



GLOBAL STANDARD

PACKAGING AND PACKAGING MATERIALS



ISSUE 5



GLOBAL STANDARD
**PACKAGING
AND
PACKAGING
MATERIALS**

LIABILITY

The BRC publishes information and expresses opinions in good faith, but accepts no liability for any error or omission in any such information or opinion, including any information or opinion contained in this publication.

Whilst the BRC has endeavoured to ensure that the information in this publication is accurate, it shall not be liable for any damages (including without limitation damages for pure economic loss or loss of business or loss of profits or depletion of goodwill or otherwise in each case, whether direct, indirect or consequential) or any claims for consequential compensation whatsoever (howsoever caused) arising in contract, tort (including negligence or breach of statutory duty), misrepresentation, restitution or otherwise, in connection with this publication or any information contained in it, or from any action or decision taken as a result of reading this publication or any such information.

All warranties, conditions and other terms implied by statute or common law are, to the fullest extent permitted by law, excluded.

Nothing excludes or limits the liability of the BRC for death or personal injury caused by its negligence, for fraud or fraudulent misrepresentation or for any matter which it would be illegal for it to exclude or attempt to exclude liability for.

The Global Standard for Packaging and Packaging Materials and the terms of the disclaimer set out above shall be construed in accordance with English law and shall be subject to the non-exclusive jurisdiction of the English Courts.

COPYRIGHT

© British Retail Consortium 2015

All rights reserved. No part of this publication may be transmitted or reproduced in any form (including photocopying or storage in any medium by electronic means) without the written permission of the copyright owner. Application for permission should be addressed to the Commercial Director of Global Standards at the British Retail Consortium (contact details below). Full acknowledgement of the author and source must be given.

The contents of this publication cannot be reproduced for the purposes of training or any other commercial activity.

No part of this publication may be translated without the written permission of the copyright owner.

Warning: Any unauthorised act in relation to a copyright work may result in both a civil claim for damages and criminal prosecution.

For more information about BRC, contact:

British Retail Consortium
Second Floor
21 Dartmouth Street
London
SW1H 9BP

Tel: +44 (0) 20 7854 8900
Fax: +44 (0) 20 7854 8901

Email: enquiries@brcglobalstandards.com
Website: www.brcglobalstandards.com

CONTENTS

PART I **THE PRODUCT SAFETY AND QUALITY MANAGEMENT SYSTEM**

Introduction to Issue 5	4
The product safety and quality management system	7

PART II **REQUIREMENTS**

How the requirements are set out in both categories	13
High hygiene category	15
1 Senior management commitment	15
2 Hazard and risk management system	17
3 Product and safety quality management	20
4 Site standards	26
5 Product and process control	32
6 Personnel	37

PART II **REQUIREMENTS**

Basic hygiene category	43
1 Senior management commitment	43
2 Hazard and risk management system	45
3 Product and safety quality management	48
4 Site standards	53
5 Product and process control	58
6 Personnel	63

PART III **AUDIT PROTOCOL**

Introduction	67
1 General protocol – audit preparation	69
2 Announced audit protocol	74
3 Unannounced audit protocol: Option 1 – full audit	80
4 Unannounced audit protocol: Option 2 – two-part audit	82
5 BRC Global Markets programme	87
6 Voluntary modules	92
7 General protocol – post audit	94

PART IV **MANAGEMENT AND GOVERNANCE**

Requirements for certification bodies	100
Technical governance of the Global Standard for Packaging and Packaging Materials	100
Achieving consistency – compliance	102

APPENDICES

Appendix 1 Registration, qualifications, training and experience requirements for auditors	106
Appendix 2 Fields of audit	108
Appendix 3 Examples of fields of audit	110
Appendix 4 Multiple sites audit protocol	111
Appendix 5 Certificate template	114
Appendix 6 Other BRC Global Standards	115
Appendix 7 Glossary	116
Appendix 8 Acknowledgements	121

PART I

THE PRODUCT SAFETY AND QUALITY MANAGEMENT SYSTEM

INTRODUCTION TO ISSUE 5

What's new for Issue 5?	4
The scope of the Standard	5
Packaging legislation	6
Benefits of the Standard	6
The certification process	6
Effective date of Issue 5	6
Acknowledgements: a 'thank you' from the BRC	6

THE PRODUCT SAFETY AND QUALITY MANAGEMENT SYSTEM

Principles of the Standard	7
The expectation of the Global Standard for Packaging and Packaging Materials	7
Preparation and planning for success	7
Hygiene categories	8



PART I

THE PRODUCT SAFETY AND QUALITY MANAGEMENT SYSTEM

INTRODUCTION TO ISSUE 5

Welcome to Issue 5 of the Global Standard for Packaging and Packaging Materials (the Standard). Originally developed and published in 2001, it was designed to protect the consumer by providing a common basis for the certification of companies supplying packaging to food producers. The Standard has been updated at regular intervals since, to reflect the latest thinking in product safety, and has now attained usage worldwide.

The Standard now provides a framework for all types of packaging manufacturers to assist them in the production of safe packaging materials and to manage product quality to meet customers' requirements. Certification against the Standard is recognised by many brand owners, retailers, food service companies and manufacturers around the world when assessing the capabilities of their suppliers. In response to demand, the Standard has been translated into many languages to facilitate implementation by packaging materials companies across the world.

The Standard has been developed to specify the product safety, quality and operational criteria that must be in place within a packaging manufacturing organisation in order for it to fulfil its obligations with regard to legal compliance and protection of the consumer. The format is designed to allow a company's premises, operational systems and procedures to be assessed against the requirements of the Standard by a competent third party – the certification body.

WHAT'S NEW FOR ISSUE 5?

The development of Issue 5 followed a wide consultation to understand stakeholders' requirements. A review of emerging issues was also carried out in the packaging industry and the industries it supplies. The information has been developed and reviewed by a working group composed of stakeholders representing different sectors of the packaging materials manufacturing industry, retailers, brand owners, certification bodies and independent technical experts.

The focus for this issue has been on:

- a move from 'good practice' to 'best practice'
- the quality management systems process in printed packaging controls
- continuing to ensure consistency of the audit process
- providing a Standard that meets retailers' and brand owners' needs to reduce the audit burden
- better recognition of the diversity of the packaging industry and its customers' demands
- encouraging greater transparency and traceability in the supply chain
- encouraging adoption of the Standard as a means of improving product safety at small sites and facilities where processes are still in development.

The requirements of Issue 5 have evolved from those of previous issues. There continues to be an emphasis on management commitment, a hazard and risk analysis-based product safety programme and a supporting quality management system. The objective has been to direct the focus of the audit towards the implementation of good manufacturing practices within the production areas while recognising the diversity and breadth of the packaging industry, and the skills required to audit it.

Unannounced audit programme

The number of unannounced audits among specifiers of food manufacturers has increased, and this has been seen to provide a greater confidence in the implementation of a food safety culture. To echo this in the supply chain, the optional unannounced audit programme has been introduced into the Standard for the first time. The two options for unannounced audits from Issue 7 of the Food Safety Standard are reflected in Issue 5 of the Packaging Standard. The unannounced programmes remain voluntary, but they provide added confidence in certification to customers and create marketing benefits where sites achieve the top BRC grade of AA+.

Global Markets programme

As the Standard continues to develop, it is important to provide opportunities to recognise and encourage the development of product safety and quality management systems at sites where implementation of the full requirements of the Standard may take time. The BRC has taken the opportunity to revise some protocol elements of the existing Enrolment Programme and to align these more closely with the Global Food Safety Initiative (GFSI) Global Markets programme for building product safety capacity. This new scheme will enable audits and recognition against a set of requirements of the Standard identified as basic level, and a further set of requirements identified as intermediate level.

Details of the new programmes can be found in the audit protocol of the Standard (see Part III).

Fields of audit

The packaging industry is incredibly diverse, with a wide range of material types, processing technologies and applications. While the material categories in Issue 4 were broadly in line with the major packaging material categories, the BRC has taken the opportunity to include those parts of the industry that were not suitably reflected, despite being crucial to product safety further down the supply chain, such as print.

Additional voluntary modules

Issue 5 has been developed to enable the incorporation of additional voluntary modules which sites can elect to include with the audit to meet particular customer or scheme needs. The BRC will continue to develop such modules and make these available on the website in response to market needs. It is expected that this flexibility will enable sites to meet regional or specific customer expectations and reduce the number of site audits.

THE SCOPE OF THE STANDARD

The Standard sets out the requirements for the manufacture of packaging and packaging materials used in food packaging and filling operations and for cosmetics, toiletries and other consumer products and materials. It is also intended to apply to:

- prior operations (e.g. production of packaging materials for conversion or printing)
- operations that are supplying packaging material from stock where additional product processing or repacking occurs; this has been demonstrated to require the same level of control as a final/integrated converting operation
- packaging manufacturers who also produce consumer-disposable goods that come into contact with food (e.g. paper plates and disposable plastic drinking cups, aluminium foil, food-grade parchment paper, cling film and disposable cutlery). These products may also be audited under the BRC's Global Standard for Consumer Products where the primary operation of the factory is the production of consumer products and not packaging manufacture
- the manufacture and supply of other materials that are unconverted or semi-converted and used or incorporated (e.g. coatings and adhesives), where this is based on a risk analysis and mutually agreed between those involved.

The Standard shall not apply to packaging or materials that do not undergo any process at the site audited, or to activities relating to wholesale, importation, distribution or storage outside the direct control of the company. The BRC has developed a series of Global Standards setting out the requirements for the wide range of activities undertaken in the production, packaging, storage and distribution of food or consumer products. Appendix 6 provides further details of the scopes of, and relationships between, the current Global Standards.

Companies that meet the requirements of a satisfactory quality management system – for example, one conforming to that specified in ISO 9001 – may already meet many of the requirements of the Standard. It is in the interest of the company to bring these points to the attention of the certification body. The auditor will verify that the procedures are adequate for the purpose of compliance with this Standard.

Exemptions on the basis of risk

The requirements have been written to reflect expectations typical of the particular product or process technology across a range of packaging formats (e.g. board, glass, metals). There may be occasions where a requirement may not be appropriate in a particular operation. Some requirements may be excluded on the basis of risk; however, in each case a documented risk assessment must be provided for the auditor to evaluate (clause 2.3).

The final audit report will include comments on any clauses deemed as not applicable or excluded on the basis of risk analysis.

PACKAGING LEGISLATION

The Standard has always been intended to assist sites and their customers to comply with legislative requirements for product safety.

Legislation covering packaging differs in detail worldwide and commonly focuses on packaging materials in contact with food. It generally requires packaging manufacturers to:

- produce packaging that does not pose a hazard to human health
- provide a processing environment which ensures that the risks of product contamination are minimised
- use raw materials or ingredients that are not injurious to human health
- preserve, protect and contain products adequately throughout the supply chain
- ensure information about the product is presented to the consumer.

The Standard has been developed to assist packaging manufacturers in meeting these requirements.

BENEFITS OF THE STANDARD

Adoption of the Standard leads to a number of benefits for packaging and packaging materials manufacturing businesses. The Standard:

- is internationally recognised, GFSI-benchmarked and provides a report and certification that can be accepted by customers in place of their own audits, thereby reducing time and cost
- provides a single standard and protocol that governs an accredited audit by third-party certification bodies, allowing a credible independent assessment of a company's product safety and quality systems
- enables certificated companies to appear in the publicly available part of the BRC Global Standards Directory, allowing recognition of their achievements and use of a logo for marketing purposes
- is comprehensive in scope, covering areas of quality, legality and product safety
- addresses part of the legislative requirements of the packaging manufacturer/supplier, packer/filler and retailer. Packaging manufacturers may also use this Standard to ensure their suppliers are following good manufacturing practices and are fulfilling legal requirements
- enables companies to ensure their suppliers are following good practice in product safety
- provides a framework for the development of quality and hygiene management systems in companies, encouraging continuous improvement, reduction in waste and increased efficiency
- provides a range of audit options, including announced and unannounced audit programmes. These will not only satisfy customer demands, but also enable companies to demonstrate compliance through a process which best suits their operation and the maturity of their product safety and quality management systems
- is part of a scheme offering an array of training, education and technical support.

THE CERTIFICATION PROCESS

The Standard is a process and product certification scheme. In this scheme, packaging manufacturers are certificated upon completion of a satisfactory audit by an auditor employed by an independent third party – the certification body. The certification body in turn shall have been assessed and judged as competent by a national accreditation body.

In order for a packaging or packaging materials manufacturing business to receive a valid certificate on completion of a satisfactory audit, the organisation must select a certification body approved by the BRC. The BRC lays down detailed requirements that a certification body must satisfy in order to gain approval and operates a comprehensive compliance programme to ensure high standards are maintained.

A list of certification bodies approved by the BRC is available on the BRC Global Standards Directory website:

www.brcdirectory.com

EFFECTIVE DATE OF ISSUE 5

As with all revisions of the Global Standards, there must be recognition that a transition period is in place between publication and full implementation. This allows time for the retraining of all auditors and allows manufacturers to prepare for the new issue of the Standard. Therefore, certification against Issue 5 will commence from 1 January 2016. All certificates issued against audits carried out prior to 1 January 2016 will be against Issue 4 and will be valid for the period specified on the certificate.

ACKNOWLEDGEMENTS: A 'THANK YOU' FROM THE BRC

The BRC wishes to acknowledge all those packaging industry experts who have contributed to the preparation of the Global Standard for Packaging and Packaging Materials Issue 5. Appendix 8 lists those who participated in the working groups.

THE PRODUCT SAFETY AND QUALITY MANAGEMENT SYSTEM

PRINCIPLES OF THE STANDARD

A business must have a full understanding of the processes and products it manufactures. It must also have systems in place to ensure that products are produced within a suitably hygienic environment and consistently meet the quality and product safety expectations of its customers. The Standard is based on the key components of: senior management commitment; risk assessment of the product and manufacturing process; and a systematic approach to managing product quality and safety.

Senior management commitment

Within a business, the safety, legality and quality of the products produced must be seen as a cross-functional responsibility, involving and using different skills and expertise in the organisation. Effective adoption of the principles of this Standard extends beyond the responsibility of a single individual or technical departments and must involve commitment from production operations, engineering, distribution management, procurement of raw materials and those concerned with customer feedback and human resource activity such as training. The starting point for effective implementation of the Standard is the commitment of senior management to the development of an all-encompassing policy as a means to guide the activities that collectively assure the production of safe and legal packaging and packaging materials.

A risk-based system

The Standard requires an evaluation of the risks to product safety and quality associated with the manufacture of packaging and packaging materials. The hazard and risk analysis process defined in the Standard should enable potential risks to be identified and controlled, either through existing prerequisite programmes, such as cleaning, pest control and maintenance, or by the introduction of specific controls. An effective hazard and risk analysis provides a basis for the management system. The development of the system requires the input of all relevant departments and must be supported by senior management.

Quality management system and suitable operating conditions

The Standard requires the organisation to document the framework of management policies and procedures by which it will achieve the main requirements of this Standard. It also expects the business to maintain the basic environmental and operational conditions that are necessary for the production of safe, legal products under suitable hygienic conditions.

THE EXPECTATION OF THE GLOBAL STANDARD FOR PACKAGING AND PACKAGING MATERIALS

The Global Standard for Packaging and Packaging Materials requires the development of and compliance with the following:

- **Senior management commitment** The resources required for demonstration of commitment to achieving the requirements of the Standard are detailed in Part II, section 1.
- **A hazard and risk analysis management plan** This provides a focus on the significant product and process safety hazards that require specific control to assure the safety of individual packaging materials, products or lines as detailed in Part II, section 2.
- **A quality management system** Details of the organisational and management policies and procedures that provide a framework by which the organisation will achieve the requirements in this Standard as given in Part II, section 3.
- **Prerequisite programmes** The basic environmental and operational conditions in a packaging business that are necessary for the production of safe and hygienic packaging materials. These control generic hazards, covering good manufacturing and good hygienic practice as detailed in Part II, sections 4–6.

PREPARATION AND PLANNING FOR SUCCESS

In order for everyone to gain the most value from certification to the Standard, retailers and other specifiers should have a clear understanding of both the demands it places on their suppliers and the benefits that ensue. Equally, manufacturers need to plan carefully to achieve certification. Both specifiers and companies seeking certification should understand that considerable effort may be needed to work towards certification, especially for companies that have no previous experience of third-party certification schemes or quality management systems certification.

It is important to set realistic timescales in which to gain certification and have a clear project plan to ensure that all the necessary actions are completed before the certification audit visit. After the audit visit, 28 days are allowed in which to correct any failures to meet the requirements of the Standard, identified by the audit report as non-conformities. This period is extended to 90 days for major non-conformities at initial audits. There is a limit to the number of non-conformities that are allowed before certification is refused (see Part III, section 2.4 for details). If the number of non-conformities exceeds that allowed, or if the non-conformities are not corrected within the allowed time frame, a complete re-audit will be needed before certification can be obtained. It is therefore not advisable to attempt an audit without adequate preparation.

For specifiers

Retailers and others contemplating specifying the use of the Standard by their suppliers are advised to inform their suppliers and the certification bodies well in advance of the implementation requirement. This will ensure that the companies have time for adequate planning and that the certification bodies have suitable infrastructure, such as auditor capacity, in place in the countries of demand and for the correct packaging fields. Retailers may want to organise internal training to ensure that the staff have a good understanding of the Standard. It may be helpful to arrange supplier briefings or other training events to explain the requirements of the scheme and other steps to implementation. Assistance with such matters is available from the BRC Global Standards team.

For packaging manufacturers

A detailed explanation of the process is given in Part III. Companies already certificated to previous versions of this Standard should work through the steps to certification but may find that many aspects have already been addressed.

HYGIENE CATEGORIES

The packaging industry produces a wide variety of packaging, involving an extensive range of materials for use in many diverse industries. Given the scope of this activity, it is essential that the audit against the Standard is appropriate for the nature of the material produced and its intended use. Customers expect that all of the packaging materials they purchase are safe for their intended use and produced to the quality agreed in the specification. It is recognised, however, that the production of packaging for some particular uses (e.g. for direct food contact) places more stringent and demanding hygiene requirements on the manufacturer.

The requirements of the Standard for Issue 5 are divided into two hygiene categories depending upon the intended use of the packaging and consequent standards of hygiene under which the packaging is produced. The decision tree (Figure 1) helps to define the appropriate hygiene category for any particular use.

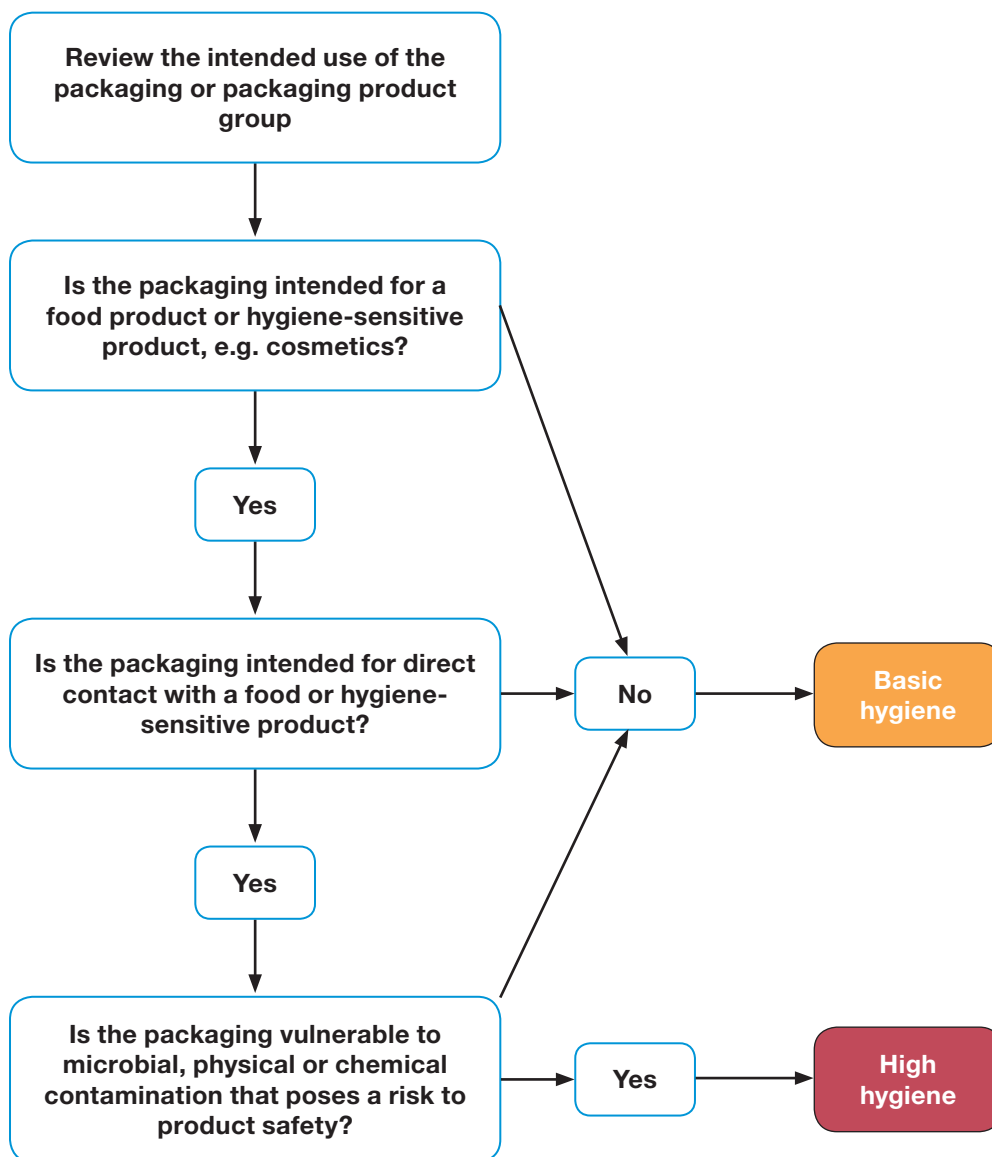
In general, the two categories of requirements can be considered as follows:

- **High hygiene** Packaging that comes into direct contact with food products or other designated hygiene-sensitive products (such as those intended for human consumption or that come into contact with the body; for example, by application to the skin).
- **Basic hygiene** Primary packaging not in direct contact with food or other hygiene-sensitive products; packaging for consumer products; and the secondary and tertiary packaging for all uses.

For further guidance, consult the decision tree in Figure 1 and Appendices 2 and 3, which provide examples of products for each manufacturing category and hygiene category.

It is recognised that many manufacturers or suppliers may produce packaging in both categories. In these circumstances they may choose either to use the higher category for the entire factory or to separate them by areas. It is not permitted for more than one category to apply within the same area.

The final determination of the appropriate packaging hygiene category is a matter for discussion between the company and its customer. The examples given in Appendix 3 are not an exhaustive list and are only provided as a guide. Where there is any doubt, the more demanding hygiene category should be adopted. If there is no clear definition of hygiene category, the company shall refer to the BRC for clarification.

**FIGURE 1 HYGIENE CATEGORY DETERMINATION DECISION TREE**

PART II

REQUIREMENTS

HOW THE REQUIREMENTS ARE SET OUT IN BOTH CATEGORIES

The format of the Standard	13
Fundamental requirements	13
Non-applicable clauses	14
Risk-based exemptions	14

HIGH HYGIENE CATEGORY

1 SENIOR MANAGEMENT COMMITMENT

1.1 Senior management commitment and continual improvement	15
1.2 Management review	16
1.3 Organisational structure, responsibilities and management authority	16

2 HAZARD AND RISK MANAGEMENT SYSTEM

2.1 Hazard and risk management team	17
2.2 Hazard and risk analysis	17
2.3 Exemption of requirements based on risk analysis	19



3 PRODUCT SAFETY AND QUALITY MANAGEMENT

3.1	Product safety and quality management system	20
3.2	Documentation control	20
3.3	Record keeping	20
3.4	Specifications	21
3.5	Internal audits	21
3.6	Supplier approval and performance monitoring	22
3.7	Management of subcontracted processes	22
3.8	Management of suppliers of services	23
3.9	Traceability	23
3.10	Customer focus and contract review	23
3.11	Complaint handling	24
3.12	Management of product withdrawals, and incidents and product recalls	24

4 SITE STANDARDS

4.1	External standards	26
4.2	Building fabric and interiors	26
4.3	Utilities	27
4.4	Security	27
4.5	Layout and product flow	27
4.6	Equipment	28
4.7	Maintenance	28
4.8	Housekeeping and cleaning	29
4.9	Product contamination control	29
4.10	Waste and waste disposal	30
4.11	Pest control	31

5 PRODUCT AND PROCESS CONTROL

5.1	Product development	32
5.2	Graphic design and artwork control	32
5.3	Packaging print control	33
5.4	Process control	33
5.5	Calibration and control of measuring and monitoring devices	34
5.6	Product inspection, testing and measuring	34
5.7	Control of non-conforming product	35
5.8	Incoming goods	35
5.9	Storage of all materials and intermediate and finished products	36
5.10	Dispatch and transport	36

6 PERSONNEL

6.1	Training and competence	37
6.2	Personal hygiene	38
6.3	Staff facilities	38
6.4	Medical screening	39
6.5	Protective clothing	40

PART II

REQUIREMENTS

HOW THE REQUIREMENTS ARE SET OUT IN BOTH CATEGORIES

The requirements to be met for certification differ between the two categories (high hygiene and basic hygiene) for food and consumer products. The requirements for the two categories are set out separately within this section. All applicable requirements for that hygiene category shall be met in order to achieve certification.

THE FORMAT OF THE STANDARD

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. This forms part of the audit and all sites must comply with the statements of intent in order to gain certification.

Below each statement of intent is a list of requirements. These identify, in greater detail, the particular points that must be met as part of achieving compliance with the statement of intent. The audit will assess compliance against both the statement of intent and the individual requirements.

COLOUR CODING OF REQUIREMENTS


There is a choice of audit protocols available for undertaking audits and certification against this Standard. Audits may be undertaken in a single visit (as either an unannounced or announced audit), or sites may opt for the split audit option, where the first part of the audit (part 1) is unannounced and concentrates on good manufacturing practices and there is a later, scheduled, announced audit (part 2) that reviews primarily records and procedures.

The audit requirements within the Standard have been colour coded to provide a guide as to which requirements would be expected to be covered on part 1 and part 2 audits where this audit option is selected. The colour coding also helps to identify the requirements that would usually be expected to be audited as part of the assessment of the production areas and facilities or would form part of such an audit trail initiated in the factory.

Key to colour coding of requirements

Requirements assessed on part 1 – audit of good manufacturing practice	
Requirements assessed on part 2 – audit of records, systems and documentation	
Requirements assessed on both parts 1 and 2	

FUNDAMENTAL REQUIREMENTS

In line with the other BRC Global Standards, the concept of fundamental requirements is crucial to the effective implementation of the requirements of the Standard. These identify particular systems or operations within them that need to be in place at the time of the audit. The fundamental requirements are marked with the word 'FUNDAMENTAL' immediately after the section heading and are denoted with the star symbol . The clauses deemed to be fundamental are:

- Senior management commitment and continual improvement (1.1)
- Hazard and risk analysis (2.2)
- Specifications (3.4)
- Internal audits (3.5)
- Traceability (3.9)
- Housekeeping and cleaning (4.8)
- Process control (5.4)
- Training and competence (6.1).

Failure to comply with the statement of intent of a fundamental clause (i.e. a major non-conformity) may lead to non-certification. This will require a further full audit to demonstrate evidence of compliance.

