedure and system <u>test</u> shall be tested to occur <u>at</u> a predetermined frequency, at <u>a minimum</u> least annually, and the results shall be retained and easily retrieved for inspection.</p> <p><u>Traceability should be achievable within 4 hours unless otherwise specified by local legislation or customer requirements.</u></p> <p><u>Traceability of all materials shall be achievable in a timely manner.</u></p>
3.10.5	<p>Where rework or any reworking <u>recycling</u> operation is performed or outsourced or subcontracted activities are carried out, traceability shall be maintained.</p>
3.10.6	<p>Traceability of test data and samples to production <u>manufacturing</u> lots shall be maintained.</p>

3.11 Corrective and preventive action

☆ **FUNDAMENTAL**

The site shall be able to demonstrate that it uses the information from identified failures-issues in its-systems the product safety and quality management system (e.g. non-conforming products, internal audits, complaints, product recalls, product testing, second and third-party audits) to complete and processes to take any necessary corrective_ and preventive actions_ and prevent recurrence.

Clause	Requirements
3.11.1	<p>The site shall have a procedure for <u>recording, handling and correcting issues identified in the product safety and quality management system.</u> the completion of root cause analysis and corrective actions and to determine preventive actions.</p> <p><u>The site procedures shall include the completion of root cause analysis and implementation of preventive action.</u></p> <p>As a minimum, root cause analysis shall be used to implement ongoing improvements and to prevent recurrence of non-conformities in the event of:</p> <ul style="list-style-type: none"> • an analysis of non-conformities for trends which shows that there has been a significant increase in a type of non-conformity • a non-conformity which places the safety, legality, integrity or quality of a product at risk (including withdrawals) • the results of internal, second- or third-party audits • customer complaints • failure of in-line testing equipment • any incidents.
3.11.2	<p><u>Where a non-conformity places the safety or legality of a product at risk, or where there is an adverse trend in quality, this shall be investigated and recorded including:</u></p> <ul style="list-style-type: none"> <u>• clear documentation of the non-conformity</u> <u>• assessment of consequences by a suitably competent and authorised person</u> <u>• the corrective action to address the immediate issue</u> <u>• appropriate timescales for corrective and preventive actions</u> <u>• the person(s) responsible for corrective and preventive actions</u> <u>• verification that the corrective and preventive actions have been implemented and are effective.</u> <p><u>When trend analysis of non-conformities shows that there has been a significant increase in a type of non-conformity, root cause analysis shall be used to identify preventive action to minimise potential for recurrence of non-conformities, and to implement ongoing improvements.</u>The site shall evaluate the effectiveness of root cause analyses, and of any corrective and preventive actions.</p>

3.12 Control of non-conforming materials

The site shall ensure that ~~out of specification~~ non-conforming raw materials, ~~intermediate product~~ work in progress and finished product is clearly identified and effectively managed to prevent unauthorised release.

Clause	Requirements
3.12.1	Clear procedures for the control of out-of-specification, or non-conforming materials or product returned to site shall be in place and understood by all personnel. These shall include the effective identification and management of materials before a decision has been made on their final disposition.
3.12.2	Non-conforming materials shall be assessed, and a decision taken to reject, accept by concession, rework, or put to alternative use. The decision and reasons shall be documented.

3.13 Complaint-handling

Customer complaints relating to product ~~hygiene~~, safety, ~~legality~~ and quality shall be handled effectively and the information used to reduce complaint levels.

Clause	Requirements
3.13.1	All complaints shall be recorded and investigated (including root cause analysis) and the results of the investigation of the issue recorded where sufficient information is provided, documented. Actions appropriate to the seriousness and frequency of the problems complaint identified shall be carried out promptly and effectively by appropriately trained staff.
3.13.2	Complaint data shall be analysed to identify significant trends. Where there has been an increase or repetition of a complaint type, root cause analysis shall be used to implement ongoing improvements to product safety, legality and quality, and to avoid recurrence. This analysis shall be made available to relevant staff.

3.14 Management of ~~product withdrawals, incidents and product recalls~~

The ~~company or site~~ shall have a ~~documented~~ procedure ~~and systems in place~~ to ~~effectively~~ manage ~~any product withdrawals, returns from customers, incidents,~~ ~~including product withdrawals, recalls, and returns from customers.~~

~~or product recalls in order to ensure that all potential risks to the hygiene, quality, safety or legality of products and the final consumer are controlled.~~

Clause	Requirements
3.14.1	An incident management procedure shall be established, implemented and maintained and A product withdrawal procedure shall be documented and include as a minimum: <ul style="list-style-type: none"> identification of the key personnel involved in assessing incident severity, impact and actions to be taken, with their responsibilities clearly defined

	<ul style="list-style-type: none"> • the actions required to effectively manage an incident to prevent release of product where product safety, legality or quality may have been affected • recovery including logistics for return, storage of recovered product and product disposal • a communications plan including methods of informing customers, <u>logistics, organisations such as regulatory bodies and/or certification body, where relevant</u> • <u>root cause analysis and corrective action to implement appropriate improvements as required.</u> <p><u>The incident management procedure shall be capable of being operated at any time.</u></p>
3.13.2	<p>The withdrawal procedure shall be capable of being operated at any time and will take into account notification to the supply chain, stock return, logistics for recovery, storage of recovered product, and disposal.</p>
3.14.2	<p>The <u>incident management procedure</u> company shall provide written guidance and instruction for relevant staff regarding the type of event that would constitute an incident.</p> <p>Incidents may include:</p> <ul style="list-style-type: none"> • <u>accidental, malicious contamination, or sabotage of product</u> • <u>product failure or significant non-conformity</u> • <u>disruption to normal production processes manufacturing operations</u> • <u>disruption to key services such as water, energy, transport distribution, refrigeration processes, staff availability and communications</u> • events such as fire, flood or natural disaster • malicious contamination or sabotage • failure of, or attacks against, digital cyber-security • <u>Spillage e.g., plastic pellets, ink, solvents etc., which may impact the environment.</u> <p><u>Personnel involved in incident management shall be trained in the procedure.</u></p> <p>A documented incident reporting procedure shall be in place.</p>
3.14.3	<p>Where a site's products are involved in a product withdrawal, or recall, the site shall assist with provision of information to customers (such as traceability) as required.</p>
3.14.4	<p>Where products that have been released from the site that could be affected by an incident, the need to withdraw products and, where appropriate, advise customers to withdraw and/or recall products, shall be considered.</p>
3.14.5	<p>The <u>incident management procedure</u> product withdrawal procedure shall be tested, at least annually, in a way that ensures its effective operation. Results of the test shall be retained and shall include timings of key activities.</p>

	The results of the test, and of any actual withdrawals incidents , shall be used to review the procedure and implement improvements as necessary.
3.14.6	<p>In the event of a significant product safety or legality incident, the site shall notify the current certification body within 3 working days.</p> <p>The site shall then provide sufficient information to enable the certification body to assess any effects of the incident on the ongoing validity of the current certificate within 21 calendar days. As a minimum, this shall include corrective action, root cause analysis and a preventive action plan. Where a site's products are involved in a product recall, the site shall assist with provision of information (such as traceability) as required.</p>
3.13.5	<p>A procedure to manage product recalls initiated by the brand owner or specifier shall be documented and include as a minimum:</p> <p>identification of the key personnel involved in assessing potential recalls, together with clearly defined responsibilities</p> <p>a communications plan that includes methods of informing customers and (where necessary) regulatory bodies in a timely manner.</p>

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4 Site standards

4.1 External standards

The site shall be of suitable size and construction, in a suitable location, and maintained to an appropriate standard to reduce the risk of contamination and facilitate the ~~production-manufacture~~ of ~~safe and legal~~ safe, legal and quality products.

Clause	Requirements
4.1.1	Consideration shall be given to local activities and the site environment, which may have an adverse impact on the safety, <u>legality</u> or quality of the finished product or raw materials, and measures shall be taken to prevent contamination. Where measures have been put in place to protect the site, they shall be regularly reviewed to ensure they continue to be effective (e.g. flood controls).
4.1.2	The external areas shall be maintained in good order. Any grassed or planted areas surrounding buildings shall be regularly tended and well maintained. External traffic routes under site control shall be suitably surfaced to avoid contamination of the product.
4.1.3	The building fabric shall be maintained to minimise potential for <u>product contamination, pest entry</u> , ingress of water and other contaminants. External silos, pipework or other access points for the product and/or raw materials shall be appropriately sealed and secured. Where possible, a clean and unobstructed area shall be provided along the external walls of the buildings used for production and/or storage.
4.1.4	Where natural external drainage is inadequate, additional drainage shall be installed. <u>External drains</u> shall be properly protected to prevent entry of pests.
4.1.5	Where external storage of raw materials is necessary, these shall be protected in order to minimise the risk of contamination.

4.2 Building fabric and interiors: raw materials handling, preparation, processing ~~manufacturing~~, packing and storage areas

The internal site, buildings and facilities shall be suitable for the intended purpose and shall be designed, constructed, maintained and monitored to effectively control the risk of product contamination.

Clause	Requirements
4.2.1	Walls shall be finished and maintained in good condition to minimise the accumulation of dirt and facilitate cleaning. Walls, floors, ceilings and pipework shall be maintained in good condition and shall facilitate cleaning.
4.2.2	<u>Doors shall be maintained in good condition.</u>

	<p><u>External doors and dock levellers shall be close-fitting, or adequately proofed.</u></p> <p><u>Where external doors to open product manufacturing areas are present, suitable precautions shall be taken to prevent pest ingress.</u></p>
4.2.3	<p>Ceilings and overhead structures shall be constructed, finished and maintained to prevent the risk of product contamination.</p> <p>Where suspended ceilings exist, they shall be constructed, finished and maintained to prevent the risk of product contamination, and accessible for cleaning and inspection for pests unless the void is fully sealed.</p>
4.2.3	<p>All internal drain openings shall be suitably protected against the entry of pests and designed to minimise odour.</p>
4.2.4	<p><u>Floors shall be suitably hard-wearing to meet the demands of the operations and withstand cleaning materials and methods. They shall be maintained in good repair and facilitate cleaning.</u></p>
4.2.5	<p>Where they constitute a risk to product, and based on the likelihood and risk of contamination, windows and roof glazing shall be protected against breakage.</p>
4.2.6	<p>Where they constitute a risk to product and based on the likelihood and risk of non-product ion glass contamination, all bulbs and strip lights, including those on flying-insect control devices, shall be adequately protected.</p>
4.2.7	<p>Suitable and sufficient lighting shall be provided to ensure a safe working environment, <u>enabling effective operations, cleaning and inspection of the product processes.</u></p>
4.2.8	<p>Suitable and sufficient ventilation shall be provided to prevent condensation, excessive dust, heat and fumes where applicable, shall be provided.</p>
4.2.9	<p><u>Based on risk, w</u>Where elevated walkways, <u>access steps, or mezzanine floors</u> are adjacent to, or pass over <u>production manufacturing</u> lines, based on risk they shall be:</p> <ul style="list-style-type: none"> • designed to prevent contamination of products and <u>production manufacturing</u> lines • easy to clean • <u>correctly appropriately</u> maintained.

4.3 Utilities

All utilities to and within the ~~production manufacturing~~ and storage areas shall be designed, constructed, maintained and monitored to effectively control the risk of product contamination.

Clause	Requirements
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4.3.1	<p>All water used in the <u>manufacturing areas that could impact product safety shall be suitable for the intended use, adequately stored and be, where appropriate, potable or suitably treated.</u></p> <p><u>Where required, the site shall comply with local legislation on water quality.</u></p> <p><u>Where water is not intended for use in manufacturing operations, systems shall be in place to minimise risks to product safety</u></p> <p>processing of the products or equipment cleaning shall be potable or suitably treated to prevent contamination.</p>
4.3.2	<p>Based on risk assessment, the microbiological <u>and/or and</u> chemical quality of water, steam, ice, air, <u>and</u> compressed air or other gases which come into direct contact with <u>packaging product</u> shall be <u>specified as suitable for the intended use or</u> regularly monitored. These shall present no risk to product safety or quality and shall comply with relevant <u>legal local regulations/legislation.</u></p>

4.4 Site security and product defence

A product defence plan shall be in place to ensure that there are systems to protect products, and sites premises and brands from malicious actions ~~while under the control of the site.~~

Clause	Requirements
4.4.1	<p>The company shall undertake a documented <u>risk assessment</u> (threat assessment) of the security arrangements and potential risks to the products from any deliberate attempt to inflict contamination or damage. This threat assessment shall include both internal and external threats.</p> <p>The output from this assessment shall be a <u>documented</u> product defence plan, <u>specifying systems and procedures to be implemented to mitigate the identified risks. These shall be monitored to ensure these are effectively applied and corrective and preventive action where monitoring indicates failure.</u></p> <p>Areas shall be assessed according to risk. <u>Areas where exposed food or hygiene; sensitive contact surfaces are present or restricted areas</u> shall be defined, clearly <u>marked/identified</u>, monitored and controlled.</p> <p>This plan shall be kept under review to reflect changing circumstances and <u>external influences/industry feedback</u>. It shall be formally reviewed at least annually <u>and whenever:</u></p> <ul style="list-style-type: none"> • <u>a new risk emerges (e.g. a new threat is publicised or identified)</u> • <u>an incident occurs where there is an identified failure in product security or product defence.</u> <p><u>Where applicable, the product defence plan shall meet the legal requirements in the country of sale or intended use.</u></p>
4.4.2	<p>Measures shall be in place to ensure only authorised personnel have access to <u>production/manufacturing</u> and storage areas, and access to</p>

	<p>the site by personnel<u>employees</u>, contractors and visitors shall be controlled.</p> <p>A visitor reporting system shall be in place. Staff<u>Personnel</u> shall be trained in site security procedures and encouraged to report unidentified or unknown visitors.</p>
4.4.3	External storage tanks, silos and any intake pipes with an external opening shall be sufficiently secure to prevent unauthorised access.

4.5 Layout, product flow and segregation

The factory layout, flow of ~~processes~~manufacturing operations and movement of personnel shall be sufficient to prevent the risk of product contamination and to comply with all relevant legislation.

Clause	Requirements
4.5.1	<p>There shall be a current map_z or plan of the site which defines:</p> <ul style="list-style-type: none"> • access points for personnel • travel routes for personnel, raw materials, intermediate work in progress and or finished products • staff facilities • routes routes for the removal of waste • flow of manufacturing operations <u>flow of manufacturing operations</u> • Areas where exposed food or hygiene-sensitive contact surfaces require additional hygiene measures such as "clean rooms" <u>Areas where exposed food or hygiene-sensitive contact surfaces require additional hygiene measures such as "clean rooms"</u> • production and process flows <u>production and process flows</u> • storage areas.
4.5.2	The process flow from intake to dispatch shall be arranged to minimise the risk of contamination _z or damage to the product.
4.5.3	Premises shall allow sufficient working space and storage capacity to enable all operations to be carried out properly under safe and hygienic conditions.
4.5.4	Sorting _z or other activities involving the direct handling of the product shall take place in areas that have, as a minimum, the same standards as production <u>manufacturing</u> areas.
4.5.5	Activities that could produce a contamination risk, such as the removal of outer packag ing , shall be carried out in a designated, segregated area.
4.5.6	If it is necessary to allow access through production areas, designated walkways shall be provided that ensure there is adequate segregation from materials.
4.5. <u>6</u>	Where possible, all facilities <u>Sites</u> shall be designed and positioned so that movement of personnel is by simple, logical routes. If it is necessary to allow access through manufacturing areas, designated walkways shall be provided that ensure that product safety, legality and quality is not compromised.

4.6 Equipment

Equipment shall be suitably ~~designed~~ for the intended purpose and shall be ~~installed~~, maintained and used ~~so as~~ to minimise the risk to product safety, legality and quality.

Clause	Requirements
4.6.1	<p>ProductionManufacturing, storage and warehousing equipment shall be designed, constructed of suitable materials, installed, commissioned and maintained for the intended purpose, enabling effective cleaning, and minimising the risk of contamination and shall minimise the risk of contamination to the product.</p> <p>Lubrication points and application methods of any lubricant shall not be able to contaminate the product.</p> <p>Equipment shall be constructed of suitable materials and be designed to ensure it can be effectively cleaned and maintained.</p>
4.6.2	<p>There shall be a documented specification prior to sourcing new, or new-to-site equipment.</p> <p>This may include:</p> <ul style="list-style-type: none"> • details of intended use of the equipment and the type of materials it will be handling • where applicable, requirements for open product contact surfaces to meet any legal requirements. <p>Depending on its intended use, new, or new-to-site equipment may require authorisation from a multi-disciplinary team which may include members of manufacturing, quality, engineering and the HARA team.</p> <p>The supplier should provide evidence that equipment meets these site requirements prior to supply. Newly installed equipment shall be properly specified before purchase. New equipment shall be tested and commissioned prior to use and a maintenance and cleaning programme established.</p>
4.6.3	<p>A risk-based commissioning procedure shall be in place to ensure that product safety and integrity is maintained during the installation of new or new-to-site equipment.</p> <p>New equipment to site shall be inspected for compliance with specification by an authorised member of staff before being accepted into operation.</p> <p>Installation work shall be followed by a documented clearance inspection to remove potential contamination.</p> <p>The commissioning procedure shall include the update of any other site procedures that are affected by the equipment, for example, training, operating procedures, cleaning, environmental monitoring, maintenance schedules or internal audits. Wooden equipment including desks, chairs, tables, etc. shall be properly sealed to enable effective cleaning. This equipment shall be kept clean, in good</p>

	condition and free from splinters or other sources of physical contamination.
4.6.4	Equipment that is not used or is taken out of service shall be cleaned and stored in a manner that does not pose a product safety risk. Notices on equipment shall be cleanable and secure.

4.7 Maintenance

An effective maintenance programme shall be in operation for ~~plant and~~ equipment ~~and support services~~ to prevent contamination risk and reduce the potential for breakdowns.

Clause	Requirements
4.7.1	A documented programme of maintenance <u>and associated records</u> shall be <u>operated in place</u> , covering all items of production manufacturing equipment and <u>plant support service equipment</u> critical to product safety, legality and quality, to prevent contamination and reduce the risk of breakdown.
4.7.2	Maintenance logs shall be maintained for all off-line testing equipment. This shall include, as a minimum: <ul style="list-style-type: none"> any adjustments the re-calibration date of any interventions.
4.7.2	In addition to any planned maintenance programme, where there is a risk of product contamination by foreign bodies arising from equipment failure or damage, the equipment shall be inspected at predetermined intervals, inspection results documented, and appropriate action taken.
4.7.3	Maintenance work shall not place product safety, quality or legality or <u>quality</u> at risk. Maintenance work shall be followed by a documented clearance procedure which records that contamination hazards have been removed and equipment <u>is</u> cleared to resume production manufacturing . <u>Tools and other maintenance equipment shall be cleared away after use and appropriately stored.</u>
4.7.5	Tools and other maintenance equipment shall be cleared away after use and appropriately stored.
4.7.4	Where temporary repairs and modifications are made, these shall be documented and controlled to ensure that the product safety, legality or quality is not at risk. These temporary measures shall be permanently repaired as soon as practicable and within a defined timescale. using tape, cardboard, etc. shall only be permitted in emergencies and where product contamination is not at risk. Such modifications shall be subject to a time limit and shall be recorded and scheduled for correction.

4.7.5	Engineering workshops shall be <u>kept clean and tidy and</u> controls shall <u>be in place</u> to prevent transfer of engineering debris to <u>production manufacturing</u> or storage areas (e.g. by provision of swarf mats).
4.7.6	Contractors involved in maintenance or repair <u>activities</u> shall be suitably monitored by a <u>staff member who shall be</u> responsible <u>staff member for their activities</u> .

4.8 Housekeeping and cleaning

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~~Housekeeping and cleaning~~ systems shall be in place which ensure that appropriate standards of equipment and environment housekeeping and cleaning hygiene are maintained and that the risk of product contamination is minimised.

