Audit Report

Global Standard Packaging and Packaging Materials Issue 5: July 2015

Audit summary			
Company name	Propac Thermoforming Ltd	BRC site code	1626545
Site name	Hyde		
Hygiene Category	High Hygiene		

Audit scope	
Scope of audit	The design and manufacture of thermoformed packaging from the intake of raw materials to the dispatch of finished goods.
Exclusions from scope	None
Justification for exclusion	N/A

Voluntary modules included		
Modules	Result	Details
Choose a module	Choose an item	
Choose a module	Choose an item	

Audit results			
Audit result	Certificated	Audit type	Announced
Audit grade	AA	Previous audit grade	A

Number of non-conformities		
	Major against SOI of Fundamental	0
	Critical	0
	Major	0
	Minor	3

Company details			
Address	Units 1 - 4 Fromac Works Junction Street Dukinfield Hyde SK14 4QN		
Country	United Kingdom	Telephone	0161 343 5220
Commercial representative Name	Malcom Gillies	Email	malcom@propacthermoforming.co.uk
Technical representative Name	Caroline Gillies	Email	caroline@propacthermoforming.co.uk

Company profile					
Plant size (square metres)	<10K sq.m	No. of employees	1-50	No. of key processes	1-3
Subcontracted processes	No				
Other certificates held	None				
Regions exported to	Europe				
Major changes or auditor observations since last BRC audit	Continued investment in the plant with the addition of an off-site storage unit for housing raw materials, the purchase of a new thermoforming machine and the refurbishment of the raw material warehouse into a production facility which is due to go live in early June 2016.				
Company description	Propac Thermoforming Limited is privately owned and operated by Malcolm and Caroline Gillies. The Company was established in 1992 and has been at its present Site for 16 years. The Company employs a total of 14 staff in a 1500 sq m facility. The Shift/Working Pattern is 6am to 4pm and 8am to 8pm. The Company operates 1 H&RM system. The Company thermoforms food and non-food containers by way of three thermoforming devices, ILLIG's RV and RD 53 and a Kiefel KMD 60. Areas visited included 2 Production Units, Warehouse and all ancillary areas. The Company continues to increase turnover with a continual focus on maintaining and developing existing Customers.				

Product and process characteristics

Field of Audit (Glass Paper Metal Rigid plastic Flexible plastic Wood and other material Print Chemical processes)	04 - Rigid plastics
Products in production at the time of the audit	Collation trays for cosmetic products made from clear rPET and polystyrene

Audit duration details

Finish date	2016-04-20		
Re-audit due date	2017-04-24	Previous audit date	2015-04-24
On-site duration	8 hours	Duration of production facility inspection	2 hours
Reasons for deviation from typical or expected audit duration	No deviation in line with contract		
Next audit type selected	Announced		

Audit duration per day

Audit days	Date	Audit start time	Audit finish time
1 (start date)	2015-04-20	08:00	16.00

Auditor information

Auditor number	Auditor Name	Role
205026	Simon Martin	Lead Auditor

Present at audit				
Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.7) Name / Job Title	Opening meeting	Site inspection	Procedure review	Closing meeting
Malcolm Gillies, Managing Director	X	X		X
Caroline Gillies, Director	X		X	X
Gary Dollard, Operations Manager	X	X		X
Janet Dollard, Administrator	X			X

Non-Conformity Summary

Major non-conformity against statement of intent of a fundamental requirement				
No.	**Requirement ref.**	**Details of non-conformity**	**Critical or Major?**	**Anticipated re-audit date**

Critical			
No.	**Clause.**	**Details of non-conformity**	**Anticipated re-audit date**

Major							
No.	**Clause**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan (based on root cause analysis)**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**