NON-APPLICABLE CLAUSES

The majority of the requirements of the Standard will apply to all packaging material manufacturers within each hygiene category. There are, however, some requirements that would not apply to some industry sectors or operations; for example, the requirements of clause 5.3 (packaging print control) are not applicable where printing of materials is not carried out. Any such specific requirements may be omitted and will be marked as not applicable (N/A) in the final audit report. The auditor will assess and decide on the applicability of any requirements that the site believes are not applicable.

RISK-BASED EXEMPTIONS

The requirements have been written to reflect expectations typical of the particular product and process technology across a range of packaging formats (e.g. board, glass, metals). There may be occasions where a requirement may not be appropriate in a particular operation. On the basis of risk some requirements may be excluded; however, in each case a documented risk assessment must be provided for the auditor to evaluate (clause 2.3).

The final audit report will include comments on any clauses deemed as not applicable or excluded on the basis of risk analysis.

HIGH HYGIENE CATEGORY

These requirements relate to packaging factories producing packaging materials for products that require the highest hygiene standards during manufacture. They involve packaging that comes into direct contact with food or other hygiene-sensitive products. Hygiene-sensitive products are defined as those that are intended for human consumption or that come into contact with the body; for example, by application to the skin.

1 SENIOR MANAGEMENT COMMITMENT

1.1 SENIOR MANAGEMENT COMMITMENT AND CONTINUAL IMPROVEMENT



FUNDAMENTAL

The company's senior management shall demonstrate that they are fully committed to the implementation of requirements of the Global Standard for Packaging and Packaging Materials. This shall include provision of adequate resources, effective communication and systems of review to ensure continual improvement. Opportunities for improvement shall be identified, implemented and fully documented.

CLAUSE	REQUIREMENTS
1.1.1	The site shall have a documented policy which states the site's intention to meet its obligation to produce safe and legally compliant products to the specified quality, and confirms its responsibility to its customers. This shall be: <ul style="list-style-type: none"> signed by the person with overall responsibility for the site communicated to all staff.
1.1.2	The site's senior management shall establish clear objectives to maintain and improve the quality, safety and legality of products manufactured, in accordance with the product safety and quality policy and this Standard. These objectives shall be: <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 reviewed at least annually.
1.1.3	The company's senior management shall provide the human and financial resources required to effectively implement the processes of the quality management system and product safety programme and maintain compliance with this Standard.
1.1.4	The company's senior management shall have a system in place to ensure that the site is kept informed of and reviews: <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 any changes to the Standard or protocol published by the BRC.
1.1.5	The site shall have a genuine, current hard copy or electronic version of the Standard available.
1.1.6	Where the site is certificated to the Standard, it shall ensure that recertification audits occur on or before the audit due date indicated on the certificate.
1.1.7	The most senior production or operations manager on site shall participate in the opening and closing meetings of the audit for the Global Standard for Packaging and Packaging Materials certification. Relevant departmental managers or their deputies shall be available as required during the audit.

CLAUSE	REQUIREMENTS
1.1.8	<p>The site's senior management shall ensure that the root causes of non-conformities identified at the previous audit against the Standard have been effectively addressed to prevent recurrence.</p> <p>A system shall be in place to close out non-conformities raised in internal, second-party and third-party audits, with consideration of the root cause.</p>

1.2 MANAGEMENT REVIEW

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

CLAUSE	REQUIREMENTS
1.2.1	Management review meetings attended by the site's senior management shall be undertaken at appropriate planned intervals; as a minimum annually.
1.2.2	<p>The review process shall include the evaluation of:</p> <ul style="list-style-type: none"> • previous management review documents, action plans and timeframes • results of internal, second-party and third-party audits • customer performance indicators, complaints and feedback • review of the hazard and risk management (HARM) system • incidents, corrective actions, out-of-specification results and non-conforming materials • resource requirements • the site's performance against the Standard and the objectives set • the effectiveness of root cause analysis and corrective actions.
1.2.3	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	The site shall have a demonstrable system in place which enables product safety, legality and quality issues to be brought to the attention of senior management and allows 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
1.3.1	<p>The site shall have a current organisation chart demonstrating the management structure of the company.</p> <p>The responsibilities for the management of activities which ensure product safety, quality and legality shall be clearly allocated and understood by the managers responsible. It shall be clearly documented who deputises in the absence of the responsible person.</p>
1.3.2	Clear communication and reporting channels shall be in place to report on and monitor compliance with the Standard.
1.3.3	The site's senior management shall ensure that all employees are aware of their responsibilities. Where documented work instructions exist for activities undertaken, the relevant employees shall have access to these and be able to demonstrate that work is carried out in accordance with the instructions.

2 HAZARD AND RISK MANAGEMENT SYSTEM

2.1 HAZARD AND RISK MANAGEMENT TEAM

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

CLAUSE	REQUIREMENTS
2.1.1	<p>The hazard and risk management system shall be developed, reviewed and managed by a multidisciplinary team that includes those responsible for quality, technical, engineering/maintenance, production operations and other relevant functions.</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	The multidisciplinary team shall have a designated team leader who shall be suitably trained and able to demonstrate competence and experience of hazard and risk analysis.
2.1.3	The team shall be able to demonstrate competence in hazard and risk analysis principles and be kept up to date with factory changes and customer requirements as they occur.

2.2 HAZARD AND RISK ANALYSIS



FUNDAMENTAL

A documented hazard and risk management system shall be in place to ensure that all hazards to product safety, quality and legality are identified and appropriate controls established.

CLAUSE	REQUIREMENTS
2.2.1	The scope of the hazard and risk analysis shall be clearly defined and documented and shall cover all products and processes included within the intended scope of certification.
2.2.2	<p>The hazard and risk analysis team shall maintain awareness of and take into account:</p> <ul style="list-style-type: none"> • historical and known hazards associated with specific processes, raw materials or intended use of the product (where known) • known likely product defects that affect safety or quality • relevant codes of practice or recognised guidelines • legislative requirements.
2.2.3	<p>A full description of the product shall be developed, which includes all relevant information on product safety, quality and integrity. As a guide this may include:</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.

CLAUSE	REQUIREMENTS
2.2.4	<p>A flow diagram shall be prepared for each product, product group or process. This shall set out each process step from the receipt of raw materials to dispatch to the customer. As a guide this shall include, as relevant:</p> <ul style="list-style-type: none"> • receipt and approval of artwork • receipt and preparation of raw materials such as additives, inks and adhesives • each manufacturing process step • in-line testing or measuring equipment • the use of rework and post-consumer recycled materials • any subcontracted processes • customer returns. <p>The accuracy of the process flow shall be validated by the hazard and risk analysis team.</p>
2.2.5	<p>The hazard and risk analysis team shall identify and record all potential hazards that are reasonably expected to occur at each step in relation to the product and process. The hazards considered shall include, where relevant:</p> <ul style="list-style-type: none"> • microbiological • foreign objects • chemical contamination (e.g. taint, odour, allergen, component transfer from inks, varnishes and glues) • potential problems arising from the use of recycled materials • legality • defects critical to consumer safety • hazards that may have an impact on the functional integrity and performance of the final product in use • potential for unintended migration of substances from the packaging material into food or other hygiene-sensitive product • potential for malicious intervention.
2.2.6	<p>The hazard and risk analysis team shall identify control measures necessary to prevent, eliminate or reduce each hazard to acceptable levels.</p> <p>Controls for identified hazards to product quality shall be appropriately managed through the prerequisite programme, as set out in section 5.</p> <p>Where control is through prerequisite programmes these shall be reviewed to ensure they adequately control the risk identified and, where necessary, improvements implemented.</p>
2.2.7	<p>For each hazard that requires control, other than by an existing prerequisite programme (as set out in sections 4–6), the control points shall be reviewed to identify those that are critical. This process shall include an assessment of the risk level for each hazard based on the likelihood of the occurrence and the severity of the outcome.</p> <p>Critical control points shall be those control points that are required to prevent, eliminate or reduce a product safety or integrity hazard to acceptable levels.</p> <p>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>
2.2.8	<p>For each critical control point, the appropriate critical limits shall be defined in order to identify clearly whether the process is in or out of control. Critical limits shall be measurable, where possible, and the rationale for their establishment clearly documented. Relevant legislation and codes of practice shall be taken into account when establishing the limits.</p>
2.2.9	<p>For each critical control point, a monitoring system shall be defined in order to ensure compliance with critical limits. Records of the monitoring shall be maintained. Documented procedures relating to the monitoring of critical controls shall be included in internal audits against the Standard (see clause 3.3).</p>

CLAUSE	REQUIREMENTS
2.2.10	The corrective action that shall be taken when monitored results indicate a failure to meet the control limit shall be established and documented. This shall include the procedures for quarantining and evaluating potentially out-of-specification products to ensure they are not released until their safety, quality and legality can be established.
2.2.11	<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 and risk analysis plan is effective and may include a review of:</p> <ul style="list-style-type: none"> • process changes • product composition changes • complaints • product failures • finished product recalls from consumers (including system tests) • product withdrawals • results of internal audits of prerequisite programmes • results from external and third-party auditors • new developments in industry associated with materials, process or product.

2.3 EXEMPTION OF REQUIREMENTS BASED ON RISK ANALYSIS

The hazard and risk analysis study shall be fully supported by the implementation of the prerequisites set out in requirements clauses 4 to 6. However, the hazard and risk analysis may indicate that some of the requirements may be exempted.

CLAUSE	REQUIREMENTS
2.3.1	Exemptions shall be documented and regarded as proposed exemptions for review at audit. Acceptance or rejection of the proposed exemptions shall be recorded in the auditor's report.
2.3.2	The site shall keep recorded exemptions to the Standard under review and provide documented evidence of this review at subsequent audit.

3 PRODUCT SAFETY AND QUALITY MANAGEMENT

3.1 PRODUCT SAFETY AND QUALITY MANAGEMENT SYSTEM

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

CLAUSE	REQUIREMENTS
3.1.1	The site's documented procedures, working methods and practices shall be collated in a navigable and readily accessible system, with consideration being given to translation into appropriate languages.
3.1.2	The system shall be fully implemented, reviewed at appropriate planned intervals and improved where necessary.

3.2 DOCUMENTATION CONTROL

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

CLAUSE	REQUIREMENTS
3.2.1	The company shall have a documented procedure to manage documents which form part of the product safety and quality system. This shall include: <ul style="list-style-type: none">• a list of all controlled documents indicating the latest version number• the method for the identification and authorisation of controlled documents• a record of the reason for any changes or amendments to documents• the system for the replacement of existing documents when these are updated.
3.2.2	Where documents and records are in electronic form these shall be suitably protected 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. Where records are in electronic form these shall be suitably backed up to prevent loss.
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 period of retention for records shall relate to the usable life of the packaging and products it is designed to contain and shall respect any customer requirements.

3.4 SPECIFICATIONS



FUNDAMENTAL

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

CLAUSE	REQUIREMENTS
3.4.1	Specifications shall be suitably detailed and accurate, and shall ensure compliance with relevant product safety and legislative requirements.
3.4.2	The company shall seek formal agreement of specifications with relevant parties. Where specifications are not formally agreed then the company shall be able to demonstrate that they have taken steps to put an agreement in place.
3.4.3	<p>A declaration of compliance shall be maintained which enables users of the packaging materials to ensure compatibility between those materials and the product with which they may be in contact.</p> <p>The declaration of compliance shall contain as a minimum:</p> <ul style="list-style-type: none"> • the nature of the materials used in the manufacture of the packaging • confirmation that the packaging materials meet relevant legal requirements • the inclusion of any post-consumer recycled materials. <p>This shall identify any limitations of use of the product and the usable life of the packaging material (where relevant).</p> <p>Products shall meet at least minimum legal requirements in the country of manufacture, and use, where known.</p>
3.4.4	The presence of manufacturer's trademarks or logo on packaging materials shall, where appropriate, be formally agreed between relevant parties.
3.4.5	A specification review process shall be operated where product characteristics change or at an appropriate predetermined interval.
3.4.6	Where specifications are in electronic form these shall be suitably protected to prevent loss or malicious intervention.

3.5 INTERNAL AUDITS



FUNDAMENTAL

The company shall be able to demonstrate that it verifies the effective application of the requirements of the Global Standard for Packaging and Packaging Materials through internal audits.

CLAUSE	REQUIREMENTS
3.5.1	<p>There shall be a scheduled programme of internal audits throughout the year with a scope which covers the hazard and risk management system, prerequisite programmes and all procedures that have been implemented to achieve this Standard. All activities shall be covered at least annually.</p> <p>The internal audit programme shall be fully implemented.</p>
3.5.2	The scope and frequency of the audits shall be established in relation to the risks associated with the activity and previous audit performance.
3.5.3	Internal audits shall be carried out by appropriately trained, competent auditors. Auditors shall be sufficiently independent from the process being audited to ensure impartiality (i.e. they must not audit their own work).
3.5.4	<p>Internal audit reports shall identify conformity as well as non-conformity.</p> <p>Results shall be notified to the personnel responsible for the process audited. Root cause analysis shall be used to determine appropriate corrective actions. Corrective actions and timescales for their implementation shall be agreed and completion of the actions verified.</p>

3.6 SUPPLIER APPROVAL AND PERFORMANCE MONITORING

The company shall operate effective, documented procedures for approval and monitoring of its suppliers.

CLAUSE	REQUIREMENTS
3.6.1	<p>The site shall have a documented supplier approval procedure and continual assessment programme in place, based upon risk analysis. These shall apply to suppliers of:</p> <ul style="list-style-type: none"> • materials • subcontracted processes <p>to the site and ensure that materials and services procured conform to defined requirements, where there is a potential impact to product safety, quality or legality.</p>
3.6.2	<p>The procedures shall include clear criteria for the assessment and approval of new suppliers. Assessment may take the form of:</p> <ul style="list-style-type: none"> • supplier certification with a scope covering the products supplied (e.g. against the appropriate BRC Global Standard, or other GFSI benchmarked scheme) • supplier questionnaires • supplier audits. <p>The site shall have an up-to-date list of approved suppliers.</p>
3.6.3	<p>Records of supplier assessment and necessary actions shall be maintained and reviewed.</p>
3.6.4	<p>The procedures shall define how exceptions are handled; for example, the use of products or services where audit or monitoring has not been undertaken. Assessment (on a batch or delivery basis) may take the form of:</p> <ul style="list-style-type: none"> • certificate of analysis • declaration of compliance.

3.7 MANAGEMENT OF SUBCONTRACTED PROCESSES

Where any process steps in the manufacture of the packaging material are subcontracted to a third party or undertaken at another site, this shall be managed to ensure it does not compromise the quality, safety or legality of the product.

CLAUSE	REQUIREMENTS
3.7.1	<p>The use of subcontractors and the status of the subcontractor with respect to the Standard shall be notified to the brand owner and/or customer.</p>
3.7.2	<p>Where any processes are subcontracted, including artwork or pre-press activity, the risks to the quality and safety of the product shall form part of the hazard and risk analysis and the company's evaluation of the system shall be held on record.</p>
3.7.3	<p>Clear specifications shall be agreed for all work outsourced to a subcontractor.</p>
3.7.4	<p>Where any process steps in the manufacture of the packaging or packaging material are subcontracted, final release of the product shall remain the responsibility of the site.</p> <p>Controls shall be in place for checks on finished work to ensure product safety and quality meets specification prior to dispatch to the final customer.</p>

3.8 MANAGEMENT OF SUPPLIERS OF SERVICES

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

CLAUSE	REQUIREMENTS
3.8.1	<p>There shall be a documented procedure for the approval and monitoring of suppliers of services. Such services may include, but are not limited to:</p> <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. <p>Providers of utilities such as water, electricity or gas may be excluded on the basis of risk.</p>
3.8.2	<p>Documented agreements shall exist with the suppliers of services which clearly define service expectations and ensure potential risks associated with the service have been addressed.</p>

3.9 TRACEABILITY



FUNDAMENTAL

The site shall be able to trace and follow all raw materials through processing to the distribution of the finished product (packaging material) to the customer and vice versa.

CLAUSE	REQUIREMENTS
3.9.1	<p>The site shall have a system which has the ability to trace and follow all raw materials from the supplier through all stages of processing and distribution of the finished product and vice versa. Where continuous processes are used or raw materials are in bulk silos, traceability shall be achieved to the best practical level of accuracy.</p>
3.9.2	<p>Identification of raw materials, intermediate products, finished products, non-conforming product and quarantined goods shall be adequate to ensure traceability.</p>
3.9.3	<p>An appropriate system shall be in place to ensure the customer can identify a product or production lot number for the product, for the purposes of traceability.</p>
3.9.4	<p>The system shall be tested to ensure traceability can be determined from raw materials to the finished product and vice versa. Records shall be retrievable in a timely manner.</p> <p>This shall take place on a predetermined frequency, at least on an annual basis, and results retained for inspection.</p>
3.9.5	<p>Where rework or any reworking operation is performed, traceability shall be maintained.</p>

3.10 CUSTOMER FOCUS AND CONTRACT REVIEW

The company's senior management shall ensure that processes are in place to determine customer needs and expectations with regard to quality, safety and legality, and ensure these are fulfilled.

CLAUSE	REQUIREMENTS
3.10.1	The company shall clearly identify those job titles responsible for communication with customers and shall have an effective system for communication.
3.10.2	Customer needs and expectations shall be documented and reviewed on a suitable frequency. Any changes to existing agreements or contracts shall be agreed, documented and communicated to appropriate departments.
3.10.3	Where customers have set particular performance criteria or indicators for monitoring, these requirements shall be communicated to relevant staff, adhered to, and reviewed at appropriate intervals.

3.11 COMPLAINT HANDLING

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

CLAUSE	REQUIREMENTS
3.11.1	All complaints shall be recorded and investigated (including root cause analysis) and the results of the investigation documented. Actions appropriate to the seriousness and frequency of the problems identified shall be carried out promptly and effectively by appropriately trained staff.
3.11.2	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.

3.12 MANAGEMENT OF PRODUCT WITHDRAWALS, AND INCIDENTS AND PRODUCT RECALLS

The site shall have a plan and systems in place to effectively manage any product withdrawals or returns from customers, incidents and product recalls in order to ensure that all potential risks to the hygiene, quality, safety or legality of products and the final consumer are controlled.

CLAUSE	REQUIREMENTS
3.12.1	A product withdrawal procedure shall be documented and shall include as a minimum: <ul style="list-style-type: none"> • identification of the key personnel involved in assessing potential product withdrawals or returns, with their responsibilities clearly defined • a communications plan including methods of informing customers • root cause analysis and corrective action to implement appropriate improvements as required.
3.12.2	The withdrawal procedure shall be capable of being operated at any time and will take into account notification to the supply chain, stock return, logistics for recovery, storage of recovered product and disposal.
3.12.3	The designated manager shall be responsible for ensuring that root cause analysis is used to determine and implement preventive action and improvements as necessary.
3.12.4	The company shall provide written guidance and training for relevant staff regarding the type of event that would constitute an incident. A documented incident reporting procedure shall be in place.

CLAUSE	REQUIREMENTS
3.12.5	The company shall determine and document the activity required to effectively manage an incident to prevent release of product where hygiene, safety or quality may have been affected.
3.12.6	<p>A procedure to manage product recalls initiated by the brand owner or specifier shall be documented and shall include as a minimum:</p> <ul style="list-style-type: none"> • identification of the key personnel involved in assessing potential recalls, together with clearly defined responsibilities • a communications plan that includes methods of informing customers and (where necessary) regulatory bodies in a timely manner • corrective action and business recovery • review of any recalls in order to conduct root cause analysis and implement appropriate improvements as required.
3.12.7	Where a site's products are involved in a product recall, the site shall assist with provision of information (such as traceability) as required.
3.12.8	<p>The product withdrawal procedure shall be tested, at least annually, in a way that ensures its effective operation. Results of the test shall be retained and shall include timings of key activities.</p> <p>The results of the test, and of any actual withdrawals, shall be used to review the procedure and implement improvements as necessary.</p>

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 of safe and legal 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 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 pest entry, ingress of water and other contaminants. External silos, pipework or other access points for the product and/or raw materials shall be appropriately sealed and secured. Where possible, a clean and unobstructed area shall be provided along the external walls of the buildings used for production and/or storage.
4.1.4	Where natural external drainage is inadequate, additional drainage shall be installed. Drains shall be properly protected to prevent entry of pests.
4.1.5	Where external storage of raw materials is necessary, these shall be protected in order to minimise the risk of contamination.

4.2 BUILDING FABRIC AND INTERIORS: RAW MATERIALS HANDLING, PREPARATION, PROCESSING, 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, floors, ceilings and pipework shall be maintained in good condition and shall facilitate cleaning.
4.2.2	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.
4.2.3	All internal drain openings shall be suitably protected against the entry of pests and designed to minimise odour.
4.2.4	Where they constitute a risk to product, and based on the likelihood and risk of contamination, windows and roof glazing shall be protected against breakage.
4.2.5	Where they constitute a risk to product, and based on the likelihood and risk of non-production glass contamination, all bulbs and strip lights, including those on flying-insect control devices, shall be adequately protected.
4.2.6	Suitable and sufficient lighting shall be provided to ensure a safe working environment, correct operation of processes, effective inspection of the product and cleaning.
4.2.7	Suitable and sufficient ventilation shall be provided.

4.3 UTILITIES

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

CLAUSE	REQUIREMENTS
4.3.1	All water used in the processing of the products or equipment cleaning shall be potable or suitably treated to prevent contamination.
4.3.2	Based on risk assessment, the microbiological and chemical quality of water, steam, ice, air, compressed air or other gases which come into direct contact with packaging shall be regularly monitored. These shall present no risk to product safety or quality and shall comply with relevant legal regulations.

4.4 SECURITY

Security arrangements shall be assessed to ensure the integrity of products and processes.

CLAUSE	REQUIREMENTS
4.4.1	<p>The company shall undertake a documented risk assessment of the security arrangements and potential risks to the products from any deliberate attempt to inflict contamination or damage. Areas shall be assessed according to risk; sensitive or restricted areas shall be defined, clearly marked, monitored and controlled.</p> <p>Identified security arrangements to reduce risks shall be documented, implemented and reviewed at least annually.</p>
4.4.2	<p>Measures shall be in place to ensure only authorised personnel have access to production and storage areas, and access to the site by employees, contractors and visitors shall be controlled.</p> <p>A visitor reporting system shall be in place. Staff 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 AND PRODUCT FLOW

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

CLAUSE	REQUIREMENTS
4.5.1	<p>There shall be a plan of the site which defines:</p> <ul style="list-style-type: none"> • access points for personnel • travel routes • staff facilities • process flow • storage areas.
4.5.2	The process flow from intake to dispatch shall be arranged to minimise the risk of contamination or damage to the product.
4.5.3	Premises shall allow sufficient working space and storage capacity to enable all operations to be carried out properly under safe and hygienic conditions.
4.5.4	Sorting 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 areas.

CLAUSE	REQUIREMENTS
4.5.5	Activities that could produce a contamination risk, such as the removal of outer packaging, 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.
4.5.7	Where possible, all facilities shall be designed and positioned so that movement of personnel is by simple, logical routes.

4.6 EQUIPMENT

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

CLAUSE	REQUIREMENTS
4.6.1	Equipment shall be designed for the intended purpose and shall minimise the risk of contamination to the product. Equipment shall be constructed of suitable materials and be designed to ensure it can be effectively cleaned and maintained.
4.6.2	Newly installed equipment shall be properly specified before purchase. New equipment shall be tested and commissioned prior to use and a maintenance and cleaning programme established.
4.6.3	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.
4.6.4	Notices on equipment shall be cleanable and secure.

4.7 MAINTENANCE

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

CLAUSE	REQUIREMENTS
4.7.1	A documented programme of maintenance shall be operated, covering all items of production equipment and plant, to prevent contamination and reduce the risk of breakdown.
4.7.2	A condition-based or preventive maintenance programme shall be in place, covering all items of equipment and plant that are critical to product safety, legality and quality.
4.7.3	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.
4.7.4	Maintenance work shall not place product safety, quality or legality at risk. Maintenance work shall be followed by a documented clearance procedure which records that contamination hazards have been removed and equipment cleared to resume production.
4.7.5	Tools and other maintenance equipment shall be cleared away after use and appropriately stored.
4.7.6	Temporary repairs/modifications using tape, cardboard, etc., shall only be permitted in emergencies and where product contamination is not at risk. Such modifications shall be subject to a time limit and shall be recorded and scheduled for correction.
4.7.7	Engineering workshops shall be controlled to prevent transfer of engineering debris to production or storage areas (e.g. by provision of swarf mats).
4.7.8	Contractors involved in maintenance or repair shall be suitably monitored by a staff member who shall be responsible for their activities.

4.8 HOUSEKEEPING AND CLEANING



FUNDAMENTAL

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

CLAUSE	REQUIREMENTS
4.8.1	Good standards of housekeeping shall be maintained, which shall include a 'clean as you go' policy.
4.8.2	<p>Documented cleaning procedures shall be in place and maintained for buildings, equipment and vehicles. The frequency and methods of cleaning shall be based on risk. Cleaning schedules and procedures shall include the following information:</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.
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 shall be kept in a suitable designated location.</p>
4.8.4	Materials and equipment used for cleaning toilets shall be segregated from those used elsewhere.

4.9 PRODUCT CONTAMINATION CONTROL

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

4.9.1 GLASS, BRITTLE PLASTICS, CERAMICS AND SIMILAR MATERIALS CONTROL

CLAUSE	REQUIREMENTS
4.9.1.1	There shall be no unnecessary non-production glass, ceramics or brittle plastic, which may pose a risk of contamination.
4.9.1.2	<p>All glass or brittle plastics other than the product shall be controlled and recorded on a register which shall include 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 potential for product contamination. <p>Glass or brittle plastics not in the production or storage areas shall be included in the register on the basis of risk.</p>
4.9.1.3	<p>Where non-production glass or brittle plastic breakage occurs, a responsible person shall be placed in charge of the clean-up operation and shall ensure that no other area is allowed to become contaminated due to the breakage. Any product that has become contaminated shall be segregated and disposed of.</p> <p>All breakages shall be recorded in an incident report.</p>

4.9.2 SHARPS CONTROL

CLAUSE	REQUIREMENTS
4.9.2.1	There shall be a documented policy for the control of the use of sharps.
4.9.2.2	Sharp blades, equipment and tools shall not be left in a position that allows them to contaminate the product.
4.9.2.3	Sharp cutting instruments used in the manufacture of packaging materials shall be controlled to prevent product contamination. This shall include control into and out of the factory.
4.9.2.4	Snap-off blade knives shall not be used.
4.9.2.5	Where open noticeboards are present in production, packing and storage areas, loose fastenings, such as drawing pins and staples, shall not be used.

4.9.3 CHEMICAL AND BIOLOGICAL CONTROL

CLAUSE	REQUIREMENTS
4.9.3.1	<p>Processes shall be in place to manage the use, storage and handling of non-production chemicals, to prevent chemical contamination. These shall include as a minimum:</p> <ul style="list-style-type: none"> • a list of approved chemicals for purchase • availability of material safety data sheets and specifications • avoidance of strongly scented products • the labelling and/or identification of containers of chemicals at all times • designated storage area with access restricted to authorised personnel • 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.

4.10 WASTE AND WASTE DISPOSAL

Suitable facilities shall be provided for the storage and disposal of process and other waste.