Clause	Requirements
4.8.1	Good <u>Appropriate</u> standards of housekeeping shall be maintained, which shall include a condition-based cleaning or 'clean as you go' policy, <u>including manufacturing, storage, and ancillary areas</u> .
4.8.2	<p>Documented cleaning procedures shall be in place and maintained for buildings, equipment and vehicles. Cleaning schedules and procedures shall include the following information:</p> <ul style="list-style-type: none"> responsibility for cleaning item/area to be cleaned frequency of cleaning method of cleaning cleaning materials to be used cleaning record and responsibility for verification. <p>The frequency and methods of cleaning shall be based on risk.</p> <p>The procedures shall be implemented to ensure that appropriate standards of cleaning are achieved.</p> <p><u>Cleaning activities shall not pose a risk to product safety.</u></p>
4.8.3	<p>Cleaning chemicals shall be fit for purpose, suitably labelled, and used in accordance with manufacturers' instructions. They shall be stored in a secured, designated location, in closed containers. Chemicals that are strongly scented or could give rise to taint and odour contamination shall not be used.</p> <p>Cleaning equipment <u>and facilities</u> shall be <u>fit for purpose, maintained in a suitable condition, cleaned and stored in a hygienic manner to prevent contamination and stored in a</u> kept in a suitable designated location.</p>
4.8.4	Materials and equipment used for cleaning toilets shall be differentiated from those used elsewhere, and physically segregated where necessary.
4.8.5	<u>The site shall consider the likelihood of survival of microorganisms on materials and the intended use of the finished product.</u> Where

	<p>appropriate, based on risk, a microbiological environmental monitoring programme shall be in place to ensure that the cleaning operations are effective in minimising the risk of contamination by microorganisms that would be detrimental to the <u>final</u> products. The programme shall consider the likelihood of the microorganisms' survival on packaging materials and their use.</p> <p>Where a programme is in place, this shall include:</p> <ul style="list-style-type: none"> • sampling protocol • identification of sample locations • frequency of tests • target <u>micro</u>organisms (e.g. pathogens, spoilage organisms and/or indicator organisms) • test methods • recording and evaluation of results. <p>The programme and its associated procedures shall be documented.</p>
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4.9 Product contamination control

All practicable steps shall be taken to identify, eliminate, avoid or minimise the risk of foreign-body, ~~or~~ chemical or allergen contamination.

4.9.1 Glass ~~and~~, brittle ~~plastics, ceramics and similar~~ materials control

Clause	Requirements
4.9.1.1	<p>There shall be no unnecessary non-production glass, ceramics or <u>other</u> brittle plastic materials present, which may pose a foreseeable risk of contamination.</p> <p>Where non-production glass, ceramics or <u>other</u> brittle plastics materials are required in <u>production manufacturing</u>, packing or storage areas, and where there is a risk of product contamination, procedures for their handling systems for their safe use shall be in place.</p> <p><u>Systems for cleaning or replacing the above items shall be in place to minimise the potential for product contamination.</u></p>
4.9.1.2	<p>Glass or <u>other</u> brittle plastics materials (other than the product) that pose a potential product contamination hazard shall be controlled and recorded on a register that includes, as a minimum:</p> <ul style="list-style-type: none"> • a list of items detailing location, number, type and condition • recorded checks of condition of items, carried out at a specified frequency that is based on the level of risk to the product • details on cleaning or replacing items to minimise the potential for product contamination. <p>Glass or brittle plastics materials not in the production or storage areas shall be included in the register on the basis of <u>based on</u> risk.</p>
4.9.1.3	<p>Where non-production glass or brittle plastic materials breakage occurs, a responsible person shall be placed in charge of the</p>

		<p>clean-up operation and shall ensure that no other area is allowed to become contaminated due to the breakage. Any product that has become contaminated shall be segregated and disposed of.</p> <p>All breakages shall be recorded in an incident report.</p>
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4.9.2 Sharps and metal control

Clause	Requirements
4.9.2.1	<p>There shall be a documented policy procedure for the controlled use and storage of sharp implements, including knives, <u>blades</u>, needles and wires, to prevent <u>product</u> contamination.</p> <p>The policy procedure shall include: control of these items into and out of the site.</p> <ul style="list-style-type: none"> • <u>issue and control of sharp implements in the manufacturing, storage and ancillary areas, such as engineering workshops and laboratories</u> • <u>record of replacement or breakage</u> • <u>snap-off blade knives shall not be used.</u>
4.9.2.2	<p>Production Manufacturing equipment that incorporates blades or sharps shall be <u>controlled and</u> monitored. Blades or other sharp implements shall not be allowed to contaminate the product.</p>
4.9.2.3	<p>Snap-off blade knives shall not be used.</p>
4.9.2.4	<p>Where open noticeboards are present in production, packing and storage areas, loose fastenings, such as drawing pins and staples, shall not be used.</p>

4.9.3 Chemical ~~and biological~~ control

Clause	Requirements
4.9.3.1	<p>Processes Procedures shall be in place to manage the use, storage and handling of non-production chemicals, <u>such as lubricants and cleaning chemicals</u> to prevent <u>chemical-product</u> contamination. These shall include, as a minimum:</p> <ul style="list-style-type: none"> • <u>a list/register</u> of approved chemicals for purchase • <u>confirmation of suitability, including food or hygiene sensitive contact</u> • <u>used in accordance with manufacturer's instructions</u> • availability of material safety data sheets and specifications • avoidance of strongly scented products, <u>where potential risks of taint contamination may occur</u> • the labelling and/or identification of containers of chemicals at all times • <u>designated storage area</u> with access restricted to authorised personnel • <u>procedures to manage any spills</u>

	<ul style="list-style-type: none"> • use by trained personnel only.
4.9.3.2	Hazard and risk analysis shall be used to identify, control and manage any potential risks from microbiological contamination and any potential allergens.

4.9.4 Allergen Management

Clause	Requirements
4.9.4.1	<p>Where a potential for contamination from allergen or intrinsic allergenic components has been identified as part of the hazard analysis and risk assessment, the site shall establish, implement, and maintain a plan for the management of allergens to minimise or eliminate the risk of contamination to and / or from the product and meet legal requirements for labelling in the country of sale.</p> <p>The plan shall be reviewed based on risk, such as changes to manufacturing operations, staff changes, raw materials and lubricants.</p>
4.9.4.2	<p>Where an allergen risk is identified, appropriate controls shall be established and implemented to eliminate or reduce the risk, through staff training, raw material specifications, segregation and handling.</p>

4.9.5 Other physical contaminants

Clause	Requirements
4.9.5.1	<p>Notices on equipment shall be cleanable and secure and shall not pose a risk to product safety, legality and quality.</p>
4.9.5.2	<p>Where it poses a risk to product, wooden equipment including desks, chairs, tables, etc. shall be properly sealed to enable effective cleaning. This equipment shall be kept clean, in good condition and free from splinters or other sources of physical contamination.</p>
4.9.5.3	<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 packing materials or closures, appropriate precautions shall be taken to minimise the risk of product contamination.</p>
4.9.5.4	<p>Site issued portable handheld equipment, e.g., mobile phones, tablets, measuring equipment and similar portable items shall be controlled by the site to minimise the risk of physical contamination.</p>
4.9.5.5	<p>Based on risk, procedures shall be implemented to minimise other types of foreign body contamination (i.e., types of contamination that are not specifically covered elsewhere in section 4.9).</p>

4.10 Waste and waste disposal

Waste materials including, substandard trademarked materials, waste water, inks, solvents and their disposal shall be managed in accordance with legal requirements and to prevent accumulation, risk of contamination and the attraction of pests.

Clause	Requirements
4.10.1	Where licensing is required by law for the removal of waste, it shall be removed by licensed contractors and records of removal shall be maintained and available for audit.
4.10.2	Process waste shall be managed to minimise release to the environment. This shall include, but is not limited to, pellet, flake, powder, dust and offcuts.
4.10.3	Internal and external waste collection containers shall be identifiable, suitable and sufficient. refuse and waste containers shall be provided, They shall be emptied at appropriate frequencies and maintained in an adequately clean condition.
4.10.4	Where appropriate, waste shall be categorised according to legislative requirements based on the intended means of disposal (such as recycling). It shall be sorted, segregated, <u>protected against contamination where necessary</u> and collected in appropriate designated waste containers.
4.10.5	Substandard trademarked materials shall be rendered unusable <u>(unless otherwise agreed with customer)</u> through a destructive process or transferred to a third party for destruction or disposal. The third party shall be a specialist in appropriate waste disposal and shall provide records of material destruction. All materials disposed of shall be recorded.
4.10.6	If substandard trademarked materials are transferred to a third party for destruction or disposal, that third party shall be a specialist in appropriate waste disposal and shall provide records of material destruction.
4.10.6	External storage of refuse waste shall be in designated areas and designed or maintained to minimise the risk of pest harbourage.

4.11 Pest management

In order to minimise the risk of infestation and risk to products, the whole site shall have an effective preventive pest management programme in place and the resources available to respond immediately to any issues which occur.

Clause	Requirements
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4.11.1	<p>A preventive pest management programme shall be maintained, covering all areas of the site under the site's control.</p> <p>The site shall assess the suitability of its pest management programme to address variation in pest activity through different seasons, and consider any additional preventive activity required.</p> <p>The site shall document and implement any required additional activity.</p>
4.11.2	<p>The site shall either contract the services of a competent pest management organisation or have appropriately trained staff for the regular inspection and treatment of the site in order to deter and eradicate infestation. The frequency of inspections shall be determined by risk assessment and documented. The risk assessment shall be reviewed whenever:</p> <ul style="list-style-type: none"> • there are changes to the building or production processes which could have an impact on the pest management programme • there has been a significant pest issue. <p>Where the services of a pest management contractor are employed, the service contract shall be clearly defined and reflect the activities of the site <u>and comply with local legislation as required</u>.</p>
4.11.3	<p>Where a site undertakes its own pest management, it shall be able to demonstrate that:</p> <ul style="list-style-type: none"> • pest management operations are undertaken by trained and competent staff with sufficient knowledge to select appropriate pest control chemicals and proofing methods and understand the limitations of use, relevant to the biology of the pests associated with the site • staff undertaking pest management activities meet any legal requirements for training or registration • sufficient resources are available to respond to any infestation issues • there is ready access to specialist technical knowledge when required • legislation governing the use of pest control products is understood and complied with • dedicated locked facilities are used for the storage of pesticides.
4.11.4	<p>Equipment such as bait stations, traps or electric fly-killing devices shall be appropriately located and operational.</p> <p><u>Where pest control products are stored on site, dedicated locked facilities shall be used.</u></p>
4.11.5	<p>Effective precautions shall be in place to prevent pests entering the premises. The building shall be suitably proofed against the entry of all pests via doors, windows, ducts, <u>drains</u> and cable entry points.</p>

		This shall include measures to prevent birds and flying mammals from entering buildings or roosting above loading or unloading areas.
4.11.6		In the event of infestation, immediate action shall be taken to eliminate the hazard. Action shall be taken to identify, evaluate the potential for contamination or damage, and authorise the release of any product potentially affected.
4.11.7		In the event of an infestation, and At appropriate intervals, the site shall request a catch analysis from flying-insect control devices to help identify problem areas. In the event of increase in <u>observed or measured</u> activity, the site shall use risk assessment to determine the <u>activity-action</u> required to eliminate the hazard.
4.11.8		Documented procedures and detailed records of pest activity, pest management inspections and recommendations shall be maintained. These shall include, as a minimum: <ul style="list-style-type: none"> • an up-to-date, signed and authorised site plan identifying numbered pest control devices and their locations • identification of the baits and/or monitoring devices on site • clearly defined responsibilities for the site management and the contractor • details of pest control products used and instructions for their effective use • detailed records of inspections, recommendations and of any pest infestation. <p>It shall be the responsibility of the site to ensure that all the relevant recommendations made by the contractor or in-house expert are implemented in a timely manner and monitored for efficacy.</p>
4.11.9		Employees Personnel shall understand the signs of pest activity and be aware of the need to report any evidence to a designated <u>manager-person</u> .

5 Product and process control

5.1 Product development

Documented product development or modification procedures shall be in place to ensure the production-manufacture of safe and legal products to defined quality parameters.

Clause	Requirements
5.1.1	<p>Customer requirements relating to the design, development, specification, manufacture and distribution of the product shall be documented and agreed with the customer.</p> <p>This shall take into consideration <u>process-manufacturing</u> requirements and end use, where possible.</p> <p>Any critical-use parameters shall be identified and defined; for example, barrier requirements, maximum/minimum use temperature, machine running, use of recycled materials, and testing requirements (including migration, where relevant).</p> <p>Special attention shall be paid to any <u>materials-products</u> that are required or requested to be manufactured from recycled materials, to ensure that they are both appropriate and legal.</p>
5.1.2	<p>The site shall clearly define and document when a <u>production manufacturing</u> trial is required.</p> <p>The site shall determine the outputs and success criteria required from a <u>production</u>-trial, and any changes and/or additions made to <u>materials-products</u>, <u>processing-manufacturing</u> characteristics or equipment as a result of <u>the-g</u> trial.</p> <p>Where appropriate, <u>production</u>-trials shall be carried out and testing shall validate that manufacturing <u>processes-operations</u> are capable of producing a safe and legal product to defined quality parameters. New products or product changes shall be subject to suitable evaluation to ensure that required <u>product</u> safety, <u>legality</u> and quality parameters can be achieved.</p> <p><u>Settings derived from successfully conducted manufacturing trials or equipment installations shall be transferred accurately to manufacturing process control documentation.</u></p>
5.1.3	<p>The company shall ensure that <u>production-manufacturing</u> is carried out using defined operating conditions which result in safe and legal products to defined quality parameters.</p>
5.1.4	<p>Where required by the customer, a technical product specification shall be prepared and, where possible, agreed with the customer or brand owner before the <u>production-manufacturing</u> process begins.</p>
5.1.5	<p>Samples as agreed with the specifier shall be retained for future reference.</p>

5.1.6	<p>A documented procedure shall in be in place to address the transfer of customer specifications or requirements to the site's own systems. This shall include (but is not limited to):</p> <ul style="list-style-type: none"> • validation of accuracy of data transferred • how changes to customer specifications are updated and communicated • how the agreed requirements for customer <u>defined testing methods-requirements</u> are met • evaluation of how changes made to the customer specifications affect the technical product specification (see clause 5.1.1). <p>Settings derived from successfully conducted production trials or equipment installations shall be transferred accurately to process control documentation.</p>
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5.2 Graphic design and artwork control

Artwork and all pre-press processes conducted by the site shall be managed to ensure that loss of information and variation from the customer's specifications are eliminated.

Clause	Requirements
5.2.1	<p>The site shall have an documented artwork management procedure covering the activities for which the site has responsibility. This may include, but is not limited to:</p> <ul style="list-style-type: none"> • collation of information to be included into artwork • receipt of artwork files from the customer • verification of completed artwork and approval by the customer <u>including any product specific claims e.g. chain of custody.</u>
5.2.2	<p>A process shall be in place to seek formal acceptance and approval of final product concepts and artworks by the specifier<u>customer</u>.</p> <p>The outcome shall be documented.</p>
5.2.3	<p>Where appropriate, print trials shall be carried out and testing shall validate that the agreed product quality and print standards can be consistently achieved.</p>
5.2.4	<p>Printing equipment such as plates, silk screens, anilox rollers, cylinders and blankets shall be verified as being correct to specification, and artwork version or agreed master prior to use, and fully traceable to the customer's approved origination material.</p>
5.2.5	<p>Customer-approved reference material, including artwork masters and colour standards used during print runs, shall be controlled to ensure minimisation of degradation and shall be returned to appropriate storage after use.</p> <p>The site shall have a policy to address requirements for the renewal of approved masters, as necessary.</p>

5.2.6	The site shall have a _documented procedure for managing changes to artwork and print specifications to manage obsolete artwork and printing materials.
5.2.7	Where artwork files and approved masters are in electronic form, these shall be suitably protected to prevent loss or malicious intervention.

5.3 ~~Packaging print control~~

Where ~~packaging materials~~products are printed or decorated, ~~_documented~~ procedures shall be in place to ensure that the information is fully legible and correctly reproduced to customer specification and complies with any legal requirements.

Clause	Requirements
5.3.1	An assessment shall be carried out for the pre-press activity, print process and handling of printed packaging (product) to identify: <ul style="list-style-type: none"> risks of loss of essential information mixing of printed product. Controls shall be established and implemented to reduce the risks identified.
5.3.2	Printing plates, cylinders, cutting dies, print blankets and any other printing equipment shall be appropriately stored to minimise damage.
5.3.3	Each print run shall be approved against the agreed standard (or master sample). This shall be recorded.
5.3.4	A system shall be in place to detect and identify printing errors during the run and to sort these errors from the acceptable printed material product.
5.3.5	Where composite print is used (a mixture of different designs printed together) , a process system shall be in place to ensure effective segregation of differing print variants.
5.3.6	Samples of printed packaging shall be retained together with production records for a period of time to be agreed with the customer/specifier/brand owner.
5.3. <u>6</u>	Any unused printed product shall be accounted for and either disposed of, or identified and appropriately stored.
5.3. <u>7</u>	Lighting in print inspection cabinets and other means of print/colour checking shall be agreed with the customer or conform to accepted industry standards.

5.4 ~~Manufacturing p~~Process control

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~~Documented~~ procedures, work instructions and ~~process~~ specifications shall be in place to ensure effective compliance with product and customer requirements ~~quality assurance of operations~~ throughout the process~~manufacturing operations~~.

Clause	Requirements
5.4.1	The hazard and risk management team site shall identify and record all potential product <u>quality</u> defects that are reasonably expected to occur at each step ₁ in relation to the product and process <u>manufacturing operations</u> . The hazards considered shall include, where applicable: product quality defects defects that may have an impact on the functional integrity and performance of the final product in use defects which result in the production of products which are outside customer specified quality parameters.
5.4.2	A review of the manufacturing and, where applicable, printing process <u>The site</u> shall identify manufacturing process control points that can prevent or limit the risk of producing products with quality defects.
5.4.3	For each manufacturing process control point, machine settings or process control limits shall be established and documented the <u>process specification</u> .
5.4.4	Where equipment settings are critical to the safety or legality of the product, changes to the equipment settings shall only be completed by trained and authorised staff. Where applicable, controls shall be password protected or otherwise restricted.
5.4.4	A bill of materials and <u>/or process</u> specification (including manufacturing process control points) shall be available for each batch or lot during production <u>manufacturing</u> .
5.4.5	Documented Manufacturing process checks shall be undertaken at start-up, following adjustments to equipment and periodically during production <u>manufacturing</u> , to ensure products are consistently produced to the agreed <u>quality</u> specification.
5.4.7	A documented clearance procedure shall be in place to ensure that at start up the line is clear of all previous work and production documents.
5.4.6	In the event of changes to product composition, processing methods or equipment failure, or deviation of the manufacturing process from specification, procedures <u>the site shall be in place to establish the quality status of the product and determine the action to be taken in accordance with clause 3.12., where appropriate, re-establish process characteristics and validate product data to ensure that product safety, legality and quality are achieved.</u>
5.4.7	<u>Where finished product is labelled and sold by quantity, the frequency and methodology of quantity control shall meet the requirements of</u>

	<u>the appropriate legislation governing quantity verification and record of checks shall be maintained.</u>
5.4.8	<u>Where the quantity of the product is not governed by legislation, the product shall conform to customer requirements and records shall be maintained.</u>
5.4.9	Where appropriate, or as a customer requirement, identifiable and traceable samples of product shall be retained, for a defined period.
5.4.10	<p><u>A manufacturing line clearance procedure shall be in place and fully implemented to ensure that at start-up and prior to any changeover, the line is clear of all previous work raw material, work in process, product and product packing and labels and manufacturing documentation.</u></p> <p>The documented line clearance procedure shall include:</p> <ul style="list-style-type: none"> • the roles of persons involved in line clearance • areas where materials can become trapped • validation of the line clearance • sign-off for continuing production. <p>The line clearance procedure shall be fully implemented for each production run.</p>
5.4.11	<u>Where a site handles products, materials or by-products that are outside the scope of the certification, these shall be controlled to ensure they do not create a product safety, legality, or quality risk to products within scope.</u>

5.5 Calibration and control of measuring and monitoring devices

The site shall be able to demonstrate that measuring and monitoring equipment is sufficiently accurate and reliable to provide confidence in measurement results.