Minor							
No.	**Clause**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan (based on root cause analysis)**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**
1	3.4.1	Finished product specifications currently do not define compliance to current relevant legislation	New product specification sheets written to include compliance with current legislation. Date of Issue 12.05.2016 Issue 2.	Current product specification sheets do not show compliance to current relevant legislations with regards to raw material. Add a line with this information to each specification and re-issue appendices 2A and 2B.	Document	2016-05-18	S. Martin

2	4.1.3	External pipe work or other access points for product and/or raw materials are appropriately sealed so as to prevent pest entry with the exception of gaps noted to the top of the roller shutter doors.	Immediate action was taken to order the brushes but the suppliers were slow to respond initially. Order placed with Rentokil initial supplies for bird control brushes to stop possible ingress of birds into the production unit.	Design of the door frame around roller shutter doors show gap where pests could enter the building. We will speak with our Pest Control company to see what they can suggest as a prevention to pest entry. We will also speak with a local engineering company to see if something suitable can be manufactured which does not interfere with the roller shutter.	Document	2016-05-18	S. Martin
3	5.6.2	There is no in-line product testing in place but hazard and risk analysis has not been used to determine this.	A hazard and risk analysis was carried out 12.05.2016 which showed that in-line testing was not safe due to the speed of the machine and danger to operatives	No In-line testing takes place but hazard and risk analysis should have been carried out to say why we do not do inline testing. Carry out an H & R analysis report.	Document	2016-05-18	S. Martin

Comments on non-conformities – not tagged, just free text. This is to explain where a large number of NCs have been raised without a major
None

Voluntary Modules Non-Conformity Summary Sheet

Critical			
No.	**Clause**	**Details of non-conformity**	**Anticipated re-audit date**

Major							
No.	**Clause**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan (based on root cause analysis)**	**Evidence provided: document, photograph, visit, other**	**Date reviewed**	**Reviewed by**

Minor							
No.	**Clause**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan (based on root cause analysis)**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**

Detailed Section

1.	Senior management commitment
1.1	Senior management commitment and continual improvement

System Validated: 20 April 2016
The company has established a Product Safety and Quality Management Policy which includes a safe and legal statement. The policy is reviewed annually at the Management Review Meeting and is communicated to all staff through company noticeboards at numerous locations around the site and via the induction program. The policy commits to a program of continuous improvement using targets and objectives. The Senior Management team at the site have demonstrated commitment to the implementation of the standard relevant to the manufacture of thermoformed products for food and non-food products. There is a dedicated BRC Team in place at the site which is supported by Senior Management. There are training programs in place to maintain and develop continuous improvement principles. The company have Quality resources in place and sets yearly Quality Objectives. Targets are reviewed at the annual Management Review meeting and adjusted as necessary.
There is dedicated BRC Resource provision on site in the form of Caroline Gillies – Company Secretary and Garry Walker – Janet Dollard – Administrator as BRC deputy. The BRC team are supported by the Production and Admin personnel. It was apparent during the assessment that adequate financial and human resource was in place to effectively maintain the requirements of the standard. The site has continued to invest heavily in both people and equipment since the last assessment.
The Company Secretary is responsible for keeping the company informed of all relevant legislation. The company consults with its' suppliers and also researches various web sites such as fsa.com foodcontactmaterials.com. The BRC website is also consulted on a regular basis. The company subscribes to various trade magazines such as Packaging News and Plastics and Rubber Weekly. Information is cascaded down from this central source as and when required.

Challenged at this Audit: 2016-SM
The Product Safety & Quality Management Policy is currently at issue 1 dated 09.11.15 and signed by Malcom Gillies – Managing Director.
Examples of current product safety, legality and quality objectives for 2016 are as follows: -

Customer complaints to be zero
Internal N/C's to be less than 5
OTIF to be 100%

The company ensures materials are safe for use with food and has a generic D of C in place. The D of C is available for all Customers on request. Migration testing is undertaken by suppliers as and when required.
2 N/C's were raised at the previous audit (against issue 4 of the standard), all of which were effectively closed out with no repetition present during the current audit.
There is an electronic copy of issue 5 of the standard in place. The company has a system to ensure re-certification occurs on or before the audit due date. The audit took place within the required timeframe in this instance. The Managing Director who has overall responsibility for the site was present at the opening and closing meeting and all relevant personnel were available during the assessment. Root cause is considered for NC's raised during internal and external audits and this is documented.