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	Suitable and sufficient refuse and waste containers shall be provided, which shall be emptied at appropriate frequencies and maintained in an adequately clean condition.
4.10.3	Where appropriate, waste shall be categorised according to legislative requirements based on the intended means of disposal (such as recycling), and sorted, segregated and collected in appropriate designated waste containers.
4.10.4	Substandard trademarked materials shall be rendered unusable through a destructive process. All materials disposed of shall be recorded.
4.10.5	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 shall be in designated areas and designed or maintained to minimise the risk of pest harbourage.

4.11 PEST CONTROL

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

CLAUSE	REQUIREMENTS
4.11.1	A preventive pest control programme shall be maintained, covering all areas of the site under the site's control.
4.11.2	The site shall either contract the services of a competent pest control organisation or shall have appropriately trained staff for the regular inspection and treatment of the site in order to deter and eradicate infestation. The frequency of inspections shall be determined by risk assessment and shall be documented. Where the services of a pest control contractor are employed, the service contract shall be clearly defined and reflect the activities of the site.
4.11.3	Where a site undertakes its own pest control, it shall be able to demonstrate that: <ul style="list-style-type: none"> • pest control operations are undertaken by trained and competent staff with sufficient knowledge to select appropriate pest control chemicals and proofing methods and understand the limitations of use, relevant to the biology of the pests associated with the site • staff undertaking pest control activities meet any legal requirements for training or registration • sufficient resources are available to respond to any infestation issues • there is ready access to specialist technical knowledge when required • legislation governing the use of pest control products is understood • dedicated locked facilities are used for the storage of pesticides.
4.11.4	Pest control equipment such as bait stations, traps or electric fly-killing devices shall be appropriately located and operational.
4.11.5	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 and cable entry points.
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 activity, the site shall use risk assessment to determine the activity required to eliminate the hazard.
4.11.8	Documented procedures and detailed records of pest activity, pest control 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 device locations • identification of the baits and/or monitoring devices on site • clearly defined responsibilities for site management and the contractor • details of pest control products used and instructions for their effective use • detailed records of pest control 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 shall understand the signs of pest activity and be aware of the need to report any evidence to a designated manager.

5 PRODUCT AND PROCESS CONTROL

5.1 PRODUCT DEVELOPMENT

Documented product development or modification procedures shall be in place to ensure the production 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 process requirements and end use, where possible.</p> <p>Any critical-use parameters shall be identified and defined; for example, barrier requirements, max/min use temperature, machine running, use of recycled materials, and testing requirements (including migration, where relevant).</p> <p>Special attention shall be paid to any materials that are required or requested to be manufactured from recycled materials, to ensure that they are both appropriate and legal.</p>
5.1.2	<p>The site shall clearly define and document when a production trial is required.</p> <p>Where appropriate, production trials shall be carried out and testing shall validate that manufacturing processes are capable of producing a safe and legal product to the required quality.</p>
5.1.3	<p>The company shall ensure that production is carried out using defined operating conditions that result in safe and legal products of the prescribed quality.</p>
5.1.4	<p>A technical product specification shall be prepared and, where possible, agreed with the customer or brand owner before the production process begins.</p>
5.1.5	<p>Samples as agreed with the specifier shall be retained for future reference.</p>

5.2 GRAPHIC DESIGN AND ARTWORK CONTROL

Artwork and all pre-press processes conducted by the site shall be managed to ensure loss of information and variation from customer specification is eliminated.

CLAUSE	REQUIREMENTS
5.2.1	<p>The site shall have a documented artwork management procedure covering the activities for which the site has responsibility. This may include, but is not limited to:</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.
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.</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 renewal of approved masters, as necessary.</p>

CLAUSE	REQUIREMENTS
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 are printed or decorated, procedures shall be in place to ensure that the information is fully legible and correctly reproduced to customer specification and any applicable legal requirements.

CLAUSE	REQUIREMENTS
5.3.1	<p>An assessment shall be carried out of the pre-press activity, print process and handling of printed packaging (product) to identify:</p> <ul style="list-style-type: none"> • risks of loss of essential information • mixing of printed product. <p>Controls shall be established and implemented to reduce the risks identified.</p>
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.
5.3.5	Where composite print is used (a mixture of different designs printed together), a process shall be in place to ensure effective segregation of differing print variants.
5.3.6	Samples of printed packaging shall be retained together with production records for a period of time to be agreed with the customer/specifier/brand owner.
5.3.7	Any unused printed product shall be accounted for and either disposed of or identified and appropriately stored.
5.3.8	Lighting in print inspection cabinets and other means of print/colour checking shall be agreed with the customer or conform to accepted industry standards.

5.4 PROCESS CONTROL



FUNDAMENTAL

Documented procedures shall be in place to ensure effective quality assurance of operations throughout the process.

CLAUSE	REQUIREMENTS
5.4.1	A review of the manufacturing and, where applicable, printing process shall identify manufacturing process control points that could significantly affect the quality of the products produced.
5.4.2	For each manufacturing process control point, machine settings or process limits shall be established and documented – the process specification.
5.4.3	A bill of materials and process specification (including manufacturing process control points) shall be available for each batch or lot during production.
5.4.4	Documented process checks shall be undertaken at start-up, following adjustments to equipment and periodically during production, to ensure products are consistently produced to the agreed quality specification.

CLAUSE	REQUIREMENTS
5.4.5	A documented clearance procedure shall be in place to ensure that at start-up the line is clear of all previous work and production documents.
5.4.6	In the event of changes to product composition, processing methods or equipment, the site shall, where appropriate, re-establish process characteristics and validate product data to ensure product safety, legality and quality are achieved.

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 (where applicable) and product safety, quality and legality. This shall include as a minimum:</p> <ul style="list-style-type: none"> • a documented list of equipment and its location • an identification code and calibration due date • prevention from adjustment by unauthorised staff • protection from damage, deterioration and misuse.
5.5.2	<p>All identified measuring equipment shall be checked and adjusted at a predetermined frequency, based on risk analysis. This shall be carried out by trained staff to a defined method to ensure accuracy within defined parameters. All results shall be documented.</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>

5.6 PRODUCT INSPECTION, TESTING AND MEASURING

The company shall use appropriate documented procedures and facilities when undertaking or subcontracting inspection and analyses critical to product safety, legality and quality.

CLAUSE	REQUIREMENTS
5.6.1	<p>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 shall be in accordance with industry-accepted practice or customer requirements and based on risk analysis.</p>
5.6.2	Hazard and risk analysis principles shall be used to determine the need for in-line product testing equipment to ensure product safety, quality and legality.
5.6.3	The accuracy of in-line equipment shall be specified (with permitted tolerances), having due regard to the product parameter being controlled.

CLAUSE	REQUIREMENTS
5.6.4	The company shall establish, document and implement procedures for the operation, routine monitoring and testing of all equipment used in product inspection, testing and measurement. This shall include: <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	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. A system, which includes off-line or randomised quality checks, shall be in place to identify and remove non-conforming product from the production lot and ensure that any appropriate action is taken in consideration of the root cause.
5.6.6	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.
5.6.7	Procedures shall be in place to ensure the reliability of test results.
5.6.8	Where the company undertakes or subcontracts analyses critical to product safety or legality, the laboratory or subcontractors shall have gained recognised laboratory accreditation or operate in accordance with the requirements and principles of ISO 17025 for the test undertaken (General requirements for the competence of testing and calibration laboratories). Documented justification shall be available where accredited methods are not undertaken.

5.7 CONTROL OF NON-CONFORMING PRODUCT

The site shall ensure that out-of-specification product is clearly identified and quarantined.

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 quarantining of materials before a decision has been made on their final disposition.
5.7.2	Non-conforming materials shall be assessed and a decision taken to reject, accept by concession, rework or put to alternative use. The decision and reasons shall be documented.
5.7.3	Corrective actions, root cause analysis and preventive actions shall be implemented to avoid recurrence of the non-conformity. Actions taken shall be documented.

5.8 INCOMING GOODS

Incoming goods shall be appropriately checked for contents, packaging integrity and potential contamination.

CLAUSE	REQUIREMENTS
5.8.1	The site shall document a raw materials and intermediate product intake procedure to ensure that incoming goods match purchase or product specifications. This may take the form of: <ul style="list-style-type: none"> • purchase orders • delivery notes.
5.8.2	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.

5.9 STORAGE OF ALL MATERIALS AND INTERMEDIATE AND FINISHED PRODUCTS

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

CLAUSE	REQUIREMENTS
5.9.1	All materials, work in progress and product shall be properly identified and protected during storage by appropriate packaging to protect the product from contamination.
5.9.2	Storage, including off-site storage, shall be controlled to protect the product from contamination, including taint or odour and malicious intervention. Where off-site storage is used, the same site standards requirements apply as for on-site storage.
5.9.3	In order to prevent contamination, documented procedures shall be in place to appropriately segregate raw materials, intermediate products and finished products.
5.9.4	The site shall ensure that hazardous chemicals are handled in such a way that risk to product safety, quality and legality is minimised.
5.9.5	Material intended for recycling shall be appropriately protected against contamination hazards.

5.10 DISPATCH AND TRANSPORT

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

CLAUSE	REQUIREMENTS
5.10.1	All products and materials shall be identified and either protected during distribution by appropriate external packaging or transported under conditions to protect the product from contamination. This shall include the risk of taint or odour and of malicious intervention.
5.10.2	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. Wooden pallets, if used, shall be sound, dry, clean and free from damage and contamination.
5.10.3	All company-owned vehicles used for deliveries shall be included in the documented cleaning schedules and kept clean and in a condition to minimise the risk of product contamination.
5.10.4	All delivery vehicles and shipping containers shall be subject to a documented hygiene-checking procedure before loading.
5.10.5	Where the company employs third-party 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. Where this is not possible, with general carriers, the packaging shall be adequate to protect the product against damage, contamination hazards, taint and odour.
5.10.6	Vehicle drivers shall comply with the site rules relevant to this Standard. Access to the site for third-party transport personnel shall be controlled and, where possible, facilities provided to negate the need to enter storage or production areas.

6 PERSONNEL

6.1 TRAINING AND COMPETENCE: RAW MATERIALS HANDLING, PREPARATION, PROCESSING, PACKING AND STORAGE AREAS



FUNDAMENTAL

The company shall ensure that all personnel are adequately trained, instructed and supervised commensurate with their activity and that they are competent to undertake their job role.

CLAUSE	REQUIREMENTS
6.1.1	All personnel, including temporary personnel and contractors, shall be appropriately trained prior to commencing work and adequately supervised throughout the working period. Induction training shall include the company hygiene rules.
6.1.2	Where personnel are engaged in activities relating to product safety, quality and legality, relevant training and competency assessment shall be in place. This may include, but is not limited to: <ul style="list-style-type: none"> • product inspection, testing and measuring • calibration • printed packaging controls • operatives at manufacturing process control points.
6.1.3	The company shall routinely review and document the competencies of all staff and provide relevant training as appropriate. This may be in the form of training, refresher training, coaching, mentoring, or on-the-job experience.
6.1.4	Records of training shall be available. These shall include: <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). Where training is undertaken by agencies on behalf of the company, records of the training shall be available.
6.1.5	The site shall put in place documented programmes covering the training needs of relevant personnel. These shall include as a minimum: <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 • the delivery of training in the appropriate language of trainees.

6.2 PERSONAL HYGIENE: RAW MATERIALS HANDLING, PREPARATION, PROCESSING, PACKING AND STORAGE AREAS

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

CLAUSE	REQUIREMENTS
6.2.1	<p>The requirements for personal hygiene shall be documented and communicated to all personnel. These shall include, as a minimum, the following instructions:</p> <ul style="list-style-type: none"> • watches shall not be worn • jewellery shall not be worn on exposed parts of the body, with the exception of a plain wedding ring or wedding wristband and sleeper earrings (continuous loop). • perfume or aftershave shall not be worn. <p>Compliance with the requirements shall be checked routinely.</p>
6.2.2	Hand washing shall be performed on entry to the production areas and at a frequency that is appropriate to minimise the risk of product contamination.
6.2.3	Personal items and belongings, including personal mobile phones, shall not be taken into production areas without the permission of the management.
6.2.4	Procedures and written instructions shall be in place to control the use and storage of personal medicines, to minimise the risk of product contamination.
6.2.5	Fingernails shall be kept short and clean. False fingernails, nail varnish/polish or nail art shall not be permitted. Where visitors cannot comply, suitable control procedures shall be in place (e.g. non-handling of product, use of gloves).
6.2.6	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 and monitored when involved in work with materials intended to come into direct contact with food or other hygiene-sensitive products. Where appropriate, in addition to the plaster, a finger stall or glove shall be worn.

6.3 STAFF FACILITIES

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

CLAUSE	REQUIREMENTS
6.3.1	Locker rooms shall be accessed without the need to enter production areas unless appropriately segregated walkways are in place.
6.3.2	Lockers shall be provided for all personnel who work in raw material handling, processing, preparation, packing and storage areas. Lockers shall be of sufficient size to accommodate all reasonable personal items and any protective clothing required.
6.3.3	Site-issued protective clothing and personal clothing shall not be stored in the same locker or shall be effectively segregated within the locker.
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.

CLAUSE	REQUIREMENTS
6.3.5	<p>Suitable and sufficient hand-washing facilities shall be available to enable cleaning of hands before commencing work, after breaks, and as necessary during the course of work. Such hand-washing facilities shall provide, as a minimum:</p> <ul style="list-style-type: none"> • sufficient quantity of water at a suitable temperature to encourage hand washing • unscented liquid soap or foam • adequate hand-drying facilities • advisory signs to prompt use (including signs in appropriate languages). <p>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.</p>
6.3.6	Toilets shall not open directly into storage, processing or production areas in order to prevent the risk of contamination to product. Toilets shall be provided with suitable and sufficient hand-washing facilities.
6.3.7	Facilities for visitors and contractors shall enable compliance with the site's hygiene policy.
6.3.8	All food brought into manufacturing premises shall be stored in a clean and hygienic state. No food shall be taken into storage, processing or production areas.
6.3.9	Eating (including the eating of confectionery and chewing of gum or tobacco), drinking and smoking shall not be allowed in the production or storage areas. If it is impractical for personnel to leave their work area, local controlled facilities (such as a fully walled area with hand-washing facilities) shall be provided.
6.3.10	Drinking of water from purpose-made dispensers and/or by using disposable conical cups or spill-proof lidded containers may be allowed, provided it is confined to a designated area away from equipment.
6.3.11	<p>Where smoking is allowed under national law, it shall only be permitted in designated controlled smoking areas which shall be isolated from production and storage areas and fitted with extraction to the exterior of the building. Adequate arrangements for dealing with smokers' waste shall also be provided at smoking facilities, both inside buildings and at external locations.</p> <p>The use of electronic cigarettes and associated materials shall not be permitted in locker rooms or in production or storage areas, and shall only be permitted in designated smoking areas.</p>

6.4 MEDICAL SCREENING

The company shall ensure that documented procedures are in place to ensure 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 aware of the symptoms of infection, disease or condition which would prevent a person working. The site shall have a procedure for the notification by personnel, including temporary personnel, of any relevant infections, diseases or conditions with which they may have been in contact or be suffering from.</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	Where permitted by law, visitors and contractors shall be required to fill in a health questionnaire or otherwise confirm that they are not suffering from any symptoms which may put product safety at risk, prior to being allowed into production, packing or storage areas.

6.5 PROTECTIVE CLOTHING

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

CLAUSE	REQUIREMENTS
6.5.1	<p>Hazard and risk principles shall be used to determine the need for protective clothing, including garments and footwear in raw materials handling, preparation, production and storage areas.</p> <p>Where no need for protective clothing has been established by risk assessment in a particular area, it shall be fully justified and shall not pose a contamination risk to the product.</p>
6.5.2	<p>The company shall use risk assessment to determine, document and communicate to all employees, including temporary personnel and contractors, the rules regarding:</p> <ul style="list-style-type: none"> • the wearing of protective clothing on the journey to work • the wearing of protective clothing in raw materials handling, preparation, production and storage areas • the wearing of protective clothing away from the production environment (e.g. removal before entering toilets, canteen or smoking areas).
6.5.3	<p>Where the need for protective clothing has been determined, appropriate clean protective clothing that cannot contaminate the product shall be worn. Sufficient sets of clothing appropriate to the activities carried out shall be provided.</p>
6.5.4	<p>Protective clothing worn in production areas shall provide adequate coverage of the upper torso.</p> <p>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>Based on the assessment of risk to the product, suitable footwear shall be worn within the factory environment.</p>
6.5.6	<p>In production and packing areas, hazard and risk analysis shall be used to determine the need for:</p> <ul style="list-style-type: none"> • snoods for beards and moustaches • scalp hair coverings.
6.5.7	<p>If gloves are used they shall be replaced regularly, be distinctive, intact and not cause a contamination risk to the product.</p>
6.5.8	<p>Protective clothing 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 • controlled laundering facilities • self-care.
6.5.9	<p>Where self-care laundry is permitted, it shall be ensured that:</p> <ul style="list-style-type: none"> • employees 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 shall be provided with suitable means to safely transport washed garments from home to the workplace • there shall be a defined process within the site for monitoring the effectiveness of the system • there shall be a procedure and system for dealing with any case where employees are unable to perform self-laundry effectively, through lack of either diligence or facilities.
6.5.10	<p>Clean and dirty clothing shall be segregated and controlled to prevent cross-contamination.</p>
6.5.11	<p>Disposable protective clothing, if used, shall be subject to adequate control to avoid product contamination.</p>

PART II

REQUIREMENTS

BASIC HYGIENE CATEGORY

1 SENIOR MANAGEMENT COMMITMENT

1.1	Senior management commitment and continual improvement	43
1.2	Management review	44
1.3	Organisational structure, responsibilities and management authority	44

2 HAZARD AND RISK MANAGEMENT SYSTEM

2.1	Hazard and risk management team	45
2.2	Hazard and risk analysis	45
2.3	Exemption of requirements based on risk analysis	47

3 PRODUCT SAFETY AND QUALITY MANAGEMENT

3.1	Product safety and quality management system	48
3.2	Documentation control	48
3.3	Record keeping	48
3.4	Specifications	49
3.5	Internal audits	49
3.6	Supplier approval and performance monitoring	50
3.7	Management of subcontracted processes	50
3.8	Management of suppliers of services	51
3.9	Traceability	51
3.10	Customer focus and contract review	51
3.11	Complaint handling	52
3.12	Management of product withdrawals, and incidents and product recalls	52



4 SITE STANDARDS

4.1	External standards	53
4.2	Building fabric and interiors	53
4.3	Utilities	54
4.4	Security	54
4.5	Layout and product flow	54
4.6	Equipment	55
4.7	Maintenance	55
4.8	Housekeeping and cleaning	55
4.9	Product contamination control	56
4.10	Waste and waste disposal	56
4.11	Pest control	57

5 PRODUCT AND PROCESS CONTROL

5.1	Product development	58
5.2	Graphic design and artwork control	58
5.3	Packaging print control	59
5.4	Process control	59
5.5	Calibration and control of measuring and monitoring devices	60
5.6	Product inspection, testing and measuring	60
5.7	Control of non-conforming product	61
5.8	Incoming goods	61
5.9	Storage of all materials and intermediate and finished products	61
5.10	Dispatch and transport	62

6 PERSONNEL

6.1	Training and competence	63
6.2	Personal hygiene	63
6.3	Staff facilities	64
6.4	Protective clothing	64

BASIC HYGIENE CATEGORY

These requirements are for manufacturers producing packaging for consumer products and the secondary and tertiary packaging for all applications (i.e. packaging that does not come into direct contact with food or other hygiene-sensitive products).

1 SENIOR MANAGEMENT COMMITMENT

1.1 SENIOR MANAGEMENT COMMITMENT AND CONTINUAL IMPROVEMENT



FUNDAMENTAL

The company's senior management shall demonstrate that they are fully committed to the implementation of requirements of the Global Standard for Packaging and Packaging Materials. This shall include provision of adequate resources, effective communication and systems of review to ensure continual improvement. Opportunities for improvement shall be identified, implemented and fully documented.

CLAUSE	REQUIREMENTS
1.1.1	<p>The site shall have a documented policy which states the site's intention to meet its obligation to produce safe and legally compliant products to the specified quality, and confirms its responsibility to its customers. This shall be:</p> <ul style="list-style-type: none"> • signed by the person with overall responsibility for the site • communicated to all staff.
1.1.2	<p>The site's senior management shall establish clear objectives to maintain and improve the quality, safety and legality of products manufactured, in accordance with the product safety and quality policy and this Standard. These objectives shall be:</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 • reviewed at least annually.
1.1.3	<p>The company's senior management shall provide the human and financial resources required to effectively implement the processes of the quality management system and product safety programme and maintain compliance with this Standard.</p>
1.1.4	<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 • any changes to the Standard or protocol published by the BRC.
1.1.5	<p>The site shall have a genuine, current hard copy or electronic version of the Standard available.</p>
1.1.6	<p>Where the site is certificated to the Standard it shall ensure that recertification audits occur on or before the audit due date indicated on the certificate.</p>
1.1.7	<p>The most senior production or operations manager on site shall participate in the opening and closing meetings of the audit for the Global Standard for Packaging and Packaging Materials certification.</p> <p>Relevant departmental managers or their deputies shall be available as required during the audit.</p>
1.1.8	<p>The site's senior management shall ensure that the root causes of non-conformities identified at the previous audit against the Standard have been effectively addressed to prevent recurrence.</p> <p>A system shall be in place to close out non-conformities raised in internal, second-party and third-party audits, with consideration of the root cause.</p>

1.2 MANAGEMENT REVIEW

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

CLAUSE	REQUIREMENTS
1.2.1	Management review meetings attended by the site's senior management shall be undertaken at appropriate planned intervals; as a minimum annually.
1.2.2	The review process shall include the evaluation of: <ul style="list-style-type: none">• previous management review documents, action plans and timeframes• results of internal, second-party and third-party audits• customer performance indicators, complaints and feedback• review of the hazard and risk management (HARM) system• incidents, corrective actions, out-of-specification results and non-conforming materials• resource requirements• the site's performance against the Standard and the objectives set• the effectiveness of root cause analysis and corrective actions.
1.2.3	Records of management reviews and action plans shall be documented.
1.2.4	Product safety, legality and quality issues shall be brought to the attention of senior management, allowing for the resolution of issues requiring immediate action.

1.3 ORGANISATIONAL STRUCTURE, RESPONSIBILITIES AND MANAGEMENT AUTHORITY

The organisational structure shall be clear, with defined responsibilities, and key staff shall be aware of their responsibilities with regard to packaging safety and quality.

CLAUSE	REQUIREMENTS
1.3.1	The site shall have a current organisation chart demonstrating the management structure of the company. The responsibilities for the management of activities which ensure product safety, quality and legality shall be clearly allocated and understood by the managers responsible. It shall be clearly documented who deputises in the absence of the responsible person.
1.3.2	The site's senior management shall ensure that all employees are aware of their responsibilities. Where documented work instructions exist for activities undertaken, the relevant employees shall have access to these and be able to demonstrate that work is carried out in accordance with the instructions.

2 HAZARD AND RISK MANAGEMENT SYSTEM

2.1 HAZARD AND RISK MANAGEMENT TEAM

The hazard and risk management system shall be managed by a multidisciplinary team competent in hazard and risk analysis.

CLAUSE	REQUIREMENTS
2.1.1	<p>There shall be a multidisciplinary team with a designated team leader who shall be suitably trained and able to demonstrate competence and experience of hazard and risk analysis.</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>

2.2 HAZARD AND RISK ANALYSIS



FUNDAMENTAL

A documented hazard and risk management system shall establish the effectiveness of the site's prerequisite programmes and identify any further risks to the safety, quality and legality of products.

CLAUSE	REQUIREMENTS
2.2.1	The scope of the hazard and risk analysis shall be clearly defined and documented and shall cover all products and processes included within the intended scope of certification.
2.2.2	<p>The hazard and risk analysis team shall maintain awareness of and take into account:</p> <ul style="list-style-type: none"> • historical and known hazards associated with specific processes, raw materials or intended use of the product (where known) • known likely product defects that affect safety or quality • relevant codes of practice or recognised guidelines • legislative requirements.
2.2.3	<p>A full description of the product shall be developed, which includes all relevant information on product safety, quality and integrity. As a guide this may include:</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>A flow diagram shall be prepared for each product, product group or process. This shall set out each process step from the receipt of raw materials to dispatch to the customer. As a guide, this shall include, as relevant:</p> <ul style="list-style-type: none"> • receipt and approval of artwork • receipt and preparation of raw materials such as additives, inks and adhesives • each manufacturing process step • in-line testing or measuring equipment • the use of rework and post-consumer recycled materials • any subcontracted processes • customer returns. <p>The accuracy of the process flow shall be validated by the hazard and risk analysis team.</p>

CLAUSE	REQUIREMENTS
2.2.5	<p>The hazard and risk analysis team shall identify and record all potential hazards that are reasonably expected to occur at each step in relation to the product and process. The hazards considered shall include, where relevant:</p> <ul style="list-style-type: none"> • foreign objects • legality • chemical contamination (e.g. taint, odour, allergen, component transfer from inks, varnishes and glues) • hazards that may have an impact on the functional integrity and performance of the final product in use • potential for unintended migration of substances from the packaging material into food or other hygiene-sensitive product.
2.2.6	<p>The hazard and risk analysis team shall identify control measures necessary to prevent, eliminate or reduce each hazard to acceptable levels.</p> <p>Controls for identified hazards to product quality shall be appropriately managed through the prerequisite programmes, as set out in section 5.</p>
2.2.7	<p>For each hazard that requires control, the control points shall be reviewed to evaluate whether existing prerequisites are effective in providing control.</p> <p>Where greater controls are required to the prerequisite programmes, improvements shall be implemented to ensure control is achieved.</p>
2.2.8	<p>For any critical control points, the appropriate critical limits shall be defined in order to identify clearly whether the process is in or out of control. Critical limits shall be measurable, where possible, and the rationale for their establishment clearly documented. Relevant legislation and codes of practice shall be taken into account when establishing the limits.</p>
2.2.9	<p>For any critical control points, a monitoring system shall be defined in order to ensure compliance with critical limits. Records of the monitoring shall be maintained. Documented procedures relating to the monitoring of critical controls shall be included in internal audits against the Standard (see clause 3.3).</p>
2.2.10	<p>The corrective action that shall be taken when monitored results indicate a failure to meet the control limit shall be established and documented. This shall include the procedures for quarantining and evaluating potentially out-of-specification products to ensure they are not released until their safety, quality and legality can be established.</p>
2.2.11	<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 and risk analysis plan is effective and may include a review of:</p> <ul style="list-style-type: none"> • process changes • product composition changes • complaints • product failures • finished product recalls from consumers (including system tests) • product withdrawals • results of internal audits of prerequisite programmes • results from external and third-party auditors • new developments in the market or industry associated with materials, process or product.

2.3 EXEMPTION OF REQUIREMENTS BASED ON RISK ANALYSIS

The hazard and risk analysis study shall be fully supported by the implementation of the prerequisites set out in requirements clauses 4 to 6. However, the hazard and risk analysis may indicate that some of the requirements may be exempted.

CLAUSE	REQUIREMENTS
2.3.1	Exemptions shall be documented and regarded as proposed exemptions for review at audit. Acceptance or rejection of the proposed exemptions shall be recorded in the auditor's report.
2.3.2	The site shall keep recorded exemptions to the Standard under review and provide documented evidence of this review at subsequent audit.

