BRC GLOBAL STANDARD
PACKAGING AND PACKAGING
MATERIALS ISSUE 5

MODULE 9
AUDITONE

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For more information about BRC Global Standards, contact:

BRC Global Standards
Floor 2
7 Harp Lane
London EC3R 6DP

Tel: +44 (0) 20 3890 5537

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

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History of Amendments	
1 February 2017	Published
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PART I
AUDIT PROTOCOL

BRC Global Standards has developed this Module in partnership with the Foundation for Strategic Sourcing (F4SS) as part of the AuditOne Initiative. The aim of the Module is to expand the scope of the audit against the BRC Global Standard for Packaging to meet the needs of all brand owners participating in the AuditOne Initiative.

The AuditOne Initiative is intended to drive value in the supply chain through trust, collaboration, inclusion, continuous improvement and openness. It provides an efficient and collaborative way to ensure the quality of raw materials, components and products that will give consumers the positive product experience and safety they deserve.

Certification to this Module in association with Issue 5 of the BRC Global Standard for Packaging and Packaging Materials is designed to:

- reduce the need for multiple audits
- demonstrate effective management of quality throughout production
- demonstrate effective change management controls
- provide confidence to customers.

SCOPE

The use of the Module is voluntary but subject to customer mandate. It is applicable to companies that manufacture packaging and packaging materials. It is also intended to apply to:

- prior operations (e.g. production of packaging materials for conversion or printing)
- operations that supply 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 that 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)
- 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 agreed by those involved.

The Standard shall not apply to packaging or materials that do not undergo any process at the site audited, nor to activities relating to wholesale, importation, distribution or storage outside the direct control of the company.

EXCLUSIONS FROM SCOPE

Where the Module is requested, the scope shall include all of the applicable processes on site. It is not possible to select products to exclude from the scope.

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 and 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).

AUDIT PLANNING

PREPARATION BY THE COMPANY

The certification body shall be notified in advance of the audit of the intention to add the Module to the scope of the audit. This ensures that sufficient additional time can be scheduled and that an auditor with the appropriate qualifications for the additional Module is selected. Auditor competency requirements are listed in the separate BRC Packaging auditor competency guideline, available from BRC Global Standards.

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 that the auditor is fully prepared to audit against the Module. This may include, for example, information from the site's customers who are members of F4SS.

AUDIT DURATION

In order for the Module to be included within the audit programme, additional time will be needed for the audit. It is expected that an additional half-day will be required to complete the auditing against the requirements of the Module. The certification body shall indicate the expected additional time requirements at the time of planning the audit.

HYGIENE CATEGORIES

The requirements of the Standard for Issue 5 are divided into two hygiene categories depending upon the intended use of the packaging and the consequent standards of hygiene under which the packaging is produced. However, only the requirements of the high hygiene category may be used with this Module. This means that sites which would have been subject to the requirements of the basic hygiene category are required to use the requirements of the high hygiene category.

THE ON-SITE AUDIT

Compliance with the requirements of the Module shall be assessed as part of the audit against the requirements of the main Standard. The Module 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-conformities.

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 1 working day after completion of the audit.

The decision to award certification for the Module will be determined independently by the certification body management, following a technical review of the audit report and the 'closing out' of non-conformities in the appropriate timeframe, and the pass/fail criteria listed in this Module. The company will be informed of the certification decision following this review.

Where this Module is audited as part of an unannounced option 2 audit programme, the requirements will be assessed at both parts of the audit.

NON-CONFORMITIES AND CORRECTIVE ACTION

The level of non-conformity assigned by an auditor against a requirement of a 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.

Non-conformities

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

- **Critical** Where there is a critical failure to comply with a product safety or legal requirement within the scope of the Module.
- **Major** Where there is a substantial failure to comply with a 'statement of intent' or any clause of the Module, 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 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 is not in doubt.

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 and the number 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 that already holds certification for the Module, certification must be immediately withdrawn.

Some customers require to be informed when their suppliers have a critical non-conformity identified or fail to gain certification against a Module. In such circumstances the company shall immediately inform those customers.

Note that a critical non-conformity to a requirement of the Module does not necessarily prevent certification against the main Standard or other Modules.

Major and minor non-conformities

The 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.