Clause	Requirements
5.5.1	<p>The site shall identify, and control in-line and off-line measuring equipment used to monitor critical control points <u>measures</u> (where applicable) and product safety, quality and <u>legality and quality</u>. This shall include, as a minimum:</p> <ul style="list-style-type: none"> • a documented list <u>register</u> of equipment and its location • <u>an identification code and re-calibration due date</u> • <u>the calibration date and any adjustments required</u> • prevention from adjustment by unauthorised staff • protection from damage, deterioration and misuse.
5.5.2	<u>The accuracy of measuring equipment shall be specified (with permitted tolerances), having due regard to the product parameter being controlled.</u>
5.5.3	All identified measuring equipment shall be checked and adjusted at a predetermined frequency, based on risk analysis <u>assessment</u> . This shall be carried out by trained staff to a defined method, to ensure

	<p>accuracy within defined parameters. All results shall be documented<u>recorded</u>.</p> <p>Where possible, calibration shall be traceable to a recognised national or international standard. Where a traceable calibration is not possible, the site shall demonstrate the basis by which standardisation is carried out.</p>
5.5.3	<p>Corrective action and reporting procedures shall be established and documented in the event of the monitoring and testing procedure identifying any failure of product inspection, testing or measuring equipment. Any such failures shall be subject to an assessment of potential risk; subsequent action may include a combination of isolation, quarantine and re-inspection of products produced since the last acceptance test of the equipment.</p> <p>The site shall conduct a root cause analysis into the equipment failure and implement the appropriate corrective action.</p>
5.5.4	<p>Where appropriate, reference measuring equipment shall be calibrated and traceable to a recognised national or international standard and records maintained.</p> <p>Where a traceable calibration is not possible, the site shall demonstrate the basis by which calibration is carried out.</p>
5.5.5	<p>Procedures shall be in place to record actions taken when a failure is identified of the equipment used for product inspection, testing or measuring. Any such failures shall be subject to an assessment of potential risk to the product.</p> <p>Where the safety, legality or quality of the product is based on equipment found to be inaccurate, action shall be taken to ensure at-risk product is not released.</p>

5.6 Product inspection, testing and measuring

The company shall undertake appropriate inspections and ~~analyses~~testing that are critical to product safety, legality, ~~integrity~~ and quality.

Clause	Requirements
5.6.1	<p>The site shall determine the need for product testing, inspection or measuring equipment to ensure product safety, legality and quality. Quality checks shall be carried out to demonstrate that the finished product is within the tolerances laid down in the agreed product specification and conforms to any critical technical/legal requirements.</p> <p>The frequency of checks and sampling shall be in accordance with industry accepted practice or customer requirements and based on risk analysis.</p> <p>The site shall define how samples used for checking in-process quality are disposed of. This may be by returning to stock, regrinding/recycling, or segregation and disposal.</p>

5.6.2	<p><u>The inspection or testing procedures used by the site shall be validated to ensure their accuracy and reproducibility.</u></p> <p>Recognised test procedures, where available shall be used. Hazard and risk analysis principles shall be used to determine the need for in-line product testing equipment to ensure product safety, quality and legality.</p>
5.6.3	<p><u>Product inspection and testing procedures shall be in place, and carried out at appropriate stages in manufacturing to demonstrate that the finished product is within the tolerances laid down in the agreed product specification. These procedures shall include:</u></p> <ul style="list-style-type: none"> • <u>frequency of product inspection or testing and sample quantity in accordance with industry-accepted practice, or customer requirements and based on risk analysis</u> • <u>identification of authorised, trained and demonstrably competent personnel carrying out the product inspection or testing</u> • <u>recording of product inspection or testing undertaken and results</u> • <u>review of the results to identify the significance and to enable action to be taken accordingly</u> • <u>definition of how samples used for product inspection or testing are managed. This may be by retaining, returning to stock, reworking/recycling, or disposal. The accuracy of in-line equipment shall be specified (with permitted tolerances), having due regard to the product parameter being controlled.</u>
5.6.4	<p><u>Where inspection or testing equipment is integrated into the manufacturing operations and is critical to product safety, legality and quality, the site shall establish and implement procedures for the operation and testing of the equipment to ensure that it is correctly set up and capable of alerting or rejecting or identifying when the product is out of specification.</u></p> <p><u>Where appropriate, verification of accuracy and effectiveness of the equipment shall be completed at:</u></p> <ul style="list-style-type: none"> • <u>the start and end of manufacturing run</u> • <u>a frequency based on the site's ability to identify, hold and prevent the release of any implicated materials should the equipment fail (e.g., during manufacturing, or when changing batches of raw materials).</u> <p>The company shall establish, document and implement procedures for the operation, routine monitoring and testing of all equipment used in product inspection, testing and measurement. This shall include:</p> <ul style="list-style-type: none"> • frequency and sensitivity of checks • authorisation of trained personnel to carry out specified tasks • documentation of test results.
5.6.5	<p><u>Inspection and testing procedures and customer-approved reference samples (where required) shall be of the most recent version and be</u></p>

	<p>available at the location where the activity is conducted. Routine off-line quality checks shall be carried out at appropriate stages in production to demonstrate that the product is within the tolerances laid down in the agreed product specification.</p> <p>A system that includes off-line or randomised quality checks shall be in place to identify and remove non-conforming product from the production lot.</p>
5.6.6	<p>Where testing critical to product safety or legality is undertaken, the internal or external testing facility shall have gained recognised accreditation or operate in accordance with the requirements and principles of ISO/IEC 17025, including competency testing where applicable. Documented justification shall be available where accredited methods or reference methods are not undertaken.</p> <p>In-line testing equipment critical to product quality or safety shall incorporate a system to identify non-conforming product for removal or divert it out of the product flow.</p> <p>The significance of the results shall be understood and acted upon.</p>
5.6.7	<p>Test methods, analytical methods and customer approved reference samples (where required) shall be of the most recent version and be available in the laboratory or where off-line testing is conducted. Samples shall be suitably stored to avoid degradation.</p>
5.6.8	<p>The test methods used by the site in both on-line and off-line testing shall be validated to ensure their sensitivity, reproducibility and range, in addition to any other relevant criteria.</p> <p>Where standardised tests are used, the site shall ensure prescribed methodologies are followed.</p> <p>Where testing shows out-of-specification results, a documented procedure for investigating these results shall be established and followed to determine whether the cause is non-conforming product or a testing failure.</p>
5.6.9	<p>Where automated inspection equipment (e.g. vision systems) is used to check print or other material features, the site shall establish and implement procedures for the operation and testing of the equipment to ensure that it is correctly set up and capable of alerting or rejecting the packaging when it is out of specification.</p> <p>As a minimum, testing of the equipment shall be completed at:</p> <ul style="list-style-type: none"> • the start of the production run • the end of the production run • a frequency based on the site's ability to identify, hold and prevent the release of any implicated materials should the equipment fail (e.g. during the production run or when changing batches of raw materials). <p>The site shall establish and implement procedures in the event of a failure in the equipment (e.g. a documented and trained manual checking procedure).</p>
5.6.10	<p>Where the company undertakes or subcontracts an analysis critical to product safety or legality, the laboratory or subcontractors shall have</p>

	<p>gained recognised laboratory accreditation or operate in accordance with the requirements and principles of ISO 17025 for the test undertaken (General requirements for the competence of testing and calibration laboratories). Documented justification shall be available where accredited methods are not undertaken.</p> <p>The significance of the laboratory results shall be understood and acted upon accordingly.</p>
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5.7—Control of non-conforming product

~~The site shall ensure that out of specification product is clearly identified and effectively managed to prevent unauthorised release.~~

Clause	Requirements
5.7.1	Clear procedures for the control of out of specification or non-conforming materials shall be in place, documented and understood by all personnel. These shall include the effective identification and management of materials before a decision has been made on their final disposition.
5.7.2	Non-conforming materials shall be assessed and a decision taken to reject, accept by concession, rework or put to alternative use. The decision and reasons shall be documented.

5.7 Incoming goods

~~The site shall ensure that incoming goods are appropriately checked for contents, packaging integrity and potential contamination.~~

Clause	Requirements
5.7.1	<p>The site shall document a raw materials and intermediate work-in-progress product intake procedure <u>shall be in place</u> to ensure that incoming goods match purchase or product specifications. This may take the form of: For example, checking of purchase orders, or delivery notes.</p> <p><u>Acceptance criteria for incoming goods shall be defined and may include testing, certificate of analysis, statement of compliance or certificate of conformance.</u></p> <p><u>All raw materials awaiting the results of testing or verification of data, shall be held until released for use.</u></p>
5.7.2	<p>There shall be a procedure for the inspection of loads incoming goods on arrival to ensure that products are free from pest infestation, contamination or damage and are in a satisfactory condition. <u>Defects identified by the site shall be reviewed as defined in clause 3.12.</u></p> <p>Unloading areas for bulk deliveries shall be clearly identified and designed to prevent product mix-ups <u>raw material cross-contamination.</u></p>

	Regarding raw materials, all complaints or defects identified by the site shall be recorded and investigated (including root cause analysis) and the results of the investigation documented.
5.3	The site shall have a procedure for the acceptance of raw materials. This may include a valid certificate of analysis (CoA) or testing. All raw materials awaiting the results of in-house testing or verification of data shall be held until released for use.
5.7.3	Receipt documents and/or product identification shall facilitate correct stock rotation of goods in storage and, where appropriate, ensure materials are used in the correct order and within the prescribed shelf life.
5.7.4	The site shall have a system in place to validate <u>verify</u> all raw materials and intermediate work in progress <u>products</u> , prior to their introduction <u>release</u> to the process <u>manufacturing operation</u> .

5.8 Storage of all materials, ~~and intermediate work in progress~~ and finished products

The handling, management and storage of all materials and products shall minimise the risk of contamination or malicious intervention, and protect product safety, ~~quality and legality~~ and quality.

Clause	Requirements
5.8.1	Procedures to maintain product safety, <u>legality</u> and quality during storage shall be risk-based, understood by the relevant staff, and implemented accordingly. They shall include, as appropriate: <ul style="list-style-type: none"> instructions for the packing of finished product segregation of products where necessary to avoid cross-contamination (physical, microbiological or allergenic), mixing of sorts<u>materials/batches</u>, or taint storage of product/materials off the floor and away from walls specific handling or stacking requirements to prevent product damage.
5.8.2	All materials, work in progress and finished product shall be properly identified and protected during storage by appropriate packaging to protect them from contamination.
5.8.3	Storage, including off-site storage <u>and external storage</u> , shall be controlled to protect the product from contamination, including taint or odour and malicious intervention. Where off-site storage is used, the same site standards apply as for on-site storage. <u>Where external storage of raw materials, pallets, work-in-progress or finished products is undertaken, these shall be stored to minimise the risk of contamination. These shall be inspected prior to entry to internal storage and manufacturing areas.</u>

5.8.4	<p>Raw materials, work in progress and finished products storage practices shall ensure effective stock rotation. Finished or intermediate product storage shall meet customer requirements (with regard to first in, first out (FIFO), where applicable), with dispatch after positive release.</p> <p>Where external storage of finished product is required, the product shall be suitably protected.</p>
5.9.5	<p>Packaging used for storage or dispatch of intermediate or finished products, such as pallets, shall be appropriately protected if stored outside and inspected for signs of damage or contamination prior to use.</p>
5.8.5	<p>In order to prevent contamination, documented procedures shall be in place to appropriately segregate raw materials, intermediate work in progress products and finished products and materials intended for recycling.</p>
5.9.7	<p>The site shall ensure that hazardous chemicals are handled in such a way that risk to product safety, quality and legality is minimised.</p>
5.9.8	<p>Material intended for recycling shall be appropriately protected against contamination hazards.</p>

5.9 Dispatch and transport

The dispatch and transport of raw materials, work in progress and finished products shall be undertaken in a manner that minimises the risk of contamination or malicious intervention and maintains product safety, legality and quality.

Clause	Requirements
5.9.1	<p>The company shall have procedures for the dispatch and transport of products, which shall include:</p> <ul style="list-style-type: none"> any restrictions on the use of combined loads (e.g. where materials from other companies are in the same transport) requirements for the security of products during transit, particularly when vehicles are parked and unattended away from a designated storage depot. <u>product release systems.</u>
5.9.2	<p>All products and materials shall be identified and either protected during distribution by appropriate external packaging or transported under conditions to protect the product from contamination. This shall include the risk of taint or odour and of malicious intervention.</p>
5.9.3	<p>All pallets shall be checked. Damaged, contaminated or unacceptable pallets shall be discarded. Wooden pallets that come into direct contact with finished products or raw materials shall not be allowed to contaminate the product. PWooden pallets, if used, shall be checked prior to use and be soundintact, dry, clean and free from</p>

	damage and contamination. <u>Unacceptable pallets shall be discarded.</u>
5.9.4	All company-owned or leased vehicles used for deliveries shall be included in the documented cleaning schedules and kept clean and in a condition that minimises the risk of product contamination.
5.9.5	All delivery vehicles and shipping containers <u>used for product movements</u> shall be <u>fit for purpose and</u> subject to a documented <u>recorded check of hygiene- cleanliness</u> and odour checking procedure before loading.
5.9.6	Where the company employs third-party <u>transport</u> contractors, there shall be a contract or agreed terms and conditions. All the requirements specified in this section shall be clearly defined in the contract or the company shall be certificated to the Global Standard for Storage and Distribution <u>or other GFSI benchmarked Standard.</u> Where this is not possible, with general carriers, the packag <u>ing</u> shall be adequate to protect the product against damage, contamination hazards, taint and odour.
5.9.7	Vehicle drivers shall comply with the site rules relevant to this Standard. Access to the site for third-party transport personnel shall be controlled and, where possible, facilities provided to negate the need to enter storage or production-manufacturing areas.

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6 Personnel

6.1 Training and competence: raw materials handling, preparation, ~~processing~~ manufacturing, packing and storage areas

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The company-site shall ensure that all personnel performing work that affects product safety, legality and quality are adequately trained, instructed and supervised commensurate with their activity and that they are competent to undertake their job role.

Clause	Requirements
6.1.1	All <u>relevant</u> personnel, including temporary personnel and contractors, shall be appropriately trained prior to commencing work and adequately supervised throughout the working period. Induction training shall include the <u>company-site personal hygiene rules</u> requirements.
6.1.2	The site shall put in place <u>procedures covering the training needs of relevant personnel</u> . These shall include, as a minimum, the: <ul style="list-style-type: none"> • <u>identification of necessary competencies for specific roles</u> • <u>provision of training, or other action to ensure personnel have the necessary competencies</u> • <u>review of the effectiveness of training and trainers</u> • <u>delivery of training in the appropriate language of trainees.</u>
6.1.3	Where personnel are engaged in activities relating to <u>manufacturing process control points and critical control measures</u> product safety, quality and legality , <u>relevant specific</u> training and competency assessment shall be in place. This may include, but is not limited to: <ul style="list-style-type: none"> product inspection, testing and measuring calibration printed packaging controls operatives at manufacturing process control points laboratory testing product defence.
6.1.4	The site shall define and document how new or changed procedures, working methods and practices related to product safety, <u>legality</u> or quality are communicated to relevant personnel.
6.1.5	<u>Records of training shall be available. These shall include the:</u> <ul style="list-style-type: none"> • <u>name of the trainee and confirmation of attendance</u> • <u>date and duration of the training</u> • <u>title or course contents, as appropriate</u> • <u>training provider (external or internal provider).</u>

	<p>Where training is undertaken by approved service providers on behalf of the company, records of the training shall be available. The company shall routinely review and document the competencies of all staff and provide relevant training as appropriate. This may be in the form of training, refresher training, coaching, mentoring or on-the-job experience.</p>
6.1.6	<p>The site shall routinely review and document the competencies of all personnel and provide relevant training as appropriate. This may be through training, refresher training, coaching, mentoring or on-the-job experience.</p>
6.1.5	<p>Records of training shall be available. These shall include:</p> <ul style="list-style-type: none"> • the name of the trainee and confirmation of attendance • the date and duration of the training • the title or course contents, as appropriate • the training provider (external or internal provider). <p>Where training is undertaken by agencies on behalf of the company, records of the training shall be available.</p>
6.1.6	<p>The site shall put in place documented programmes covering the training needs of relevant personnel. These shall include, as a minimum:</p> <ul style="list-style-type: none"> • identifying the necessary competencies for specific roles • providing training or other action to ensure staff have the necessary competencies • reviewing the effectiveness of training and trainers • the delivery of training in the appropriate language of trainees.

6.2 Personal hygiene: raw materials handling, preparation, processing/manufacturing, packing and storage areas

~~The site's personal hygiene standards requirements shall be developed established to minimise the risk of product contamination from personnel. These standards shall be appropriate to the products produced/manufactured and be adopted by all personnel, including agency-supplied staff those supplied by agencies, visitors and contractors and visitors to the production facility shall comply.~~

Clause	Requirements
6.2.1	<p>The requirements for personal hygiene at sites producing materials for direct contact with food or other hygiene sensitive products shall be based on risk assessment and appropriate to the hazards posed to the intended use of the finished product.</p> <p>These requirements shall be documented and communicated to all relevant personnel. These shall include, as, considering at a minimum, the following instructions/topics:</p> <ul style="list-style-type: none"> • wearing of wrist bands, wrist-worn devices or watches shall not be worn • jewellery, including piercings shall not be worn on exposed parts of the body, with the exception of a plain wedding ring, wedding wristband or, medical alert jewellery or medical monitoring devices

	<ul style="list-style-type: none"> • — fingernails <u>including length, hygiene, shall be kept short and clean and free from nail varnish,</u> • false fingernails and nail art shall not be worn • excessive perfume or aftershave, shall not be worn where there is a tainting risk. <p>Requirements at sites producing materials not for contact with food shall be based on risk assessment.</p> <p>Compliance with the site's se requirements shall be checked routinely.</p>
6.2.2	The presence of p Personal items and belongings, including personal mobile phones, <u>shall not be taken into production in manufacturing and storage areas without the permission of the management shall be controlled and managed by the site.</u>
6.2.3	The site shall use risk assessment to determine the procedures and written instructions necessary to control The use and storage of personal medicines in production manufacturing and storage areas <u>shall be controlled and managed by the site, to minimise the risk of product contamination.</u>
6.2.4	All cuts and grazes on exposed skin shall be covered by an appropriately coloured plaster that is different from the product colour, (preferably blue). These shall be site-issued controlled <u>according to the level of product handling and to the intended use of the finished product, and monitored when people are involved in work with materials intended to come into direct contact with food or other hygiene-sensitive products.</u> Where appropriate, in addition to the plaster, a finger stall or glove shall be worn.
6.2.5	Hand-washing shall be performed on entry to the production areas prior to commencing work, after breaks and as often as appropriate to the level of risk to the finished product, and at a frequency that is appropriate to minimise the risk of product contamination.
6.2.6	Where visitors cannot comply with site hygiene requirements <u>rules,</u> suitable control procedures shall be in place (e.g. non-handling of product, use of gloves).

6.3 Staff Personnel facilities

Staff Personnel facilities shall be sufficient to accommodate the required number of personnel and shall be designed and operated to minimise the risk of product contamination. ~~Such facilities shall be kept in a good and clean condition.~~

Clause	Requirements
6.3.1	<u>Changing and</u> l ocker rooms shall be accessed without the need to enter production manufacturing areas, unless appropriately segregated walkways are in place.
6.3.2	<u>Appropriately sized</u> l ockers shall be provided for all personnel who work in raw material handling, <u>preparation, processing manufacturing,</u>

	preparation, packing and storage areas. Lockers shall be of sufficient size to accommodate all reasonable personal items and any protective clothing required.
6.3.3	Site-issued protective clothing and personal clothing shall not be stored in the same locker, or shall be appropriately segregated based on risk within the locker, <u>based on risk</u> .
6.3.4	Eating (including the eating of confectionery and chewing of gum or tobacco), drinking and smoking shall not be allowed in locker and changing rooms.
6.3.4	Suitable <u>located</u> and sufficient hand-washing facilities shall be available to enable cleaning of hands before commencing work, after breaks, and as necessary during the course of work. Such hand-washing facilities shall provide, as a minimum: <ul style="list-style-type: none"> • sufficient quantity of water at a suitable temperature to encourage hand-washing • unscented liquid <u>/-soap or foam soap</u> • adequate hand-drying facilities • advisory signs to prompt use (including signs in appropriate languages). Where materials are handled that will be in direct contact with food or other hygiene sensitive products, hand-washing facilities shall be sited at the entrance to the production area.
6.3.5	Toilets shall not open directly into storage, processing or production/manufacturing and storage areas, in order to prevent the risk of contamination to product. Toilets shall be provided with suitable and sufficient hand-washing facilities, <u>as defined in requirement 6.3.4</u> .
6.3.6	Facilities for visitors and contractors shall enable compliance with the site's <u>personal hygiene requirements</u> .
6.3.7	All food brought into manufacturing premises onto site shall be stored in a clean and hygienic state. No food shall be taken into storage, processing or production/manufacturing, storage, laboratory or engineering areas.
6.3.8	Eating (including the eating of confectionery and chewing of gum or tobacco), drinking and smoking shall not be allowed in the production manufacturing, or storage and other areas, <u>such as laboratory, engineering, locker and changing rooms</u> . If it is impractical for personnel to leave their work area <u>for these purposes, local designated</u> , controlled facilities (such as a fully walled area with hand-washing facilities) shall be provided.
6.3.9	Drinking of water from purpose-made dispensers and/or by using disposable conical cups or spill-proof lidded containers may be allowed, provided it is confined to a <u>designated areas</u> , away from <u>product and manufacturing</u> equipment.