3 PRODUCT SAFETY AND QUALITY MANAGEMENT

3.1 PRODUCT SAFETY AND QUALITY MANAGEMENT SYSTEM

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

CLAUSE	REQUIREMENTS
3.1.1	The site's documented procedures, working methods and practices shall be collated in a navigable and readily accessible system, with consideration being given to translation into appropriate languages.
3.1.2	The system shall be fully implemented, reviewed at appropriate planned intervals and improved where necessary.

3.2 DOCUMENTATION CONTROL

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

CLAUSE	REQUIREMENTS
3.2.1	The company shall have a documented procedure to manage documents which form part of the product safety and quality system. This shall include: <ul style="list-style-type: none">• a list of controlled documents indicating the latest version number• the method for the identification and authorisation of controlled documents• a record of the reason for any changes or amendments to documents• the system for the replacement of existing documents when these are updated.
3.2.2	Where documents and records are in electronic form these shall be suitably protected 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. Where records are in electronic form these shall be suitably backed up to prevent loss.
3.3.2	Any alteration 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 period of retention for records shall relate to the usable life of the packaging and products it is designed to contain and shall respect any customer requirements.

3.4 SPECIFICATIONS



FUNDAMENTAL

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

CLAUSE	REQUIREMENTS
3.4.1	Specifications shall be suitably detailed and accurate, and shall ensure compliance with relevant product safety and legislative requirements.
3.4.2	The company shall seek formal agreement of specifications with relevant parties. Where specifications are not formally agreed then the company shall be able to demonstrate that they have taken steps to put an agreement in place.
3.4.3	<p>Where packaging for food or other hygiene-sensitive products is produced, a declaration of compliance shall be maintained which enables users of the packaging materials to ensure compatibility between those materials and the product with which they may be in contact.</p> <p>The declaration of compliance shall contain as a minimum:</p> <ul style="list-style-type: none"> • the nature of the materials used in the manufacture of the packaging • confirmation that the packaging materials meet relevant legal requirements • the inclusion of any post-consumer recycled materials. <p>This shall identify any limitations of use of the product and the usable life of the packaging material (where relevant).</p> <p>Products shall meet at least minimum legal requirements in the country of manufacture, and use, where known.</p>
3.4.4	The presence of manufacturer's trademarks or logo on packaging materials shall, where appropriate, be formally agreed between relevant parties.
3.4.5	A specification review process shall be operated where product characteristics change or at an appropriate predetermined interval.
3.4.6	Where specifications are in electronic form these shall be suitably protected to prevent loss or malicious intervention.

3.5 INTERNAL AUDITS



FUNDAMENTAL

The company shall be able to demonstrate it verifies the effective application of the requirements of the Global Standard for Packaging and Packaging Materials through internal audits.

CLAUSE	REQUIREMENTS
3.5.1	<p>There shall be a scheduled programme of internal audits throughout the year with a scope which covers the hazard and risk management system, prerequisite programmes and all procedures that have been implemented to achieve this Standard. All activities shall be covered at least annually.</p> <p>The internal audit programme shall be fully implemented.</p>
3.5.2	The scope and frequency of the audits shall be established in relation to the risks associated with the activity and previous audit performance.
3.5.3	Internal audits shall be carried out by appropriately trained, competent auditors. Auditors shall be sufficiently independent from the process being audited to ensure impartiality (i.e. they must not audit their own work).
3.5.4	<p>Internal audit reports shall identify conformity as well as non-conformity.</p> <p>Results shall be notified to the personnel responsible for the process audited. Root cause analysis shall be used to determine appropriate corrective action. Corrective actions and timescales for their implementation shall be agreed and completion of the actions verified.</p>

3.6 SUPPLIER APPROVAL AND PERFORMANCE MONITORING

The company shall operate effective, documented procedures for approval and monitoring of its suppliers.

CLAUSE	REQUIREMENTS
3.6.1	<p>The site shall have a documented supplier approval procedure and continual assessment programme in place, based upon risk analysis. These shall apply to suppliers of:</p> <ul style="list-style-type: none"> • materials • subcontracted processes <p>to the site and ensure that materials and services procured conform to defined requirements, where there is a potential impact to product safety, quality or legality.</p>
3.6.2	<p>The procedures shall include clear criteria for the assessment and approval of new suppliers. Assessment may take the form of:</p> <ul style="list-style-type: none"> • supplier certification with a scope covering the products supplied (e.g. against the appropriate BRC Global Standard, or other GFSI benchmarked scheme) • supplier questionnaires • supplier audits. <p>The site shall have an up-to-date list of approved suppliers.</p>
3.6.3	<p>Records of supplier assessment and necessary actions shall be maintained and reviewed.</p>
3.6.4	<p>The procedures shall define how exceptions are handled; for example, the use of products or services where audit or monitoring has not been undertaken. Assessment (on a batch or delivery basis) may take the form of:</p> <ul style="list-style-type: none"> • certificate of analysis • declaration of compliance.

3.7 MANAGEMENT OF SUBCONTRACTED PROCESSES

Subcontractors shall be managed effectively to prevent any risk of contamination or damage and ensure that product is produced to specification.

CLAUSE	REQUIREMENTS
3.7.1	<p>The use of subcontractors and the status of the subcontractor with respect to the Standard shall be notified to the brand owner and/or customer.</p>
3.7.2	<p>Where any processes are subcontracted, including artwork or pre-press activity, the risks to the quality and safety of the product shall be assessed. Any risks shall be communicated to relevant personnel and effectively managed.</p>
3.7.3	<p>Clear specifications shall be agreed for all work outsourced to a subcontractor.</p>
3.7.4	<p>Where any process steps in the manufacture of the packaging or packaging material are subcontracted, final release of the product shall remain the responsibility of the site.</p> <p>Controls shall be in place for checks on finished work to ensure product safety and quality meets specification prior to dispatch to the final customer.</p>

3.8 MANAGEMENT OF SUPPLIERS OF SERVICES

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

CLAUSE	REQUIREMENTS
3.8.1	<p>There shall be a documented procedure for the approval and monitoring of suppliers of services. Such services may include, but are not limited to:</p> <ul style="list-style-type: none"> • pest control • transport and distribution • storage and dispatch • calibration services • waste management. <p>Providers of utilities such as water, electricity or gas may be excluded on the basis of risk.</p>
3.8.2	<p>Documented agreements shall exist with the suppliers of services which clearly define service expectations and ensure potential risks associated with the service have been addressed.</p>

3.9 TRACEABILITY



FUNDAMENTAL

The site shall be able to trace and follow all raw materials through processing to the distribution of the finished product (packaging material) to the customer and vice versa.

CLAUSE	REQUIREMENTS
3.9.1	<p>The site shall have a system which has the ability to trace and follow all raw materials from the supplier through all stages of processing and distribution of the finished product and vice versa. Where continuous processes are used or raw materials are in bulk silos, traceability shall be achieved to the best practical level of accuracy.</p>
3.9.2	<p>Identification of raw materials, intermediate products, finished products, non-conforming product and quarantined goods shall be adequate to ensure traceability.</p>
3.9.3	<p>An appropriate system shall be in place to ensure the customer can identify a product or production lot number for the product, for the purposes of traceability.</p>
3.9.4	<p>The system shall be tested to ensure traceability can be determined from raw materials to the finished product and vice versa. This test shall take place at least annually.</p>
3.9.5	<p>Where rework or any reworking operation is performed, traceability shall be maintained.</p>

3.10 CUSTOMER FOCUS AND CONTRACT REVIEW

The company's senior management shall ensure that processes are in place to determine customer needs and expectations with regard to quality, safety and legality, and ensure these are fulfilled.

CLAUSE	REQUIREMENTS
3.10.1	<p>The company shall identify those job titles responsible for communication with customers and shall have an effective system for communication.</p>
3.10.2	<p>Customer needs and expectations shall be documented and reviewed on a suitable frequency. Any changes to existing agreements or contracts shall be agreed, documented and communicated to appropriate departments.</p>
3.10.3	<p>Where customers have set particular performance criteria or indicators for monitoring, these requirements shall be communicated to relevant staff, adhered to, and reviewed at appropriate intervals.</p>

3.11 COMPLAINT HANDLING

Customer complaints relating to product safety or quality shall be effectively handled and information used to reduce complaint levels.

CLAUSE	REQUIREMENTS
3.11.1	Actions appropriate to the seriousness and frequency of identified problems shall be carried out promptly and effectively by appropriately trained staff.
3.11.2	Complaint data shall be analysed to identify significant trends. Where there has been a significant increase or repetition of a complaint type, root cause analysis shall be used to implement ongoing improvements to product safety, legality and quality, and to avoid recurrence. This analysis shall be made available to relevant staff.

3.12 MANAGEMENT OF PRODUCT WITHDRAWALS, AND INCIDENTS AND PRODUCT RECALLS

The site shall have systems in place to effectively manage any product withdrawals or returns from customers, incidents and product recalls in order to ensure that all potential risks to the quality and legality of products are controlled.

CLAUSE	REQUIREMENTS
3.12.1	A product withdrawal procedure shall be documented and shall include as a minimum: <ul style="list-style-type: none"> • identification of the key personnel involved in assessing potential product withdrawals or returns, with their responsibilities clearly defined • a communications plan including methods of informing customers • root cause analysis and corrective action to implement appropriate improvements as required.
3.12.2	The withdrawal procedure shall be capable of being operated at any time and will take into account notification to the supply chain, stock return, logistics for recovery, storage of recovered product and disposal.
3.12.3	The designated manager shall be responsible for ensuring that root cause analysis is used to determine and implement preventive action and improvements as necessary.
3.12.4	The company shall provide written guidance and training for relevant staff regarding the type of event that would constitute an incident. A documented incident reporting procedure shall be in place.
3.12.5	The company shall effectively manage an incident to prevent release of product where safety or quality may have been affected.
3.12.6	A procedure to manage product recalls initiated by the brand owner or specifier shall be documented and shall include as a minimum: <ul style="list-style-type: none"> • identification of the key personnel involved in assessing potential recalls, together with clearly defined responsibilities • a communications plan that includes methods of informing customers and (where necessary) regulatory bodies in a timely manner • corrective action and business recovery • review of any recalls in order to conduct root cause analysis and implement appropriate improvements as required.
3.12.7	Where a site's products are involved in a product recall, the site shall assist with provision of any information (such as traceability) as required.
3.12.8	The product withdrawal procedure shall be tested at least annually to ensure its effective operation. The results of the test, and of any actual withdrawals, shall be used to review the procedure and implement improvements as necessary.

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 of safe and legal 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 quality of the finished product. Measures shall be taken to prevent contamination.
4.1.2	The external areas shall be maintained in good order. Any grassed or planted areas surrounding buildings shall be regularly tended and well maintained. External traffic routes under site control shall be suitably surfaced to avoid contamination of the product.
4.1.3	The building fabric shall be maintained to minimise potential for pest entry, ingress of water and other contaminants. External silos, pipework or other access points for the product and/or raw materials shall be appropriately sealed and secured. Where possible, a clean and unobstructed area shall be provided along the external walls of the buildings used for production and/or storage.
4.1.4	Where natural external drainage is inadequate, additional drainage shall be installed. Drains shall be properly protected to prevent entry of pests.
4.1.5	Where external storage of raw materials is necessary, these shall be protected in order to minimise the risk of contamination.

4.2 BUILDING FABRIC AND INTERIORS: RAW MATERIALS HANDLING, PREPARATION, PROCESSING, PACKING AND STORAGE AREAS

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

CLAUSE	REQUIREMENTS
4.2.1	Walls, floors, ceilings (including suspended ceilings) and pipework shall be maintained in good condition and shall facilitate cleaning.
4.2.2	Where they constitute a risk to product, and based on the likelihood and risk of contamination, windows and roof glazing shall be protected against breakage.
4.2.3	Where they constitute a risk to product, and based on the likelihood and risk of non-production glass contamination, all bulbs and strip lights, including those on flying-insect control devices, shall be adequately protected.
4.2.4	Suitable and sufficient lighting shall be provided to ensure a safe working environment, correct operation of processes, effective inspection of the product and cleaning.
4.2.5	Suitable and sufficient ventilation shall be provided.

4.3 UTILITIES

Product quality shall not be compromised by the location, construction and delivery of the utilities to and within the production and storage areas.

CLAUSE	REQUIREMENTS
4.3.1	All water used in the processing of the products or equipment cleaning shall be potable or suitably treated to prevent contamination.
4.3.2	Air, compressed air or other gases that come into direct contact with the packaging shall present no risk to product safety or quality and shall comply with any relevant legal regulations.

4.4 SECURITY

Product and process integrity shall be assured through appropriate site security provision.

CLAUSE	REQUIREMENTS
4.4.1	<p>The company shall undertake a documented risk assessment of the security arrangements and potential risks to the products from any deliberate attempt to inflict contamination or damage. Areas shall be assessed according to risk; sensitive or restricted areas shall be defined, clearly marked, monitored and controlled.</p> <p>Identified security arrangements to reduce risks shall be documented, implemented and reviewed at least annually.</p>
4.4.2	<p>Measures shall be in place to ensure only authorised personnel have access to production and storage areas, and access to the site by employees, contractors and visitors shall be controlled.</p> <p>A visitor reporting system shall be in place. Staff 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 AND PRODUCT FLOW

Premises and plant shall be logically designed, constructed and maintained.

CLAUSE	REQUIREMENTS
4.5.1	<p>There shall be a plan of the site which defines:</p> <ul style="list-style-type: none">• access points for personnel• travel routes• staff facilities• process flow• storage areas.
4.5.2	The process flow from intake to dispatch shall be arranged to minimise the risk of contamination or damage to the product.
4.5.3	Premises shall allow sufficient working space and storage capacity to enable all operations to be carried out properly.
4.5.4	If it is necessary to allow access through production areas, designated walkways shall be provided that ensure there is adequate segregation from materials.

4.6 EQUIPMENT

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

CLAUSE	REQUIREMENTS
4.6.1	Equipment shall be constructed of suitable materials and be designed to ensure it can be effectively cleaned and maintained.
4.6.2	Newly installed equipment shall be properly specified before purchase. New equipment shall be tested and commissioned prior to use and a maintenance programme established.

4.7 MAINTENANCE

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

CLAUSE	REQUIREMENTS
4.7.1	A documented programme of maintenance shall be operated, covering all items of production equipment and plant to prevent contamination and reduce the risk of breakdown.
4.7.2	Maintenance work shall not place product quality or legality at risk. Maintenance work shall be followed by a documented clearance procedure which records that equipment is cleared to resume production.
4.7.3	Tools and other maintenance equipment shall be cleared away after use and appropriately stored.
4.7.4	Temporary repairs/modifications using tape, cardboard, etc., shall only be permitted in emergencies and where product contamination is not at risk. Such modifications shall be subject to a time limit and shall be recorded and scheduled for correction.
4.7.5	Engineering workshops shall be controlled to prevent transfer of engineering debris to production or storage areas (e.g. by provision of swarf mats).
4.7.6	Contractors involved in maintenance or repair shall be suitably monitored by a staff member who shall be responsible for their activities.

4.8 HOUSEKEEPING AND CLEANING



FUNDAMENTAL

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

CLAUSE	REQUIREMENTS
4.8.1	Good standards of housekeeping shall be maintained, which shall include a 'clean as you go' policy.
4.8.2	Documented cleaning procedures shall be in place and maintained for buildings, equipment and vehicles. The frequency and methods of cleaning shall be based on risk. Cleaning schedules and procedures shall include the following information: <ul style="list-style-type: none"> • item/area to be cleaned • frequency of cleaning • method of cleaning • cleaning materials to be used.
4.8.3	Cleaning chemicals shall be fit for purpose, suitably labelled, secured in closed containers and used in accordance with manufacturers' instructions. Materials and equipment used for cleaning toilets shall be segregated from those used elsewhere.

4.9 PRODUCT CONTAMINATION CONTROL

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

4.9.1 GLASS, BRITTLE PLASTICS, CERAMICS AND SIMILAR MATERIALS CONTROL

CLAUSE	REQUIREMENTS
4.9.1.1	<p>The company shall use risk assessment to determine whether glass or brittle plastics (other than the product in the production and storage areas) pose a risk to product safety or integrity.</p> <p>Where a potential hazard is identified, the glass or brittle plastic shall be controlled and recorded on a register which shall include:</p> <ul style="list-style-type: none">• recorded checks of condition of items, carried out at a suitable predetermined frequency• details on cleaning or replacing items to minimise potential for product contamination.
4.9.1.2	<p>Where non-production glass or brittle plastic breakage occurs, a responsible person shall be placed in charge of the clean-up operation and shall ensure that no other area is allowed to become contaminated due to the breakage. Any product that has become contaminated shall be segregated and disposed of.</p> <p>All breakages shall be recorded in an incident report.</p>

4.9.2 SHARPS CONTROL

CLAUSE	REQUIREMENTS
4.9.2.1	There shall be a documented policy for the control of the use of sharps.
4.9.2.2	Sharp blades, equipment and tools shall not be left in a position that allows them to contaminate the product.
4.9.2.3	Snap-off blade knives shall not be used.

4.9.3 CHEMICAL AND BIOLOGICAL CONTROL

CLAUSE	REQUIREMENTS
4.9.3.1	<p>Processes shall be in place to manage the use, storage and handling of non-production chemicals, to prevent chemical contamination. These shall include as a minimum:</p> <ul style="list-style-type: none">• a list of approved chemicals for purchase• avoidance of strongly scented products• the labelling and/or identification of containers of chemicals at all times.

4.10 WASTE AND WASTE DISPOSAL

Suitable facilities shall be provided for the storage and disposal of process and other waste.

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	Where appropriate, waste shall be categorised according to legislative requirements based on the intended means of disposal (such as recycling), and segregated and collected in appropriate designated waste containers.
4.10.3	Substandard trademarked materials shall be rendered unusable through a destructive process. All materials disposed of shall be recorded.

4.11 PEST CONTROL

The company shall be responsible for minimising the risk of pest infestation on the site.

CLAUSE	REQUIREMENTS
4.11.1	A preventive pest control programme shall be maintained, covering all areas of the site under the site's control.
4.11.2	The site shall either contract the services of a competent pest control organisation or shall have appropriately trained staff for the regular inspection and treatment of the site in order to deter and eradicate infestation.
4.11.3	Where a site undertakes its own pest control, it shall be able to demonstrate that: <ul style="list-style-type: none"> • pest control operations are undertaken by trained and competent staff with sufficient knowledge to select appropriate pest control chemicals and proofing methods and understand the limitations of use, relevant to the biology of the pests associated with the site • staff undertaking pest control activities meet any legal requirements for training or registration • sufficient resources are available to respond to any infestation issues • there is ready access to specialist technical knowledge when required • legislation governing the use of pest control products is understood • dedicated locked facilities are used for the storage of pesticides.
4.11.4	Pest control equipment such as bait stations, traps or electric fly-killing devices shall be appropriately located and operational.
4.11.5	In the event of infestation, immediate action shall be taken to eliminate the hazard. Action shall be taken to evaluate the potential for contamination or damage to packaging and checks instigated before release.
4.11.6	A pest control manual shall be maintained which shall include: <ul style="list-style-type: none"> • an up-to-date site plan identifying numbered pest control device locations • identification of the baits and/or monitoring devices on site • details of pest control products used and instructions for their effective use • detailed records of pest control inspections and of any pest infestation.
4.11.7	Employees shall understand the signs of pest activity and be aware of the need to report any evidence to a designated manager.

5 PRODUCT AND PROCESS CONTROL

5.1 PRODUCT DEVELOPMENT

Documented product development or modification procedures shall be in place to ensure the production 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 process requirements and end use, where possible.</p> <p>Any critical-use parameters shall be identified and defined; for example, barrier requirements, max/min use temperature, machine running, use of recycled materials, and testing requirements (including migration, where relevant).</p> <p>Special attention shall be paid to any materials that are required or requested to be manufactured from recycled materials, to ensure that they are both appropriate and legal.</p>
5.1.2	<p>The site shall clearly define and document when a production trial is required.</p> <p>Where appropriate, production trials shall be carried out and testing shall validate that manufacturing processes are capable of producing a safe and legal product to the required quality.</p>
5.1.3	<p>The company shall ensure that production is carried out using defined operating conditions that result in safe and legal products of the prescribed quality.</p>
5.1.4	<p>A technical product specification shall be prepared and, where possible, agreed with the customer or brand owner before the production process begins.</p>
5.1.5	<p>Samples as agreed with the specifier shall be retained for future reference.</p>

5.2 GRAPHIC DESIGN AND ARTWORK CONTROL

Artwork and all pre-press processes conducted by the site shall be managed to ensure loss of information and variation from customer specification is eliminated.

CLAUSE	REQUIREMENTS
5.2.1	<p>The site shall have a documented artwork management procedure covering the activities for which the site has responsibility. This may include, but is not limited to:</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.
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.</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 renewal of approved masters, as necessary.</p>

CLAUSE	REQUIREMENTS
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 are printed or decorated, procedures shall be in place to ensure that the information is fully legible and correctly reproduced to the customer's specification and legal requirements.

CLAUSE	REQUIREMENTS
5.3.1	<p>An assessment shall be carried out of the pre-press activity, print process and handling of printed packaging (product) to identify:</p> <ul style="list-style-type: none"> • risks of loss of essential information • mixing of printed product. <p>Controls shall be established and implemented to reduce the risks identified.</p>
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.
5.3.5	Where composite print is used (a mixture of different designs printed together), a process shall be in place to ensure effective segregation of differing print variants.
5.3.6	Samples of printed packaging shall be retained together with production records for a period of time to be agreed with the customer/specifier/brand owner.
5.3.7	Any unused printed product shall be accounted for and either disposed of or identified and appropriately stored.
5.3.8	Lighting in print inspection cabinets and other means of print/colour checking shall be agreed with the customer or conform to accepted industry standards.

5.4 PROCESS CONTROL



FUNDAMENTAL

Documented procedures shall be in place to ensure effective quality assurance of operations throughout the process.

CLAUSE	REQUIREMENTS
5.4.1	A review of the manufacturing and, where applicable, printing process shall identify manufacturing process control points that could significantly affect the quality of the products produced.
5.4.2	For each manufacturing process control point, machine settings or process limits shall be established and documented – the process specification.
5.4.3	A bill of materials and process specification (including manufacturing process control points) shall be available for each batch or lot during production.
5.4.4	Documented process checks shall be undertaken at start-up, following adjustments to equipment and periodically during production, to ensure products are consistently produced to the agreed quality specification.

CLAUSE	REQUIREMENTS
5.4.5	A documented clearance procedure shall be in place to ensure that at start-up the line is clear of all previous work and production documents.
5.4.6	In the event of changes to product composition, processing methods or equipment, the site shall, where appropriate, re-establish process characteristics and validate product data to ensure that product safety, legality and quality are achieved.

5.5 CALIBRATION AND CONTROL OF MEASURING AND MONITORING DEVICES

Measuring equipment used to monitor manufacturing process control points, product quality and legality shall be calibrated.

CLAUSE	REQUIREMENTS
5.5.1	The site shall identify and control in-line and off-line measuring equipment used to monitor product safety and quality.
5.5.2	Where possible, calibration shall be traceable to a recognised national or international standard. Where a traceable calibration is not possible, the site shall demonstrate the basis by which standardisation is carried out.
5.5.3	Results and any actions taken when measuring equipment is found to be operating outside the specified limits shall be documented.

5.6 PRODUCT INSPECTION, TESTING AND MEASURING

The company shall use appropriate documented procedures and facilities when undertaking or subcontracting inspection and analyses critical to product safety, legality and quality.

CLAUSE	REQUIREMENTS
5.6.1	Quality checks shall be carried out to demonstrate that the finished product is within the tolerances laid down in the agreed product specification and conforms to legal requirements. The frequency of checks shall be in accordance with industry-accepted practice or customer requirements and based on risk analysis.
5.6.2	Hazard and risk analysis principles shall be used to determine the need for in-line product testing equipment to ensure product safety, quality and legality.
5.6.3	The accuracy of in-line equipment shall be specified (with permitted tolerances), having due regard to the product parameter being controlled.
5.6.4	The company shall establish, document and implement procedures for the operation, routine monitoring and testing of all equipment used in product inspection, testing and measurement.
5.6.5	Routine off-line quality checks shall be carried out at appropriate stages in production to demonstrate that the product is within the tolerances laid down in the agreed product specification.
5.6.6	Procedures shall be in place to ensure the reliability of test results.
5.6.7	Where the company undertakes or subcontracts analyses critical to product safety or legality, the laboratory or subcontractors shall have gained 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.

5.7 CONTROL OF NON-CONFORMING PRODUCT

The site shall ensure that out-of-specification product is clearly identified and quarantined.

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 quarantining of materials before a decision has been made on their final disposition.
5.7.2	Non-conforming materials shall be assessed and a decision taken to reject, accept by concession, rework or put to alternative use. The decision and reasons shall be documented.
5.7.3	Corrective actions, root cause analysis and preventive actions shall be implemented to avoid recurrence of the non-conformity. Actions taken shall be documented.

5.8 INCOMING GOODS

Incoming goods shall be appropriately checked for contents, packaging integrity and potential contamination.

CLAUSE	REQUIREMENTS
5.8.1	The site shall document a raw materials and intermediate product intake procedure to ensure that incoming goods match purchase or product specifications. This may take the form of: <ul style="list-style-type: none"> • purchase orders • delivery notes.
5.8.2	Receipt documents and/or product identification shall facilitate correct stock rotation of goods in storage.

5.9 STORAGE OF ALL MATERIALS AND INTERMEDIATE AND FINISHED PRODUCTS

The risk of contamination of raw materials and finished products shall be minimised while in storage.

CLAUSE	REQUIREMENTS
5.9.1	All materials, work in progress and product shall be properly identified and protected during storage by appropriate packaging to protect the product from contamination.
5.9.2	Storage, including off-site storage, shall be controlled to protect the product from contamination.
5.9.3	The site shall ensure that hazardous chemicals are handled in such a way that risk to product quality and legality is minimised.
5.9.4	Material intended for recycling shall be appropriately protected against contamination hazards.

5.10 DISPATCH AND TRANSPORT

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

CLAUSE	REQUIREMENTS
5.10.1	All products and materials shall be identified and either protected during distribution by appropriate external packaging, or transported under conditions to protect the product from contamination.
5.10.2	All pallets shall be checked. Damaged, contaminated or unacceptable pallets shall be discarded. Wooden pallets, if used, shall be sound, dry, clean and free from damage and contamination.
5.10.3	All company-owned vehicles used for deliveries shall be visually checked for cleanliness before loading. Unsatisfactory lorries shall not be loaded.
5.10.4	Where the company employs third-party contractors there shall be a contract or agreed terms and conditions. Where this is not possible, with general carriers, the packaging shall be adequate to protect the product against damage, contamination hazards, taint and odour.
5.10.5	Vehicle drivers shall comply with the site rules relevant to this Standard. Access to the site for third-party transport personnel shall be controlled and, where possible, facilities provided to negate the need to enter storage or production areas.

6 PERSONNEL

6.1 TRAINING AND COMPETENCE: RAW MATERIALS HANDLING, PREPARATION, PROCESSING, PACKING AND STORAGE AREAS



FUNDAMENTAL

The company shall ensure that all employees are adequately trained, instructed and supervised commensurate with their activity and that they are competent to undertake their job role.