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

AFTER THE AUDIT

There will be no grading of the Module, but the numbers and types of non-conformity raised against the requirements of the Module will determine whether the site passes or fails the audit. The Module will either be certificated (pass) or not (fail) according to the criteria set out in Table 1.

TABLE 1 SUMMARY OF PASS/FAIL CRITERIA USED FOR CERTIFICATION

NUMBERS AND TYPES OF NON-CONFORMITY			
CRITICAL	MAJOR	MINOR	PASS/FAIL
0	0	9 or fewer	Pass
0	1	5 or fewer	Pass
1	0	0	Fail

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

AUDIT REPORTING

Following each audit, a written report shall be prepared, for which a specific combined report template is available for the Module and the Standard. 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, any applicable audit summary sections shall, in addition, always be reported in English. The report addendum covering the requirements for the Module shall be prepared and dispatched to the company within 42 calendar days of the completion of the full BRC Global Standard and Module audit.

The combined audit report shall be uploaded to the BRC Global Standard Directory in a timely manner, irrespective of whether a certificate for the Module is issued. The owner of the audit report may allocate access to the audit report with the addendum to customers or other parties in the directory.

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

CERTIFICATION

After a review of the audit report for the 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 Global Standard for Packaging and Packaging Materials and issued by the certification body within 42 calendar days of the combined audit.

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

ONGOING AUDIT FREQUENCY AND RECERTIFICATION

Scheduling re-audit dates

If certification to the Module is to be maintained, the Module shall be included within each subsequent audit of the Global Standard for Packaging and Packaging Materials. The rules for scheduling the next audit and maintaining certification will follow the audit choice for the Standard (i.e. announced, unannounced option 1 or unannounced option 2).

PART II
REQUIREMENTS

RELATIONSHIP OF THE MODULE TO THE GLOBAL STANDARD FOR PACKAGING AND PACKAGING MATERIALS

Certification to this Module can only be achieved if the site is fully compliant with the requirements of the high hygiene category of the Global Standard for Packaging and Packaging Materials Issue 5. All applicable clauses of the Standard shall include provision for this Module to achieve certification. The list below shows some examples of applicable clauses as listed in the Standard.

3.1	Product safety and quality management system
3.2	Documentation control
3.3	Record keeping
3.5	Internal audits
3.9	Traceability
3.11	Complaint handling
3.12	Management of product withdrawals, and incidents and product recalls
5.7	Control of non-conforming product
6.1	Training and competence: raw materials handling, preparation, processing, packing and storage areas

HOW THE MODULE IS ARRANGED

The scope of the Module is closely aligned with the requirements of the Standard. Where the requirements extend beyond those of the clause in the Standard, the numbering of the Module reflects its location in the Standard, but the clause number is preceded by the Module number (9).

9 REQUIREMENTS OF THE AUDITONE MODULE

9.1 SENIOR MANAGEMENT COMMITMENT

9.1.4 OPERATIONAL RECOVERY PLAN

The company's senior management shall ensure that the continuing operation of the company is safeguarded through a business recovery plan.

CLAUSE	REQUIREMENT
9.1.4.1	Electronic files, records, data and systems shall be suitably protected and backed up. A test of the system shall be carried out at least once per year, or whenever any significant changes are made to the system.

As part of an effective quality management system (QMS) the site needs to have a system in place that is suitable to enable recovery in a force majeure situation, such as power failure affecting electronic stock management systems. This may mean daily backups to an off-site server which is suitably protected through its own systems against any situation which may put data at risk.

The test of the system should ensure that the backed-up data is complete and not corrupted. This may be a self-check function of the backup system. As a guide, the site should be considering the usable life of its materials to determine how far back into its archives it makes the test, bearing in mind that complaints from customer product recalls may occur when the packaging material is in use and on the market.

9.3 PRODUCT SAFETY AND QUALITY MANAGEMENT

9.3.1 PRODUCT SAFETY AND QUALITY MANAGEMENT SYSTEM

CLAUSE	REQUIREMENT
9.3.1.3	The site shall define and document how new procedures, working methods and practices are communicated to relevant personnel.