6.3.10	<p>Where smoking, including electronic cigarettes, is allowed within buildings under national law, it shall only be permitted in designated controlled smoking areas which shall be provided isolated from production manufacturing and storage areas and fitted with sufficient extraction equipment to the exterior of the building.</p> <p>Adequate arrangements for dealing with smokers' waste shall also be provided at smoking facilities, both inside buildings and at external locations.</p> <p>The use of electronic cigarettes and associated materials shall not be permitted in locker rooms, nor in production or storage areas, and shall only be permitted in designated smoking areas.</p>
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6.4 Medical screening

Sites ~~that manufacture packaging for direct contact with food or other hygiene-sensitive products~~ shall ensure that ~~documented~~ procedures are in place to ensure that health conditions likely to adversely affect product safety are monitored and controlled.

Clause	Requirements
6.4.1	<p>Where there is handling of materials intended for direct contact with food or other hygiene-sensitive products, the site shall make employees personnel, including temporary personnel, aware of the symptoms of infection, disease or conditions which would prevent a person affect working in contact with the product, based on risk to the intended use of the finished product, or where local legislation is in place.</p> <p>The site shall have a procedure for thewhich enables notification by personnel, including temporary personnel, to the site of any relevant symptoms, infections, diseases or conditions, with which they may have been in contact with or may be suffering from.</p> <p>Where there may be a risk to product safety, personnel suffering from any of the above shall be excluded from work involving contact with the product.</p> <p>Employees, contractors and visitors suffering from any of the above shall be excluded from work involving the handling of direct food contact or other hygiene-sensitive product packaging for as long as the symptoms persist.</p>
6.4.2	<p>Where permitted by law, visitors and contractors shall be required to fill incomplete a health questionnaire or otherwise confirm that they are not suffering from any symptoms of infection, disease or conditions which may put product safety at risk, prior to being allowed into production manufacturing, packing or storage areas.</p>
6.4.3	<p>Medical screening for sites producing materials that will not come into direct contact with food or other hygiene-sensitive products shall be implemented on the basis of risk.</p>

6.5 Protective clothing

Appropriate protective clothing shall be worn in production manufacturing and storage areas to minimise the risk of product contamination.

Clause	Requirements
6.5.1	<p><u>Based on risk assessment, and appropriate to the hazards posed to the intended use of the finished product, wearing of the following in manufacturing and storage areas, shall be considered:</u></p> <ul style="list-style-type: none"> • <u>Hair coverings and/or</u> • beard snoods, where appropriate, shall be worn in production areas at sites manufacturing materials for direct contact with food or other hygiene sensitive products. <p>Hazard and risk principles shall be used to determine the need for any other</p> <ul style="list-style-type: none"> • <u>protective clothing</u> <p>, including garments and</p> <ul style="list-style-type: none"> • <u>protective footwear in areas handling raw materials, and in preparation, production and storage areas.</u> • <u>protective gloves</u> <p>Where risk assessment has determined that protective clothing these are is not required in a particular area, it shall be fully justified and not pose a contamination risk to the product.</p>
6.5.2	<p><u>Where worn, sufficient, site-issued sets of protective clothing shall be provided.</u></p> <p><u>Protective clothing worn by personnel, temporary personnel, contractors and visitors in manufacturing and storage areas shall be clean and provide adequate coverage of personal clothing.</u></p> <p><u>The protective clothing shall have no external pockets on the upper body garments or sewn-on buttons. The company shall use risk assessment to determine, document and communicate to all employees, including temporary personnel and contractors, the rules regarding the wearing of protective clothing in all situations, including:</u></p> <ul style="list-style-type: none"> • during the journey to work • in raw materials handling, preparation, production and storage areas • when away from the production environment (e.g. removal before entering toilets, canteen or smoking areas).
6.5.3	<p><u>Disposable protective clothing, if used, shall be suitably designed and subject to adequate control to avoid product contamination. Where protective clothing is required, appropriate clean protective clothing that cannot contaminate the product shall be worn. Sufficient sets of clothing appropriate to the activities being carried out shall be provided.</u></p>

6.5.4	<p>If gloves are used, they shall be replaced regularly, be distinctive, intact and not cause a contamination risk to the product. Protective clothing worn in production areas shall provide adequate coverage. Where there is handling of materials intended for direct contact with food or other hygiene-sensitive products, the clothing shall have no external pockets on the upper body garments or sewn-on buttons. Changes of such clothing shall be available at all times as required.</p>
6.5.5	<p>The site shall define the rules regarding the wearing of protective clothing in all situations, including:</p> <ul style="list-style-type: none"> • to and from site • when away from the manufacturing areas, (e.g., removal before entering toilets, canteen, ancillary areas, or smoking areas). <p>Based on the assessment of risk to the product, suitable footwear shall be worn within the factory environment.</p>
6.5.6	<p>If gloves are used they shall be replaced regularly, be distinctive, intact and not cause a contamination risk to the product.</p>
6.5.6	<p>Protective clothing, <u>including health and safety clothing</u>, shall be kept clean and laundered. Laundering shall be carried out by one of the following methods:</p> <ul style="list-style-type: none"> • professional laundry service • in-house • <u>site-controlled</u> laundering facilities • home laundry.
6.5.7	<p>Where home laundry <u>of protective clothing</u> is permitted, the site shall ensure that:</p> <ul style="list-style-type: none"> • employees-personnel have received written instructions regarding the laundering process to be used and these shall be reinforced as part of an induction or other in-house training programme • employees-personnel shall be provided with a bag or other suitable means to safely transport washed <u>garments-protective clothing</u> from home to the <u>workplacesite</u> • there shall be a defined process within the site <u>is a system</u> for monitoring the effectiveness of <u>the system home laundering</u> • there shall be a procedure and system for dealing with any case where employees-personnel are unable to perform home laundry effectively, either through lack of diligence or inadequate facilities.
6.5.8	<p><u>Storage of clean protective clothing on site shall be controlled to prevent cross-contamination.</u></p>
6.5.9	<p>Clean and dirty clothing shall be segregated and controlled to prevent cross-contamination.</p>
6.5.10	<p>Disposable protective clothing, if used, shall be subject to adequate control to avoid product contamination.</p>

7 Requirements for traded products

Traded products are defined as products that would normally fall within the scope of the Standard and are stored at the site being audited, but are not manufactured, reworked, or packed at that site.

The site's management of these products is covered by the requirements in this section.

All the relevant requirements from sections 1 to 6 must also be fulfilled in addition to the requirements outlined in this section.

Where a site wishes to be audited against section 7 of the Standard, all the products and raw materials traded must be included in the audit scope. It is not permitted to include some traded products or raw materials and exclude others.

Non-conformities against clauses within section 7 of the Global Standard will be recorded on the audit report and included in the calculation of the site's grade.

Where a site has traded products or raw materials on site, but wishes them to be excluded from the scope of the audit, this will be recorded as an exclusion from scope on the audit report and certificate. The BRCGS Packaging Certificated logo can be used, but shall not be used for promoting traded products, even when included in the certificated scope.

~~The company shall operate procedures for approval of the last manufacturer or packer of packaging products which are traded to ensure that trade packing products are safe, legal and manufactured in accordance with any define product specifications.~~

7.1 Hazard and Risk Assessment of Traded Products

The site shall operate a HARA plan for the operations for which it is responsible.

<u>Clause</u>	<u>Requirements</u>
<u>7.1.1</u>	<p><u>The company shall either:</u></p> <ul style="list-style-type: none"> <u>have a HARA plan specifically for the traded products handled on site, or</u> <u>incorporate the traded products into its existing HARA (section 2).</u> <p><u>The scope of the traded products HARA plan shall include the products and the processes for which the site is responsible. At a minimum, this shall include receipt, storage and dispatch.</u></p>

7.2 Approval and performance monitoring of manufacturers/packers of traded ~~packaging~~ products

~~The company shall operate procedures for approval of the last manufacturer/er packer of ~~packaging-traded~~ products ~~which are traded~~ to ensure that ~~products~~ traded ~~packaging products~~ are safe, legal and manufactured in accordance with any defined product specifications.~~

<u>Clause</u>	<u>Requirements</u>
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<p>7.2.1</p>	<p>The company shall conduct have a documented supplier approval procedure which identifies the process for initial and ongoing approval of suppliers and the manufacturer/processor of each product traded. The requirements shall be based on the results of a risk assessment of the products traded which shall include consideration of considering:</p> <ul style="list-style-type: none"> • the nature of the product and associated risks • customer-specific requirements • legislative requirements in the country of sale or importation of the product • the brand identity of the products, (i.e. customer own brand or branded product).
<p>7.2.2</p>	<p>Based on the risk assessment (requirement 7.2.1) tThe company shall have a procedure for the initial and on-going approval of the manufacturers/packer of traded products. This approval procedure shall be based on risk and include, either one or a combination of:</p> <ul style="list-style-type: none"> • a valid certification to the applicable Global Standard or other GFSI-benchmarked standard. valid certification to a globally-recognised product safety management system e.g. certification to the applicable Global Standard or GFSI-benchmarked Standard. Or, certification to a globally-recognised quality management system that incorporates an assessment of traceability and confirmation that products supplied are safe and legal e.g. declaration of compliance. The scope of the certification shall include the traded -products purchased. • supplier audits, with a scope to include product safety, traceability, hazard and risk management systems a review of the product safety system, traceability and prerequisite controls and good manufacturing practices, undertaken by an experienced and demonstrably competent product safety and quality management auditor. A full audit report shall be available. Where theis supplier audit is completed by a second or third party, the company shall be able to: <ul style="list-style-type: none"> • demonstrate the competency of the auditor • confirm that the scope of the audit includes a product safety, traceability, HARA-review of the product safety system, and traceability and good manufacturing practices prerequisite control • obtain, review and review-approve a copy of the full audit report. • a manufacturer/packer self-audit questionnaire or manufacturer/packer-provided information may be used for approval, where a valid risk-based justification is provided. The questionnaire shall have a scope that includes the product safety system for the product supplied, verification of traceability system, and prerequisite controls, and it shall be reviewed and approved by a demonstrably competent person. <p>Where approval cannot be based on the above, then the company shall be able to demonstrate their criteria for approval and evaluation of the manufacturer/packer to ensure that all traded products comply</p>

	<p><u>with requirements associated with product safety, legality and quality and meet specifications.</u></p> <p><u>Ongoing approval of manufacturers/packers shall be at agreed intervals based on risk, and manufacturers/packers shall be required to notify the site of any significant changes in the interim, including any change in certification status.</u>By exception, and only where a valid risk-based justification is provided, initial and ongoing approval may be based on:</p> <ul style="list-style-type: none"> • a historical trading relationship supported by documented evidence of performance reviews demonstrating satisfactory performance • a manufacturing site questionnaire which has been reviewed and verified by a demonstrably competent person • a specific customer requirement to supply product from a manufacturer where liability is with the customer.
7.2.3	Records shall be maintained of the manufacturer's or packer's approval process, including audit reports or verified certificates confirming the product safety status of the manufacturing/packing sites supplying the products traded. There shall be a process of review, and records of follow-up of any issues identified at the manufacturing/packing sites with the potential to affect <u>packaging</u> products traded by the company.
7.2.4	There shall be a <u>performance review of documented process for the ongoing review of</u> manufacturers or packers, based on risk and using defined performance criteria, which shall include: <ul style="list-style-type: none"> • complaints • results of any product tests • regulatory warnings/alerts • customer rejections or feedback. <p>The process shall be fully implemented.</p>

7.3 Specifications

Specifications or information to meet legal requirements and assist customers in the safe usage of the product shall be maintained and available to customers.

Clause	Requirements
7.3.1	Specifications shall be available for all <u>traded</u> products. These shall either be in the agreed format as supplied by the customer or, where this is not specified, include key data to meet legal requirements and assist the customer in the safe usage of the product. Specifications may be in the form of a printed or electronic document, or part of an online specification system.
7.3.2	The <u>company site</u> shall seek formal agreement of the specifications with relevant parties. Where specifications are not formally agreed, the <u>company site</u> shall be able to demonstrate that it has taken steps to put an agreement in place.

7.3.3	Companies/Sites shall operate demonstrable processes to ensure that any customer-specified requirements are met. This may be by inclusion of customer requirements within buying specifications or by undertaking further work on the purchased product to meet the customer's specification (e.g. sorting or grading of product).
7.3.4	Specifications shall be reviewed whenever products /packaging or suppliers/manufacturers/packers change or at least every 3 years <u>appropriate predetermined intervals</u> . The date of review and the approval of any changes shall be recorded.

7.4 Product inspection and ~~laboratory testing~~

The site shall operate processes to ensure that the traded products received comply with ~~buying~~ specifications and that the supplied product is in accordance with ~~any~~ customer specification requirements.

Clause	Requirements
7.4.1	The site shall use Risk assessment <u>shall be used to identify where</u> product sampling or testing is required <u>requirements</u> to verify that the <u>traded</u> products are in accordance with buying specifications and meet <u>product safety, legality and quality</u> and safety requirements. Where verification is based on sampling, the sample rate and assessment process shall be risk-based. Records of the results of assessments or analysis shall be maintained.
7.4.2	Where verification of conformity is provided by the supplier (e.g. certificates of conformity or analysis), the company shall use risk assessment to determine whether periodic independent product analysis may be required to ensure confidence in the information provided.
7.4.3	Where claims are made about the <u>traded</u> products being handled , including the provenance, chain of custody or assured status of a product , supporting information shall be available from the supplier or independently to verify the claim.
7.4.4	Where the company undertakes or subcontracts analyses which are testing critical to <u>traded</u> product safety or legality <u>is undertaken</u> , the <u>internal or external testing facility laboratory or subcontractors</u> shall have gained recognised laboratory accreditation or operate in accordance with the requirements and principles of ISO/ <u>IEC</u> 17025, <u>including competency testing where applicable</u> . Documented justification shall be available where non accredited test methods <u>or reference methods</u> are not used <u>undertaken</u> .
7.4.5	Test and inspection results shall be retained and reviewed to identify trends. Appropriate actions shall be implemented promptly to address any unsatisfactory results or trends.

7.5 Product legality

The company shall have processes in place to ensure that the traded products ~~traded~~ comply with the legal requirements in the country of sale, where known.

Clause	Requirements
7.5.1	<p>The company shall have documented processes to verify the legality of <u>traded</u> products which are traded. These shall include, as applicable:</p> <ul style="list-style-type: none"> labelling information compliance with relevant legal compositional requirements compliance with quantity or volume requirements. <p>Where such responsibilities are undertaken by the customer, this shall be clearly stated in contracts.</p>

7.6 Traceability

The company site shall be able to trace all traded product ~~lots~~ back to the last manufacturer/packer and forward to the customer ~~of the company~~.

Clause	Requirements
7.6.1	<p>The site shall maintain a traceability system for all batches of <u>traded</u> product which that identifies the last manufacturer or packer of the product. Records shall also be maintained to identify the recipient of each batch of <u>traded</u> product from the <u>company site</u>.</p>
7.6.2	<p>The <u>company site</u> shall test the traceability system at least annually to ensure that traceability can be determined back to the last manufacturer/<u>packer</u> and forward to the recipient of the <u>traded</u> product from the company. This shall include identification of the movement of the product through the chain from the manufacturer/<u>packer</u> to receipt by the <u>company site and distribution to the customer including (e.g. each movement and intermediate place of storage)</u>.</p>
7.6.3	<p>The traceability test shall include the reconciliation of quantities of product received by the <u>company site</u> for the chosen batch of product lot. <u>Traceability should be achievable within 4 hours (1 day when information is required form external parties)</u>.</p>

PART III

AUDIT PROTOCOL

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Introduction

The Global Standard Packaging Materials (the Standard) provides companies with a series of options with which to be audited and certificated. This flexible approach is in response to market demand and allows companies to choose an audit option which best suits their customers' requirements, ~~factory~~ manufacturing operations and the maturity of their product safety systems.

~~The general audit protocol in section 1 of this part (Part III) describes the requirements for auditing and certification which are applicable to both audit programmes (announced and unannounced). This should be read and fully understood. The process is summarised in Figure 1.~~

~~The audit protocol describes how these audit processes operate and explains the rules around the audit and certification to the Standard. This is an essential element of the Standard and should be read and fully understood.~~

~~Each of the audit options has its own particular characteristics and these are described in detail in sections 2 and 3. However, it may be subject to minor change, and reference should be made to the BRCGS website~~
~~Every effort has been made to ensure that the content of the Standard is accurate at the time of publication. However, it may be subject to minor change. Any additions or amendments to this normative document will be published as 'position statements' (see section 6.2). Reference should be made to the BRCGS website (www.brcgs.com), where changes will be published.~~

Conformance by the company to the requirements of the Standard and its suitability for the awarding and continuing retention of certification will be assessed by an independent audit company – the certification body. Certification will be graded according to the audit option selected and the number and type of non-conformities, which shall also influence the frequency of ongoing audits. This part describes the process to be followed by a company seeking certification.

~~Figure 1 summarises the steps to be followed for all companies wishing to gain certification.~~

Figure 1 – Audit protocol – how to gain certification

1. General protocol – audit preparation

1.1 Selection of an audit option

There are three options and processes available for sites to demonstrate their commitment to the Standard, as summarised in Figure -2.

Figure -2– Audit options flow diagram

1.1.1 Announced audit programme (with mandatory unannounced audit every 3-years)

This is available for existing certificated sites and those new to certification. For announced audits, the audit date is agreed with the certification body in advance of the audit and all requirements of the Standard are audited within the audit visit. Once every 3-years, the audit will be unannounced; the certification body will notify the site within 3-months of the previous audit due date. This will ensure that the site is aware that an unannounced audit will take place in the coming year. However, the actual date of the unannounced audit will not be communicated to the site in advance.

For an announced audit, successful sites are awarded a certificate with a grade of AA, A, B, C or D, depending on the number and type of non-conformities identified. For the mandatory unannounced audit, successful sites will receive an unannounced grade of AA+, A+, B+, C+ or D+, depending on the number and type of non-conformities identified.

More details on the announced audit programme can be found in section- 2.

1.1.2 Blended announced audit programme (with mandatory unannounced audit every 3- years)

The blended announced audit programme uses information and communication technology (ICT) to remotely audit documented systems and records. The audit is split into two separate parts: a remote audit followed by an on-site audit. The remote audit (first part) uses ICT to focus predominantly on documented systems and records, while the on-site audit (second part) focuses predominantly on production, storage and other on-site areas. A blended audit can only be offered by the certification body following a risk assessment which:

- confirms that a robust audit is possible (e.g. remote technology is available at the site)
- assesses the percentage of the audit that can be completed remotely. -

More details on the risk assessment can be found in section -3.1.5.

At the time of publication, the blended audit option is available for announced recertification audits only and not for initial audits (i.e. the first BRCGS audit at a site). Successful sites are awarded a certificate with grade AA, A, B, C or D, depending on the number and type of non-conformities identified.

More details on the blended announced audit protocol can be found in section 3.

1.1.3 Unannounced audit programme

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The unannounced audit option is available to all sites; although sites which are not currently certificated need to recognise that the audit may not take place for up to 1 year from the date of application. The unannounced audit option provides sites with the opportunity to demonstrate the maturity of their quality systems and successful sites are awarded grades of AA+, A+, B+, C+ or D+ depending upon the type and number of non-conformities identified at the audit.

The conducting of an independent, unannounced review of the production facilities, systems and procedures under this scheme provides a site's customers with added confidence in the site's ability to consistently maintain standards. This may influence the frequency of customer audits, where conducted, and other performance measures applied by the customer.

More details on the unannounced audit programme highlighting the differences between the announced and unannounced protocols can be found in section 3.

1.2 Self-assessment of compliance with the Standard

It is essential that the site is assessed against the current issue of the Standard and any current position statements, all of which are available on the BRCGS website.

The Standard should be read and understood and a preliminary self-assessment should be conducted by the company against the Standard to prepare for the audit. Any areas that need to be improved to meet the requirements should be addressed by the company to prevent a non-conformity being raised at the audit.

Further information, guidance and training to ensure compliance with the Standard, including a downloadable self-assessment tool, are available from the BRCGS website. BRCGS also has a full range of further guidelines and supporting materials available through the website or, for certificated sites, from BRCGS Participate.