1.2	Management review

System Validated: 20 April 2016
There is an annual Management Review Meeting undertaken at the site.

Challenged at this Audit: 2016-SM

The last annual Management Review meeting was conducted on the 23.03.16. Present at the meeting was the Managing Director, the Company Secretary and the Operations Manager. The minutes were reviewed during the assessment and the agenda items were found to meet the requirements of the standard. Minutes are circulated to all attendees with action points allocated to designated personnel when raised. The review process reviews targets and objectives and re-sets where necessary. Objectives are detailed in section 1.1 above. Site issues are resolved via the Control of Non-conforming Product procedure.

1.3	Organisational structure, responsibilities and management authority

System Validated: 20 April 2016
There is a documented Organogram in place as part of the QMS along with documented Job Descriptions for all employees. It is clearly documented in the QMS who deputises in the absence of key personnel on site including the Management Representative.

Challenged at this Audit: 2016-SM
The Organisational Chart is currently at issue 2, dated Jan 01.03.16. The organogram is displayed as a tiered structure starting at the M.D. and ending at the Production Operatives. The Managing Director has responsibility for the site. Dept. Heads such as the Operations Manager, Engineering Manager and Company Secretary, report directly to the Managing Manager.
The Competent Manager is Caroline Gillies – Company Secretary. The Deputy Manager is Janet Dollard – Administrator.
Job descriptions are in place for all key personnel and were reviewed for the Managing Director, Operations Manager, and Company Secretary & Engineering Manager.
Absence cover for key staff is documented as part of the QMS under section 1.3, example being, the M.D. deputising in the absence of the Operations Manager.

Non-applicable clauses	

2. Hazard and risk management system

2.1	Hazard and risk management team

System Validated: 20 April 2016
There is a multidisciplinary H&RM Team in place at the site.

Challenged at this Audit: 2016-SM
There is a multidisciplinary H&RM Team in place at the site with Caroline Gillies – Company Secretary as H&RM Team Leader. The Team Leader has approximately 17 years' industry experience and has been trained in HACCP Principles by REM Associates on 27.02.12.

The multi-disciplinary H&RM team are all time served industry professionals who all bring a range of skills to the process. The team also includes the M.D. & Operations Manager who have been internally trained by the Team Leader.

2.2	Hazard and risk analysis

System Validated: 20 April 2016
There is a documented H&RM System in place at the site at issue 1, dated 10.12.15. The study covers all site operations and is supported by a Process Flow Diagram and a detailed Hazard Analysis. Potential hazards have been identified along with established hazard controls.

Challenged at this Audit: 2016-SM
The scope of the analysis is the scope of assessment and covers the design and manufacture of thermoformed products for the food and non-food applications from raw material source to the delivery of finished product to the Customer. The system is designed to meet agreed customer expectations, and satisfies statutory, regulatory and safety expectations.
The Hazard Analysis is in accordance with the requirements of the BRC standard. The team are well versed in potential industry hazards. The site analysis covers potential hazards and contamination sources within the process inclusive of allergens, taint and odour, & component transfer. The study is inclusive of risk assessments with a foundation of prerequisites supplemented with identified hazards controlled via quality procedures, SOP's & work instructions. The prerequisites and QMS work instructions maintain product integrity to produce a safe and legal product meeting customer requirements. The system has been developed to produce safe & legal products. Relevant legislation and codes of practice such as EC1935/2004, EC 2023/2006 and EU10 /2011 have been fully considered in the construction of the system.
Products are described as thermoformed trays, punnets and blister packs used to store and transport a wide range of Products such as fresh vegetable and cosmetic products. Products incorporate virgin and recycled materials. Company and Supplier D of C's confirm compliance to relevant industry legislation and also include materials used in the manufacturing process, specifically rPET and Polystyrene and also include the product limitations of use where applicable.
There is a Process Flow diagram in place defining all the operations undertaken on site. Process step examples as follows: -