It is common within any organisation for documents that are used operationally to be changed from time to time. When documents are changed, it is essential that not only are changes reflected in the site's document control system but also that the content of the changes is appropriately communicated to those personnel for whom it is relevant. This may take the form of, for example, formal training where changes are more significant, or a briefing of the changes at a 'toolbox'-type session at the start of a shift.

9.3.3 RECORD KEEPING

CLAUSE	REQUIREMENT
9.3.3.5	A policy shall state that production records and all other records associated with product safety, quality and legality shall be written indelibly. Any alterations to records shall be authorised and justification for the alteration shall be recorded.

Any data associated with production, relating to product safety, quality or legality should be recorded in such a way that deletion or alteration is detectable.

This requirement may link to section 1.3 with regards to management authority designation concerning who is able to permit or justify alterations or deletions to records.

9.3.11 COMPLAINT HANDLING

CLAUSE	REQUIREMENT
9.3.11.3	All complaints regarding raw material defects identified by the site shall be recorded and investigated (including root cause analysis) and the results of the investigation documented.

The Standard states that complaints from customers relating to product safety, quality or hygiene should be recorded, with complaint data contributing to analysis to identify improvements. In addition, this Module states that all complaints that the site has received regarding raw materials supplied to it are to be recorded and investigated.

In this way, the site benefits from the additional data that contributes to the monitoring of suppliers and helps to properly identify the root cause of issues raised. It also enables the site to identify opportunities to work with its suppliers.

9.4 SITE STANDARDS

9.4.1 EXTERNAL STANDARDS

CLAUSE	REQUIREMENT
9.4.1.6	Where production and storage areas are surrounded by grassed or planted areas, there shall be a vegetation-free zone around the buildings.

The purpose of a clear area without grass or other plants around the site's buildings is to ensure that exterior walls are clear and any potential points for pest ingress (e.g. gaps or holes) that may cause product quality concerns are clearly visible.

The Standard already states that any grassed or planted areas surrounding buildings shall be regularly tended and well maintained. This Module extends that so that a clear area immediately around buildings is in place. The auditor will be looking for evidence that the site has established what clear areas are required and how that has been implemented and maintained.

9.4.6 EQUIPMENT

CLAUSE	REQUIREMENT
9.4.6.5	The lubrication points and application methods of any lubricant shall not be able to contaminate the product.

It is common for production equipment to have points at which lubrication is added. The purpose of this requirement is to ensure that where this is the case, neither the lubrication point nor the lubricant itself can cause a product quality hazard, such as visual or physical contamination.

Where lubrication points are located directly above the product flow, for example, excess lubrication could drip onto the material.

Where no engineered solutions, such as drip trays, have been implemented, suitable mitigation procedures should be put in place to prevent potential product contamination.

9.4.8 HOUSEKEEPING AND CLEANING

CLAUSE	REQUIREMENT
9.4.8.5	The conditions required in production and storage areas shall be specified. There shall be a regular documented check that conditions match those required and corrective action taken where necessary.

The Standard does not set out the specific conditions that are required in order to keep a site compliant with the requirements. It recognises that as all production sites are different, it is for the site itself to determine how its housekeeping and cleaning plan should operate. This requirement, however, states that the site should define its operating conditions for the benefit of its employees so they can easily understand how they should be operating. Where multiple languages may be in use, the most straightforward way to enable understanding would be to use photographs or other pictorial representation.

9.4.8.6	The site shall ensure that equipment, in-process and finished articles are subject to sufficient segregation to reduce the risk of mixing.

The aim of this Module requirement is to ensure that employees are aware of the potential risks arising from microbiological, physical or chemical contamination, as well as potential risks of mixing from materials at different stages of production that are placed adjacent to each other.

9.4.11 PEST CONTROL

CLAUSE	REQUIREMENT
9.4.11.10	The site shall assess the suitability of its pest control programme to address variations in pest activity through different seasons, and consider any additional preventive activity that may be required. The site shall document and implement this additional activity.

In many regions of the world the changing seasons will mean that the nature of pest activity changes. There may be increased incidences of flying insects, rodents or birds, all becoming a potential source of physical, chemical and microbiological contamination. The auditor will need to see that the site has taken typical seasonal variations in temperature and humidity into account and ensured that its pest control programme addresses them at the right time.