An optional on-site pre-assessment may be carried out by the selected certification body in preparation for the audit to provide guidance to the site on the process of certification.

Certification bodies shall ensure that any pre-assessment meets the requirements for accreditation. For example, consultancy cannot be provided by the certification body that will later undertake the certification audit, so the same auditor cannot be used for both the pre-assessment and the certification audit.

Manufacturing units that are newly built or 'commissioned' shall ensure that systems and procedures in place are compliant before an initial audit is undertaken. It is at the discretion of the company when it wishes to invite a certification body to carry out an audit; however, it is unlikely that full compliance can be satisfactorily demonstrated at an audit undertaken less than 3 months from commencement of operation. This is likely to be the situation even where the site for certification uses quality systems developed by other certificated companies in the group. Timescales for audits shall be agreed between the site and the certification body.

~~Some sites may be able to improve this timescale, such as a small site, a site that has already implemented ISO 9001, or one that is part of a group with established management systems.~~

~~With respect to a new production site within an established company, the new site's systems and procedures may reflect those systems already established in other sites within the company, but sufficient documentation must be in place to enable a full~~

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~~audit so that compliance can be assessed against BRCGS requirements for the new site.~~

1.3 Selection of a certification body

Audits against a Global Standard are only recognised if these are undertaken by certification bodies that are recognised and approved by BRCGS. BRCGS cannot advise on the selection of a specific certification body; however, they have a comprehensive programme of measurement of certification body performance around specified key performance indicators (KPI's), the results of which are converted to a ~~5~~-star rating and published with the listing of all approved certification bodies on in the BRCGS Directory. ~~The company should ensure that its selected certification body is accepted by its customers (e.g. only 4- or 5-star-rated certification bodies may be accepted by some customers).~~

1.4 Company/certification body contractual arrangements

A contract shall exist between the company and the certification body in accordance with the requirements of ISO/IEC 17065, detailing the scope of the audit and the reporting requirements. The contract shall also contain clauses which allow the effective management of the scheme by BRCGS and accreditation of the certification body by their accreditation body. These are essential to ensure confidence in the way in which the scheme is managed and consistency achieved, which benefits all certificated sites. In particular, it is a condition of certification to the scheme that:

- A copy of the audit report and any subsequent certificate or audit result shall be supplied to BRCGS and may be supplied to the accreditation body in the agreed format for the Standard. As a GFSI-benchmarked Standard, records may be viewed in conjunction with any GFSI compliance audit. Other documents in relation to the audit shall be made available to BRCGS upon request. All documents submitted to BRCGS shall be copies of original documents. Documents provided will be treated as confidential.
- Where agreements are in place, BRCGS may make audit reports and certificates available to customers of sites. Sharing can be removed by the site at any time through the BRCGS Directory.
- The auditor(s) may be accompanied by other personnel for training, assessment or calibration purposes. This activity may include:
 - training of new auditors by the certification body
 - routine certification body shadow audit programmes
 - witness audits by accreditation bodies
 - witness audits by BRCGS.



BRCGS reserves the right to conduct its own audit or visit to a site once certificated in response to complaints or as part of routine compliance activity to ensure the integrity of the scheme. Such visits may be announced or unannounced.

BRCGS may contact the site directly in relation to its certification status, for feedback on certification body performance or for investigation into reported issues.

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This publication sets out the requirements against which sites will be audited. Contracts between the certification body and the site shall include a clause acknowledging these obligations. This contract will be formulated by the certification body.

Non-compliance with any of these contractual ~~obligations may affect the status of certification of the site~~ shall be communicated to BRCGS and may result in additional certification integrity activities being undertaken. Non-compliance may also affect the certification status of the site.

1.5 Service fee

BRCGS requires a service fee to be collected by the certification body from the company for every audit undertaken. This covers the service package that allows the company to access a suite of BRCGS products, including BRCGS Participate, BRCGS Professional and the BRCGS Directory. The certificate and audit report shall be uploaded to the BRCGS Directory but shall not be valid until the service fee and the certification body's audit fees have been received, irrespective of the outcome of the certification process.

For more information about what is available in the service package, see www.brcgs.com.

1.6 Scope of audit

1.6.1 Defining the audit scope

The scope of the audit (products produced and manufacturing ~~processes~~ operations) shall be agreed between the site and the certification body in advance of the audit to ensure the allocation of an auditor (or auditors) with the correct category and product knowledge. As listed in Appendix 1

The audit shall include all applicable requirements within the Standard and all manufacturing operations ~~production processes~~ undertaken for the products included within the scope at the site seeking certification.

The audit scope and any permitted exclusions shall be clearly defined and unambiguous both on the audit report and on any certificate issued. ~~The wording of the scope will be verified by the auditor during the site audit.~~ The wording of the scope description of the product and where applicable, the application of the packaging material, shall enable a recipient of the report or certificate to clearly identify whether the products supplied have been included within the scope.

The scope description on reports and certificates shall include:

- the manufacturing categories and products manufactured
- a description of the manufacturing activities undertaken at the site that fall within the scope of the Standard
- clear description of products purchased for resale by a site ('traded products')
- clear indication of where the site contracts outsourced manufacturing steps.

□ The scope description shall enable a recipient of the report or certificate to clearly identify whether the products supplied have been included in the audit. The wording of the scope will be verified by the auditor during the site audit.

1.6.2 Exclusions from scope

The fulfilment of the certification criteria relies on clear commitment from the site management to adopt the best-practice principles outlined within the Standard and to the development of a product_safety and quality management culture within the business. It follows therefore that the exclusion of products from the scope of certification shall only be permitted by exception.

The BRCGS Packaging Certificated logo can only be used by sites that have no exclusions, other than for traded products (section7).

The exclusion of products produced at a site will only be acceptable where:

- the excluded products can be clearly differentiated from products within scope and
- the products are produced in a physically segregated area of the factory.

□ Where exclusions are requested, these shall be agreed with the certification body in advance of the audit and verified by the auditor during the site audit. Exclusions shall be clearly stated on the audit report and certificate and the justification recorded on the audit report.

The certification of products shall include an audit of the entire operation from raw materials reception to end-product dispatch. It is not possible to exclude either parts of the operations undertaken at the site, or parts of the Standard. Where exclusions are accepted, the auditor shall assess any hazards presented by excluded areas or products ~~(e.g. foreign body risks)~~ and will therefore need to audit those manufacturing processes operations, products and manufacturing areas (clause 5.4.10).

Non-conformities may be raised relating to the excluded area where this poses a risk to the products within the audit scope.

~~The auditor retains the right to refuse the exclusion request where the criteria are not adequately met.~~

~~Traded products can be excluded from the audit scope; in that situation the requirements of section 7 will not be applicable. Where excluded, this will be recorded as an exclusion from scope on the audit report and on the certificate. The BRCGS packaging logo can be used, however, it cannot be used for promoting traded products, even when they form part of the certificated scope.~~

~~Products purchased for resale by a site (i.e. traded products) can form an agreed exclusion and therefore the requirements of section 7 (Part II) will not be applicable. It should be noted that the BRCGS logo cannot be used for promoting traded products even when they form part of the certificated scope~~

1.6.3 Defining the limits of a site

Audit reports and certificates, and therefore audit scopes, are expected to be site-specific. However, in some circumstances, a company may own additional facilities

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or storage at more than one location, all operated under common management as a single operation, and these may be included under a single certification. This will be considered exceptional, but allowable, where all the following conditions are met:

- All sites are under the same organisation's ownership
- All sites operate within the same documented product safety and quality management systems
- The sites manufacture product which is part of the same manufacturing process (i.e. sequential steps in the manufacture are completed at different sites)
- The sites solely supply the other sites, with no additional customers
- The sites are no more than 30 miles/50 km apart.

All sites must be visited as part of the same audit schedule (i.e. within the same timeframe).

It must be clearly stated on the report and certificate that the audit has consisted of visits to more than one site address (e.g. the die cutting of paperboard sheets at Sector 2 Industrial Zone, Packville, and the window patching with cellulose film, folding and gluing to form sweet packing cartons at Sector 23 Industrial Zone, Packville).

1.6.4 Auditing activities where the head office is located separately Additional manufacturing locations and head office assessments

When undertaking audits of sites which are part of a larger manufacturing group, it is not uncommon for some of the requirements within the scope of the Standard to be undertaken by a central or head office.

The detailed requirements for acceptance and management of such circumstances within the audit protocol are defined in Appendix -4.

~~The audit scope is expected to be site specific. There are, however, exceptional circumstances where the activities are undertaken at more than one location and where these can be included within a single report and certificate. This includes: the audit of a head office to review procedures controlled from that office the audit of more than one location where a single production process is carried out across two or more sites.~~

1.6.5 Storage facilities – off-site

While storage facilities on the same site as the ~~production~~ manufacturing facility shall always be included within the audit of the site, it is not uncommon for sites to also own additional off-site storage facilities. Where additional storage facilities are owned and managed by the company in the vicinity of the ~~production~~ manufacturing site facility (i.e. within a radius of 30 miles/ 50 -km), these shall be identified on the audit report and either audited as part of the site audit or specifically excluded.

1.6.6 Additional modules

In addition to the core Standard, BRCGS has developed a range of additional modules which may ~~apply only to particular types of operation or may look in greater depth at a particular market concern.~~ be added to the routine audit. These modules are voluntary and designed to enable sites to demonstrate compliance with specific sets of requirements – to reduce multiple audits or to meet specific geographic or customer requirements.

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~~Where such additional modules are undertaken these will be listed on the scope of the report and certificate. If an additional module that is applicable to a site is not selected, this shall be identified as an exclusion to ensure this is clear to the reader of the report or certificate.~~

~~A list of additional modules for the Packaging Standard is available on the BRCGS website (www.brcgs.com).~~

~~A list of the modules, the applicable requirements and any specific protocol for a module is available on the BRCGS website, BRCGS Participate and the BRCGS Store. The modules can be added to any of the full certification audit options (i.e. announced, blended or unannounced). The general protocol for the modules is set out in section -5.~~

1.7 Auditor selection

It is the responsibility of the site to ensure that adequate and accurate information is given to the certification body, detailing the products it manufactures and the ~~process manufacturing~~ technologies it uses, to enable the certification body to select an appropriate auditor (or audit team) with the required skills to undertake the audit. Auditors must be skilled to audit in the relevant ~~product manufacturing category, as listed in Appendix 2~~.

The certification body, auditors and the site shall be aware of the need to avoid a conflict of interest when arranging for auditors to visit the site. The site may decline the services of a particular auditor offered by the certification body. The same auditor is not permitted to undertake audits on more than five ~~three~~ consecutive occasions at the same site.

Where the audit is not being carried out by the auditor(s) in the native language of the site, an appropriate translator shall be provided who has knowledge of the technical terms used during the audit.

2 Announced audit protocol (with mandatory unannounced audit every 3 years)

This is an announced audit programme with one mandatory unannounced audit every 3 -years.

All sites shall have at least one unannounced audit every 3 -years. For sites with annual (12-month) audits, this will result in at least every third audit being unannounced. Sites that receive a grade C or D at any of their audits will still be expected to undergo an unannounced audit at least every 3 -years, but there will be a larger number of announced audits in the interim.

2.1 Audit planning

2.1.1 Preparation by the company

~~For initial audits~~For announced audits, the site shall agree a mutually convenient date, with due consideration given to the amount of work required to meet the requirements of the Standard.

There is a requirement on the site to be prepared for the audit, to have appropriate documentation for the auditor to assess and to have appropriate staff available at all times during the on-site audit.

The site shall ensure that the ~~production manufacturing~~ operations ~~schedule~~ at the time of the audit covers products for the intended scope of the certification. Where possible, the widest range of products shall be in production for the auditor to assess.

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Where the product range is large or diverse, the auditor has the discretion to continue the audit until sufficiently satisfied that the intended scope of the certification has been assessed. Where a significant manufacturing operation is undertaken during a different period of the year from the audit, a separate audit will be required to assess that production method. ~~The need for an additional audit will depend on the nature of the additional process and products and how they vary from the process and products in the audit scope.~~

For the mandatory unannounced audit, the certification body shall notify the site of the year when the unannounced audit will take place. The actual date of the unannounced audit will not be communicated to the site. This discussion shall occur within 3 months of the previous audit to ensure that the site is aware of the year in which the unannounced audit will take place.

2.1.2 Information to be provided to the certification body for audit preparation
The site shall supply the certification body with background information prior to the audit ~~day~~ to ensure the auditor (or audit team) is fully prepared and to provide the best opportunity for the audit to be completed efficiently. The information will be requested by the certification body and may include but is not limited to:

- background and structure of the company
- a summary of the site's hazard analysis and risk assessment and any critical control measures points (CCPs)
- process flow diagram
- simple site plan
- management organisational chart
- list of products or product groups included within the audit scope
- description of the site and building fabrication
- typical staff shift patterns
- production schedules, to allow audits to cover relevant manufacturing operations (e.g. night-time manufacture or where some manufacturing operations are not carried out every day or are only carried out at certain times of the day)
- outline of any outsourced processes
- recalls that have occurred since the last BRCGS audit
- recent significant quality issues, withdrawals or customer complaints ~~recent significant quality issues, recalls withdrawals or customer complaints and any other relevant performance data~~
- any requested exclusions from scope
- outline of operational controls, such as internal audits, testing and traceability
- significant changes to the management structure, ownership, site or manufacturing operations since the last BRCGS audit.
- Audit history

Where the site is contracted with a new certification body, the site shall make the previous audit report with GFSI certification history and certificate available to the certification body, where this is a new contract, even if this was more than a year ago.

Submitting accurate and detailed information prior to the audit, and in the format requested by the certification body, may reduce the duration of the on-site audit have an effect on the calculated duration of the on-site audit, therefore sites are encouraged to fulfil such requests in a timely manner.

The time needed for the auditor and certification body to assess all the submitted documentation is additional to the duration of the audit.

Additional information will be required for the unannounced audit (see section 4.1.3).

2.1.3 Scheduling the mandatory unannounced audit

The certification body is responsible for managing the audit process and ensuring that within the 3-year period, all certificated sites receive at least one unannounced audit. The certification body shall notify the site of the year when the unannounced audit will take place, without communicating the actual date of the unannounced audit. This discussion shall occur within 3 months of the previous audit to ensure that the site is aware of the year in which the unannounced audit will take place.

The unannounced audit will replace the normal scheduled (announced) audit. It can occur at any stage within the last 4 months of the audit cycle, including the last 28 calendar days before the date that the announced audit is due (i.e. the unannounced audit must occur within the 4 months leading up to the audit due date). The audit must take place during normal site operation, unless other arrangements have been agreed with the site.

The site shall not be notified of the proposed audit date in advance.

If the site chooses to change certification body or GFSI-benchmarked scheme, this does not change the requirement for the site to receive an unannounced audit. Therefore, the site must ensure that the new certification body is aware that the site is already certificated and provide the date of its last unannounced audit. The certification body will also require evidence of the site's audit history (e.g. a copy of the most recent audit report) so that the 3-year cycle can be maintained.

Sharing the last audit report is a mandatory requirement of the BRCGS audit protocol (see section 2.1.2). Where a site fails to share its last report in a timely manner, the new certification body will have access to the last audit report through the BRCGS Directory. If a site fails to have an unannounced audit within the 3-year period, its final announced audit may be refused by BRCGS and the site will become uncertificated until an unannounced audit has been completed.

2.1.4 Nominating non-audit days for the mandatory unannounced audit

Applicable only to the mandatory unannounced audit.

Compliance with the Standard is expected to be maintained at all times, so the site should always be 'audit ready'. However, there may be dates when an audit genuinely cannot take place, such as when there is a planned customer visit. Therefore, a site may nominate up to 10 days when it is not available for an audit.

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Sites on a 6-month audit schedule (e.g. sites certificated to the Standard with grade C or D) may nominate up to 5 days.

Days when the site is not operating (e.g. public holidays and site shutdowns) are not included with the nominated 10 days (or 5 days). The certification body must be notified of any such non-operational days, including the dates and reasons, at least 4 weeks in advance. The certification body may challenge the reason where this does not appear appropriate, and at its discretion accept these nominated dates. Certification bodies are expected to operate discretion in the case of emergencies.

It is a condition of the unannounced audit that the auditor shall be granted access to the site for the audit on arrival (see Section- 2.7.4).

2.1.5 Duration of the audit

Before the audit takes place, the certification body shall indicate the approximate duration of the audit. The typical duration of an audit is 1.5-3 days (typically 8-9 hours/day, but never in excess of 10 hours/day) at the site. Audits are usually on consecutive days, although there may be circumstances when this is not the case. A calculator has been developed to assess the expected time required to undertake an audit of any site to ensure consistency, and this shall be used as the basis for calculating the total audit duration. The calculator is available on the BRCGS website.

The calculation for the audit duration is based on:

- the number of employees – as full-time equivalent manufacturing and warehousing employees per main shift, including seasonal workers
- the size of the manufacturing facility, including any external covered or uncovered storage areas in square metres
- the number of hazard analysis and risk assessment (HARA) studies included within scope – a HARA study corresponds to a family of products with similar hazards and similar manufacturing technologies.

□ It is recognised that other factors may also influence the calculation but are considered less significant and therefore shall not influence the audit duration by more than 30% of the total calculated audit time. These factors include:

- whether it is an initial certification audit
- shortfalls in the information provided prior to the audit, as specified in section 2.1.2
- the complexity of the manufacturing operation process
- the number of product manufacturing lines
- the age of the site and the impact on material flow
- the labour intensity of the manufacturing operations processes
- communication difficulties (e.g., language) the audit not being carried out in the first language of the auditor or the company
- the number of non-conformities recorded in the previous audit (requiring additional time to review the relevant systems and confirm implementation of effective preventive action)

- difficulties experienced during the audit requiring further investigation.
 - the quality of site preparation (e.g. documentation, hazard analysis and risk assessment, product safety and quality management systems).
 -

□ If additional storage facilities, locations or head office assessments are included within the audit process, additional time shall be allocated for this over and above that indicated by the audit calculator.

~~In the event that the audit against the Standard includes additional BRCGS modules or is intended to be combined with other audit standards, the total audit time will need to be appropriately extended. Details of combined audits shall be specified on the audit report.~~

Where the audit against the Standard includes modules or is intended to be combined with other audit standards, the total audit time will need to be appropriately extended. Details of combined audits shall be specified on the audit report.

The calculation for audit duration shall determine the expected amount of time needed to undertake the audit at the site. Additional time will be required for the review of any documentary evidence provided and completion of the final audit report.

Deviation from the calculated audit timeframe must be justified and specified on the audit report.

2.2 The on-site audit

The on-site audit consists of the following stages:

- **Opening meeting** - to confirm the scope and process of the audit.
- **Manufacturing ~~Production and storage~~ facility inspection** – to review the practical implementation of the systems, including observing product changeover procedures and interviews of personnel.
- **Document review** – a review of the documented HARA and product safety and quality management systems.
- **Traceability challenge** – including a review of all relevant records of manufacturing production (e.g. raw material intake, ~~production~~ manufacturing records, finished product checks and specifications). This is a vertical audit – as specified within the BRCGS guidance document on audit techniques.
- **Review of the manufacturing facility inspection** – to verify and conduct further documentation checks.
- **Final review of findings by the auditor(s)** – preparation for the closing meeting.
- **Closing meeting** – to review audit findings with the site. (Note that non-conformities are subject to subsequent independent verification by the certification body management.

There is no requirement for the auditor to carry out the audit in the order listed, apart from the opening and closing meetings, but the audit must include all elements.

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The site shall fully assist the auditor at all times. It is expected that at the opening and closing meetings those attending on behalf of the site will be senior managers who have the appropriate authority to ensure that corrective action can be progressed if non-conformities are found. The most senior production or operations manager on site at the time of the audit or their nominated deputy shall be available at the audit, attend the opening and closing meetings, and be available for a discussion on product safety and quality culture (see Part II, clause 1.1.9).

The audit process gives emphasis to the practical implementation of product safety and quality procedures and general good manufacturing practices. It is expected that approximately At a typical audit, 30-50% of the total audit duration e.g. in a 1.5-day audit that a minimum of four hours of the audit will be spent auditing production manufacturing and site facilities, interviewing staff, observing operations and reviewing documentation in manufacturing areas with the relevant staff.

During the audit, detailed notes shall be made by the auditor regarding the site's conformities and non-conformities against the Standard and these will be used as the basis for the audit report.– The audit shall assess the nature and severity of any non-conformity and shall discuss this with the accompanying site representative at the time.