Purchase of RM
Tool Purchase
RM Storage
Manufacturing Steps
Collation
Packing
Delivery
Despatch
Customer Returns

The flow chart has been verified by the team during the last H&RM review undertaken as part of the annual Management Review meeting and also via a standalone review on the 06.04.16. All manufacturing process steps have been detailed within the flow.
The site has considered and documented potential hazards relating to the manufacturing processes undertaken. Hazards have been identified along with a substantial focus on maintaining and monitoring the site-wide PRP's. Risk is assessed through traditional HACCP methodology to determine if it is a CCP. Typical hazards include but are not limited to pests, dust, product not manufactured to specification, incorrect material, glass, foreign bodies and the potential for malicious intervention.
Control measures have been identified for all hazards associated with the manufacturing process in the form of PRP's & various Quality Procedures and Works Instructions and include but are not limited to: -

PPM
Protective Clothing
Hygiene Rules
Glass Control
Blade Control
Training
Pest Control
Housekeeping
Traceability

Purchasing Procedure
Chemical Control
QC Checks
Security procedures

The site has carried out an assessment as part of the Hazard Analysis to determine the need for CCP's. The outcome of the assessment was that there are no CCP's present in the process.

Any other out of specification material that is identified throughout the process follows the "Control of Non-Conforming Product" procedure. Corrective and preventative actions are documented accordingly.
Hazard & Risk analysis review takes place as a minimum, annually. The team review all aspects of study and documents the findings accordingly. The review was last conducted as part of the annual Management Review meeting and also via a standalone review on the 06.04.16 where changes were made to the system taking into account the changes to site processes.
If or when a significant change occurs the team are reconvened to re-evaluate the risk analysis study.

2.3	Exemption of requirements based on risk analysis

System Validated: 20 April 2016
The system has been implemented in accordance with the requirements of the standard.

Challenged at this Audit: 2016-SM
There have been no exemptions requested based on risk.

Non-applicable clauses	2.2.8, 2.2.9 & 2.3.2

3. Product safety and quality management system

3.1	Product safety and quality management system

System Validated: 20 April 2016
There is a QMS in place designed to meet the requirements of the BRC Packaging standard. The QMS at the site is both hard copy and electronic & logically addresses the necessary requirements and has recently been updated to cover the changes made from issue 4 to issue 5 of the standard. The system cross-references all the relevant Quality Procedures, Hygiene Procedures, Works Instructions and SOP's necessary to successfully maintain the system. All key employees have read only access to the QMS documents held on the system. The Company Secretary is the only person on site who can make changes to and authorise the QMS documentation. The QMS is reviewed on an on-going basis when any changes to systems or processes occur, or when there is a revision to the BRC Standard. The QMS is also reviewed at the Management Review meeting and through the internal audit process.

Challenged at this Audit: 2016-SM
The Quality Manual is split down into multiple sections to address the various sections of the standard and is currently at issue 1 (having been re-written for issue 5 of the standard) and is dated 10.12.15.

3.2	Documentation control

System Validated: 20 April 2016
The site has effective document control procedures in place.

Challenged at this Audit: 2016-SM

There is a procedure for controlling documentation in place as procedure IPMPR-010 at issue 4, dated 21.01.16. Document control protocol is title, reference number, issue number and date. Documents are controlled by document master lists and change control protocols. All changes to documents and records are recorded on the "Document Master List" Doc. Ref. Appendix 1 at issue 4, dated 13.04.16 along with the reason for the change. Site documentation is controlled and amended when applicable, in collaboration with relevant process owners, by the Company Secretary, who then authorises all new or amended documents before re-issue. Obsolete documents are retained for 2 years and then discarded. Electronic documents are protected on password protected systems which incorporate anti-virus & firewall controls.