9.4.11.11	Risk assessment and ongoing data should be used to determine whether the type or positioning of lighting is adversely attracting insects, and/or to highlight any mitigation where required. Internal and external lighting for production and storage buildings shall be designed and constructed so as to avoid attracting insects through windows or other openings.

The intention of this Module requirement is to reduce the risk of pest entry via light attraction. As a guide, anything within 8–10 metres of buildings should be unattractive to flying pests.

The site should use a risk assessment approach to selecting the location for the installation of lighting and to determine whether ingress of pests by this route is likely to cause a problem.

Where sites have existing lighting in place, the solution to pest ingress issues may be through ingress mitigation or relocation of lighting units.

9.4.11.12	The site shall use a documented risk and ongoing assessment to determine whether there should be double sets of doors between external and internal areas. The site shall conduct ongoing assessments to determine whether the closing systems are effective, where implemented.

In some instances, additional specific measures may be required to mitigate the risk of contamination from external to internal areas. This Module requirement means that the site is obliged to use risk assessment to determine whether double sets of doors might be necessary. Note that the auditor will not be looking for double sets of doors themselves but for a risk assessment and ongoing analysis to provide evidence of the need, or otherwise, for double-door entry to internal areas. Part of this risk assessment will be the nature of the grounds (e.g. dusty or tarmacked) immediately outside the door and the activity (or its sensitivity to cross-contamination) that is carried out inside.

The risk assessment may be conducted as part of the site's hazard and risk analysis.

9.4.12 AMBIENT ENVIRONMENT

The site shall ensure that local environmental factors, such as temperature and humidity, do not affect product quality (from raw materials through to finished products).

CLAUSE	REQUIREMENT
9.4.12.1	The site shall evaluate the impact of typical local environmental conditions, such as temperature and humidity, on the quality and process characteristics (e.g. machine settings). Any hazards identified and the measures established to manage their impact shall be documented and validated.

The site should be aware that the local temperature and humidity may have an impact on the process characteristics. For example, higher ambient temperatures may mean that dwell time in a printer's ultraviolet (UV) unit needs to be reduced in order to retain the appropriate product quality. The site will need to evaluate and document the typical local atmospheric conditions and demonstrate that it has measures in place to manage their effects and maintain control of quality.

9.5 PRODUCT AND PROCESS CONTROL

9.5.1 PRODUCT DEVELOPMENT

CLAUSE	REQUIREMENT
9.5.1.6	A documented procedure shall be place to address the transfer of customers' specifications to the site's own systems. This shall include (but is not limited to): • validation of the accuracy of data transferred • how changes to customer specifications are updated and communicated • how customer testing method requirements are met • evaluation of how changes made to the customer specification affect the technical product specification (clause 5.1.1).

Depending on the nature of the product development, the agreement of a product specification and the systems in place at the site, data may need to be transferred by an employee. Where this is the case it is important that the site recognises that subsequent changes, or even human error, might mean that transferred data is not correct.

In any case, validation of data at suitable periods is advised to ensure that the correct information is used. This may link with periodic customer focus and contract review work (clause 3.10).

9.5.1.7	New products or product changes shall be subject to suitable testing to ensure that the required quality parameters can be achieved.

Each time a new product is produced, or a variation of a product is made where previous process characteristics have been validated, the site should ensure that it can meet the product specification set by its customers, including the required quality parameters.

In the case of a customer requirement, if supply or performance characteristics change then the customer shall be notified, and this shall be agreed and documented.

If the performance characteristics of raw materials change the customer should be notified accordingly.

9.5.1.8	The site shall determine what outputs and success criteria are required from a production trial, any changes and/or additions made to materials, and processing characteristics or equipment.

The site should define the categories of typical changes made within it, how such changes will be controlled and how they are to be assessed as being successful. This approach should also be applied to other changes that could be made, such as new automation or inventory control systems.

How and under what conditions a change will be tested (as well as to what success criteria) should be documented in the form of an approved validation protocol. The customer specification may form part of this; it may also include other operating parameters such as acceptable scrap, production rates or ranges, or environmental operating conditions.

The results produced against the approved protocol should be documented, showing clearly the conclusions found and whether further testing is required.

9.5.1.9	Settings derived from successful production trials or equipment installations shall be transferred accurately to process control documentation.