CLAUSE	REQUIREMENTS
6.1.1	All personnel, including temporary personnel, shall be appropriately trained prior to commencing work and adequately supervised throughout the working period.
6.1.2	Where personnel are engaged in activities relating to product safety, quality and legality, relevant training and competency assessment shall be in place. This may include, but is not limited to: <ul style="list-style-type: none"> • product inspection, testing and measuring • calibration • printed packaging controls • operatives at manufacturing process control points.
6.1.3	The company shall routinely review and document the competencies of staff and provide relevant training as appropriate. Records of this review shall be maintained.
6.1.4	Records of training shall be available. These shall include: <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). Where training is undertaken by agencies on behalf of the company, records of the training shall be available.
6.1.5	The site shall put in place documented programmes covering the training needs of relevant personnel.

6.2 PERSONAL HYGIENE: RAW MATERIALS HANDLING, PREPARATION, PROCESSING, PACKING AND STORAGE AREAS

The company's personal hygiene standards shall be developed to minimise the risk of product contamination from personnel. These standards shall be appropriate to the products produced and be adopted by all personnel, including agency-supplied staff, contractors and visitors to the production facility.

CLAUSE	REQUIREMENTS
6.2.1	The requirements for personal hygiene shall be determined on the basis of risk, documented and communicated to all personnel. This shall address: <ul style="list-style-type: none"> • hand washing • wearing of jewellery, including wristwatches.
6.2.2	Personal items and belongings, including personal mobile phones, shall not be taken into production areas without the permission of the management.

6.3 STAFF FACILITIES

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

CLAUSE	REQUIREMENTS
6.3.1	Eating (including the eating of confectionery and chewing of gum or tobacco), drinking and smoking shall not be allowed in locker and changing rooms.
6.3.2	Suitable and sufficient hand-washing facilities shall be available to enable cleaning of hands before commencing work and as necessary during the course of work. Such hand-washing facilities shall provide, as a minimum: <ul style="list-style-type: none"> • sufficient quantity of water at a suitable temperature to encourage hand washing • unscented liquid soap or foam • adequate hand-drying facilities • advisory signs to prompt use (including signs in appropriate languages).
6.3.3	Toilets shall not open directly into storage, processing or production areas in order to prevent the risk of contamination to product. Toilets shall be provided with suitable and sufficient hand-washing facilities.
6.3.4	Facilities for visitors and contractors shall enable compliance with the site's hygiene policy.
6.3.5	Eating (including the eating of confectionery and chewing of gum or tobacco), drinking and smoking shall not be allowed in production or storage areas.
6.3.6	Drinking of water from purpose-made dispensers and/or by using disposable conical cups or spill-proof lidded containers may be allowed, provided it is confined to a designated area away from equipment.

6.4 PROTECTIVE CLOTHING

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

The risk of product contamination from clothing, hair or personal items shall be minimised.

CLAUSE	REQUIREMENTS
6.4.1	Hazard and risk principles shall be used to determine the need for protective clothing, including garments and footwear in raw materials handling, preparation, production and storage areas. Where no need for protective clothing has been established by risk assessment, it shall be fully justified and shall not pose a contamination risk to the product.
6.4.2	The company shall use risk assessment to determine, document and communicate to all employees, including temporary personnel and contractors, the rules regarding: <ul style="list-style-type: none"> • the wearing of protective clothing on the journey to work • the wearing of protective clothing in raw materials handling, preparation, production and storage areas • the wearing of protective clothing away from the production environment (e.g. removal before entering toilets, canteen or smoking areas).
6.4.3	Where protective clothing is used it shall be kept adequately clean. Changes of clothing shall be available as required.
6.4.4	Where protective clothing is used, clean and dirty clothing shall be segregated and controlled to prevent cross-contamination.
6.4.5	Disposable protective clothing, if used, shall be subject to adequate control to avoid product contamination.

PART III

AUDIT PROTOCOL

INTRODUCTION

1 GENERAL PROTOCOL - AUDIT PREPARATION

1.1	Selection of an audit option	69
1.2	Self-assessment of compliance with the Standard	71
1.3	Selection of a certification body	71
1.4	Company/certification body contractual arrangements	71
1.5	Registration fee	72
1.6	Scope of audit	72
1.7	Auditor(s) selection	73

2 ANNOUNCED AUDIT PROTOCOL

2.1	Audit planning	74
2.2	The on-site audit	75
2.3	Non-conformities and corrective action	76
2.4	Grading of the audit	78
2.5	Audit reporting	78
2.6	Certification	78
2.7	Ongoing audit frequency and recertification	79



3 UNANNOUNCED AUDIT PROTOCOL: OPTION 1 - FULL AUDIT

3.1	Audit planning	80
3.2	The on-site audit	81
3.3	Non-conformities and corrective action	81
3.4	Grading of the audit	82
3.5	Audit reporting	82
3.6	Certification	82
3.7	Ongoing audit frequency and recertification	82

4 UNANNOUNCED AUDIT PROTOCOL: OPTION 2 - TWO-PART AUDIT

4.1	Audit planning	82
4.2	The on-site audits	84
4.3	Non-conformities and corrective action	86
4.4	Grading of the audit	86
4.5	Audit reporting	86
4.6	Certification	86
4.7	Ongoing audit frequency and recertification	86

5 BRC GLOBAL MARKETS PROGRAMME

5.1	Audit planning	87
5.2	The on-site audit	89
5.3	Non-conformities and corrective action	90
5.4	Grading of the audit	91
5.5	Audit reporting	91
5.6	Basic or intermediate-level recognition	91
5.7	Ongoing audit frequency and recertification	91

6 VOLUNTARY MODULES

6.1	Audit planning	92
6.2	Non-conformities and corrective action	93
6.3	Grading of the audit	93
6.4	Audit reporting	93
6.5	Certification	94
6.6	Ongoing audit frequency and recertification	94

7 GENERAL PROTOCOL - POST AUDIT

7.1	Communication with certification bodies	94
7.2	Extension to scope	95
7.3	Certification withdrawal	95
7.4	Appeals	95
7.5	Surveillance of certificated companies	96
7.6	BRC logos	96
7.7	The BRC Global Standards Directory	96

PART III

AUDIT PROTOCOL

INTRODUCTION

The Global Standard for Packaging and Packaging Materials 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 operations and the maturity of their product safety and quality management systems.

The general audit protocol describes the requirements for auditing and certification which are applicable to all of the audit programmes for both hygiene categories. This should be read and fully understood. The process is summarised in Figure 2.

Each of the audit options has its own particular characteristics and these are described in detail in sections 2–6 of this part (Part III). Section 7 sets out the process and marketing opportunities for all sites after certification.

Every effort has been made to ensure that the content of this audit protocol is accurate at the time of publication. However, it may be subject to minor change, and reference should be made to the BRC Global Standards website (www.brcglobalstandards.com), where changes will be published.

Conformance by the company to the requirements of the Global Standard for Packaging and Packaging Materials 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.

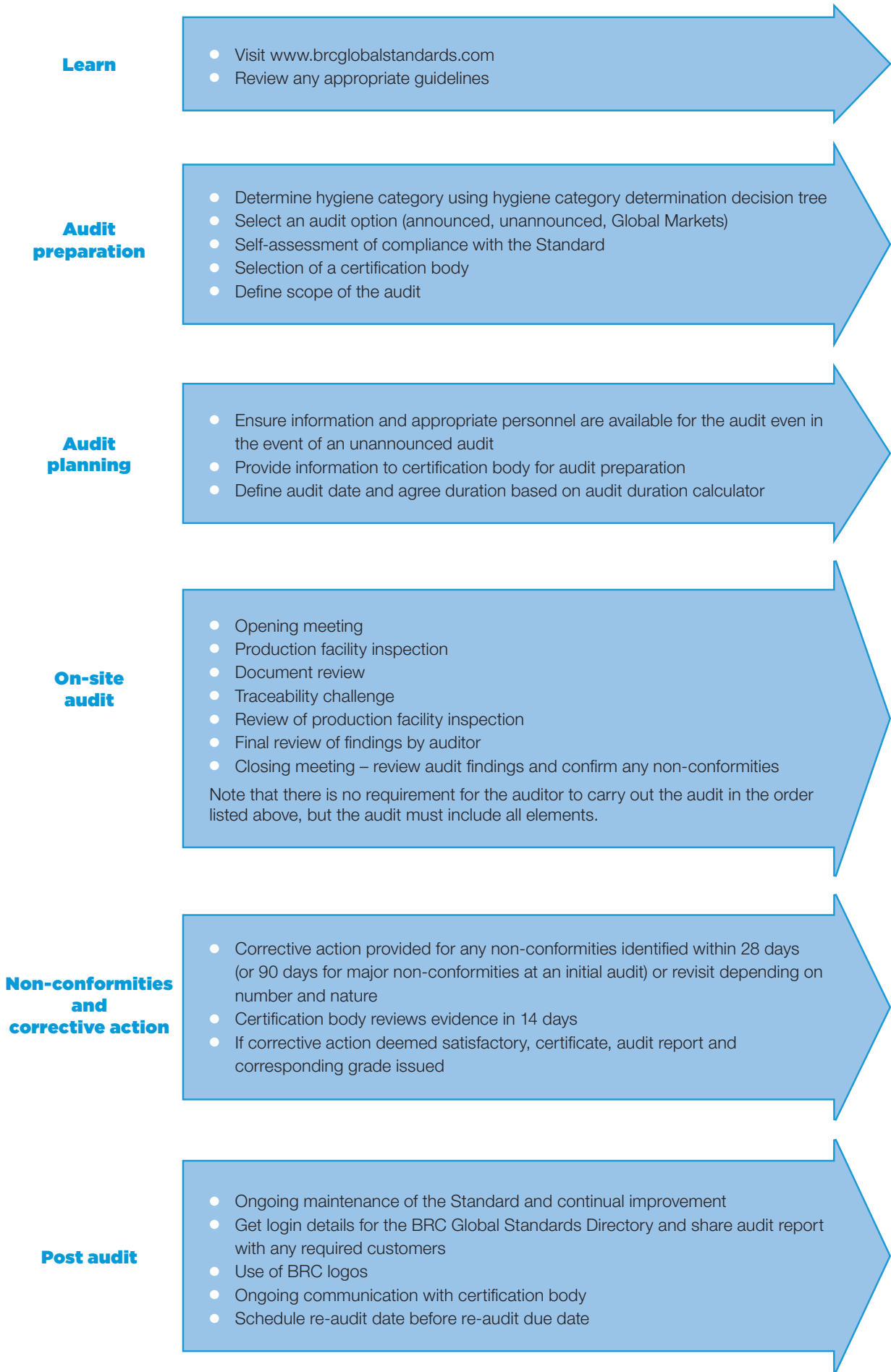


FIGURE 2 AUDIT PROTOCOL – HOW TO GAIN CERTIFICATION

1 GENERAL PROTOCOL – AUDIT PREPARATION

1.1 SELECTION OF AN AUDIT OPTION

There are a number of options and processes available for sites to demonstrate their commitment to the Global Standard for Packaging and Packaging Materials. All audit options are available to both hygiene categories.

1.1.1 Announced audit programme

This is available for existing certificated sites and those new to certification. 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.

Successful sites are awarded a certificate with the 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 Part III, section 2.

1.1.2 Unannounced audit programme

The unannounced audit options are available to all certificated sites. The unannounced audit options provide sites with the opportunity to demonstrate the maturity of their 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 (or even occurrence) of customer audits, where conducted, and other performance measures applied by the customer.

There are two options for unannounced audits, which allow companies to decide the one best suited to their business requirements; the grading and reporting for each is the same. For option 1, the whole Standard is audited on a single unannounced audit visit, typically lasting 1–3 days.

For option 2, the audit visit is split into two separate visits, each typically lasting 1–2 days. The first visit, which is unannounced, predominantly audits factory good manufacturing practices. The second part of the audit, which is planned, looks predominantly at the documented systems and records. This approach allows companies to ensure that appropriate managers are available to assist with the audit of documentation.

The unannounced audit process for options 1 and 2 is summarised in Figure 3. More details on the unannounced audit programme can be found in Part III, sections 3 and 4.

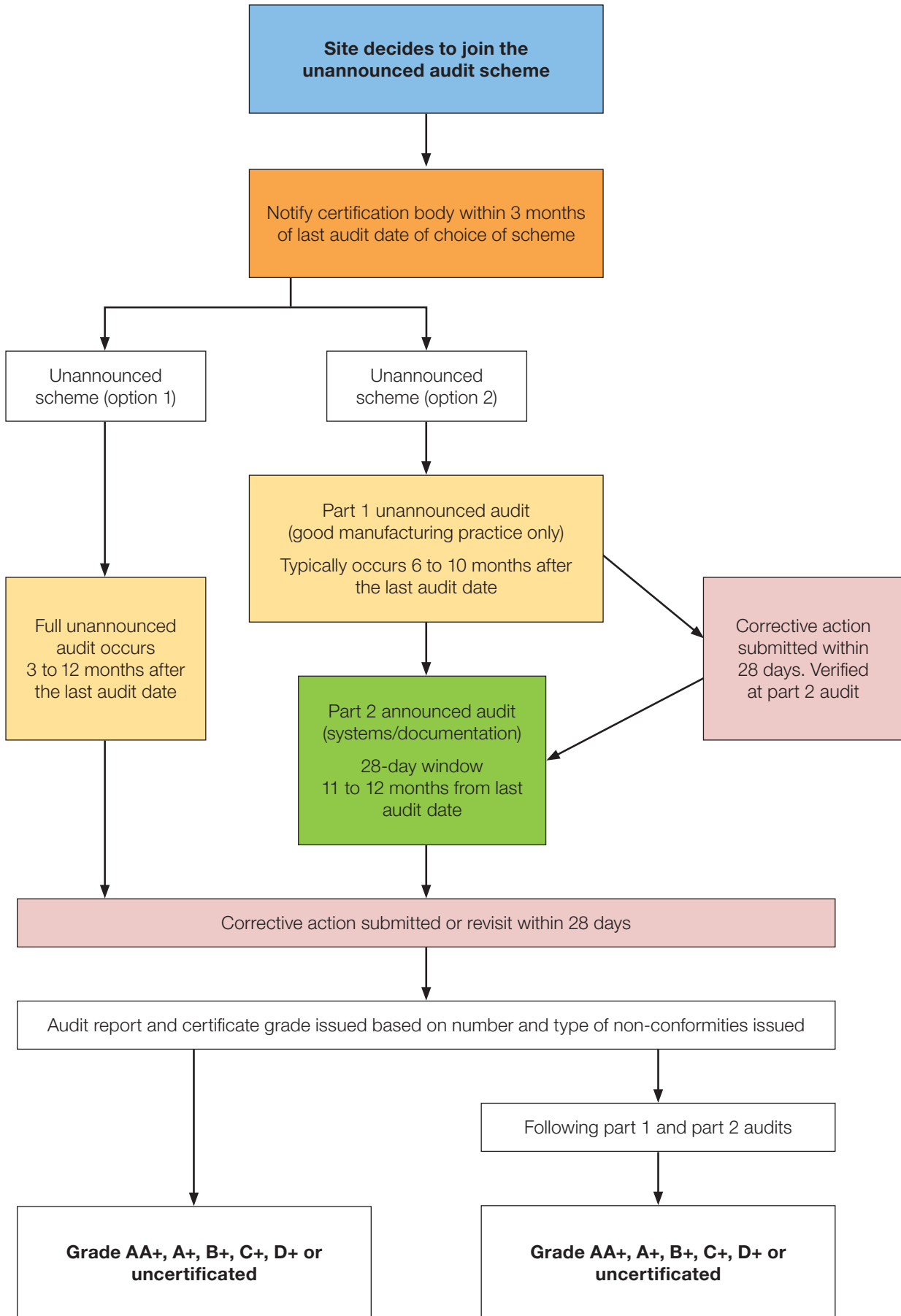


FIGURE 3 THE UNANNOUNCED AUDIT PROCESS

1.1.3 BRC Global Markets programme

This three-step programme is modelled on the GFSI Global Markets programme for small and/or less developed businesses/primary producers. It is most suitable for companies that are new to the Standard and in the process of developing their product safety and quality management systems. It is recognised that many sites need a little time to develop their systems and culture to meet the full BRC certification requirements.

The programme is also applicable to some very small sites, particularly where the full requirements for certification may not always be practicable or add value to the business.

The programme allows sites to be audited against specific requirements of the BRC Global Standard identified as basic-level or intermediate-level product safety and quality management requirements and attain recognition at basic or intermediate levels before progressing eventually to full certification. This allows sites to develop their product safety and quality management processes in a progressive way and demonstrate their commitment to their customers.

Registration for the programme is carried out by the certification body with the BRC on behalf of the site and enables access to information provided by the BRC on the standards. The audit at the appropriate level is undertaken at a date agreed with the certification body and the attainment of a particular level recognised in the BRC Global Standards Directory.

More details on the BRC Global Markets programme can be found in Part III, section 5.

1.2 SELF-ASSESSMENT OF COMPLIANCE WITH THE STANDARD

It is essential that the site is assessed against the current issue of the Standard; this can be checked on the BRC Global Standards website (www.brcglobalstandards.com).

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 of non-conformity should be addressed by the site.

Further information, guidance and training to ensure compliance with the Standard, including downloadable self-assessment tools, is available at www.brcglobalstandards.com. The BRC also has a full range of further guidelines and supporting materials available through the BRC website and via the BRC Participate subscription service.

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. It should be noted, however, that under the rules for accredited certification, consultancy cannot be provided during any pre-assessment offered by the certification body that will later undertake the certification audit.

Manufacturing units that are newly built or commissioned must ensure that systems and procedures in place are compliant before an initial BRC audit is undertaken. It is at the discretion of the company when they wish 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.

Some sites may be able to improve this timescale, such as a small site, a site that has already implemented ISO 9001, or those that are 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 systems already established with other sites within the company, but sufficient documentation must be in place to enable a full audit to establish compliance against BRC requirements for the new site.

1.3 SELECTION OF A CERTIFICATION BODY

Audits against the BRC Global Standards are only recognised if these are undertaken by certification bodies that are recognised and approved by the BRC. The BRC cannot advise on the selection of a specific certification body; however, the BRC has a comprehensive programme of measurement of certification body performance around specified key performance indicators (KPIs), the results of which are converted to a 5-star rating and published with the listing of all BRC-approved certification bodies on www.brcdirectory.com.

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 the BRC 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 the BRC and may be supplied to the accreditation body in the agreed format for the BRC Global Standard used. Other documents in relation to the audit shall be made available to the BRC upon request. All documents submitted to the BRC shall be copies of original documents. Documents provided to the BRC will be treated as confidential.
- 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 the BRC.

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

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

This publication sets out the requirements for sites that want to apply to be audited against the Standard and for sites issued with a certificate. 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.

1.5 REGISTRATION FEE

The BRC will require a registration fee to be collected by the certification body from the company for every audit undertaken. The certificate and audit report shall not be valid until the registration fee and the certification body's audit fees have been received, irrespective of the outcome of the certification process.

1.6 SCOPE OF AUDIT

1.6.1 Hygiene category

The Packaging Standard contains two sets of requirements which are each designed to be applicable to packaging and packaging materials for different applications. Sites shall use the hygiene category determination decision tree (Part 1) to determine which set of requirements are applicable to their site. Appendix 3 contains examples of products and packaging materials for each hygiene category, although this list is not exhaustive.

1.6.2 Defining the audit scope

The scope of the audit – products produced and manufacturing processes – shall be agreed between the site and the certification body in advance of the audit to ensure the allocation of auditor(s) with the correct product and process knowledge and qualifications, as listed in Appendix 1.

The audit shall include all applicable requirements within the Standard and all 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 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. This shall include a description of processing activities undertaken at the site that fall within the scope of this Standard, where this adds clarity for the user of the report or certificate (e.g. the flexo printing and slitting of form-fill-seal (FFS) laminate film for fresh produce).

1.6.3 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 BRC logo can only be used by sites that have no exclusions.

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. Exclusions shall be clearly stated on the audit report and certificate and the justification recorded on the audit report.

The certification of products must include audit of the entire process from raw material intake to end-product dispatch. It is not possible to exclude parts of the process undertaken at the site or parts of the Standard. Where exclusions are accepted, the auditor(s) shall assess any hazards presented by excluded areas or products (e.g. foreign-body risks) and 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.

1.6.4 Additional manufacturing locations and head office assessments

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 head office
- the audit of more than one location where a single production process is carried out across two or more sites.

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

1.6.5 Storage facilities – off-site

While the storage facilities on the same site as the production facility shall always be included within the audit of the site, it is not uncommon for sites to also own additional, off-site, facilities. Where the company owns or manages additional storage facilities in the vicinity of the production site (i.e. within a radius of 50 km), these shall be identified on the audit report and audited as part of the site audit or against a GFSI-recognised storage and distribution Standard.

1.6.6 Additional voluntary modules

In addition to the core Standard, the BRC will develop a range of additional voluntary modules which may apply only to particular types of operation or may look in greater depth at a particular market concern. Where such voluntary modules are undertaken these will be listed on the scope of the report and certificate. If a voluntary 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 voluntary modules for the Packaging Standard is available on the BRC Global Standards website (www.brcglobalstandards.com).

1.7 AUDITOR(S) 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 technologies it uses, to enable the certification body to select an appropriate audit team with the required skills to undertake the audit. Auditors must be skilled to audit in the relevant products and processes, as listed in Appendix 2.

The certification body, auditors and the site must be aware of the need to avoid conflict of interest when arranging for an auditor(s) 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 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

2.1 AUDIT PLANNING

2.1.1 Preparation by the company

For initial 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(s) to assess and to have appropriate staff available at all times during the on-site audit.

The site shall ensure that the production schedule at the time of the audit covers products for the intended scope of the certification. Where possible, the widest range of these products shall be in production for the auditor(s) to assess. Where the product range is large or diverse, the auditor(s) has the discretion to continue the audit until sufficiently satisfied that the intended scope of the certification has been assessed. Where a significant production process is undertaken only during a different period of the year from the audit, a separate audit may 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.

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(s) 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:

- a summary of the site's hazard and risk analysis 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
- typical shift patterns
- production schedules, to allow audits to cover relevant processes
- recent significant quality issues, recalls, withdrawals or customer complaints and other relevant performance data
- any requested exclusions from the scope of the audit.

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

2.1.3 Audit duration

Before the audit takes place, the certification body shall indicate the approximate duration of the audit. The typical duration of an audit will vary from 1 to 3 days (8 hours per day) at the site. A calculator has been developed to assess the expected time required to undertake the audit of any particular site to ensure consistency and this shall be used as the basis for calculating the total audit duration. Full details can be found on the BRC Global Standards website (www.brcglobalstandards.com).

The calculation for the audit duration is based on:

- the number of employees – as full-time equivalent employees per main shift, including seasonal workers
- the size of the manufacturing facility – including storage facilities on site
- the number of hazard and risk analysis (HARA) studies included within scope – a HARA study corresponds to a family of products with similar hazards and similar production technology for the purpose of the calculator.

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

- the complexity of the manufacturing process
- the number of product lines
- the age of the site and its impact on material flow
- the labour-intensity of processes
- audit not carried out in first language of the auditor or the company
- the number of non-conformities recorded in the previous audit
- difficulties experienced during the audit requiring further investigation
- the quality of site preparation (e.g. documentation, hazard analysis, quality management systems).

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

In the event that the audit against this Standard includes voluntary BRC 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 amount of time to be expected 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 seven stages:

- Opening meeting – to confirm the scope and process of the audit.
- Production facility inspection – to review practical implementation of the systems, including observing product changeover procedures and interview of personnel.
- Document review – a review of the documented HARA and quality management systems.
- Traceability challenge – including a review of all relevant records of production (e.g. raw material intake, production records, finished product checks and specifications). This is a vertical audit – as specified within the BRC guidance document on audit techniques.
- Review of production 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.

The site shall fully assist the auditor(s) 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 operations manager on site at the time of the audit, or their nominated deputy, shall be available at the audit and attend the opening and closing meetings.

The audit process gives emphasis to the practical implementation of product safety and quality management procedures and general good manufacturing practices. It is expected that 30–50% of the audit duration will be spent auditing production and site facilities, interviewing staff, observing processes and reviewing documentation in production 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 auditor(s) 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 non-conformities that have been identified during the audit but 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(s) of the corrective action to close non-conformities must be given. A written summary of the non-conformities discussed at the closing meeting will be documented by the auditor(s) either at the closing meeting or within one working day after completion of the audit.

At the closing meeting the auditor(s) shall provide the site with an explanation of the BRC Global Standards Directory, which allows secure access to audit data to both the client and their nominated customers, together with the feedback systems available to communicate with the certification body and with the BRC.

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.

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 severity and risk and 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 requirement.
- **Major** Where there is a substantial failure to comply with the statement of intent of a clause or any 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 manufactured.
- **Minor** Where a 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 with 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 no more than one major non-conformity is 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 consideration shall be given to raising the status of repeated minor non-conformities to a major non-conformity.

2.3.2 Procedures for handling non-conformities and corrective action

Following identification of any non-conformities during the audit, the site must undertake corrective action to remedy the immediate issue (correction) and undertake an analysis of the underlying cause of the non-conformity (root cause) to develop a preventive action plan addressing the root cause and preventing recurrence.

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

Critical non-conformities or 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 per Table 1.

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-day period – although there may be some exceptions. Therefore, the re-audit shall not take place any earlier than 28 days from the audit date.

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

It is a requirement of some customers that they shall be informed when their suppliers have a critical non-conformity identified or where 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.

TABLE 1 SUMMARY OF GRADING CRITERIA, ACTION REQUIRED AND AUDIT FREQUENCY

GRADE ANNOUNCED	GRADE UNANNOUNCED	CRITICAL	MAJOR	MINOR	CORRECTIVE ACTION	AUDIT FREQUENCY
AA	AA+			5 or fewer	Objective evidence within 28 calendar days	12 months
A	A+			6 to 10	Objective evidence within 28 calendar days	12 months
B	B+			11–16	Objective evidence within 28 calendar days	12 months
B	B+		1	10 or fewer	Objective evidence within 28 calendar days	12 months
C	C+			17 to 24	Objective evidence within 28 calendar days	6 months
C	C+		1	11 to 16	Objective evidence within 28 calendar days	6 months
C	C+		2	10 or fewer	Objective evidence within 28 calendar days	6 months
D	D+			25 to 30	Revisit required within 28 calendar days	6 months
D	D+		1	17 to 24	Revisit required within 28 calendar days	6 months
D	D+		2	11 to 16	Revisit required within 28 calendar days	6 months
Not certificated		1 or more			Certificate not granted. Re-audit required	
Not certificated				31 or more	Certificate not granted. Re-audit required	
Not certificated			1	25 or more	Certificate not granted. Re-audit required	
Not certificated			2	17 or more	Certificate not granted. Re-audit required	
Not certificated			3 or more		Certificate not granted. Re-audit required	

Note that shaded cells indicate zero non-conformities.

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 root cause of the non-conformity. The root cause shall be identified and an action plan to correct this, including timescale, provided to the certification body. The proposed preventive action shall be included in the audit report.

Close-out of non-conformities can be achieved either by objective evidence being submitted to the certification body, such as updated procedures, records, photographs or invoices for work undertaken, or by the certification body undertaking a further on-site visit.

Where the number and level of non-conformities identified at the audit would result in a grade of D or D+ being awarded, the closure of non-conformities shall be by means of a further site visit to review the action taken. This visit shall be within 28 calendar days of the audit if a certificate is to be issued.

For initial audits only, if there is no temporary solution or if there is a justifiable delay to implementing a permanent solution (e.g. lead time on capital expenditure) for a major non-conformity, then provided that an acceptable statement of explanation is received by the certification body within 28 calendar days, the company may remain in the certification programme for up to 90 calendar days. It 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 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 1.1.8.