At the closing meeting, the auditor(s) shall present their findings and reconfirm all the non-conformities that have been identified during the audit; however, they shall not make comment on the likely outcome of the certification process. Information on the process and timescales for the site to provide evidence to the auditor of the corrective action needed to close any non-conformities must be given. A written summary of the non-conformities discussed at the closing meeting will be documented by the auditor either at the closing meeting or within 1 working day after completion of the audit.

The site will be required to confirm who was present as part of audit team at the audit, when they were present and what role they took during the audit, including the auditor(s) and any trainee, witnesses, technical experts or translators etc. present on site for each day of the audit, including start and finish times.

The declaration includes a clear statement that the site representative understands their responsibility in confirming the accuracy of information, and the consequences to certification status should the information be inaccurate.

A copy of the declaration will be left with the site.

The process for confirming this will be dependent on the Certification Body protocols.

At the closing meeting, the auditor will also provide the site with an explanation of the BRCGS Directory– which allows secure access to audit data to both the client and its nominated customers with the feedback systems available to communicate with the certification body and with BRCGS.

After completion of the certification process BRCGS will email the site contact with instruction on how to manage the sites entry in the BRCGS Directory and the BRCGS compliance programme, and how to register for service package benefits. The BRCGS Directory allows both the client and its nominated customer s secure access to the audit data, and the BRCGS compliance programme provides feedback systems enabling sites to communicate with the certification body and the BRCGS team.

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The decision to award certification and the grade of the certificate will be determined independently by the certification body management, following a technical review of the audit report ~~and the closing of non-conformities in the appropriate timeframe, (including non-conformities) and confirmation of the site's post-audit actions, including:~~

- ~~closing out of any non-conformities~~
- ~~completion of root cause analysis~~
- ~~development of a preventive action plan.~~

~~□ All site actions shall be completed within the appropriate timescale.~~

The company will be informed of the certification decision following this review.

2.3 Non-conformities and corrective action

The level of non-conformity assigned by an auditor against a requirement of the Standard is an objective judgement with respect to ~~level severity and risk and~~. It is based on evidence collected and observations made during the audit. This is verified by the certification body management.

2.3.1 Non-conformities

There are three levels of non-conformity:

- **Critical**– Where there is a critical failure to comply with a product safety or legal ~~issue requirement~~.
- **Major**– Where there is a substantial failure to ~~meet comply with the statement of a clause or any requirements of~~ the requirements of a 'statement of intent' or any ~~clause requirement~~ of the Standard, or ~~where~~ a situation is identified which would, on the basis of available objective evidence, raise significant doubt as to the conformity of the product being ~~supplied manufactured~~.
- **Minor**– Where a ~~clause requirement~~ has not been fully met but, on the basis of objective evidence, the conformity of the product is not in doubt.

~~□ The objective of the audit is to provide a true reflection of the standard of the operation and level of conformity against the Standard. Consideration should therefore be given to awarding a single major non-conformity where minor non-conformities are repeatedly raised against a particular clause of the Standard. Clustering of a significant number of minor non-conformities against a clause and recording this as a single minor non-conformity is not permitted.~~

~~The certification body shall justify a high number (more than 20) of minor non-conformities where one or no major non-conformities are given. This shall be detailed on the audit report.~~

~~Any non-conformities from the previous audit shall be checked during the current audit to confirm that corrective action has been taken and is operating effectively. Any repetition of these same non-conformities in the current audit shall be noted and raising the status of repeated minor non-conformities to a major non-conformity shall be considered.~~

2.3.2 Procedures for handling non-conformities and corrective action

Following identification of any non-conformities during the audit, the site shall undertake corrective action to remedy the immediate issue, ~~(correction) and undertake an analysis of~~ the underlying cause of the non-conformity (root cause), ~~to~~

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and develop a preventive action plan to address the root cause and prevent recurrence.

The process for 'closing out' non-conformities depends upon the level of non-conformity and the number of non-conformities identified.

Critical non-conformities or a combination of non-conformities resulting in non-certification

In some circumstances the number or severity of non-conformities raised at the audit prevents the site from being certificated following that audit. This will be the case where:

- a critical non-conformity is raised and/or
- a major non-conformity against the statement of intent of a fundamental clause is raised and/or
- the number or type of non-conformities exceeds the limits for certification, as shown in Table 2.

□ The grading of non-conformities will be reviewed by the independent certification process of the certification body as soon as possible after the audit. Where the review confirms that a certificate cannot be awarded, the site will be required to undertake another full audit before assessment for certification.

Due to the nature and number of non-conformities, it is unlikely that these non-conformities can be addressed, and fully effective improvements implemented and established, within a 28-~~calendar~~-day period, although there may be some exceptions. Therefore, the re-audit shall not take place any earlier than 28 calendar days from the audit date.

Where this occurs at a certificated site, certification must be ~~withdrawn~~ immediately ~~withdrawn~~.

It is a requirement of some customers that they shall be informed when their suppliers have a critical non-conformity identified or when they fail to gain certification. In such circumstances the company shall immediately inform its customers and make them fully aware of the circumstances. Information on the corrective actions to be taken in order to address the non-conformities will also be provided to customers where required.

Major and minor non-conformities

No certificate shall be issued until major and minor non-conformities have been demonstrated as having been corrected, either permanently or via a temporary solution that is acceptable to the certification body.

For each non-conformity raised, the site shall, in addition to undertaking the necessary immediate corrective action, undertake a review of the underlying cause (root cause) of the non-conformity. The root cause shall be identified and a preventive ~~an~~-action plan to correct it, including timescale, shall be provided to the certification body. A summary of the root cause and proposed preventive action The proposed preventive action shall be included in the audit report.

Close-out of non-conformities can be achieved either by in any of the following ways:

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- objective evidence being submitted to the certification body, such as updated procedures, records, photographs or invoices for work undertaken
- remote audit techniques being used to assess corrective actions
- or by the certification body undertaking a further on-site visit.

An example of evidence submitted for the correction of a non-conformity is give in appendix 8

Where ~~the number and level of non-conformities identified at the audit would result in a~~ the audit would result in a grade of C or C+ with two major non-conformities, or a D or D+ if unannounced grade being awarded, the closure of non-conformities shall be by means of a further site visit or remote assessment (see section 2.4.1) to review the action taken. This visit shall be within 28 calendar days of the audit if a certificate is to be issued.

If satisfactory evidence of corrective action, the root cause analysis and a preventive action plan are not provided within the 28-calendar-day period allowed for submission following the audit, certification will not be granted. The site will then require a further full audit in order to be considered for certification.

For initial audits only, ~~if there is no temporary solution or if there is a justifiable delay to implementing a permanent solutions (e.g. lead time on capital expenditure) for a major non-conformity, then provided that an acceptable statement of explanation is received by the certificaotin body within 28 calendar days, the company may remain in the certification programme for up to 90 calendar days~~ are allowed to provide objective evidence of correction of any non-conformities identified at the audit. The site will, however, remain uncertificated and will only be certificated following verification of the corrective action being implemented.

~~For all minor non-conformities and major non-conformities raised at recertification audits, if satisfactory evidence is not provided within the 28-calendar-day period allowed for submission following the audit, certification will not be granted. In both instances, if the site cannot close out the non-conformity within the time period, the site will require a further full audit in order to be considered for certification.~~

Non-conformities from the previous certification audit shall also be checked during the next site audit to verify effective close-out ~~of the non-conformities and their root cause. Where the correction has been ineffective then a non-conformity shall be raised against clause 1.1.9.~~

For each non-conformity at the last audit, the auditor will therefore expect to see the following:

- **Corrective actions**– The site is required to implement corrective actions and report them to the certification body within 28 calendar days of the audit. The auditor shall therefore expect to see the corrective actions from the previous audit in operation (e.g. that the updated procedure submitted to the certification body as evidence of corrective action following the last audit is in use).
- **Root cause analysis**– After being completed by the site following the last audit, the root cause analysis will have been submitted to the certification body, and full details should be available if the auditor requires them.

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- **Preventive action** – At the time of the previous certification decision, the site will have submitted a preventive action plan to the certification body but might not have completed the actual preventive action. The auditor will therefore expect to see evidence that the site has been effective in preventing recurrence of the non-conformity.

□ Where the corrective action or preventive action has been ineffective, a non-conformity shall be raised against clause 1.1.10 in Part II.

The certification body shall review objective evidence of corrective action completed prior to awarding a certificate.

Audit confirmation

~~Following each audit, confirmation of completion shall be available on the BRCGS Directory within 10 calendar days. Details shall include the date of the audit, the audit scope and the non-conformity found. No audit grade will be included since the certification details, including the details of the non-conformity, will be under independent technical review prior to confirmation.~~

2.4 Grading of the audit

The purpose of the certification grading system is to indicate to the user of the report the commitment of the site to continual compliance and will dictate the future audit frequency. The grade is dependent on the number and severity of the non-conformities identified at the time of the audit. Non-conformities are verified by a technical review process by the certification body management. If the review results in a change in the number and/or severity of non-conformities, the site shall be notified.

Table 2 Summary of grading criteria, action required and audit frequency

Grade		Critical	Major	Minor	Corrective action	Audit frequency
Announced	Unannounced					
AA	AA+			5 or fewer	Objective evidence	12 months
A	A+			6–10	within	
B	B+			11–16	28 calendar days (90	
B	B+		1	10 or fewer	days for initial audits	
C	C+			17–24	Objective evidence	6 months
C	C+		1	11–16	within	
					28 calendar days (90	
					days for initial audits)	
C	C+		2	10 or fewer	Revisit required	6 months
D	D+			25–30	within	
D	D+		1	17–24	28 calendar days (90	
D	D+		2	11–16	days for initial audits)	

Not certified		1 or more			Certificate not granted. Re-audit required
				31 or more	
			1	25 or more	
			2	17 or more	
			3 or more		

Note that shaded cells indicate zero non-conformities.

2.4.1 Revisits

Where a revisit is required to review the action taken in response to the non-conformities identified at the audit (i.e. some sites with grade C and all sites with grade D), this will be scheduled to be completed within the timescale for certification (i.e. 28 calendar days for certification sites, and 90 days calendar days for initial audits.

The certification body shall assess whether a physical on-site revisit is required or whether a remote audit will provide an effective assessment of the actions taken to close out the non-conformities. Where a remote audit is considered effective, the certification body can offer this option to the site.

The primary focus of the revisit (whether physical or remote) will be on reviewing the effectiveness of the corrective actions taken. However, if any new non-conformities are identified then these must also be satisfactorily resolved before a certificate can be issued, although they will not affect the grading. The action taken to correct the non-conformity shall be recorded in the final audit report.

2.4.2 Documentary evidence and remote auditing

Where a revisit is not required, suitable evidence of corrective action shall be provided to the certification body within 28 calendar days of the audit (or for initial audits, 90 days for any major non-conformities). The evidence shall clearly demonstrate that adequate corrective actions have been taken and implemented. There are two options for submitting this evidence:

- **A remote audit of the corrective action**– To confirm that effective corrective action has been implemented (e.g. a review of documents, discussions with site staff, using webcams)
- **Provision of suitable documentary evidence**– For example, updated procedures, records, photographs, and invoices for work completed.
-

□ Where appropriate, if satisfactory corrective action cannot be effectively demonstrated to the satisfaction of the certification body, a revisit may be required before a certificate can be issued.

2.5 Audit reporting

Following each audit, a full written report shall be prepared in the agreed format. The report shall be produced in English or in another language, dependent upon user needs. Where the report is produced in a language other than English, the audit summary sections shall always be reported in English in addition to the other language.

The audit report shall provide the company and ~~users of the report such as~~ customers or prospective customers with a profile of the company and an accurate summary of the performance of the site against the requirements of the Standard.

The audit report must assist the reader to be informed of:

- the product safety controls in place and improvements since the last audit
- 'best practice' systems, procedures, description of equipment and fabrication of the facility
- non-conformities, the corrective action taken and plans to correct the root cause (preventive actions).

□ The report shall accurately reflect the findings of the auditor during the audit. Reports shall be prepared and issued so that the certification decision is confirmed within 42 calendar days of the completion of the full audit. Subsequently, the audit report shall be uploaded to and available from the BRCGS Directory within 49 days of the final day of the audit.

The BRCGS Directory is the source of accurate, authenticated and up-to-date certification status information. It enables a one-click audit report sharing option. Audit reports shall remain the property of the company commissioning the audit and shall not be released, whole or in part, to a third party unless the company has given prior consent or the release is otherwise required by law.

The audit report shall be uploaded to the BRCGS Directory in a timely manner irrespective of whether a certificate is issued. The owner of the audit report may allocate access to the audit report to customers or other parties in the BRCGS Directory.

The audit report and associated documentation including auditor's notes shall be stored safely and securely for a period of 5 years by the certification body, unless otherwise required by legislation.

2.6 Certification

After a review of the audit report and documentary evidence provided in relation to the non-conformities identified, a certification decision shall be made by the designated independent certification manager. Where a certificate is granted, this shall be issued by the certification body within 42 calendar days of the audit. The certificate shall conform to the format shown in Appendix 7. Logos used on certificates (e.g. the BRCGS and accreditation body logos) shall comply with their respective usage rules.

~~The certificate will detail:-~~

- ~~• the scope of the audit and any accepted exclusions from scope~~
- ~~• the audit option chosen (i.e. announced or unannounced) or whether the certificate is a reissue for an extension to scope~~
- ~~• the six-digit auditor registration number of the lead auditor.~~

~~The date of the audit specified on the certificate shall be the date of the audit relating to the granting of that certificate, irrespective of whether later visits were made to verify corrective action arising from the audit.~~

While the certificate is issued to the site, it remains the property of the certification body, and that body controls its ownership, use and display.

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2.7 Ongoing audit frequency and recertification

2.7.1 Scheduling re-audit dates

~~The ongoing audit schedule and choice of audit programme shall be agreed between the site and the certification body. The frequency of announced audits will be 6 or 12 months and is dependent upon the performance of the site at an audit as reflected by the grade (see Table 1).~~

~~The re-audit due date of the subsequent audit shall be calculated from the date of the first day of the initial audit (irrespective of whether further site visits were made to verify corrective actions arising from the initial audit) and not from the certificate issue date.~~

~~Subsequent audits of certificated sites shall be carried out either 6 or 12 months after the previous audit due date, depending on the number and type of non-conformities identified at that audit (see Table 2). If it is an announced audit, it shall be scheduled to occur within a 28-calendar-day time period up to the next audit due date. This allows sufficient time for corrective action to take place in the event of any non-conformities being raised, without jeopardising continued certification.~~

~~Table 3 provides worked examples in accordance with the announced and mandatory unannounced recertification audits.~~

~~It is the responsibility of the site to maintain certification, and the BRCGS Directory sends automatic reminders. Where an audit is delayed beyond the due date, except in justifiable circumstances (see section 2.7.3), this shall result in a major non-conformity being awarded at the next audit. Justifiable circumstances shall be documented in the audit report.~~

~~For details on scheduling the mandatory unannounced audit, see section 2.1.3. The unannounced audit shall take place during normal site operations unless other arrangements have been agreed in advance with the site. However, the site must not be notified of the proposed audit date in advance.~~

~~The unannounced audit certificate will supersede the existing certificate. It will be issued within 42 days of the audit, assuming that certification is achieved (based on the number and severity of non-conformities and completion of corrective actions). The certificate will have an expiry date based on the expiry date of the previous certificate, plus 6 or 12 months (depending on the grade achieved).~~

~~The site shall be responsible for maintaining valid certification, while the certification body shall assume responsibility for maintaining the ongoing audit programme. Where a site cannot be certificated because of the number or level of non-conformities identified during the audit, the site will require a further full audit before certification can be considered. Once the site has addressed the non-conformities that were raised, the new audit can be arranged. The reaudit shall not take place any sooner than 28 calendar days from the audit date. If the audit was a mandatory unannounced audit, the re-audit may be announced. The re-audit shall be completed by the same certification body unless a concession is granted by BRCGS for a change of certification body during this period. It should be noted that the site must have at least one unannounced audit every 3 years, and this frequency is not expected to change as a result of a failed audit.~~

Table 3– Worked examples of an initial audit followed by announced and unannounced recertification audits

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<u>Announced/unannounced</u>	<u>Audit date</u>	<u>Next audit due date</u>
<u>Initial audit at site (announced)</u>	<u>1–2 June 2025</u>	<u>1 June 2026</u>
<u>Re-audit (announced)</u>	<u>20–21 May 2026 (audit within 28 calendar days prior to the audit due date)</u>	<u>1 June 2027</u>
<u>Re-audit (1 in 3 unannounced) (Audit window 01/02 - 01/06)</u>	<u>1–2 March 2027 (audit within 4 months prior to the audit due date)</u>	<u>1 June 2028</u>
<u>Re-audit (announced)</u>	<u>20–21 May 2028 (audit within 28 calendar days prior to the audit due date)</u>	<u>1 June 2029</u>
<u>Re-audit (announced)</u>	<u>20–21 May 2029 (audit within 28 calendar days prior to the audit due date)</u>	<u>1 June 2030</u>
<u>Re-audit (1 in 3 unannounced) (Audit window 01/02 - 01/06)</u>	<u>10–11 March 2030 (audit within 4 months prior to the audit due date)</u>	<u>1 June 2031</u>

If the site chooses to change certification body or GFSI-benchmarked scheme, this does not change the requirement for the site to receive an unannounced audit. Therefore, the site must ensure that the new certification body is aware that the site is already certificated and provide the date of its last unannounced audit. The certification body will also require evidence of the site's audit history (e.g. a copy of the most recent audit report) so that the 3 year cycle can be maintained.

2.7.2 Certificate expiry – justifiable circumstances

There will be some circumstances where the certificate cannot be renewed on the 6-month or 12-month basis due to the inability of the certification body to conduct an audit. These justifiable circumstances, which would not result in the assigning of a major non-conformity (Part II, clause 1.1.102), are applicable when the site is:

- situated in a specific country or an area within a specific country where there is government advice not to visit and there is no suitable local auditor
- within a statutory exclusion zone that could compromise product/personal safety
- in an area that has suffered a natural or unnatural disaster, rendering the site unable to produce or the auditor unable to visit
- affected by conditions that do not allow access to the site or restrict travel (e.g. heavy snow)

Moving the audit date to a more 'acceptable' later date for reasons of combining audits, lack of personnel or undertaking building work are not acceptable reasons for missing the due date.

It is not a justifiable reason to delay audits where sites are not in full manufacture; however, audits must be undertaken while products are being manufactured. ~~There may be periods in the year where a manufacturing site has an operational~~

~~'shutdown' (i.e. the site is not producing any products and a small staff may be on site for maintenance, installation of new equipment and other activities). Where a re-audit due date falls within this period, the audit may only be brought forward, and the site shall ensure that all requirements are complied with during the shutdown and upon restarting production.~~

If the renewal of the certificate is prevented due to these exceptional circumstances, the customer may still decide to take products from that site for an agreed time, as customers may still ~~be able to~~ demonstrate legal compliance by other means, such as risk assessment and complaints records, to show that the site is still competent to continue production manufacture until another audit can be arranged.

2.7.3 Audits undertaken prior to due dates

The due date of a renewal audit occurs within a 28-calendar-day window prior to the 6-month or 12-month anniversary of the initial audit.

In some circumstances it is possible to undertake the audit earlier than the due date; for example, to reset the audit dates to allow combined audits with another scheme, or to include a product that is produced during a different period. Where an audit date is brought forward, the following rules shall apply:

- The audit report will detail the reasons why an audit has been brought forward
- The next audit due date will be 'reset' to the 12 months (or 6 months, depending on grade) from this 'new' audit date
- The certificate (should it be issued) shall have an expiry date of 12 months (or 6 months, depending on grade) plus 42 calendar days from the new audit date.

~~□ 2.7.4 Refusal of a company to undertake the unannounced audit~~

~~Sites are obliged to accommodate the auditor and allow the audit to commence upon the auditor's arrival at the site. Sites can nominate days when the audit cannot take place; however, they must do so in advance (see section 2.1.4).~~

~~Therefore, if the auditor arrives for the audit and is denied access, the site's certification will be suspended. The site shall remain suspended until a new unannounced audit can be completed. Since the new audit will be unannounced, the site shall not be told the new audit date, which may occur at any time within the 4 months following the refused audit. The audit shall be completed by the same certification body unless a concession is granted by BRCGS for a change of certification body during this period.~~

~~Liability for the auditor's time shall be covered by the certification body's contract with the site. Therefore, if access is denied, the site may also be liable for the auditor's costs.~~

2.7.5 Non-availability of key staff at the opening and closing meetings or during the audit

The Standard requires the most senior production or operation manager (i.e. the person who is responsible for the 'hands on' running of the site) to be present at the opening and closing meetings (clause 1.1.9) and for relevant staff to be available during the audit.