Once the change (e.g. new equipment, material or processing modification) has successfully demonstrated repeatable quality output, the settings or procedures should then be managed by the site's process control systems. This ensures that the validated conditions are not changed to the detriment of the quality control of the product.

9.5.1.10	The site's test methods used in both online and offline testing shall be validated to ensure their validity, sensitivity, reproducibility and range, in addition to any other relevant criteria.

The intent here is to ensure that site-developed test methods (other than simple compendial methods or where measurement is purely dependent on effective calibration) are giving reliable results that allow for effective release (or otherwise) of in-process or finished goods.

9.5.4 PROCESS CONTROL

CLAUSE	REQUIREMENT
9.5.4.7	The documented line clearance procedure shall include: • the roles of persons involved in line clearance • areas where materials can become trapped • validation of the line clearance • sign-off for continuing production. The line clearance procedure shall be fully implemented for each production run.

When each person involved in line clearance properly understands their role, then whether or not there is the potential for materials to be trapped, the associated risk is reduced. The key here may be to train the people involved in the potential ramifications of trapped materials to product safety and the quality of output.

9.5.6 PRODUCT INSPECTION, TESTING AND MEASURING

CLAUSE	REQUIREMENT
9.5.6.9	Samples for checking in-process quality shall be selected either according to customer requirements or by industry-standard testing protocols.

Sites will select product for quality checks throughout a production lot or batch. This requirement simply means that where the customer specifies a particular quality level, this must be met. Where no customer requirement is in place, the site should use industry standards to determine the appropriate frequency of checks. The selection of the tool will depend on process characteristics and the site might use a risk-based approach to determine what to use and when.

9.5.6.10	The site shall define how samples used for checking in-process quality are disposed of. This may be by returning to stock, regrind/recycling, or segregation and disposal.

Where samples are pulled from the production flow for testing, the site should determine and document what it does with the samples. This may be to prevent the introduction of non-conforming product to the production flow, where the testing itself might compromise product quality. Alternatively it may be to ensure that any products that have been handled are not reintroduced to the product flow where this may cause a product safety or quality issue.

Where no samples are pulled from the production line, this requirement may be marked as 'non-applicable' (n/a).

9.5.6.11	Test methods, analytical methods and customer-approved reference samples shall be available. They shall be kept up to date, either in the laboratory or where offline testing is conducted, and shall be suitably stored to avoid degradation.

To ensure consistency of testing, results and reference materials, the site should ensure that where its laboratories use tests or compare product with master samples, these are available at the point at which they are needed. Where the site uses reference samples, efforts should be made to minimise the risk of degradation of the sample, and sites should have a renewal programme to maintain the integrity of this process.

9.5.6.12	Traceability of test data and samples to production lots shall be maintained.

Where testing is carried out offline, it is essential that the site is able to identify the production batches or lots from which the testing samples have originated. This ensures that results are linked to the correct batch and assists the site in validating its ongoing product quality results.

CLAUSE	REQUIREMENT
9.5.6.13	Where testing shows out-of-specification results, there shall be a documented procedure for how these are investigated to determine whether the cause is non-conforming product or a testing failure. (An out-of-specification sample shall be retested only to demonstrate an analytical error, not to reverse a previous result.)

Ultimately, this requirement concerns how the laboratory conducts its activities. It ensures that the integrity of results cannot be questioned and that the laboratory is able to maintain consistency. The site should have a procedure for when testing produces out-of-specification results, even if the test equipment itself may have caused that result (e.g. testing equipment failure or poor sample quality).

The site should compare its customer specification with what the site is actually doing in regard to production and the testing of produced materials. Certain customers may have specific requirements that the site is not carrying out because they are not a broad requirement across all of its production lines.

The translation of customer specification test methods to the site's own comparable methods must demonstrate, through validation or otherwise, that the results yielded are identical.

9.5.6.14	Maintenance logs shall be maintained for all offline testing equipment. This shall include as a minimum: • adjustments • recalibration • date of any interventions.

The site should keep records of what adjustments, repairs or calibrations have been carried out, and by whom. This will give assurance that errors or trends in measurements can be referenced to the equipment logs.

9.5.8 INCOMING GOODS

CLAUSE	REQUIREMENT
9.5.8.3	All incoming raw materials shall be appropriately validated or tested before use. All raw materials awaiting results of in-house testing or validation of data shall be held until released for use.