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

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.

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, in addition, always be reported in English.

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 and quality controls in place and improvements since the last audit
- 'best practice' systems, procedures, equipment or fabrication in place
- non-conformities, the corrective action taken and plans to correct the root cause.

The report shall accurately reflect the findings of the auditor during the audit. Reports shall be prepared and dispatched to the company within 42 calendar days of the completion of the full audit.

The audit report shall be uploaded to the BRC Global Standards 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 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.

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 5.

Logos used on certificates (e.g. BRC 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(s) of 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.

2.7 ONGOING AUDIT FREQUENCY AND RECERTIFICATION

2.7.1 Scheduling re-audit dates

The ongoing audit schedule and choice of audit programme will 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 due date of the subsequent audit shall be calculated from the date of the initial audit, irrespective of whether further site visits were made to verify corrective action arising from the initial audit, and not from the certificate issue date.

The subsequent announced audit shall be scheduled to occur within a 28-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, while maintaining certification.

It is the responsibility of the site to maintain certification. Where an audit is delayed beyond the due date, except in justifiable circumstances, this shall result in a major non-conformity being awarded at the next audit. Justifiable circumstances shall be documented in the audit report.

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 (clause 1.1.6), can include when the site is:

- situated in a specific country or an area within a specific country where there is government advice to not visit and there is no suitable local auditor
- within a statutory exclusion zone
- 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 is not an acceptable reason for missing the due date.

It is not a justifiable reason to delay audits where sites are not in full production; however, audits must be undertaken while there are products 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 be brought forward only, 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 demonstrate legal compliance by other means, such as risk assessment and complaints records, to show that the site is still competent to continue production until another audit can be arranged.

2.7.3 Audits undertaken prior to due dates

The due dates of renewal audits occur within a 28-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 these due dates, for example to reset the audit dates to allow combined audits with another scheme. 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 audit due date will be 'reset' to be 12 or 6 months, depending on grade, from this audit date.
- The certificate should be issued with an expiry date of 12 months (or 6 months, depending on grade) + 42 days from the 'new' audit date.
- Under no circumstances should a certificate have a validity of more than 12 months.

3 UNANNOUNCED AUDIT PROTOCOL: OPTION 1 – FULL AUDIT

This option involves a single unannounced audit against all of the requirements of the Standard. The date of the audit shall not be notified to the site in advance of the audit. The unannounced audit will replace the normal scheduled audit. Although the audit may occur at any stage between months 3 and 12 of the audit due date, this shall typically be within the last 4 months of the certification cycle.

3.1 AUDIT PLANNING

3.1.1 Selection of the unannounced audit option 1 programme

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 opportunity for the site to select an alternative certification body if required while allowing the audit to be undertaken at a time of the certification body's choosing.

3.1.2 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 safety and compliance with the Standard.

3.1.3 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(s) 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 7.1 and 7.2), the site shall inform the certification body 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 and risk analysis 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
- typical shift patterns
- production schedules, to allow audits to cover relevant processes
- recent significant quality issues, withdrawals or customer complaints and other relevant performance data.

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

As the audit will be unannounced it is likely that the certification body will also require additional information to plan for the logistics of the audit process. This may include:

- recommended local hotels
- specific site directions, 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.

3.1.4 Nominating non-audit days

The unannounced option 1 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.

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.

Certification bodies are expected to operate discretion in the case of emergencies.

It is a condition of electing to join the unannounced scheme 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.

3.1.5 Audit duration

Sufficient information shall have been provided to the certification body when selecting this option to allow for the selection of an auditor with the correct product and process knowledge and qualifications, and to allow sufficient time for the audit. The audit duration shall be calculated using the BRC audit calculator and the same time shall be allowed for the unannounced audit as would be expected for the usual announced audit.

The typical duration of an audit will vary from 1 to 3 days (8 hours per day) at the site. To ensure consistency, a calculator has been developed to assess the expected time required to undertake the audit of any particular site and this shall be used as the basis for calculating the total audit duration. Full details can be found on the BRC Global Standards website (www.brcglobalstandards.com).

The calculation for the audit duration is based on:

- the number of employees – as full-time equivalent employees per main shift, including seasonal workers
- the size of the manufacturing facility – including storage facilities on site
- the number of hazard and risk analysis (HARA) studies included within scope – a HARA study corresponds to a family of products with similar hazards and similar production technology for the purpose of the calculator.

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

- the complexity of the manufacturing process
- the number of product lines
- the age of the site and its impact on material flow
- the labour-intensity of processes
- audit not being carried out in first language of the auditor or the company
- the number of non-conformities recorded in the previous audit
- difficulties experienced during the audit requiring further investigation
- the quality of site preparation (e.g. documentation, hazard analysis, quality management systems).

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

In the event that the audit against this Standard includes voluntary BRC 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 amount of time to be expected 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.

The expected audit duration shall be notified to the site by the certification body in advance of the audit.

3.2 THE ON-SITE AUDIT

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

3.3 NON-CONFORMITIES AND CORRECTIVE ACTION

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

3.4 GRADING OF THE AUDIT

The process for grading is the same as for the announced audit scheme (see section 2.4). The grade awarded following certification shall be based on the number and level of non-conformities, as outlined in Table 1. Note that the grade will have the addition of a plus symbol after the grade (i.e. AA+, A+, B+, C+ or D+).

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 'Unannounced option 1'.

3.6 CERTIFICATION

The certification requirements are the same as for the announced audit scheme (see section 2.6). However, the certificate shall state 'Unannounced option 1'.

This certificate will supersede the existing certificate. The certificate shall be issued within 42 days of the audit and will have an expiry date based on the expiry date of the previous certificate plus 12 months, providing the site remains within the unannounced audit 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 based 6 or 12 months from the date of the unannounced audit.

3.7 ONGOING AUDIT FREQUENCY AND RECERTIFICATION

3.7.1 Scheduling re-audit dates

The site can choose whether to:

- remain within the unannounced option 1 programme
- transfer to the unannounced option 2 programme
- revert to the announced audit programme.

If the site wishes to remain in the option 1 programme the next audit will be unannounced. The audit may occur at any stage from 3 months after the last audit date through to 42 days prior to the certificate expiry date; however, this shall typically be within the last 4 months of the certification cycle. 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 responsibility of the certification body to ensure that the audit is undertaken within the certification window and the late audit non-conformity clause (1.1.6) shall not apply.

If the site opts to move to the unannounced option 2 programme, the rules for that programme shall apply and the announced systems audit shall occur within the 28-day window based on the initial audit date.

If the site wishes to withdraw from the unannounced audit programme, the next audit will be scheduled to occur within the 28 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.

4 UNANNOUNCED AUDIT PROTOCOL: OPTION 2 – TWO-PART AUDIT

The option 2 unannounced audit scheme divides the audit requirements into two separate audits. The first audit looks predominantly at the issues considered to be factory-based good manufacturing practices and is carried out as an unannounced audit. The second audit is predominantly based on reviewing documentation and records and can be planned to ensure the appropriate management staff are available to retrieve and discuss the records.

The planned part 2 audit allows this part of the audit to be combined with other planned certification audits where these are used to reduce audit costs.

4.1 AUDIT PLANNING

4.1.1 Selection of the unannounced audit option 2 programme

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 opportunity for the site to select an alternative certification body, if required, while allowing the audit to be undertaken at a time of the certification body's choosing.

The unannounced part 1 audit shall occur at any stage between months 6 and 10 of the audit cycle (i.e. 2 to 6 months before the audit due date). This allows sites to correct any non-conformities identified at the audit to enable these to be reviewed at the part 2 audit.

The part 2 audit of documentation and records shall be planned to occur in the 28 days up to and including the anniversary of the last audit date (i.e. in the same time window as an announced audit). The date for this audit is agreed with the site in advance of the audit.

4.1.2 Preparation by the company

The audit process for the option 2 scheme involves two separate audit visits and preparation for each may be slightly different.

Part 1 Unannounced audit

The actual audit date for the unannounced good manufacturing practices audit 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 safety and compliance with the Standard.

Part 2 Announced audit

The second half of the audit is planned and primarily concerned with auditing the documented systems and records. It is important that the relevant managers or deputies are available to assist in providing information required for the success of the audit. The part 2 audit will also include a visit to the factory and review of actions taken following the previous part 1 unannounced audit.

The site shall ensure that the production programme at the time of the audit covers products for the intended scope of the certification. Where possible, the widest range of these products shall be in production for the auditor(s) to assess. Where a product type or processing method was not in production at the time of the part 1 unannounced audit then every effort should be made to ensure this is in production for part 2.

Where a significant production process is undertaken only during a different period of the year from either audit, a further separate audit will be required to assess that production method.

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

This is as per unannounced audit option 1 (see section 3.1.3).

4.1.4 Nominating non-audit days

The unannounced option 2 programme allows sites the opportunity to nominate 10 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. The certification body may challenge the reason where this does not appear appropriate.

Days when the factory is not operating, such as weekends, public holidays, planned shutdowns for site holidays or maintenance, are not included in the 10 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 scheme 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

Sufficient information shall have been provided to the certification body when selecting this option to allow for the selection of an auditor(s) with the correct product and process knowledge and qualifications, and to allow sufficient time for the audit. The total audit duration (i.e. parts 1 and 2) shall be calculated using the BRC audit calculator and the same total time shall be allowed for the unannounced audit option 2 as would be expected for the usual announced audit. The time for the part 2 audit may be adjusted

based on the findings from the unannounced part 1 audit; for instance, more time may be required if there are a large number of non-conformities with corrective actions to review following the part 1 audit.

The typical duration of an audit will vary from 1 to 3 days (8 hours per day) at the site. A calculator has been developed to assess the expected total time required to undertake the audit of any particular site, to ensure consistency, and this shall be used as the basis for calculating the total audit duration. Full details can be found on the BRC Global Standards website (www.brcglobalstandards.com).

The calculation for the audit duration is based on:

- the number of employees – as full-time equivalent employees per main shift, including seasonal workers
- the size of the manufacturing facility – including storage facilities on site
- the number of hazard and risk analysis (HARA) studies included within scope – a HARA study corresponds to a family of products with similar hazards and similar production technology for the purpose of the calculator.

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

- the complexity of the manufacturing process
- the number of product lines
- the age of the site and its impact on material flow
- the labour-intensity of processes
- audit not being carried out in first language of the auditor or the company
- the number of non-conformities recorded in the previous audit
- difficulties experienced during the audit requiring further investigation
- the quality of site preparation (e.g. documentation, hazard analysis, quality management systems).

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

In the event that the audit includes voluntary BRC modules or is intended to be combined with other audit Standards, the total audit time will need to be appropriately extended. Voluntary modules shall be audited during the part 2 audit and additional time shall be added to this part of the audit. Details of combined audits shall be specified on the audit report.

The calculation for audit duration shall determine the amount of time to be expected 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.

The expected audit duration shall be notified to the site by the certification body in advance of the audit.

4.2 THE ON-SITE AUDITS

4.2.1 Part 1 Unannounced audit

Sites opting for the unannounced scheme shall be obliged to accommodate the auditor and allow the audit to start immediately on arrival at the site. The audit process will be focused on the production facility and some supporting documentation will be required to complete a particular audit trail. It is expected that after a brief opening meeting the auditor will start the production facility audit within 30 minutes of arriving on site.

The part 1 unannounced audit will focus largely on the clauses identified with the following colour code within the Standard:

Requirements assessed on part 1 – audit of good manufacturing practice	
Requirements assessed on both parts 1 and 2	

The part 1 unannounced audit consists of the following stages:

- Opening meeting – to confirm the scope and process of the audit.
- Production facility inspection – to review practical implementation of the systems, including observing product changeover procedures and interview of personnel.
- A review of documentation needed to complete the audit trail (e.g. pest control records).
- 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.)

4.2.2 Part 2 Announced audit

The part 2 announced audit will focus largely on the clauses identified with the following colour code within the Standard:

Requirements assessed on part 2 – audit of records, systems and documentation	
Requirements assessed on both parts 1 and 2	

The part 2 documentation audit consists of the following stages:

- Opening meeting – to confirm the scope and process of the audit.
- Production facility inspection – to review the factory standards and in particular the corrective actions taken in response to non-conformities identified during the part 1 audit.
- Document review – a review of the documented HARA and quality management systems.
- Traceability challenge – including a review of all relevant records of production (e.g. raw material intake, production records, finished product checks and specifications). This is a vertical audit – as specified within the BRC guidance document on audit techniques.
- 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.)

The site shall fully assist the auditor(s) 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 operations manager on site, or their nominated deputy, shall be available at the audit and attend the opening and closing meetings.

During both parts of the audit, detailed notes shall be made regarding the site's conformities and non-conformities against the Standard and these will be used as the basis for the audit report. The auditor(s) shall assess the nature and severity of any non-conformity.

At the closing meetings the auditor(s) shall present their findings and reconfirm all non-conformities that have been identified during the audit but shall not make comment on the likely outcome of the certification process. Information on the process and timescales for the company to provide evidence to the auditor(s) of the corrective action to close non-conformities must be given.

A written summary of the non-conformities discussed at the closing meeting will be documented by the auditor(s) either at the closing meeting or within one working day after completion of each part of the audit.

At the final closing meeting the auditor(s) shall provide the site with an explanation of the BRC Global Standards Directory, which allows secure access to audit data to both the client and their nominated customers, together with the feedback systems available to communicate with the certification body and with the BRC.

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.

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

4.3 NON-CONFORMITIES AND CORRECTIVE ACTION

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

Evidence of the action taken to correct non-conformities identified at the part 1 audit shall be submitted to the certification body within 28 days of that audit and will be subject to further review at the part 2 audit.

If a critical non-conformity and/or the number and level of non-conformities identified at the part 1 audit would result in the failure to achieve a certificate, the existing certificate for the site shall be immediately withdrawn.

4.4 GRADING OF THE AUDIT

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

The grade awarded following certification shall be based on the number and level of non-conformities, as outlined in Table 1. Note that the grade will have the addition of a plus symbol after the grade (i.e. AA+, A+, B+, C+ or D+).

The grade awarded is based on the combination of non-conformities identified at the part 1 and the part 2 audits. Although the non-conformities identified on the part 1 audit should have been corrected before the part 2 audit, these shall be included in calculating the grade.

4.5 AUDIT REPORTING

The audit reporting requirements are the same as for the announced audit scheme (see section 2.5). However, the report shall state 'Unannounced option 2'.

The full audit report will include information and non-conformities identified at both the part 1 and part 2 audits. The final report will not be produced until after completion of the part 2 audit.

4.6 CERTIFICATION

The certification requirements are the same as for the announced audit scheme (see section 2.6); the certificate, however, shall state 'Unannounced option 2'.

This certificate will supersede the existing certificate. The certificate shall be issued within 42 days of the part 2 audit and will have an expiry date based on the expiry date of the previous certificate plus 12 months, providing the site remains within the unannounced audit scheme. If the site decides to return to the announced audit programme, the certificate expiry date will be 6 or 12 months, depending upon the grade achieved.

4.7 ONGOING AUDIT FREQUENCY AND RECERTIFICATION

4.7.1 Scheduling re-audit dates

The site can choose whether to:

- remain within the unannounced option 2 programme
- transfer to the unannounced option 1 programme
- revert to the announced audit programme.

If the site wishes to remain in the option 2 programme, the audits will be undertaken as indicated by the audit planning rules above.

If the site opts to move to unannounced option 1, the rules for that programme will apply and the full unannounced audit will occur between 3 and 12 months after the initial audit date.

If the site wishes to withdraw from the unannounced audit programme, the next audit will be scheduled to occur within the 28 days up to and including the audit due date indicated on the certificate.

It is the responsibility of the certification body to ensure that the unannounced part 1 audit is undertaken within the audit window. It is the responsibility of the company to ensure that the announced part 2 audit takes place within the certification window to avoid the late audit non-conformity clause (1.1.6).

5 BRC GLOBAL MARKETS PROGRAMME

The Global Markets programme is designed for sites which are either very small and for which the full Standard may not be appropriate, or for sites which are in the development process of their product safety and quality management systems.

The programme is based on the principles of the GFSI Global Markets programme for small and/or less developed businesses/ primary producers. Requirements from the full BRC Global Standard for Packaging and Packaging Materials have been identified that form audit requirements at the basic and intermediate levels, before progression to full certification. It allows an audit and recognition of attainment of compliance at two levels below full BRC certification (i.e. basic or intermediate level).

- Basic requirements – cover the minimum requirements within the BRC Standard to enable the production of safe, legal products.
- Intermediate requirements – incorporate the basic requirements but in addition include more robust systems for product safety and quality management from the full Standard.

A full guideline on the scheme together with the details of the requirements at each level and the appropriate audit checklists are available on the BRC Global Standards website and within the BRC Participate subscription service.

Audits for the BRC Global Markets programme must be undertaken by BRC-recognised certification bodies. The rules on scope and exclusions from scope in the general protocol apply (Part III, section 1.6). The BRC Global Markets programme is summarised in Figure 4.

5.1 AUDIT PLANNING

5.1.1 Preparation by the company

All audits for the Global Markets programme at the basic and intermediate level are announced. The site shall agree a mutually convenient date, with due consideration given to the amount of work required to meet the requirements of the basic or intermediate level.

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

The site shall ensure that the production programme at the time of the audit covers products for the intended scope of the certification. Where possible, the widest range of these products shall be in production for the auditor(s) to assess. Where the product range is large or diverse, the auditor(s) has the discretion to continue the audit until sufficiently satisfied that the intended scope of the certification has been assessed. Where a significant production process is undertaken only during a different period of the year from the audit, a separate audit will be required to assess that production method.

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

The company shall supply the certification body with background information prior to the audit day to ensure the auditor(s) 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:

- confirmation of the audit level, basic or intermediate
- a summary of the company's hazard and risk analysis (HARA) and any critical control points (CCPs)
- a simple process flow diagram or process description
- a simple site plan
- the main management contacts and positions
- the list of products or product groups included within the audit scope
- typical shift patterns
- production schedules, to allow audits to cover relevant processes (e.g. night-time manufacture or where production processes are not carried out each day)
- recent quality issues, withdrawals or customer complaints and other relevant performance data.

The company shall make the previous year's audit report and level of recognition available to the certification body, where this is a contract with a new certification body.

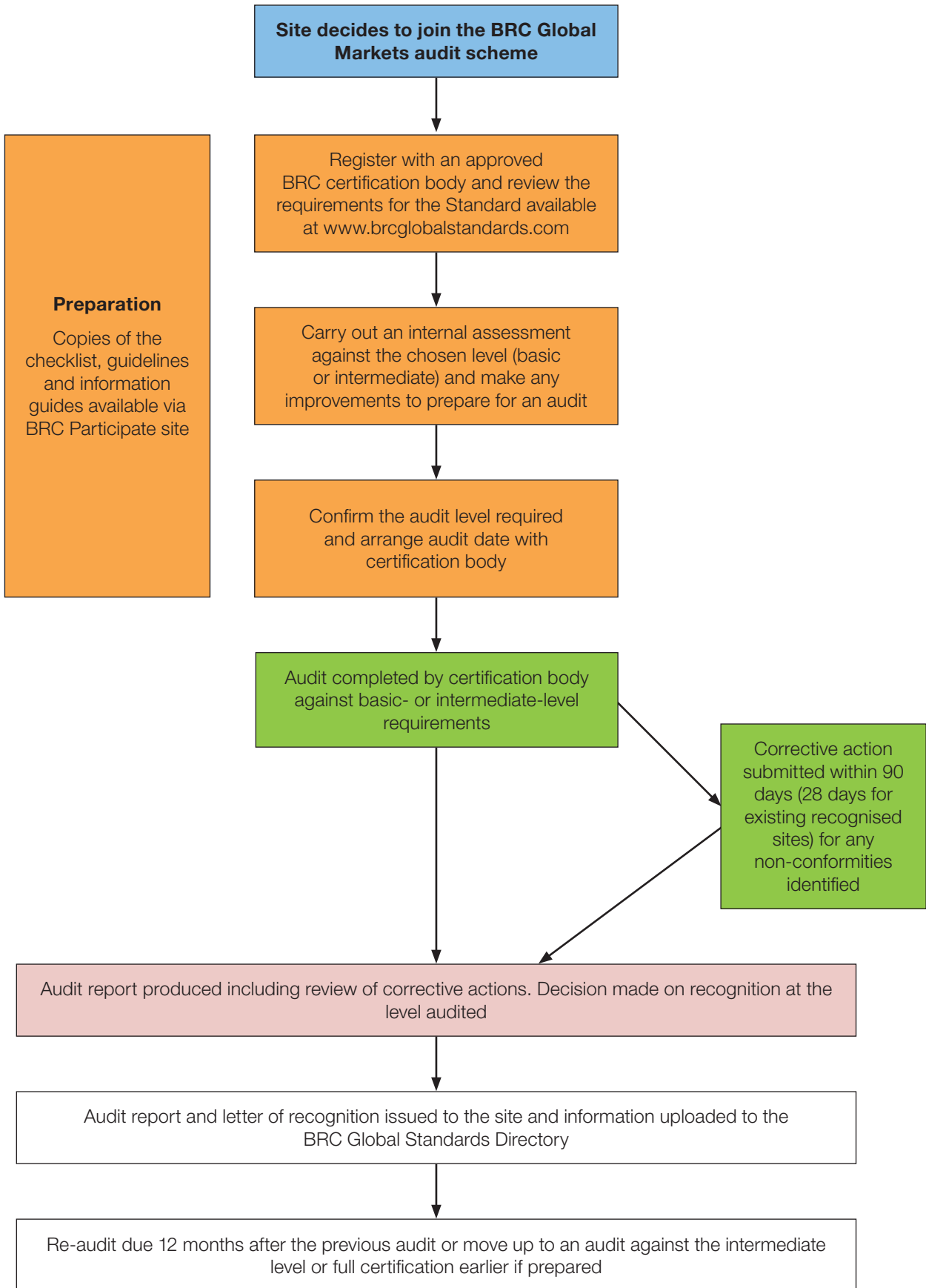


FIGURE 4 BRC GLOBAL MARKETS PROGRAMME

5.1.3 Audit duration

Before the audit takes place, the certification body shall indicate the approximate duration of the audit. The typical duration of the basic-level audit is 1 day (8 hours per day) at the site. The intermediate-level audit will typically take 1.5 days (8 hours per day).

The audit duration is based on:

- the required audit level – basic or intermediate
- the number of employees – as full-time equivalent employees per main shift, including seasonal workers
- the size of the manufacturing facility – including storage facilities on site
- the number of HARA studies included within scope – a HARA study corresponds to a family of products with similar hazards and similar production technology
- the complexity of the manufacturing process
- the number of product lines
- the age of the site and its impact on material flow
- the labour-intensity of processes
- communication difficulties (e.g. language)
- the number of non-conformities recorded in any previous audit.

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

The calculation for audit duration shall determine the amount of time to be expected 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.

5.2 THE ON-SITE AUDIT

The on-site audit consists of the following stages:

- Opening meeting – to confirm the scope and process of the audit.
- Production facility inspection – to review practical implementation of the systems, including observing product changeover procedures, and interview of personnel.
- Document review – a review of the documented HARA and applicable quality management systems.
- Traceability challenge.
- Review of production 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 above but the audit must include all elements.

The site shall fully assist the auditor(s) 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 operations manager on site, or their nominated deputy, shall be available at the audit and attend the opening and closing meetings.

The audit process gives emphasis to the practical implementation of product safety and quality management procedures and general good manufacturing practices. It is expected that 30–50% of the audit will be spent auditing production and site facilities, interviewing staff, observing processes and reviewing documentation in production areas with the relevant staff.

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

At the closing meeting, the auditor(s) shall present their findings and reconfirm all non-conformities that have been identified during the audit. Information on the process and timescales for the company to provide evidence to the auditor(s) of the corrective action to close 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 one working day after completion of the audit.

At the closing meeting the auditor(s) shall provide the site with an explanation of the BRC Global Standards Directory, which allows secure access to audit data to both the client and their nominated customers, together with the feedback systems available to communicate with the certification body and with the BRC.

The decision to award basic or intermediate-level recognition 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.

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

5.3 NON-CONFORMITIES AND CORRECTIVE ACTION

The levels of non-conformity and corrective actions required are the same as for the full BRC certification scheme.

5.3.1 Non-conformities

There are three levels of non-conformity:

- **Critical** Where there is a critical failure to comply with a product-safety or legal requirement.
- **Major** Where there is a substantial failure to comply with the statement of intent of a clause or any 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 manufactured.
- **Minor** Where a 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 with 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.

5.3.2 Procedures for handling non-conformities and corrective action

Following identification of any non-conformities during the audit, the company must undertake corrective action to remedy the immediate issue (correction). It is also strongly encouraged that an analysis of the underlying cause of the non-conformity (root cause) is undertaken to allow any preventive actions to be taken to prevent recurrence.

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

Critical non-conformities

The grading of non-conformities will be reviewed by the certification body as soon as possible after the audit. Where the review confirms that a non-conformity is classed as critical, the site will be required to undertake another full audit before attainment of basic or intermediate level.

Where this occurs at a site which has previously been awarded basic or intermediate-level recognition, this recognition must be immediately withdrawn.

It is a requirement of some customers that they shall be informed when their suppliers have a critical non-conformity identified or fail to retain basic or intermediate-level recognition. 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 basic or intermediate-level recognition 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.

Close-out of non-conformities can be achieved either by objective evidence being submitted to the certification body, such as updated procedures, records, photographs or invoices for work undertaken, or by the certification body undertaking a further on-site visit.

Where a high number of non-conformities are identified or the type of issues identified would make it very difficult to confirm compliance through documentary evidence alone, the certification body would need to revisit the site to confirm correction.

Sites that have not yet achieved basic level are allowed up to 90 days after the audit date to correct and provide evidence of corrective action. Where sites have already achieved basic and/or intermediate level, 28 calendar days are allowed for submission.

If satisfactory evidence of correction is not provided within the timescale an award of basic or intermediate level cannot be granted and a further audit will be required before an award of basic or intermediate level can be considered.

5.4 GRADING OF THE AUDIT

There is no grading of the awards of basic or intermediate level. The numbers and type of non-conformity will, however, be indicated on the audit report.

5.5 AUDIT REPORTING

Following each audit, a full written report shall be prepared in the designated 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, in addition, always be reported in English.

The audit report shall provide the company and customers or prospective customers with a profile of the company and an accurate summary of the performance of the site against the requirements appropriate to the chosen level.

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

- the product safety and quality management controls in place and improvements since the last audit
- 'best practice' systems, procedures, equipment or fabrication in place
- non-conformities and the corrective action taken.

The report shall accurately reflect the findings of the auditor during the audit.

Reports shall be prepared and dispatched to the company within 42 calendar days (104 days for sites that have not previously attained basic level) of the completion of the full audit.

The audit report shall be uploaded to the BRC Global Standards Directory in a timely manner irrespective of whether basic or intermediate level is attained. The owner of the audit report may allocate access to the audit report to customers or other parties in the 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.

5.6 BASIC OR INTERMEDIATE-LEVEL RECOGNITION

After a review of the audit report and documentary evidence provided in relation to the non-conformities identified, a decision shall be made on whether to award recognition of attainment of the basic or intermediate level. Please note attainment of a level is not certification; certification is only achieved by successful compliance with the full BRC Global Standard.