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Where a key member of staff (most senior production or operations manager is absent on the day of the audit due to other commitments, a nominated deputy must be available (clause 1.1.9).

Therefore, the absence of a key member of staff shall not be accepted as a reason to prevent an audit going ahead.

2.7.6 No ~~production~~-manufacturing activity on the day of the unannounced audit
 As part of the audit planning, the site must notify the certification body of any days or times when operations are not undertaken. If the unannounced audit takes place on a date when the site is supposed to be operational, but on arrival the auditor finds that there is either no ~~production~~-manufacturing or the only products being handled are outside the scope of the audit, then the audit cannot go ahead. A further unannounced audit will need to be arranged.

Liability for the auditor's time shall be covered within the certification body's contract with the site (see section 2.7.4).

2.7.7 Changing the certification body for an early re-audit

In addition to the situations described in section 2.7.3, an early re-audit may occasionally be requested by a site – usually shortly after the previous audit or following a failure to be certificated. This often occurs because the site wants to improve its audit grade. In this situation, the early re-audit must be completed by the certification body that issued the current certificate.

However, in exceptional circumstances and if agreed in advance by BRCGS, a site may be permitted to change the certification body for this early reaudit. Justification for changing the certification body in this situation shall be provided in writing to the new certification body, who in turn shall submit it to BRCGS for consideration through the formal concession process. Where a change in certification body in this instance has not been agreed in advance, a re-audit by the new certification body will be null and void and will not be accepted in the BRCGS Directory.

This requirement applies only when an early re-audit has been requested; it does not change the process for re-audits completed to the normal 6- or 12-month schedule.

3 Blended announced audit protocol – two-part announced audit

This is a two-part audit consisting of a remote audit followed by an on-site audit.

The blended announced audit scheme allows the certification body to consider which requirements of the Standard may be audited using ICT to conduct an off-site remote assessment. This divides the audit requirements into two separate audits, comprising:

- **the off-site remote audit** – predominantly based on a review of documents and records, and may be planned to ensure that the appropriate staff are available to retrieve and discuss the records
- **the subsequent on-site audit** – mainly focused on the site's operating practices (manufacturing production facility inspection) housekeeping, fabrication, manufacturing operations, storage and product handling. This will also include the traceability vertical audit.

The certification body shall have a documented process for undertaking blended audits that ensure compliance with IAF MD4:2018.

Additional information on the processes for blended audits is available in BRCGS080: Blended Audits – Remote Auditing Using ICT (available from the BRCGS website). Sites opting for the blended announced audit option are also required to have an unannounced audit at least once every 3 years (see section 2).

Audit planning

3.1.1 Selection of the blended audit option

This option is available for recertification audits only, not for the first BRCGS audit at a site or for audits at sites not holding a current BRCGS certificate.

The blended audit can be used irrespective of the site's previous grade (i.e. all grades from AA to D are eligible); however, the grade will be taken into account during the pre-audit risk assessment (see section 3.1.5).

The certification body can decide whether to offer and/or accept the blended audit option following the risk assessment.

Before planning the remote audit element of the audit, the certification body shall consider the willingness of the site to consent to the use of remote auditing by ICT. The availability of ICT is also a factor in the effective completion of this audit. It is important that both parties mutually agree to this option.

3.1.2 Preparation by the company

The preparation by the company is mainly the same as for the announced audit scheme (see section 2.1.1).

However, additional consideration is needed for the remote part of the audit. Examples include ensuring the availability of appropriate IT systems, agreement on any confidentiality, security and data protection (CSDP) requirements (see section 3.1.6), and the need to facilitate the audit in a quiet environment to avoid background

noises and interference (e.g. considering the availability of office space and the use of noise-cancelling technology such as 'mufflers on microphones or headsets).

3.1.3 Information to be provided to the certification body for audit preparation

The information to be provided to the certification body is same as for the announced audit scheme (see section 2.1.2.).

3.1.4 Scheduling the mandatory unannounced audit

Sites opting for the blended announced audit option are required to have an unannounced audit at least once every 3 years. Details of the protocol for the mandatory unannounced audit are given in section 2.

3.1.5 Pre-audit risk assessment

The certification body shall undertake a full risk assessment to determine whether audit objectives can be achieved remotely. The risk assessment shall include the ability of the company to receive a remote audit, including the:

- historical audit performance of the site, including the risks from complaints and recalls
- availability of documentation and records in electronic form, and the site's willingness to share these remotely (including any limitations)
- capability of the certification body to conduct the remote audit (e.g. trained auditors, access to an IT system that both the certification body and the company will be able to use)

- capability of the site staff to utilise technologies used in remote audit techniques, including on-site video.

Any limitations on document-sharing and record-sharing shall be understood before the audit.

The pre-audit risk assessment is not included in the calculation of the audit duration.

3.1.6 Confidentiality, security and data protection

The certification body shall consider local data protection and privacy laws (as stated in IAF MD4:2018, clause 4.1). It is important that, if ICT (such as video) is utilised, the relevant consents have been sought from the individuals involved to ensure compliance with local privacy regulations.

To prepare for the use of ICT, all requirements (certification, legal and customer) related to confidentiality, security and data protection shall be identified, and actions taken to ensure their effective implementation. Evidence of agreements related to confidentiality, security and data protection (CSDP) must be available. The CSDP criteria shall be acknowledged by all participants, and measures to ensure confidentiality and security shall be confirmed during the opening meeting.

Where documented information is analysed, it shall be shared in a secure and agreed system, such as a cloud-based, virtual private network or other file-sharing system utilising CSDP guidelines. Once the audit is complete, the auditor shall delete from their system, or remove access to, any documented information and records that are not required to be retained as objective evidence.

Auditors must not take screenshots or record videos of auditees as audit evidence. Any screenshots of documents, records or other kinds of evidence must be authorised in advance by the site being audited. In the case of non-fulfilment of these measures or non-agreement of information security and data protection measures, the certification body shall not use the blended audit option.

3.1.7 Selection of clauses for remote and on-site audits

As a minimum, the on-site audit shall include inspection/physical verification of good manufacturing practices and implementation of the product safety and quality management system, including hazard analysis and risk assessment and related activities (e.g. the effective operation of prerequisite programmes, verification of the process flow diagram, critical control measure monitoring and verification) and the traceability challenge.

In addition, the requirements in the Standard are colour-coded to indicate which requirements may be audited remotely and which requirements must be audited during the on-site audit (see Table 4).

Table 4– Key for colour-coding of requirements

<u>Audit of records, systems and documentation</u>	<u>Remote permitted</u>
<u>Audit of production facilities and good manufacturing practices</u>	<u>On-site</u>
<u>Requirements assessed in both</u>	

Clauses that are dual-coloured must be audited during both parts of the audit. It is important to note that although the colour-coding indicates the clauses that may be audited remotely, the certification body's pre-audit risk assessment (see section 3.1.5) may identify clauses that require on-site assessment, even though they relate to documents or records.

3.1.8 Duration of the blended audit

The total audit duration is the same regardless of whether the audit is completed fully on site (announced or unannounced) or as a blended audit using both remote and on-site auditing (see section 2.1.5).

The duration does not include time spent on audit planning, the risk assessment or report writing.

The remote part of the audit shall not exceed 5700% of the total audit duration. It should be noted that 7050% represents the maximum proportion of the audit that may be completed remotely. The actual duration of the remote audit will be dependent on the certification body assessment (i.e. the risk assessment in section 3.1.5). Therefore, it may be significantly less than the maximum permitted in some circumstances; for example, if:

- additional risks are identified
- specific documents are not available for the remote audit
- the nature or volume of complaints or recalls is a concern
- the historical performance of the site has been a concern
- the certification body identifies clauses that need to be audited on site, even when they relate to documents or records.
-

□ If additional storage facilities, locations or head office assessments are included within the audit process (see sections 1.6.3-1.6.5 and Appendix 34) then additional time shall be allocated for this.

The time allocated for the on-site audit may also be adjusted based on the findings from the remote audit; for instance, more time may be required if a large number of non-conformities require an on-site review of corrective actions.

For the head office or central function, the remote audit can be completed using the colour-coding of the relevant clauses of the Standard. In some situations, this may mean that the auditor does not need to visit the head office as all the clauses are appropriate for remote audits. If the head office contains a mixture of clauses (i.e. some that require on-site audit and others that may be audited remotely), the site may elect to have either:

- a full on-site head office audit or
- a remote head office audit with the remaining on-site elements being assessed at each of the site audits.

The expected audit duration shall be notified to the site by the certification body in advance of the audit. Deviation from the expected audit duration must be justified and specified in the audit report.

3.1.9 Auditor selection

The auditor conducting the blended audit shall be fully competent and qualified in the appropriate manufacturing categories (i.e. the same auditor category requirements apply to both the remote and on-site audits).– (See Part III section 1.7) Where audit teams are used, the audit report shall indicate whether each auditor has completed remote and/or on-site activities.

If a technical expert is used during the audit, the documents shared by the site shall also be made accessible to the expert.

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Where different auditors are used for the remote and on-site audits, there shall be a clear handover process prior to the on-site audit to ensure that the auditor has all the necessary information to complete the audit in full and that all the requirements of the Standard are fully covered, either remotely or on site.

3.2 The site audit

3.2.1 The off-site remote audit

Scheduling the remote audit

The audit shall be announced, and the site shall agree a mutually convenient date with the certification body.

The remote audit shall be conducted first (i.e. before the on-site audit). However, where the BRCGS audit is combined with the audit for another GFSI-benchmarked Standard, the sequence of the two parts of the audit may be reversed (i.e. the on-site audit would be completed first, followed by the remote audit).

The remote audit shall take place within the 56 calendar days before the audit due date. This is to ensure that:

- there is sufficient time to complete the on-site audit before the audit due date (and within 28 calendar days of the remote audit, although it is recommended that the remote and on-site audits are as close to each other as possible)
- the site has sufficient time (28 calendar days) to close out any non-conformities raised (see section 3.3)
- the certification body has sufficient time (42 calendar days) to make a certification decision after the on-site audit and before the site's current certificate expires.

Preparation for the remote audit

Preparation for the audit can be summarised in the following steps:

- The certification body shall prepare a clear audit plan which highlights the documents that will be needed remotely. This plan shall be shared with the site prior to the audit.
- The certification body shall agree with the site the technical requirements for the remote audit – for example, internet access, meeting software that is usable by both site and auditor, and hardware (including webcams/cameras and microphones).
- BRCGS recommends that the certification body tests the compatibility of the ICT platform with the site, especially prior to the first blended audit at the site or when new ICT platforms will be used. If testing reveals issues that cannot be rectified then the audit shall be completed as a full on-site audit.
- Use of webcams/cameras shall be agreed.
- When assigning work to audit team members, including technical experts, this should take into consideration their ability to utilise the remote technologies.
- The remote audit shall be facilitated in a quiet environment wherever possible to avoid background noise and interference. The use of noise-

cancelling technology (e.g. 'mufflers on microphones' or headsets) should be considered.

- When no agreement is reached for the use of ICT for a remote audit, the audit will revert to a full on-site audit.

□ If it is not possible to maintain satisfactory conditions during the scheduled time of the remote audit, the auditor may decide to terminate it. This shall be recorded in the report. The remote audit may continue at a later date agreed between the two parties within the period described above.

In the event of the technology failing during the remote audit, the certification body and the site can reschedule, providing this occurs within the 28-calendar day window. The site may be liable to pay for the lost audit day where the failure is a site issue, and this should be covered in the contract between the certification body and the site. Ultimately, if the audit cannot be completed remotely then the auditor will need to complete the audit on site. This on-site audit will follow the protocol for the announced audit option (see section 2) and shall be completed prior to the audit due date.

Completing the remote audit

The remote audit consists of the following stages:

- **Opening meeting** – To confirm the scope and process of the audit
- **Document review** – The documents will have been confirmed by the certification body; for example, verification of the product safety and quality management system (e.g. hazard analysis and risk assessment, critical control measures monitoring)
- **Interviews/discussions with personnel** – For example, to discuss the document, policy or record being audited
- **Final review of findings** – Conducted by the auditor in preparation for the closing meeting
- **Closing meeting** – To review the audit findings with the site and confirm any non-conformities.

Good practice is to include sufficient breaks in the audit plan (for a remote audit these may need to be more frequent), so that site personnel and auditors are not continuously using a computer screen for a prolonged period.

The remote audit may also include a live video if required. Any live video shall not be recorded, but a record shall be kept of its duration and what was covered. This information is to be recorded in the audit report.

3.2.2 The on-site audit

Planning for the on-site audit

This is the same as for the announced audit option (see section 2.1).

The on-site audit shall be conducted within 28 calendar days of the remote audit and during the audit due window of the current certificate (i.e. during the 28 calendar days prior to the audit due date). It is recommended that the time between the remote and on-site audits is as short as practicable. In exceptional (but justifiable) circumstances, the certification body may ask BRCGS for an extension of up to 90 days.

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Completing the on-site audit

To ensure consistency, it is strongly recommended that the on-site audit should be carried out by the same auditor who carried out the remote audit. If this cannot be arranged, a clear handover process shall be in place prior to the on-site audit to ensure that the auditor has all the necessary information to fully complete the audit and that all the requirements of the Standard are covered, either remotely or on site. All auditors shall be qualified in the appropriate product categories (i.e. the same auditor category requirements apply to the remote audit and the on-site audit).

The on-site audit consists of the following stages:

- **Opening meeting**– To confirm the scope and process of the audit
- **Audit of site and storage facilities**– To audit practical implementation of systems, including, for example, auditing good manufacturing practices, accuracy of process flow diagram, product changeover and line start-up procedures
- **Any requirements identified**– For on-site audit during the risk assessment and remote audits
- **Discussions with site staff and managers**– For example, to confirm on-site procedures, the implementation of product safety and quality culture plans, process monitoring including critical control measures
- **Vertical audit, traceability challenge**– Including a review of all relevant records of production (e.g. raw material intake, production records, finished product checks and specifications)
- **Verification of the hazard analysis and risk assessment**– Review of critical control measures, prerequisites monitoring)
- **Review of production facility inspection** To verify and conduct any further comparison of documentation with actual practice
- **Final review of findings by the auditor** Preparation for the closing meeting
- **Closing meeting** To review the audit findings with the site (note that non-conformities are subject to subsequent independent verification by the certification body management).
-

□ The site shall fully assist the auditor at all times. It is expected that at the opening and closing meetings those attending on behalf of the site will be senior managers who have the appropriate authority to ensure that corrective action can be progressed if non-conformities are found. The most senior production or operations manager on site at the time of the audit shall be available to attend the opening and closing meetings and be available for a discussion on product safety and quality culture. Where the most senior production or operations manager is not on site at the time of the audit, the defined deputy must attend (see Part II, clause 1.1.9).

The audit process gives emphasis to the practical implementation of product safety procedures and general good manufacturing practices. At a typical audit, 30-50% of the total audit duration e.g. in a 1.5-day audit that a minimum of four hours of the audit will be spent auditing manufacturing and site facilities, interviewing staff.

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observing operations and reviewing documentation in manufacturing areas with the relevant staff.

At the closing meeting, the auditor shall present their findings and reconfirm all the non-conformities that have been identified during the audit; however, they shall not make comment on the likely outcome of the certification process. Information on the process and timescales for the site to provide evidence to the auditor of the corrective action needed to close any non-conformities must be given. A written summary of the non-conformities discussed at the closing meeting will be documented by the auditor either at the closing meeting or within 1 working day after completion of the audit.

The site will be required to confirm who was present as part of audit team at the audit, when they were present and what role they took during the audit, including the auditor(s) and any trainee, witnesses, technical experts or translators etc. present on site for each day of the audit, including start and finish times.

The declaration includes a clear statement that the site representative understands their responsibility in confirming the accuracy of information, and the consequences to certification status should the information be inaccurate

A copy of the declaration will be left with the site.

The process for confirming this will be dependent on the Certification Body protocols. At the closing meeting, the auditor will also provide the site with an explanation of the BRCGS Directory (which allows both the client and its nominated customers secure access to audit data) and the BRCGS compliance programme (including the feedback systems available to communicate with the certification body and the BRCGS team).

The decision to award certification and the grade of the certificate will be determined independently by the certification body management, following a technical review of the audit report (including non-conformities) and confirmation of the site's post-audit actions, including:

- closing out of any non-conformities
- completion of root cause analysis
- development of a preventive action plan.

All site actions shall be completed within the appropriate timescale.

The company will be informed of the certification decision following this review. After completion of the certification process, BRCGS will email the site contact with instructions on how to manage the site's entry in the BRCGS Directory and the BRCGS integrity programme, and how to register for service package benefits. The BRCGS Directory allows both the client and its nominated customers secure access to audit data, and the BRCGS integrity programme provides feedback systems enabling sites to communicate with the certification body and the BRCGS team

3.3 Non-conformities and corrective action

Any non-conformities identified during the remote and on-site audits shall follow the existing requirements of the scheme (see section 2.3). Evidence of the action taken to correct any non-conformities shall be submitted to the certification body within 28 calendar days of the on-site audit (i.e. within 28 calendar days of the completion of the blended audit).

For initial audits only, up to 90 calendar days are allowed to provide objective evidence of correction of any non-conformities identified at the audit. The site will,

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however, remain uncertificated and will only be certificated following verification of the corrective action being implemented

Verification of the preventive action plan and implementation of the corrective actions may take various forms (including further on-site assessment or the scrutiny of evidence submitted through ICT). Verification must be carried out by the certification body's technically competent personnel, who must use appropriate methods.

If a critical non-conformity or the number and level of other non-conformities identified at the remote audit (i.e. the first part of the audit) or the on-site audit (i.e. the second part of the audit), or as a result of the sum of both parts of the audit, would result in failure to achieve a certificate, the existing certificate for the site shall be immediately withdrawn. Where the critical non-conformity and/or number of non-conformities occurs during the remote (first) part of the audit, the existing certificate shall still be withdrawn immediately (i.e. after the remote audit) and not delayed until the second part of the audit has been completed.

3.4 Grading of the audit

The process for grading is the same as for the announced audit scheme (see section 2.4).

However, the grade awarded is based on the combination of non-conformities identified at the two audits (i.e. the sum of the non-conformities identified at the remote audit and the on-site audit).

Any non-conformities identified during the remote audit that were closed out and corrected before the on-site audit are still counted when calculating the grade.

3.5 Audit reporting

The audit reporting requirements are the same as for the announced audit scheme (see section 2.5). However, the report shall state 'Blended announced audit'. The audit report shall clearly identify the extent to which any ICT has been used in carrying out the audit and the effectiveness of ICT in achieving the audit objectives. The audit report shall include all the summarised information and findings of the remote audit and the on-site audit so that a single report can be uploaded to the BRCGS Directory.

The report shall also reference the dates and the duration of the two audits, including the records of the people who attended them. The requirements assessed during the remote audit shall be identified by an asterisk placed at the beginning of the information.

The final report will not be produced until the on-site audit has been completed.

3.6 Certification

The certification requirements are the same as for the announced audit scheme (see section 2.6).

The design of and information on the certificate are the same as for all audits against the Standard, except that the certificate shall state 'Blended announced audit'. The dates of both audits (remote and on-site) shall be included on the certificate. This certificate will supersede any existing certificate. It shall be issued within 42 days of the on-site audit and will have an expiry date based on the expiry date of the previous certificate plus 6 or 12 months, depending on the grade achieved.

3.7 Ongoing audit frequency and recertification

This is the same as for the announced audit option (see section 2.7).

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Sites that have opted into the blended announced audit option are required to complete a mandatory unannounced audit every 3 years (see section 2.1.3).

3.7.1 Scheduling re-audit dates

Subsequent announced audits can remain in the blended announced audit programme, irrespective of the site's previous grade (i.e. sites graded from AA to D can receive a remote audit). However, the certification body will include the previous grade within the pre-audit risk assessment (see section 3.1.5).

4 Unannounced audit protocol

This is a fully on-site unannounced audit.

The protocol of unannounced audits generally follows that of announced audits above; where it differs, this is outlined as follows.

This option involves a single unannounced audit against all the relevant requirements of the Standard.

~~This option requires that~~ The date of the audit shall not be notified to the site in advance of the audit. The audit will be unannounced and replace the normal scheduled audit. Although the audit may occur at any point from 9 months before the audit due date, it shall typically be within the last 4 months of the certification cycle. It can occur at any stage within the last 4 months of the audit cycle, including the 28 calendar days before the audit due date (i.e. at any point from 4 months before the audit due date).