The data within a certificate of analysis (CoA) should be checked to ensure that it is valid, meets the requirements of the supplier's own specification and matches the packaging supplier's own tests. Either supplier data or in-house testing can be used to determine whether the product meets specific requirements (e.g. for moisture content), which will ensure that only fit materials are used in production. This process ensures effective process control of the characteristics of incoming goods.

Each batch of incoming materials should either have a CoA or there should be evidence that the requirements of the process and the customer specification are met by the incoming goods. It may be that the site is able to validate its processes to accept the potential variation in parameters of incoming goods, working within tolerances acceptable to meet customer specifications.

Risk assessment may be used to determine the most appropriate way to assess the validity of incoming goods (e.g. in-process validation of incoming goods for fibre-based products, or CoA for inks and adhesives).

9.5.9 STORAGE OF ALL MATERIALS AND INTERMEDIATE AND FINISHED PRODUCTS

CLAUSE	REQUIREMENT
9.5.9.6	All raw materials shall have a defined and documented expiry date and a procedure defining how they should be handled where they exceed this date. Where raw materials have no reasonable expiry date (e.g. cullet for glass manufacture), this shall be documented.

Raw materials will typically have a useful lifetime which may relate to the conditions they are stored under (see also clause 9.4.12) and the properties of the materials themselves. Some materials are higher risk than others; for example, paper is hygroscopic and once its relative humidity (RH) exceeds acceptable tolerances, the paper becomes unusable through warp and dimensional changes. Managing raw material usage within these defined parameters will support the performance and manufacturing characteristics of the finished goods.

However, it is recognised that some raw materials will not have an expiry date or will have a very extended life. These will typically be raw materials further up the conversion process (such as resins, cullet, aluminium, steel and cellulose-based pulp), where further processing alters the characteristics of the materials to a product with a different shelf life, such as paperboard.

9.5.9.7	Warehousing equipment shall be kept in a good state of repair and cleanliness.

Equipment used in the warehousing area, such as forklift trucks, racking and pallet trucks, may have an impact on product quality through the potential to introduce foreign-body contamination. In order to minimise such risks, it is vital to keep these pieces of equipment in a good state of repair. The site might choose to include all warehousing equipment on the cleaning and maintenance schedules, or to create procedures specific to the area.

9.5.9.8	Materials shall be stored away from walls to aid cleaning and inspection of production and storage areas.

As a guide, there should be enough room for a person to walk between internal walls and any stored materials, to ensure that cleanliness standards can be maintained. Tight spaces can also offer harbourage for pests so it is important that these are avoided.

9.5.9.9	To minimise the risk of mix-ups and cross-contamination, different materials shall not be stored on the same pallet unless they are physically segregated.

To minimise the risk of mix-ups or cross-contamination, materials that can be stored on the same pallet (e.g. small items such as self-adhesive labels) should be physically separated from others (e.g. by the use of corrugated separators). There should also be appropriate procedures to reduce the risk of inadvertent picking.

Adequate physical segregation measures would include, for example, packing finished products in separate sealed boxes, or other measures that mitigate the risk of inadvertent erroneous picking.

9.5.11 PRODUCT HANDLING

The handling and management of intermediate and finished products shall ensure that their quality is maintained.

Interpretation

There are many points during a packaging material's production and processing at which quality and integrity might be affected. The intention here is to ensure that the handling of intermediate or finished products by personnel or automated equipment does not subject products to unacceptable hazards.