Where recognition is granted this shall be confirmed in writing by the certification body within 42 calendar days of the audit (104 days where sites have not previously achieved recognition). The letter of recognition shall include the following details:

- company name
- address of the site audited
- scope of the audit and any permitted exclusions
- date(s) of the audit
- the level attained (i.e. Global Markets basic or intermediate level)
- the name and address of the awarding certification body
- expiry date of recognition (i.e. 1 year and 42 days after the full audit date).

5.7 ONGOING AUDIT FREQUENCY AND RECERTIFICATION

5.7.1 Scheduling re-audit dates

In order to maintain recognition at either basic or intermediate level, the site shall be re-audited every 12 months. The due date of the re-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 action arising from the initial audit.

The subsequent announced audit shall be scheduled to occur within a 28-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 recognition.

The Global Markets programme is designed to encourage continuous improvement and assist sites in developing their product safety and quality management systems to a point where they can achieve full certification. Sites can at any time request an audit either to move from basic level to intermediate level or for full certification.

6 VOLUNTARY MODULES

The Standard has been designed to enable the addition of voluntary modules to the routine audit. The voluntary modules will enable sites to demonstrate compliance to specific sets of requirements in order 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 issues for a module will be available on the BRC Global Standards website (www.brcglobalstandards.com) and on the BRC Participate subscription service.

The voluntary modules can be added to any of the full certification audit options. The general protocol for the voluntary modules is as follows.

6.1 AUDIT PLANNING

6.1.1 Preparation by the company

The certification body shall be notified in advance of the audit that a particular voluntary module is intended to be added to the scope of the audit. This ensures sufficient additional 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 programme at the time of the audit covers products for the intended voluntary module where this is applicable.

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

The company shall supply the certification body with any additional background information requested prior to the audit day to ensure the auditor(s) is fully prepared to audit against the additional module, and to provide the best opportunity for the audit to be completed efficiently.

6.1.3 Audit duration

In order for the voluntary modules to be included within the audit programme, additional time will be needed for the audit. The certification body shall indicate the expected additional time requirements at the time of planning the audit.

The actual additional time will depend upon the module or combination of modules chosen.

6.1.4 The on-site audit

Compliance with the requirements of the chosen voluntary modules shall be assessed as part of the audit against the requirement of the main Standard and is expected to be integrated into the audit programme as appropriate.

During the audit, detailed notes shall be made regarding the site's conformities and non-conformities against the requirements of the additional module, and these will be used as the basis for an addendum to the audit report. The auditor(s) shall assess the nature and severity of any non-conformity.

At the closing meeting, the auditor(s) shall present their findings and discuss all non-conformities that have been identified against the module during the audit. 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 one working day after completion of the audit.

The decision to award certification for the voluntary module 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.

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

6.2 NON-CONFORMITIES AND CORRECTIVE ACTION

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

6.2.1 Non-conformities

Non-conformities against requirements of a voluntary module shall be graded in the same way as non-conformities identified against requirements of the main Standard, namely:

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

6.2.2 Procedures for handling non-conformities and corrective action

Following identification of any non-conformities against the requirements of the module during the audit, the company must undertake corrective action to remedy the immediate issue (correction). The process for 'closing out' non-conformities depends upon the level of non-conformity and the numbers of non-conformities identified.

Critical non-conformities

If a critical non-conformity is identified against a requirement of the module then the site cannot be certificated for this module without a further full audit of the module.

Where this occurs at a site which already holds certification for the module, certification of the module must be immediately withdrawn.

If it is a requirement of customers that they shall be informed when their suppliers have a critical non-conformity identified or fail to gain certification against a module, the company shall immediately inform its customers.

Note a critical non-conformity against a requirement of a voluntary module does not necessarily prevent certification against the main Standard or other voluntary modules.

Major and minor non-conformities

A voluntary module cannot be included on a certificate 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.

Close-out of non-conformities can be achieved either by objective evidence being submitted to the certification body, such as updated procedures, records, photographs or invoices for work undertaken, or by the certification body undertaking a further on-site visit.

If satisfactory evidence is not provided within the 28 calendar-day period allowed for submission following the audit, certification for the module will not be granted. The site will then require a further full audit in order to be considered for certification of the module.

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

6.3 GRADING OF THE AUDIT

There will be no grading of the voluntary modules. The modules will either be certificated or not.

Any non-conformities identified when assessing a voluntary module **shall not** be taken into account when deciding the grade for certification against the Global Standard for Packaging and Packaging Materials.

6.4 AUDIT REPORTING

Following each audit, a written report shall be prepared in the agreed format for the particular module and this will form an addendum to the Global Standard for Packaging and Packaging Materials audit report. The addendum 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, any applicable audit summary sections shall, in addition, always be reported in English.

The report addendum covering the requirements for the voluntary module shall be prepared and dispatched to the company within 42 calendar days of the completion of the full audit.

The full BRC audit report, together with the addendum for the voluntary module, shall be uploaded to the BRC Global Standards 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 with addendum to customers or other parties in the 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.

6.5 CERTIFICATION

After a review of the audit report for the voluntary module and documentary evidence provided in relation to the non-conformities identified, a certification decision shall be made by the designated independent certification manager. Where certification is granted, this shall be included on the certificate for the BRC Global Standard for Packaging and Packaging Materials and issued by the certification body within 42 calendar days of the audit. Where a voluntary module is not currently covered by the certification body's accreditation, this shall be identified on the certificate.

Note the voluntary modules are certificated as an addendum to the Global Standard for Packaging and Packaging Materials. Where certification to the Global Standard for Packaging and Packaging Materials is not achieved, certification for the module cannot be awarded irrespective of whether the requirements of the module have been met.

6.6 ONGOING AUDIT FREQUENCY AND RECERTIFICATION

6.6.1 Scheduling re-audit dates

If certification to the voluntary module is to be maintained, the module shall be included within each subsequent Global Standards for Packaging and Packaging Materials audit. The rules for scheduling the next audit and maintaining certification will follow the audit choice for the Global Standards for Packaging and Packaging Materials (i.e. Announced, Unannounced option 1 or Unannounced option 2).

7 GENERAL PROTOCOL – POST AUDIT

7.1 COMMUNICATION WITH CERTIFICATION BODIES

In the event that any circumstances change within the site that may affect the validity of continuing certification, the site must immediately notify the certification body. This may include:

- legal proceedings with respect to product safety or legality
- product recall
- significant damage to the site (e.g. natural disaster such as flood or damage by fire)
- change of ownership
- significant change to the operation or scope.

The certification body in turn shall take appropriate steps to assess the situation and any implications for the certification, and shall take any 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 certification
- suspend certification pending further investigation
- require further details of corrective action taken 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 certification status of a site shall be recorded in the BRC Global Standards Directory.

7.2 EXTENSION TO SCOPE

Once certification has been granted, any additional significant products manufactured or processes undertaken by the site, which are required to be included in the scope of certification, 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. printing by lithographic technology where formerly only flexographic printing was within scope)
- inclusion of new products which introduce a significant new risk to the facility.

A revisit is less likely, for example, where:

- new products are added 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 their client 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 process, documentation trails and closing meeting). The revisit should be announced, irrespective of whether the site is certificated to the announced or unannounced scheme.

Identified non-conformities should be documented and actioned within the normal protocol of the Standard; in other words the company has 28 (or 90) 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 a standard BRC audit report. A short explanation of the nature of the visit, what was audited and the conclusions shall 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 supplier 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.

7.3 CERTIFICATION WITHDRAWAL

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

- evidence that the site no longer complies with the requirements 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.

7.4 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.

Individual certification bodies' documented appeals procedures 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.

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

7.5 SURVEILLANCE OF CERTIFICATED COMPANIES

For certificated companies, where appropriate, the certification body or the BRC 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 partial audit. Refusal of access to the site 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 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 the BRC by the certification body and the status in the BRC Global Standards Directory 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.

7.6 BRC LOGOS

Achieving BRC certification is something of which to be proud. Companies that achieve certification and have no exclusions from their scope are qualified to use the BRC logo on site stationery and other marketing materials. Information and conditions relating to the use of the BRC logo is available at www.brcglobalstandards.com.

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 BRC logo is not a product certification mark and shall not be used on products or product packaging. Any certificated site found to be misusing the mark will be subject to the BRC complaints/referral process (see Part IV) and may risk suspension or removal of its certification.

The BRC logo may not be used by companies that do not include all products within the audit scope.

7.7 THE BRC GLOBAL STANDARDS DIRECTORY

The BRC Global Standards Directory (www.brcdirectory.com) is the database of all audits conducted against a BRC Global Standard, all certification bodies, all auditors and their recognised audit categories.

The directory holds full copies of all audit reports in read-only PDF. This includes archived audit documents from 2008 onwards.

Certification bodies are responsible for maintaining site name, address, audit content and certificate status. All certification bodies are assessed and graded by the BRC on how quickly and accurately they update audit data.

Audit reports can only be accessed following secure sign-in.

The directory also features a publicly accessible search function which displays certification data only. The public directory lists only currently certificated sites, not those expired or withdrawn.

Sites wishing to be excluded from public listing should contact their certification body.

7.7.1 Site code

Each audited site is allocated a unique seven-digit reference number known as a site code. This can be used to authenticate the validity of any certificate.

A site code is created when a site is audited for the first time and remains unchanged regardless of subsequent auditing certification bodies or audit status.

Site codes are located on the top right-hand corner of the first page of the audit report and on the corresponding certificate.

The listing for any certificated site can be located in the public directory by adding the site code to the 'Site Code' search field. If no results are returned for a search, contact the BRC to confirm certification authenticity.

7.7.2 Audit sharing

The directory allows audit owners to share their audit reports with customers, including retailers, manufacturers, suppliers and other specifiers.

When audit sharing is set up, customers can access 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 doctored by the audit owner. As such, audits obtained via the directory can be considered as complete and authenticated.

7.7.3 Notification emails

The 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.

For further information on the directory or audit sharing, contact the BRC Directory Services team via submissions@brcglobalstandards.com.

PART IV MANAGEMENT AND GOVERNANCE

REQUIREMENTS FOR CERTIFICATION BODIES

TECHNICAL GOVERNANCE OF THE GLOBAL STANDARD FOR PACKAGING AND PACKAGING MATERIALS

International advisory boards	100
Technical Advisory Committee	102
The certification body co-operation groups	102

ACHIEVING CONSISTENCY – COMPLIANCE

Calibrating auditors	103
Feedback	103
Complaints	103



PART IV

MANAGEMENT AND GOVERNANCE

REQUIREMENTS FOR CERTIFICATION BODIES

The Global Standard for Packaging and Packaging Materials is a process and product certification scheme. In this scheme, businesses are certificated upon completion of a satisfactory audit by an auditor employed by an independent third party – the certification body. The certification body in turn shall have been assessed and judged as competent by a national accreditation body.

The process of certification and accreditation is outlined in Figure 5.

In order for a business to receive a valid certificate on completion of a satisfactory audit, the organisation must select a certification body approved by the BRC. The BRC lays down detailed requirements that a certification body must satisfy in order to gain approval.

As a minimum, the certification body must be accredited to ISO/IEC 17065 by a national accreditation body affiliated to the International Accreditation Forum and recognised by the BRC.

Further details are available in the document 'Requirements for organisations offering certification against the criteria of the BRC Global Standards', which is available from the BRC on request.

Companies looking to become certificated to the Standard should assure themselves that they are using a genuine certification body approved by the BRC. A list of all certification bodies approved by the BRC is available on the BRC Global Standards Directory (www.brcdirectory.com).

The BRC recognises that in certain circumstances, such as for new certification bodies wishing to commence auditing against the Standard, accreditation may not yet have been achieved. This is because the accreditation process itself requires some audits to have been completed which will then be reviewed as part of the accreditation audit of the certification body. The certification body must be able to conduct audits as part of the process of achieving accreditation and so some unaccredited audits will be performed. This will be permitted where the organisation can demonstrate:

- an active application for accreditation against ISO/IEC 17065 from an approved national accreditation body
- that accreditation will be achieved within 12 months of the date of application and that the experience and qualifications of the auditors in the relevant product and process technology are consistent with those specified by the BRC
- a contract is in place with the BRC and all other contracted requirements have been met.

The acceptability of audit reports generated by certification bodies awaiting accreditation but meeting the above criteria is at the discretion of individual specifiers.

TECHNICAL GOVERNANCE OF THE GLOBAL STANDARD FOR PACKAGING AND PACKAGING MATERIALS

The Standard and associated scheme is managed by the BRC with governance and technical advice provided through a number of stakeholder groups (see Figure 6), each of which works to a set of defined terms of reference.

INTERNATIONAL ADVISORY BOARDS

The technical management and operation of the Standard is governed by the BRC International Advisory Boards. These consist of senior technical representatives of international retail and manufacturing businesses in Europe, America and Asia.

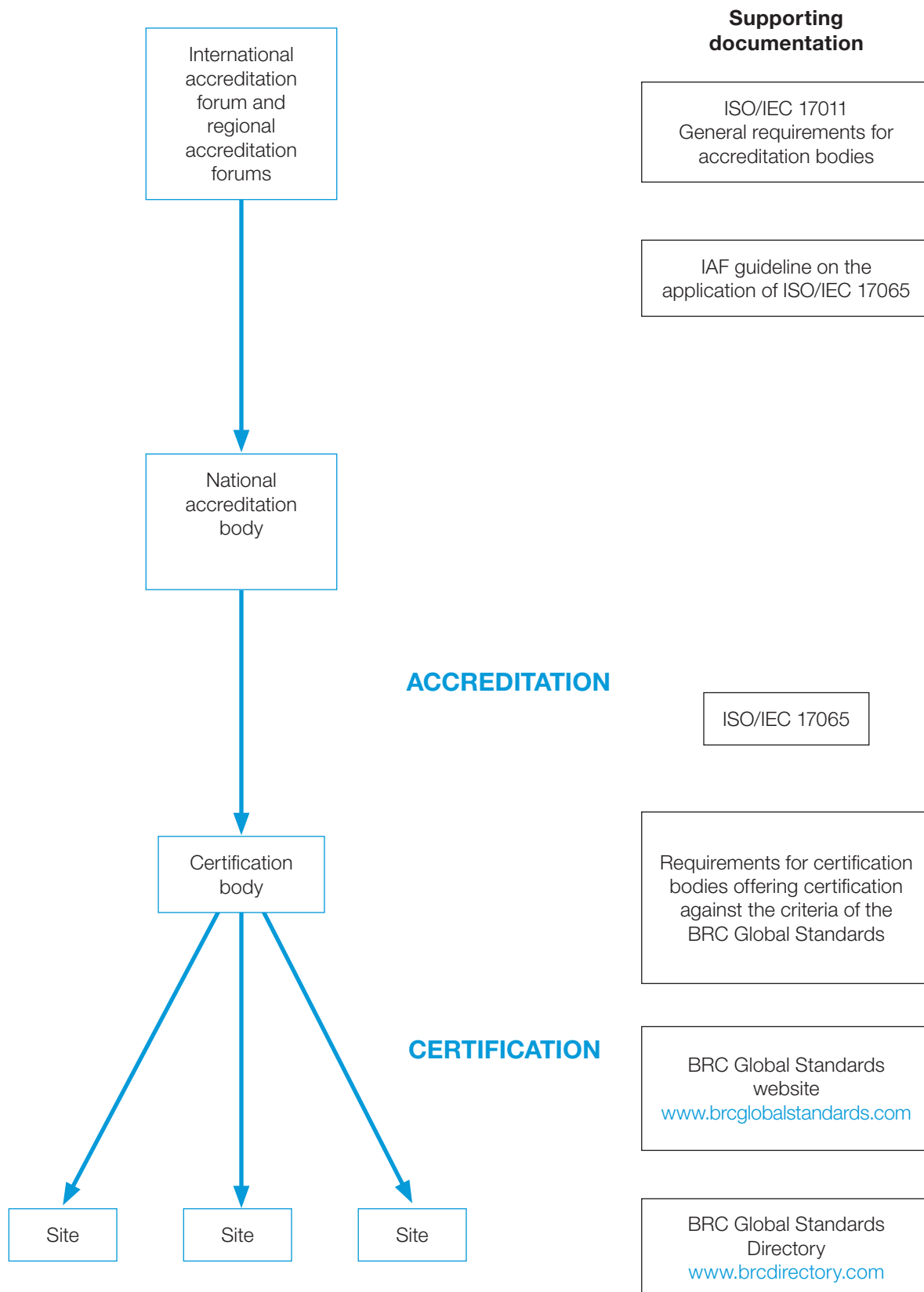


FIGURE 5 PROCESS FOR ACCREDITATION OF CERTIFICATION BODIES

The functions of the advisory boards are to provide strategic advice on the development and management of the BRC Global Standards and the activities to ensure the effective management of the certification bodies and audit process.

TECHNICAL ADVISORY COMMITTEE

Each BRC Global Standard is supported by at least one Technical Advisory Committee (TAC), which meets regularly to discuss technical, operational and interpretational issues relating to the Standard. The BRC provides the technical secretariat for these groups.

The TAC for the Global Standard for Packaging and Packaging Materials is made up of senior technical managers representing the users of the Standard and includes representatives of retailers, packaging manufacturers, trade associations for each sector, certification bodies and independent technical experts.

The Standard is reviewed every 3 years to assess the need for updating or production of a new issue. This work is undertaken by the TAC, which is expanded for the purpose to include other available expertise.

The TAC also reviews auditor competence requirements, proposed training materials and supplementary technical documents supporting the Standards.

THE CERTIFICATION BODY CO-OPERATION GROUPS

The BRC encourages and facilitates meetings of the certification bodies participating in the scheme (co-operation groups) to discuss matters arising on the implementation of the Standard and discuss issues of interpretation. These groups report regularly to the BRC on operational issues, implementation and suggested improvements. Representatives from the co-operation groups attend the TAC meetings.

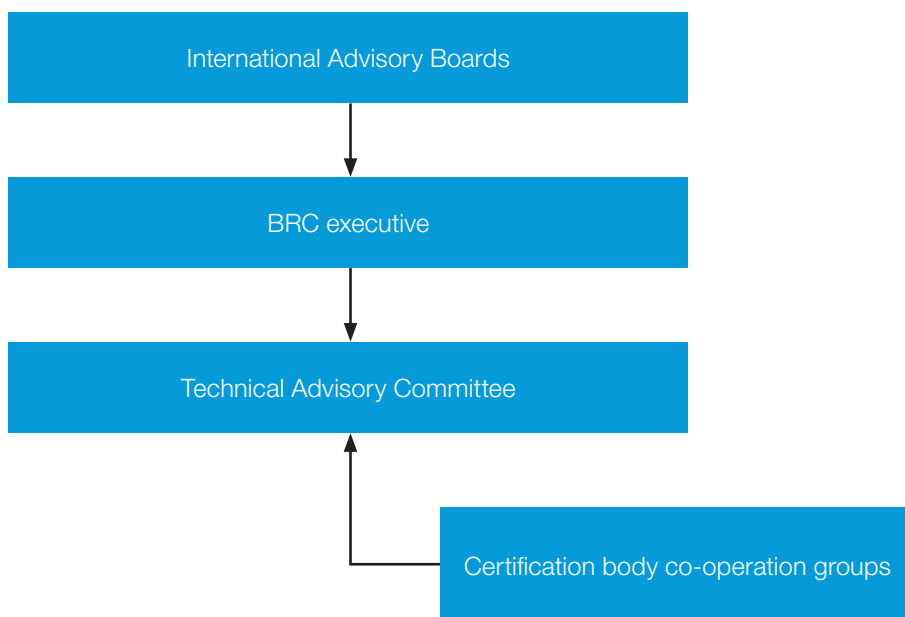


FIGURE 6 GOVERNANCE OF THE BRC SCHEMES

ACHIEVING CONSISTENCY – COMPLIANCE

The maintenance of a high and consistent standard of audit and certification, and the ability of the certificated sites to maintain the standards achieved at the audit, are essential to confidence in the scheme and to the value of certification. The BRC therefore has an active compliance programme to supplement the work of accreditation bodies and ensure high standards are maintained.

The BRC scheme may only be certificated by certification bodies registered and approved by the BRC and accredited by a BRC-recognised accreditation body. All auditors undertaking audits against the Standard must meet the BRC auditor competency requirements and shall be registered with the BRC. The qualifications, training and experience requirements for auditors who conduct audits against the BRC Global Standard for Packaging and Packaging Materials are detailed in Appendix 1. All audits undertaken against the Standard shall be uploaded to the BRC Global Standards Directory, which provides the BRC with an oversight of the activity of the certification bodies and the opportunity to review the quality of the reports produced.

To support the Standard, the BRC operates a compliance programme which reviews the performance of the certification bodies, samples the quality of audit reports, assesses levels of understanding of the scheme requirements and investigates any issues or complaints. As part of this programme the BRC provides feedback on the performance of each certification body through a key performance indicator (KPI) programme.

As part of the compliance programme the BRC audits the offices of certification bodies and accompanies auditors on audits at sites to observe the performance of auditors. The BRC may also undertake independent visits to certificated sites to ensure standards of product safety, quality and legality are being maintained in line with its certification status and ensure that the audit and reporting process is to the expected standard.

CALIBRATING AUDITORS

A key component of the scheme is the calibration of the auditors to ensure a consistent understanding and application of the requirements. All certification bodies are required to have processes to calibrate their own auditors. An essential element of the training and calibration of auditors is the witnessed audit programme. Auditors are observed during an audit and provided with feedback on the performance of the audit. In order to ensure consistency between certification bodies and for the purposes of accreditation, an audit may be witnessed by a BRC representative or accreditation body auditor. Guidelines apply to these activities to ensure that sites are not disadvantaged by the presence of two auditors. This process forms an essential part of the scheme and sites are obliged to permit witnessed audits as part of the conditions for certification.

FEEDBACK

Companies audited against the Standard may wish to provide feedback to the certification body or the BRC on the performance of the auditor. Such feedback sent to the BRC will be considered in confidence. Feedback provides a valuable input to the BRC monitoring programme for certification body performance.

COMPLAINTS

The BRC has implemented a formal complaint process, which is available to organisations involved with the Global Standards. This is available on the website (www.brcglobalstandards.com).

From time to time, failure to apply the principles and criteria of the BRC Global Standards at certificated sites may be reported to the BRC by, for example, retailers and companies conducting their own audits. In this event, the BRC will conduct an investigation as appropriate and may undertake announced or unannounced visits to a certificated site.

APPENDICES

APPENDIX 1

Registration, qualifications, training and experience requirements for auditors

106

APPENDIX 2

Fields of audit

108

APPENDIX 3

Examples of fields of audit

110

APPENDIX 4

Multiple sites audit protocol

111

APPENDIX 5

Certificate template

114

APPENDIX 6

Other BRC Global Standards

115

APPENDIX 7

Glossary

116

APPENDIX 8

Acknowledgements

121



APPENDIX 1

REGISTRATION, QUALIFICATIONS, TRAINING AND EXPERIENCE REQUIREMENTS FOR AUDITORS

All auditors conducting audits against the BRC Global Standard for Packaging and Packaging Materials are required to be registered with the BRC. The registration process identifies that auditors have undergone the required training and identifies the fields of packaging in which they have expertise. Evidence of an auditor's qualifications, experience and training has to be submitted to the BRC prior to them carrying out audits. All registered auditors receive a unique registration number, which is included on the audit report and is automatically cross-checked against their competence before the certification is accepted onto the BRC Directory.

The verification of competence to carry out a specific audit shall be carried out by the certification body.

It is the responsibility of the certification body to ensure that processes are in place to monitor and maintain the competence of the auditor to the level required by the Standard.

The BRC publishes a detailed guide to registered certification bodies on auditor competency requirements; expectations of the initial assessment of auditor competence; ongoing training; and assessment procedures. This is reviewed and updated periodically by the Technical Advisory Committee. The following outlines the requirements of auditors who may be registered to audit against the Standard.

EDUCATION

Auditors will be drawn generally from two distinct disciplines: those with expertise and a qualification in food or biosciences, and those with expertise and a qualification in packaging technology. This main qualification will be supported by a minimum secondary qualification in the other disciplines as appropriate. Where equivalence of qualification is unclear, this shall be referred to the BRC for review.

The auditor shall have:

- a degree or diploma in packaging and have successfully completed a food safety/hygiene qualification at least equivalent to a UK level 3 qualification (see www.brcglobalstandards.com for information), or
- a degree or diploma in a food or bioscience-related discipline and have successfully completed the PIABC EQIPT or equivalent examination in packaging.

WORK EXPERIENCE

The auditor shall have a minimum of 3 years' post-qualification experience related to their main qualification discipline. This shall involve work in quality assurance, technical management or risk management functions within manufacture, retailing, inspection or enforcement, and the auditor shall be able to demonstrate an understanding and knowledge of specific fields of packaging for which they are approved. The verification to carry out work within specific fields of packaging will be carried out by the certification body.

PROFESSIONAL QUALIFICATIONS

The auditor must have:

- passed a registered management system lead assessor course (e.g. IRCA) or the BRC third-party auditor course delivered by a BRC-approved trainer
- completed a training course in hazard analysis and critical control point (HACCP), based on the principles of Codex Alimentarius, of at least two days' duration, or be able to demonstrate competence in the understanding and application of HACCP principles. It is essential that the HACCP course is recognised by the industry as being appropriate and relevant.

AUDIT TRAINING

Auditors must have successfully completed a period of supervised training in practical assessment including witnessed assessment of a minimum of three audits at a variety of organisations against the Standard.

Certification bodies must be able to demonstrate that every auditor has appropriate training and experience for the particular fields for which they are considered competent. Auditor competence shall be recorded at the level of each field of audit as indicated in Appendix 2.

Certification bodies must establish a training programme for new auditors, which will incorporate:

- a Global Standard for Packaging and Packaging Materials awareness course delivered by a BRC-approved trainer
- a period of initial training covering product safety, hazard and risk management, and prerequisite programmes that will include access to relevant laws and regulations
- a period of supervised training to cover management systems, audit techniques and specific fields of audit knowledge
- assessment of knowledge and skills for each packaging field
- documented sign-off on the satisfactory completion of the training programme.

Each auditor's training programme shall be managed and approved by an assessor who can demonstrate that they are technically competent in the packaging fields in which training is given.

Full, detailed training records of the individual must be maintained by the certification body throughout the term of employment, and retained for a minimum period of 5 years after leaving the employment of the certification body.

APPENDIX 2

FIELDS OF AUDIT

MANUFACTURING CATEGORY	TYPICAL PACKAGING COMPONENTS/MATERIALS/ARTICLES
Glass manufacture and forming	Glass bottles Jars and pots Decanters and glass closures Tumblers, ampoules Ceramic bottles, jars and decanters
Paper making and conversion	Paper Board and liner Corrugated board Paper bags and sacks Paper labels, tags and neck collars Solid and corrugated board cartons and sleeves Liquid-containing cartons Layer pads Corrugated cases, trays and fitments Pulp and bagasse, fibre-based trays Paper containers, paper cups, spirally wound tubes Cutting, creasing and gluing of corrugated, sheet or reel-fed paper and board
Metal forming	Tinfoil Tinfoil and aluminium containers, cans, and aerosol containers Tubes Closures (RO/ROPP and crowns) Aluminium foil, foil trays and containers
Rigid plastics forming	Bottles and jars, caps and closures, tubes Preforms, injection-moulded components Thermoformed trays, tubs and pots Buckets and pails, bulk containers In-mould labelled containers

MANUFACTURING CATEGORY	TYPICAL PACKAGING COMPONENTS/MATERIALS/ARTICLES
Flexible plastics manufacture	Cast and blown plastic film, including vacuum metallised films and labels Multi-ply laminates of combinations of paper, plastics and aluminium foil Flexible intermediate bulk containers Regenerated cellulose film Plastic bags, pouches and sachets Non-edible casings
Other manufacturing	Pallets, boxes and crates, decorative wooden boxes Wood for food and cosmetic use, wooden utensils (e.g. for lollipops) Natural cork, rubber Hessian sacks, jute products, woven string (plastic or cotton)
Print processes	Any packaging material which is printed without pre- or post-print conversion and using the following print processes: <ul style="list-style-type: none"> • Flexographic, lithographic, gravure, letterpress (and offset) • Screen, tampo or digital print • Decoration by hot or cold stamping/blocking
Chemical processes	Resins Adhesives Inks, varnishes and coatings

Composites shall be categorised by the component that contributes the highest percentage composition of the product, where the material makes up to 75% of the component (by weight).