4.1 Audit planning

4.1.1 Selection of the unannounced audit programme

~~Where the site is currently certificated, it~~ The site shall notify its certification body within 3 months of the last audit date of its intention to join or remain within the unannounced audit programme. This allows the site to select an alternative certification body if required. Although the audit may occur at any point from 9 months before the audit due date, it shall typically be within the last 4 months of the certification cycle. while allowing the audit to be undertaken at a time of the certification body's choosing.

Non-certificated sites may opt into the unannounced audit programme on the understanding that the initial audit may not occur for up to 12 months from the request.

4.1.2 Preparation by the company

The actual audit date will not be provided by the certification body and it is therefore important that the site has arrangements in place to receive an audit and facilitate the audit process.

Success at an unannounced audit relies upon the ability of the site to share information and knowledge within the site, to have effective deputies to cover in the absence of a particular manager, and a shared responsibility within the management team for product ~~feed~~ safety and compliance with the Standard.

4.1.3 Information to be provided to the certification body for audit preparation.

~~The site shall supply the certification body with background information when it opts into the unannounced audit programme to ensure the auditor is fully prepared and to provide the best opportunity for the audit to be completed efficiently. Where any changes occur on site (as those listed in sections 5.1 and 5.2 below), the site shall inform the certification body of these immediately once it has opted into the unannounced audit programme. The information will be requested by the certification body and may include (but is not limited to):-~~

- ~~• a summary of the site's hazard analysis and risk assessment and any critical control points (CCPs)~~
- ~~• the process flow diagram~~
- ~~• a simple site plan~~
- ~~• the management organisational chart~~
- ~~• the list of products or product groups included within the audit scope~~
- ~~• any requested exclusions from the audit scope~~
- ~~• typical shift patterns~~
- ~~• production schedules, to allow audits to cover relevant processes~~
- ~~• recent significant quality issues, withdrawals or customer complaints and any other relevant performance data.~~
- ~~•~~

~~The site shall make the previous year's audit report and certificate available to the certification body where this is a new contract.~~

~~As the audit will be unannounced it is likely that the certification body will also require~~ **In addition to the information specified in section 2.1.2,** the certification body will require information to plan for the logistics of the audit process. This may include:

- recommended local hotels
- specific site directions, GPS location, site entrance requirements, car parking
- a list of contacts when first arriving on site
- specific protective clothing arrangements
- any specific security arrangements to follow to gain access to the site
- any health and safety or other company information that needs to be reviewed by the auditor on arrival (e.g. health and safety video) to avoid unnecessary delays before entering production.

4.1.4 Nominating non-audit days

~~The unannounced audit programme allows sites the opportunity to nominate 15 days when the site is not available for an audit.~~

~~The dates must be provided at least 4 weeks in advance and the reason must be provided (e.g. a planned customer visit). The certification body may challenge the reason where this does not appear appropriate and at its discretion accept these nominated dates.~~

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~~Days when the factory is not operating, such as weekends, public holidays or planned shutdowns for site holidays or maintenance, are not included in the 15 days. Any such non-production days shall be notified to the certification body when opting into the unannounced scheme.~~

~~Compliance with the Standard is expected to be maintained at all times and the site should therefore always be 'audit ready'. However, there may be dates when an audit genuinely cannot take place, such as a planned customer visit. The unannounced audit programme therefore allows sites to nominate up to 10 days when they are genuinely not available for an audit. Sites on a 6month audit schedule (e.g. sites certificated to the Standard with grades C or D) may nominate a maximum of 5 days.~~

~~The dates and the reasons must be provided to the certification body within 3 months of opting into the programme. At the discretion of the certification body, other unavailable dates may be accepted when provided at least 4 weeks in advance of the next unavailable date. The certification body may challenge the reason where this does not appear appropriate and at its discretion accept these nominated dates.~~

~~Days when a site is not operating (e.g. weekends, public holidays and planned shutdowns for site holidays or maintenance) are not included within the 10 days (or 5 days). Any such non-production days shall be notified to the certification body when opting into the unannounced scheme.~~

Certification bodies are expected to operate discretion in the case of emergencies. It is a condition of electing to join the unannounced audit programme that the auditor shall be granted access to the site for the audit on arrival. If access is denied, the site will be liable for the auditor's costs and will revert to the announced audit scheme. At the discretion of the certification body, the existing certificate may also be suspended or withdrawn.

4.1.5 Audit duration

The typical duration of an audit does not differ from that of an announced audit, subject to the variances described in [section 2.1.5](#).

4.2 The on-site audit

Sites opting for the unannounced audit programme shall be obliged to accommodate the auditor and allow the audit to start immediately on arrival at the site. The audit process will follow the same procedures as outlined for an announced audit. There will be a short opening meeting, after which the site manufacturing ~~production~~ facility inspection will be expected to commence within 30 minutes of the auditor arriving on site.

The on-site audit will follow the same stages as an announced audit (see section 2.2).

4.3 Non-conformities and corrective action

Non-conformities and corrective actions are the same as for the announced audit (see [section 2.3](#)).

4.4 Grading of the audit

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The process for grading is the same as for the announced audit (see section 2.4). The grade awarded following certification shall be based on the number and severity of the non-conformities, as outlined in Table 2. Note that the grade will have the addition of a plus symbol after the grade (i.e. AA+, A+, B+, C+ or D+) to indicate that the audit was unannounced.

4.5 Audit reporting

The audit reporting requirements are the same as for the announced audit; however, the report shall state 'unannounced option' (see section 2.5).

4.6 Certification

The certification requirements are the same as for the announced audit (see section 2.6). However, the certificate shall state 'unannounced option'. This certificate will supersede the existing certificate. ~~The certificate shall be issued within 42 calendar days of the audit and~~ The certificate shall have an expiry date based on that of the previous certificate plus 6 or 12 months, depending on the grade, provided that the site remains within the unannounced audit programme scheme. ~~This ensures that where the audit occurs before the expiry of the current certificate and the site remains within the unannounced scheme, it is not disadvantaged by a shorter certificate life and increased frequency of audits.~~

If the site decides to return to the announced audit programme, the certificate expiry date will be 6 or 12 months from the date of the unannounced audit.

This ensures that where the audit occurs before the expiry of the current certificate and the site remains within the unannounced programme, it is not disadvantaged by a shorter certificate life and increased frequency of audits.

4.7 Ongoing audit frequency and recertification

4.7.1 Scheduling re-audit dates

The site can choose whether to:

- remain within the unannounced programmes (fully on site)
- revert to the announced audit programme (fully on site or blended).

If the site wishes to remain in an unannounced programme, the next audit will be unannounced. ~~The audit may occur at any stage from 3 months after the last audit date to 42 calendar days prior to the certificate expiry date; however, this shall typically be within the last 4 months of the certification cycle. The audit may occur at any stage within the last 4 months of the audit cycle, including the 28 calendar days before the audit due date.~~ This allows sufficient time for corrective action to take place in the event of any non-conformities being raised without jeopardising continued certification.

It is the sites responsibility to ensure all requirements are met to ensure that the unannounced audit can be undertaken in accordance with the audit protocol (clause 1.1.8).

It is the responsibility of the certification body to ensure that the audit is undertaken within the certification window so that the late audit non-conformity clause (Part II, clause 1.1.8) shall not apply.

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If the site wishes to withdraw from the voluntary unannounced audit programme, the next audit will be scheduled to occur within the 28 calendar days up to and including the anniversary of the last audit date; this ensures that the maximum time between audits is not more than a year. Where the site received a grade of C+ or D+ at the last audit and wishes to withdraw from the voluntary unannounced audit programme, the next audit due date will be 6 months after the last audit date, and the audit will occur within the 28 calendar days prior to this date.

5 Additional modules

The Standard has been designed to enable additional modules to be included with the routine audit. The additional modules will enable sites to demonstrate compliance with specific sets of requirements to meet specific market or customer requirements.

It is expected that modules will be developed and become available for use throughout the life of this issue of the Standard. A list of the modules, the applicable requirements and any specific protocol for a module will be available on the BRCGS website and on BRCGS Participate.

The additional modules can be included ~~added with either to any~~ of the full certification audit options ~~(i.e. announced, blended or unannounced).~~

The general protocol for the additional modules broadly follows the principles of the Standard; however, details will be given with each module.

The site should inform the certification body that an additional module is to be included within the scope of the audit. This ensures that sufficient extra time can be scheduled and that an auditor with the appropriate qualifications for the additional module is selected.

The site shall ensure that the production-manufacturing programme at the time of the announced audit covers products for the intended additional module where this is applicable. Where the site has opted into the unannounced audit programme, detailed information shall be given to the certification body regarding production manufacturing planning so that an appropriate audit date can be selected. At its discretion, where there is a lack of information or no potential for choice of audit dates, the certification body may be unable to accommodate the request for the additional module at the unannounced audit.

There will be no grading of the additional modules. The modules will either be certificated or not. Any non-conformities identified when assessing a module shall not be taken into account when deciding the grade for certification against the Standard.

Note that the modules are certificated separately from the Standard; however, where certification to the Standard is not achieved, certification for the module cannot be awarded, irrespective of whether the requirements of the module have been met.

6 General protocol – post audit

6.1 Communication with certification bodies

If any ~~In the event that any~~ circumstances change within the site that may affect the validity of continuing certification, the site ~~shall~~ must immediately notify the

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certification body promptly or within the timescales defined within the Standard. Circumstances may include:

- legal proceedings with respect to product safety or legality, or that which significantly affects the operation of the site
- significant product safety, legality or quality incidents
- significant damage to the site (e.g. natural disaster such as flood or damage by fire)
- change of ownership (see glossary)
- any significant change to the manufacturing operations or scope
- significant staff changes or prolonged shutdowns (e.g. considerable staff losses or the loss of key product safety roles).

The certification body in turn shall take appropriate steps to assess the situation and any implications for the certification and shall take appropriate action.

Information shall be provided to the certification body by the site on request so that an assessment can be made as to the effect on the validity of the current certificate. The certification body may, as appropriate:

- confirm the validity of the ~~certificate is not affected~~ certification
- suspend certification pending further investigation
- require further details of the corrective action, root cause analysis and preventive action plan implemented by the site
- undertake a site visit to verify the control of processes and confirm continued certification
- withdraw certification
- issue a new certificate with the new owner's details.
-

Changes to the certification status of a site shall be recorded in the BRCGS Directory.

In the event of an incident, the effectiveness of corrective and preventive actions taken by the site will also be reviewed at the next scheduled BRCGS audit to confirm their implementation and continued effectiveness.

6.2 Position statements

During the lifetime of the Standard, the BRCGS technical advisory committee (TAC) (see Part IV) may be asked to:

- review the wording of a requirement in the Standard or protocol
- provide an interpretation for a requirement
- rule on the grading of a non-conformity against a clause.

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The outcome will be published on the BRCGS website as a 'position statement'. Position statements are binding on how the audit and certification processes are carried out. They are considered to be an extension of the Standard. Sites shall be aware of any published position statements relating to the Standard and, where necessary, ensure that the information is transferred into action. Non-compliance with a relevant position statement may result in a non-conformity against clause 1.1.79 or a specific clause of the Standard.

Position statements are published on the BRCGS website and on BRCGS Participate. They are also communicated electronically to companies and certification bodies (e.g. in bulletins and newsletters).

More information on the development and publication of position statements can be found in Appendix 9.

6.3 Extension to scope

Once certification has been granted, any subsequent changes that are required to be included in the scope of certification (e.g. additional significant products manufactured or processes undertaken by the site) must be communicated to the certification body. The certification body shall assess the significance of the new products or processes and decide whether to conduct a site visit to examine the aspects of the required extension to scope.

A revisit is required before granting a scope extension in the following circumstances:

- inclusion of manufacturing facilities not taken into account in the original audit
- inclusion of a new processing technology (e.g. blow moulding where previously only injection moulding was included) within the scope
- inclusion of new products which introduce a significant new risk to the facility (e.g. new inclusion of recycled material)

~~A revisit is less likely where : new products are added to the are extensions to the existing ranges produced on existing equipment.
a new polymer is added to the portfolio of a thermoformer but the process does not change
a simple additional process is included in the activities of the site.~~

Where an extension to scope is required shortly before the certificate is due to expire, it may be more appropriate to undertake a full audit and issue a new certificate. This option should be agreed between the certification body and its client site prior to undertaking the extension to scope audit.

When a revisit is considered necessary, the duration of this visit will vary depending on the aspects to be examined for the required extension to scope. The site visit should be conducted along the same principles as the original audit (i.e. including an opening meeting, inspection of the operation of the manufacturing operations process, documentation trails and closing meeting). The revisit should be announced, irrespective of whether the site is certificated to the announced or unannounced programme scheme.

Identified non-conformities should be documented and actioned within the normal protocol of the Standard, in other words, (i.e. the company has 28 or 90) calendar

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days to provide appropriate evidence of close-out and the certification body should review the information and confirm the certification decision in the normal manner. The additional non-conformities raised at the site visit will affect neither the current certificated grade nor continued certification. However, if practices are seen that give the certification body cause to doubt continued certification (e.g. the identification of a critical non-conformity) then the certification body shall arrange a full re-audit of the site. In these circumstances the current certificate shall be withdrawn.

A visit report should be documented but shall not be in the format of the standard BRCGS audit report. A short explanation of the nature of the visit, what was audited and the conclusions should be given. The visit report should document what controls are in place and confirm the effectiveness of these controls. It should be clear in the report what aspects were looked at and what was excluded.

The site's current certificate will be superseded by any new certificate issued. The certificate must use the same expiry date as detailed on the original certificate. The due date of the next full audit will therefore remain the same and this should be made clear to the site by the certification body when arranging extension to scope visits. The grade shall also remain the same.

The certificate should include identification that it was a scope extension and the date of the visit.

6.4 Certification withdrawal

The certificate may be withdrawn by the certification body in some circumstances where the site may no longer comply with the requirements of the Global Standards certification scheme and ISO/IEC 17065. Examples of these instances are:

- evidence that the site no longer complies with the requirements and protocol of the Standard, raising significant doubt of the conformity of the products produced
- failure to implement adequate corrective action plans within appropriate timescales
- evidence of falsification of records
- failure to fulfil contractual obligations (e.g. payment failure).
-

□ 6.5 Appeals

The company has the right to appeal the certification decision made by the certification body and any appeal should be made in writing to the certification body within 7 calendar days of receipt of the certification decision.

The certification body shall have a documented procedure for the consideration and resolution of appeals against the certification decision. These investigative procedures shall be independent of the individual auditor and certification manager. The documented appeals procedure of the relevant certification body will be made available to the site on request. Appeals will be finalised within 30 calendar days of receipt. A full written response will be given after the completion of a full and thorough investigation into the appeal.

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It should be noted that where an appeal is made against a non-conformity, this does not delay or postpone the corrective action, root cause analysis or development of a preventive action plan (see section 2.3.2). The relevant information is still expected within 28 calendar days of the completion of the audit.

In the event of an unsuccessful appeal, the certification body has the right to charge costs for conducting the appeal.

6.6 Surveillance of certificated companies

For certificated companies, ~~where appropriate,~~ the certification body or BRCGS may carry out further audits or question activities to validate continued certification at any time. These visits may take the form of announced or unannounced visits to undertake either a full or part audit. These audits form part of the BRCGS ~~integrity compliance~~ programme with random visits to certificated sites. Refusal of access to the site or unwillingness to cooperate with the auditor may affect certification status.

Any non-conformities identified at a visit must be corrected and closed out within the normal protocol (i.e. within 28 calendar days of the visit) and reviewed and accepted by the certification body. If there is no intention on behalf of the site to take appropriate corrective actions or the corrective actions are deemed inappropriate, certification shall be withdrawn. The ultimate decision to suspend or withdraw certification remains with the certification body. Any change in certification status shall be notified to BRCGS by the certification body and the status in the BRCGS Directory shall be amended accordingly.

In the event that certification is withdrawn or suspended by the certification body, the company shall immediately inform its customers and make them fully aware of the circumstances relating to the withdrawal or suspension. Information on the corrective actions to be taken ~~in order~~ to reinstate certification status should also be provided to customers.

6.7 BRCGS logos

Achieving BRCGS certification is something of which to be proud. Companies that achieve certification and have no exclusions from their scope (see section 1.6.2) are qualified to use the BRCGS packaging logo on site stationery and other marketing materials. ~~Information and conditions relating to the use of the BRCGS logo are available at www.brcgs.com.~~

Where a site has traded products or raw materials on site but wishes them to be excluded from the scope of the audit, this will be recorded as an exclusion from scope on the audit report and certificate. The BRCGS Packaging Certificated logo can be used, but shall not be used for promoting traded products, even when included in the certificated scope.

~~Information and conditions relating to the use of the BRCGS logo is available from brcgs.com/resources/brcgs-brand-guidelines brcgs.com/resources/brcgs-brand-guidelines. Note that the packaging logo shall not be used in promoting products purchased for resale by a site (traded products).~~

If a site is no longer certificated because of certificate expiry, withdrawal or suspension, it shall no longer use the logo or certificate claiming certification.

The BRCGS logo is not a product certification mark and neither it nor any reference certification may be used on products or product packaging. Any certificated site found to be misusing the logo will be subject to the BRCGS complaints and referral process (see Part IV) and may risk suspension or removal of its certification.

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The BRCGS logo may not be used by companies that do not include all products that are manufactured, processed, packed or labelled on site within the audit scope.

6.8 BRCGS Directory

The BRCGS Directory (www.brcgsdirectory.com) is the database of all audits conducted against a BRCGS Standard and all BRCGS-approved certification bodies and all auditors ~~and their recognised audit categories.~~

The Directory hosts holds full copies of all audit reports and certificates in PDF format, including historic audit records from 2008 onwards.

Audit data can only be added to or edited on Directory by BRCGS-approved certification bodies, who are also responsible for assigning audit records, and by extension access, to the audit-owning entity.

Directory allows audit owners to 'share' their audit records with other participant users. Audit sharing configuration and access to confidential data is available to appropriately credentialed users only and requires sign-in.

Certification bodies are exclusively responsible for maintaining site records, including the site's name, address and contact details audit content and certificate status. All certification bodies are assessed and graded by BRCGS according to how quickly and accurately they update audit data.

~~The Directory also features a publicly accessible search function displaying certification data only. The public directory lists only currently certificated sites, not those whose certification status has expired or been withdrawn.~~

~~Sites wishing to be excluded from public listing should contact their certification bodies. BRCGS will launch a new directory during the life of this issue of the Standard which will bring enhancements to all users. For further information on the directory or audit sharing, contact the BRCGS Directory team via submissions@brcgs.com.~~

6.8.1 Site code

All audited sites are allocated a unique 6-, 7- or 8-digit reference number known as a site code. ~~This can be used to authenticate the validity of any certificate.~~ Site codes are generated when a site record is initially created and added to the Directory by a certification body. The site code remains unchanged, regardless of subsequent auditing certification bodies, Standard status or audit status.

Site codes can be located on the top right-hand corner of the first page of all audit reports and on corresponding certificates.

The listing for any certificated site can be located in the public area of the Directory by adding the site code to the 'site code' search field. If no results are returned for a search, contact BRCGS to confirm certification authenticity.

6.8.2 Audit-sharing

The **BRCGS** Directory allows audit owners to share their audit reports with customers, including retailers, manufacturers, suppliers and other Directory-registered specifiers.

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Once audit-sharing has been configured ~~set-up~~, customers can access the full current, archived and future audit documents (as they become available) without any further administration.

An audit owner can cancel sharing at any time. ~~All sharing changes take immediate effect.~~ Audit documents shared in the Directory cannot be edited or otherwise changed ~~doctored~~ by the audit owner; therefore, audits obtained from the Directory can be considered as complete and authenticated.

6.8.3 Site-sharing

Only certification bodies authorised by the site owner can edit a site record. In the event of a transfer from one certification body to another, the new certification body must be given access to the site's records before a new audit can be added for that site or any edits to the site details can be made. Site-sharing can be arranged by the site owner on the Directory or by BRCGS upon request.

6.8.4 Notification emails

The BRCGS Directory notifies audit owners, and anybody who has shared access to the audit, if a site's certification is suspended, withdrawn or expires without replacement. Notifications are via automated email and can be turned off if not required.

6.8.5 Directory assistance and contacting BRCGS

For further information regarding the BRCGS Directory, including how to configure audit-sharing with a customer or site-sharing with a certification body, visit the BRCGS Directory and click on the 'Audit & Site Sharing' and 'Contact' tabs.