CLAUSE	REQUIREMENT
9.5.11.1	Packaging used for storage or dispatch of intermediate or finished products, such as pallets, shall be appropriately covered if it is stored outside and inspected for signs of damage or contamination before use.
To ensure that the materials used to transport and protect manufactured products do not themselves cause a product safety or quality hazard, any type of packaging material for finished products should be stored so that it remains dry and in good condition. Where pallets are stored outside but covered, the site should still ensure they are fit for purpose with a visual check of their condition to prevent products being loaded and contaminated.	
9.5.11.2	Finished products shall not be stored outside.
Finished products should be protected from potential sources of contamination that may affect product quality, and they should be stored in locations where their condition will be preserved.	
9.5.11.3	The site shall have a system in place to validate all raw materials and intermediate products before they are introduced to the process.
The intention of this clause is to ensure specific attention is paid when new materials or lots (e.g. reels, colours, inks, printed materials or resins) are used in the process. A check should be made to confirm that the new material or lot meets the product schedule and specification, and this should be documented. Ideally, automation should be used to prevent human error, but these automated systems should still be checked. Where the risk is considered high and automation does not exist, double confirmation should be used.	
9.5.11.4	Unloading areas for bulk deliveries shall be clearly identified and designed to prevent product mix-ups.
Sites may want to use a 5S (Sort, Set in order, Shine, Standardise, Sustain) or similar approach to organising work spaces, particularly where large volumes of materials are handled, in order to minimise the risk of product mixing. In any case, identification of materials should be simple and easy.	
9.5.11.5	Finished product storage shall meet customer requirements with regards to first-in first-out (FIFO), where applicable, with dispatch after quality release.
Many customers will have specific requirements about how finished product is dispatched to them. Therefore, it is essential that any specific requirements are understood and communicated throughout the organisation. Personnel in charge of dispatch of finished product should be particularly aware of product release procedures that might be specific to one customer but not another, and should be able to demonstrate that these are followed.	

9.5.12 PRODUCT RELEASE

The final product release to the customer shall be determined by a suitably trained, competent and independent person.

Interpretation

It is vital that release of product to a customer is carried out by a suitably independent person, who is not subject to influence from commercial pressures. This will ensure that only product that conforms to the customer's quality specification reaches its destination. Any non-conforming product should be handled suitably, in accordance with the Standard and this Module.

CLAUSE	REQUIREMENT
9.5.12.1	The site shall have a procedure that defines how the release of products shall be approved by an authorised person. This procedure shall ensure that only product meeting the specification is shipped.
The procedure should specify that the quality assurance personnel responsible for authorising release of products in relation to the customer specification are independent in their decisions. Release of production lots should be made once quality data demonstrates it meets the customer specification. This approach may also be relevant for packaging properties relating to internal work in progress that requires testing before passing to final assembly.	

9.5.13 PRODUCT LABELLING

The labelling of intermediate and finished product shall facilitate identification throughout the supply chain.

Interpretation

To maintain traceability, the site should ensure that labelling and identification are sufficient, so that at any point a raw material or an intermediate or finished product can be identified and full traceability enabled.

CLAUSE	REQUIREMENT
9.5.13.1	All coding applied to intermediate or finished products shall be checked for legibility and accuracy against production records.
The site should have a system in place to ensure that coding applied to products is accurate and not just based on customer requirements as to what is checked. It is important to consider both humans and computers: all text must be legible and all information to be scanned must be readable by a computer.	
9.5.13.2	Labelling or any other type of identification shall be applied at the line of manufacture upon completion.
The risk of mislabelling or misidentification increases when a product is carried away from the point at which production takes place. The site might have processes in place as part of its 5S procedure to ensure that identification is applied at the right point to prevent mix-ups or wrong allocation of product.	
9.5.13.3	The site shall have a documented procedure in place controlling label reprints and pallet labelling.
The reprinting of labels can increase the risk of mix-ups or incorrect data being applied to the label, as well as removing the original production information. All original labels that have been replaced by reprints should be made unusable.	

9.6 PERSONNEL

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

CLAUSE	REQUIREMENT
9.6.1.6	The effectiveness of trainers shall be monitored and verified.
This requirement is relevant to the effectiveness of both internal and external training. Are trainers able to convey information and achieve results from delegates? The site might consider training the trainers themselves (via professional courses or otherwise) to improve their effectiveness.	
9.6.1.7	The site shall ensure that the competency of personnel responsible for laboratory testing and assessment is maintained and developed.
Over time, results derived from repeated measurements can drift as small changes in technique occur, often subconsciously. Maintaining accuracy of analysis therefore requires frequent comparison of results – checking for variability both in the method/instrument of measurement and in or between the operator(s) performing the measurements (e.g. by using gauge repeatability and reproducibility or gauge R&R) – so that any differences can be corrected.	

BRC Global Standards
Floor 2, 7 Harp Lane
London EC3R 6DP
Tel: +44 (0)20 3890 5537
Email: enquiries@brcglobalstandards.com

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