Where the main material is less than 75% of the component, the next material categories shall also be used.

The assembly of aerosol valves, actuators and dispensing systems shall be categorised according to the majority material. Where additional materials are used (e.g. metal springs) the next material category shall also be used.

APPENDIX 3

EXAMPLES OF FIELDS OF AUDIT

Further examples may be found on the Global Standards website, www.brcglobalstandards.com.

Users are advised to refer to the category determination decision tree (see Figure 1).

It must be stressed that this is not an exhaustive list and only provides examples. The final packaging category determination should be agreed between the company and their customer and discussed with the certification body.

HIGH HYGIENE

This category applies to packaging manufacturers producing packaging used for products where particularly high standards of hygiene are required in the production of the packaging material.

Direct contact with products that are consumed or applied to the skin:

- plastic film laminate for cooked/uncooked meats
- plastic film for bread
- plastic laminate for toothpaste tube
- lipstick case mechanism
- caps for bottles of mouthwash
- packaging for facial wet wipes
- tube for eyeliner
- tub for baby ointment
- caps for bottles of shampoo
- packaging for sanitary products or baby nappies/diapers
- skincare product containers.

Packaging that is in direct contact with a food product that has a natural barrier:

- corrugated case used for packing bananas or avocados
- moulded pulp/expanded polystyrene box for eggs.

BASIC HYGIENE

This category applies to packaging manufacturers producing packaging for products that are less vulnerable to hygiene risk.

Packaging that will be used for a product that is already in an impermeable pack:

- labels used for any product in plastic/glass jars or metal cans
- corrugated case for film over wrapped biscuits where the case is filled in a different area to the biscuit wrapping.

Packaging for products that are not consumed or applied to the skin:

- clothing (coat hangers or shirt bags)
- textiles (sheets, oven gloves or curtains)
- homeware (pots/pans, cutlery or crockery)
- household products (kettles, toasters or china ornaments)
- DIY products (chisels, screws, curtain rails or mastic)
- automotive products.

APPENDIX 4

MULTIPLE SITES AUDIT PROTOCOL

SCOPE OF AUDIT

The scope of a BRC audit needs to be agreed between the site and the certification body prior to the audit.

The audit, report and certificate shall be site-specific. However, in some exceptional circumstances more than one site may be included under a single certification.

Audits may cover multiple site addresses where **all** of the following rules apply:

- all sites are under the same organisation ownership
- all sites are operated against the same documented quality management systems
- sites manufacture product which is part of the same manufacturing process
- the sites solely supply the other sites with no additional customers
- the sites are no more than 30 miles/50 km apart.

AUDIT PLANNING

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

The certification body's audit plan needs to clearly show the sites that shall be audited.

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 manufacture of PET parisons and preforms at The Total Bottle Company, Bottlehampton, and blow moulding at The Total Bottle Company, Bottle End, Hampshire).

AUDITING OF ACTIVITIES WHERE THE HEAD OFFICE IS LOCATED SEPARATELY

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. Typically this may apply to activities such as purchasing, supplier approval, product development, product recall and, occasionally, this extends to a group-shared quality management system – document control and procedures.

All requirements within the scope of the Standard must be assessed as satisfactory before a certificate can be issued. This requires that any centrally managed systems are included within the audit process; however, there are alternative processes for achieving this.

There are two approaches to auditing the requirements which are managed at a central office:

- Request and review information while at the manufacturing site as part of the site audit – standard audit.
- Undertake a separate audit of the centrally managed processes at the group/head office location – two-stage audit.

APPROACH 1: REQUESTING AND REVIEWING INFORMATION AT THE MANUFACTURING SITE

This is recommended only where:

- satisfactory links can be established with the central office (telephone or video conferencing links to allow interview of relevant personnel; fax or email links to allow documents to be requested and viewed), and arrangements in place to ensure availability of relevant personnel
- the amount and type of information can be effectively reviewed and challenged remotely.

Where a site elects for the information to be assessed during the manufacturing site audit and satisfactory information cannot be provided during the audit, unsubstantiated requirements shall be recorded as non-conformities on the site audit report.

Reporting

The audit report shall make it clear where a requirement is managed by a central office together with a comment on how the company complies with the requirement.

Non-conformities

Non-conformities raised against a centrally operated requirement shall be recorded on the audit report and included within the count of non-conformities contributing to the site grade.

Corrective action shall be assessed in the same way as for non-conformities raised at the manufacturing site and must be satisfactorily corrected before a certificate can be issued to the site.

Subsequent manufacturing site audits

The central system requirements shall be challenged and evidence of compliance be provided at each manufacturing site audit.

APPROACH 2: TWO-STAGE AUDITS – CENTRAL SYSTEM AND SEPARATE MANUFACTURING SITE AUDITS

This approach is recommended where it is not practical to effectively assess requirements from the manufacturing site. For example where:

- practical arrangements to allow assessment cannot be provided
- there are too many centrally managed requirements to effectively review remotely.

This shall be offered to the site being audited and undertaken when requested by the site.

Stage 1 – Central system audit

The audit of the central system shall be completed before undertaking the manufacturing site audit.

The audit shall assess both how the central system complies with the relevant requirement of the Standard and how this links to the manufacturing site operation.

Reports for the central system audit

The certification body may produce a report of the central system audit for the benefit of the company. However, as this audit will only include some of the requirements of the BRC Standard:

- no grade may be allocated
- no certificate may be issued
- the report must be in a format which is clearly different from the full BRC audit report.

The central system report shall not be uploaded to the BRC Global Standards Directory but the findings of the central system audit shall be incorporated into the final audit report of each of the associated manufacturing sites.

Recording non-conformities identified at the central system audit

All non-conformities identified at the central office audit shall be recorded on the audit report of the first manufacturing site audited following the central systems audit – irrespective of whether these have been closed out before that audit or not.

However, only those non-conformities raised at the central office audit which have not been closed out to the satisfaction of the certification body at the time of the manufacturing site audit shall be counted when calculating the grade for the manufacturing site.

Any non-conformities identified at the head office audit which are still outstanding at the time of further manufacturing site audits (second, third, etc.) shall be included on that manufacturing site report and be included when calculating the grade for the site.

Closure of central systems corrective actions

Corrective actions required following the central office audit shall be assessed in the same way as corrective actions raised at the manufacturing site and must be satisfactorily corrected before a certificate can be issued to the manufacturing sites. This may be by documentary evidence or a revisit, as appropriate.

Stage 2 – Manufacturing site(s) audit

Information from the central office audit, including any evidence of corrective actions taken, shall be made available to the auditors of the associated manufacturing sites by the certification body.

The auditor shall establish that the central systems components assessed are the same as those operating at the manufacturing site. The auditor shall verify any corrective actions already taken following the central systems audit.

Audit duration

It may be possible to reduce the duration of the manufacturing site audit to take account of systems already audited at a central office.

BRC audit report

The final audit report shall be applicable to the manufacturing site.

The central office audit shall be commented upon in the Company Profile; for example: 'An audit was carried out at the central office at on the to assess requirements as indicated in the report'.

The key personnel may include the names of key staff present at the central office audit.

The manufacturing site(s) audit report shall include information about how both the site and the central system comply with the requirements of the Standard. The report shall indicate where a requirement is managed by a central office and provide an explanation of how that requirement is satisfied.

Corrective action

The time limit allowed for evidence of corrective action to be provided starts from the date of the manufacturing site audit.

It is the responsibility of the site to ensure that head office corrective actions have been provided to the certification body in order to allow the site to become certificated. This will require effective communication with the central systems office.

Where central systems corrective actions have been accepted prior to the first manufacturing site audit, this shall be indicated on the first manufacturing site audit report and the date of acceptance of the action indicated in the 'action taken' section of the non-conformity report.

Certificate

The certificate, where awarded, is issued to the manufacturing site. The re-audit date for the manufacturing site is based on the grade achieved and shall be 6 or 12 months from the initial audit date.

The central office audits shall be carried out every 12 months and shall occur before the anniversary of the audit of the first manufacturing site.

Audits of other manufacturing sites associated with the central system

Usually there will be several manufacturing sites associated with a central system. The information from the annual central system audit shall be used for each subsequent manufacturing site audit.

Non-conformities originally raised at the central office and effectively corrected before the audit of that manufacturing site shall not be recorded as non-conformities on the site audit report. Any outstanding non-conformities at the time of the manufacturing site audit shall, however, be included within that site's report and calculation for grading purposes.

The BRC shall be contacted for advice before carrying out audit programmes for more complex arrangements of sites and centralised systems.

APPENDIX 5

CERTIFICATE TEMPLATE

Auditor number

CERTIFICATION BODY NAME OR LOGO

[Certification body name, certification body number] certifies that, having conducted an audit

For the scope of activities:

High hygiene or Basic hygiene

Fields of audit:

Including voluntary modules of:

Exclusions from scope:

**At COMPANY NAME
SITE CODE
AUDIT SITE ADDRESS**

Has achieved Grade:

Meets the requirements set out in the

**BRC GLOBAL STANDARD for PACKAGING AND PACKAGING MATERIALS
ISSUE 5: JULY 2015**

Audit programme: [announced, unannounced option 1 or option 2, reissued after extension to scope]

Date(s) of audit: [include two date ranges for unannounced option 2. If an extension to scope, include original audit date and visit date]

Certificate issue date:

Re-audit due date: from _____ to _____

Certificate expiry date:

Accreditation
body logo

Authorised by

BRC logo

Name and full address of certification body

Certificate traceability reference

This certificate remains the property of [name of certification body]

If you would like to feedback comments on the BRC Global Standard or the audit process directly to BRC, please contact enquiries@brcglobalstandards.com or call the Tell BRC Hot line +44 (0)20 7717 5959.

APPENDIX 6

OTHER BRC GLOBAL STANDARDS

The BRC has developed a range of Global Standards which set out the requirements for the manufacture of food and consumer products, the packaging used to protect the products and the storage and distribution of these products. The other BRC Standards complement the Food Safety Standard and provide a resource for the auditing and certification of suppliers.

The **BRC Global Standard for Food Safety** is an auditing Standard that sets out the requirements for the manufacture of processed foods and the preparation of primary products supplied as retailer-branded products, branded food products and food or ingredients for use by food service companies, catering companies and food manufacturers.

The **BRC Global Standard for Storage and Distribution** is an auditing standard that sets out the requirements for the storage, distribution, wholesaling and contracted services for packaged and unpackaged food products, packaging materials and consumer goods. The Standard is not applicable to storage facilities under the direct control of the production facility management, which is covered by the relevant manufacturing Standard (e.g. the BRC Global Standard for Food Safety).

The **BRC Global Standard for Consumer Products** is an auditing standard applicable to the manufacture and assembly of consumer products. This specifically excludes food-associated products such as vitamins, minerals and herbal supplements, which fall within the scope of the BRC Global Standard for Food Safety.

The **BRC Global Standard for Agents and Brokers** is an auditing standard which enables companies to be audited and certificated where they buy and sell products or provide services to other parties but are unable to gain certification to the production or storage and distribution standards because there is no product present to be audited.

APPENDIX 7

GLOSSARY

Accreditation	The procedure by which an authoritative body gives formal recognition of the competence of a certification body to provide certification services against a specified Standard.
Agent	A company that facilitates trade between a site or company and their raw material or packaging suppliers or their customers through the provision of services, but does not at any point own or take title to the goods.
Allergen	A known component which causes physiological reactions due to an immunological response.
Announced audit	An audit where the company agrees the scheduled audit day in advance with the certification body.
Artwork	The elements that constitute a mechanical drawing, supplied as type, proofs and illustrations.
Audit	A systematic examination to measure compliance of practices with a predetermined system, and whether the system is implemented effectively and is suitable to achieve objectives, carried out by certified bodies.
Auditor	A person possessing the appropriate competence and skills to carry out an audit.
Batch	A discrete quantity of products made using the same operation and raw materials (alternative term is 'lot').
Brand owner	The owner of a brand logo or name who places the said logo or name onto retail products.
Branded product	Products bearing the logo, copyright or address of a company that is not a retailer.
BRC Global Markets programme	A recognition and audit scheme designed for sites which are either very small and for whom the full Standard may not be appropriate or for sites which are developing their food safety management systems.
Broker	A company which purchases or 'takes title to' products for resale to businesses (e.g. manufacturers, retailers or food service companies) but not to the ultimate consumer.
Calibration	A set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or reference material, and the corresponding values realised by standards.
Certificate suspension	Revocation of certification for a given period, pending remedial action on the part of the company.
Certificate withdrawal	Where certification is revoked. Certification may only be regained following successful completion of the full audit process.
Certification	The procedure by which an accredited certification body, based on an audit and assessment of a company's competence, provides written assurance that a company conforms to a standard's requirements.
Certification body	Provider of certification services, accredited to do so by an authoritative body and registered with the BRC.
Clause	A specific requirement or statement of intent that a site must comply with in order to achieve certification.
Company	The entity with legal ownership of the site which is being audited against a BRC Global Standard.
Competence	Demonstrable ability to apply skill, knowledge and understanding of a task or subject to achieve intended results.

Compliance	Meeting the regulatory or customer requirements concerning product safety, legality and quality.
Consumer	The end-user of the finished product, commodity or service.
Contamination	Introduction or occurrence of an unwanted organism, taint or substance to packaging, food or the food environment. Contamination includes physical, chemical, biological and allergen contamination.
Contract packer	A company that packages the final product into consumer packaging.
Contractor or supplier	A person or organisation providing services or materials.
Control	To manage the conditions of an operation to maintain compliance with established criteria, and/or the state wherein correct procedures are being followed and criteria are being met.
Control measure	Any action or activity that can be used to prevent or eliminate a product safety hazard or reduce it to an acceptable level.
Controlled document	A document which is identifiable and for which revisions and removal from use can be tracked. The document is issued to identified individuals and their receipt of the document is recorded.
Correction	Action to eliminate the cause of a detected non-conformity.
Critical control point (CCP)	A step at which control can be applied and is essential to prevent or eliminate a food or product safety hazard or reduce it to an acceptable level.
Cross-docking	Material is unloaded at distribution premises, and handled, but not formally put away into storage. This may be a staging area where inbound materials are sorted, consolidated and temporarily stored until the outbound shipment is complete and ready to ship.
Customer	A business or person to whom a service or product has been provided, either as a finished product or as a component part of the finished product.
Customer focus	A structured approach to determining and addressing the needs of an organisation to which the company supplies products and which may be measured by the use of performance indicators.
Decoration	An addition, adornment or embellishment applied to a material; may contain legally required text.
Despatch/dispatch	The point at which the product leaves the factory site or is no longer the responsibility of the company.
Distribution	The transportation of goods within any container (goods on the move) by road, rail, air or ship.
Exclusion	Not included in the scope of the audit: this can be a physical area of the certificated site or a product category.
Flow diagram	A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular item.
Food safety	Assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.
Functional barrier	A material that prevents harm to human health by stopping or retarding the passage of atmospheric gases, water vapour or volatile flavours and aromas that can cause unacceptable changes in the composition of food and its organoleptic characteristics. Alternatively, it is a barrier that can prevent shock or compression damage to a consumer product.
Fundamental requirement	A requirement of the Standard that relates to a system which must be well established, continuously maintained and monitored by the company as absence or poor adherence to the system will have serious repercussions on the integrity or safety of the product supplied.
Global Food Safety Initiative (GFSI)	Managed by the Consumer Goods Forum, a project to harmonise and benchmark international food safety standards (www.mygfsi.com).
Good hygiene practice	The combination of process, personnel and/or service control procedures intended to ensure that products and/or services consistently achieve appropriate levels of hygiene.
Good manufacturing practice (GMP)	Implemented procedures and practices undertaken using best practice principles.
Hazard	An agent of any type with the potential to cause harm (usually biological, chemical, physical or radiological).

Hazard and risk analysis (HARA)	A system that identifies, evaluates and controls hazards which are significant for product safety, quality and legality.
Hygiene-sensitive product	A product intended for human consumption or that comes into contact with the body; for example, by application to the skin.
Importer	A company facilitating the movement of products across an international border. Usually the first recipient of the products in that country.
Incident	An event that has occurred that may result in the production or supply of unsafe, illegal or non-conforming products.
Initial audit	The BRC audit at a company/site which is not in possession of a valid BRC certificate. This may be the first audit at a site or a subsequent audit of a site whose certification has lapsed.
Integrity (packaging)	Once a packaging container has been filled and sealed, its integrity is based upon its ability to contain, protect and preserve the contained product during its intended use.
Internal audit	General process of audit, for all the activity of the company. Conducted by or on behalf of the company for internal purposes.
Job description	A list of the responsibilities for a given position at a company.
Key staff	Those staff whose activities affect the safety, legality and quality of the finished product.
Legality	In compliance with the law in the place of production and in the countries where the product(s) is/are intended to be sold.
Lot	See definition of 'batch'.
Manufacturer	A company that produces product from raw materials and/or components and supplies product to a customer.
Master sample	See definition of 'reference sample'.
May	Indicates a requirement or text which provides guidance but is not mandatory for compliance to the Standard.
Monitoring	A planned sequence of observations or measurements of defined control parameters to assess whether predefined limits are being met.
Non-applicable	Any specific requirement that refers to an activity that does not occur on a site.
Non-conformity	The non-fulfilment of a specified product safety, legal or quality requirement or a specified system requirement.
Outer packaging	Packaging which is visible when the product is released from the site. For example, a cardboard box could be considered outer packaging even if wrapped in clear film.
Performance indicators	Summaries of quantified data that provide information on the level of compliance against agreed targets (e.g. customer complaints, product incidents, laboratory data).
Positive release	Ensuring a product or material is of an acceptable standard prior to release for use.
Potable water	Water being safe to drink, free from pollutants and harmful organisms and conforming to local legal requirements.
Premises	A physical building or place owned by the company and audited as part of a site.
Prerequisite	The basic environmental and operational conditions in a packaging or packaging materials site that are necessary for the production of safe packaging materials. These conditions provide the necessary control of generic hazards required for good manufacturing and hygienic practice and shall be taken into full consideration within the hazard and risk management system.
Preventive action	Action to eliminate the fundamental, underlying cause (root cause) of a detected non-conformity and prevent recurrence.
Primary packaging	That packaging which constitutes the unit of sale, used and disposed of by the consumer (e.g. bottle, closure and label).
Print/printing	Decoration of a pack by any print process, such as litho, flexo, gravure, tampo, screen, digital etc.

Procedure	Agreed method of carrying out an activity or process which is implemented and documented in the form of detailed instructions or process description (e.g. a flowchart).
Product recall	Any measures aimed at achieving the return of an unfit product from customers and final consumers.
Product withdrawal	Any measures aimed at achieving the return of out-of-specification or unfit products from customers, but not from final consumers.
Protective clothing	Clothing designed to protect the product from potential contamination by the wearer.
Provenance	The origin or the source of raw materials.
Quality	Meeting the customer's specification and expectation.
Quality assurance	A system for ensuring a desired level of quality in the development, production or delivery of products and services.
Quality control	A system for establishing and maintaining a desired level of quality in a product through planning, use of proper equipment, continued inspection and corrective action, as required.
Quantity check/mass balance	A reconciliation of the amount of incoming raw material against the amount used in the resulting finished products, also taking into account process waste and rework.
Quarantine	The status given to any material or product set aside while awaiting confirmation of its suitability for its intended use or sale.
Raw material	Any base material or semi-finished material used by the organisation for the manufacture of a product.
Recognised laboratory accreditation	Laboratory accreditation schemes that have gained national and international acceptance, awarded by a competent body and recognised by government bodies or users of the Standard (e.g. ISO/IEC 17025 or equivalents).
Recycled	Material that has been reprocessed from recovered (reclaimed) material, including post-consumer or post-industrial waste, and made or incorporated into a final product or a component for incorporation into goods or services.
Reference sample	Agreed product or components for referral by the manufacturer for production.
Regrind	Excess materials or reject containers that are ground into a raw material before being returned to production. Typically this is an in-house process.
Regulatory	A law, rule or other order prescribed by an authority that has been designed to regulate conduct or conformity to regulatory requirements.
Requirement	Those statements comprising a clause with which compliance will allow sites to be certificated.
Retail brand	A trademark, logo, copyright or address of a retailer.
Retailer	A business selling products to the public by retail.
Retailer-branded products	Products bearing a retailer's logo, copyright, address or ingredients used to manufacture within a retailer's premises. These are products that are legally regarded as the responsibility of the retailer.
Retained production sample	Representative product or components taken from a production run and securely held for future reference.
Risk	The likelihood of occurrence of harm from a hazard.
Risk analysis	A process consisting of three components: risk assessment, risk management and risk communication.
Risk assessment	The identification, evaluation and estimation of the levels of risk involved in a process to determine an appropriate control process.
Root cause	The underlying cause of a problem, which, if adequately addressed, will prevent a recurrence of that problem.
Sampling plan	A documented plan defining the number of samples to be selected, the acceptance or rejection criteria and the statistical confidence of the result.
Schedule	A tabulated statement giving details of actions and/or timings.

Secondary packaging	Packaging that is used to collate and transport sales units to the retail environment (e.g. corrugated case).
Senior management	Those with strategic/high-level operational responsibility for the company and the capability to authorise the financial or human resources necessary for the implementation of the Standard.
Shall	Signifies a requirement to comply with the contents of the clause.
Should	Signifies that compliance with the contents of the clause or requirement is expected or desired.
Site	A unit of a company; the entity which is audited and which is the subject of the audit report and certificate.
Specification	An explicit or detailed description of a material, product or service.
Specifier	A company or person requesting the product or service.
Standard, the	The Global Standard for Packaging and Packaging Materials Issue 5
Subcontractor	A firm, company or individual carrying out a process on products on behalf of the site being certificated to this Standard.
Supplier	The person, firm, company or other entity to which a site's purchase order to supply is addressed.
Suspension	Where certification is revoked for a given period, pending remedial action on the part of the company.
Traceability	Ability to trace and follow raw materials, components and products, through all stages of receipt, production, processing and distribution both forwards and backwards.
Traded goods	Goods not manufactured or part-processed on site but bought in and sold on.
Trend	An identified pattern of results.
Unannounced audit	An audit undertaken on a date unknown to the company in advance.
User	The person or organisation who requests information from the company regarding certification.
Utilities	Commodities or services, such as electricity or water, that are provided by a public body.
Validation	Obtaining evidence through the provision of objective evidence that a control or measure, if properly implemented, is capable of delivering the specified outcome.
Vehicle	Any device used for the conveyance of product that is capable of being moved upon highways, waterways or airways. Vehicles can be motorised (e.g. a lorry) or non-motorised (e.g. container or rail truck).
Verification	The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control or measure is or has been operating as intended.
Where appropriate	In relation to a requirement of the Standard, the company will assess the need for the requirement and, where applicable, put in place systems, processes, procedures or equipment to meet the requirement. The company shall be mindful of legal requirements, best practice standards, good manufacturing practice and industry guidance, and any other information relating to the manufacture of safe and legal product.
Work in progress/work in process	Partially manufactured products, intermediates or materials waiting for completion of the manufacturing process.
Workwear	Company-issued or authorised clothing designed to protect the product from potential contamination by the wearer.

APPENDIX 8

ACKNOWLEDGEMENTS

The BRC is grateful to the following people who helped to develop Issue 5 of the BRC Global Standard for Packaging and Packaging Materials. Their names are listed alphabetically below.

Peter Addington	BRC Global Standards
Tim Allchin	BPI Films
Mark Armstrong	Asda
Bart Baelus	Van Genechten Packaging
Richard Baldwin	UKAS
John Bentham	PAFA
Karen Betts	BRC Global Standards
Sabrina Bianchini	DNV Italia
Lorena Black	Sierra Packaging and Converting
David Brackston	BRC Global Standards
Elif Caglayan	Gungor Plastik
Alan Campbell	Campden BRI
Mark Caul	Tesco
Adam Chappell	SAI Global
Paolo Confalonieri	DNV-GL
Andrew Dalglish	NSF Certification UK Ltd
Roy Dixon	The Packaging Society
Txomin Echarri Sucunza	DS Smith Packaging Pamplona (Bertako)
Iain Ferguson	Co-operative
Brian Fowler	QA International Certification Ltd
Anna Gandolfini	Barilla G. & R. F.II SpA
Carol Garle	NSF International
Jean-Louis Gastineau	SOYEZ Frères SA
Ralph Geyer	Hygenius Consultancy/ATE
Alex Gifford	Unilever
Joanna Griffiths	BRC Global Standards
Dr Ahmed Hammad	ISOQAR Egypt
Almudena Hernandez Cimiano	Aenor
Martin Hodgson	British Glass
Dimitrios Ignatiadis	Athanasios Hatzopoulos SA
Milagros Igual	Sai Global

Angelie Jansen	ISACert BV
Etienne Jérémy	MM Packaging France
Peter Kai	SIG Combibloc
Miss Wariya Kalom	Biodegradable Packaging for Environment Public Company Ltd
Matthew Kensall	Sainsbury's
John Kukoly	BRC Global Standards
Darren McGrath	DS Smith Packaging UK
Neil Milvain	SGS
Pardo José Montava	Cartonajes Unión, SL
Ian Morris	The Packaging Society
Christodoulos Naziris	Athanasios Hatzopoulos SA
Sergio Nestori	
Simon Oxley	Marks and Spencer
Peter Pacepavicius	RSPH
Peter Parr	ISOQAR Ltd
Debbie Parry	Sainsbury's
Neil Parsons	Logoplaste UK Ltd – Coleford site
Tomás A. Pérez	Norgraft Packaging, SA
Marcello Pezzi	CPI
Dr Sylvia Pfaff	FIS Europe
Reinhard Pichler	QCE-Quality Consult Est
Ian Purse	Food Standards Solutions
Christine Rhodes	Fort Dearborn Company
Lidia Madelin Rivera Peña	Nesplas
Terry Robins	Robins Packaging Consultants Ltd
Dr Ulrich Röhr	SQS
Anna Schooler	Whakatane Mill Ltd
Paul Simmons	Colpac Ltd
Martina Stankevičienė	UAB MAKSIMA
Dagmar Strauß	LRQA
Catherine Tipper	FPA
Sue Williams	SAI Global
Adriano Zamarian	Taghleef Industries
Anna Zaniboni	CSI SpA

BRC Global Standards
21 Dartmouth Street
London SW1H 9BP
Tel: +44 (0)20 7854 8900
Fax: +44 (0)20 7854 8901
Email: enquiries@brcglobalstandards.com



To learn more about the BRC Global Standards certification programme please visit
WWW.BRCGLOBALSTANDARDS.COM

To learn more about the BRC Global Standards online subscription service please visit
WWW.BRCPARTICIPATE.COM

To purchase printed copies or PDFs from its full range of BRC Global Standards publications please visit
WWW.BRCBOOKSHOP.COM