3.3	Record keeping

System Validated: 20 April 2016
Records are kept on site in accordance with the requirements of the standard.

Challenged at this Audit: 2016-SM
Record Keeping is covered under section 3.3 of the Quality Manual. Hard copy records of quality inspections and approvals are held in bespoke job bags relevant to each order. Records are initialled or signed by the relevant Operator or Manager. All changes to documents and records are recorded along with the reason for the change. The system is both computer & hard copy based. Records pertaining to product safety, legality, and integrity are maintained. The retention time for records relating to product safety, quality and legality is defined as a minimum of 2 months. Examples of site records are: -

Purchase orders
Maintenance records
Cleaning records
Pest control records
Non-conforming goods records

3.4	Specifications

System Validated: 20 April 2016
Specifications were challenged and found to exist for Raw Material, Finished Product and Services.

Challenged at this Audit: 2016-SM
Specifications were challenged for raw material and were observed for rPET reels supplied by A&K Ecofilm and polystyrene reels supplied Plastirol. Specifications are suitably detailed and include expected performance criteria, composition, applications. Associated legislative requirements are detailed on the suppliers accompanying D of C's. Finished Product specification reviewed for Product Code PA-ZZ-032-30010 Shallow Black 140g Tray for Blue Earth Foods Ltd. Finished product specifications currently do not define compliance to current relevant legislation. All products are manufactured on site and sold within the EU & conform to current legislation such as EC1935/2004, EC2023/2006 and EU10/2011. Specifications are formally agreed between the customer and the company after the specification and design process has been completed and the specification has been signed off. Specifications are agreed with customers for all orders prior to any production run taking place. The company ensures materials are safe for use with food and a generic Declaration of Compliance in place for all products produced at the site which is available to Customers on request. The D of C is fully compliant with the requirements of the standard and includes the materials used in the composition of products, legislative requirements/compliance and also defines product usage parameters. The D of C is signed by the Operations Manager and is dated 05.04.16 and is valid for 1 year. Trademarks are not applied to the packaging. There is a specification review process in place. The order processing procedure entails conducting a specification review on each order by the CST. All changes or amendments to existing specifications are reviewed prior to production. Electronic specifications are held on password protected systems with anti-virus controls.

A non-conformance has been raised against clause 3.4.1 of the standard. Finished product specifications currently do not define compliance to current relevant legislation. See minor 1.

3.5	Internal audits

System Validated: 20 April 2016
There are formal procedures in place for internal auditing of site operations. The Internal Audit procedure is Doc. Ref. CP05 at issue 1, dated 10.11.15. Internal audits are undertaken at a pre-defined frequency based on the risks associated with the activity.
There is an audit schedule in place for as an appendix to the procedure with audits covering the scope of site operations and ensures all key activities, processes and procedures implemented to achieve the standard are subject to Internal Audit at least annually.
Internal audits are conducted by the Company Secretary and M.D. to ensure impartiality. The Company Secretary has been trained formally by REM Associates in Dec 2011 and has in turn internally trained the M.D.

Challenged at this Audit: 2016-SM
Internal Audits were challenged during the assessment as follows: -

1. Section 4 of the standard – Audited by the Company Secretary on the 24.03.16. 8 N/C's were raised (all of which have been closed out) and sufficient documented evidence of conformity was in place deatiled on the asociated Internal Audit report.
2. Section 5 of the standard – Audited by the Company Secretary on the 30.03.16. 1 N/C's were raised (which has been closed out) and sufficient documented evidence of conformity was in place deatiled on the asociated Internal Audit report.
3. Section 6 of the standard – Audited by the Company Secretary on the 18.03.16. 2 N/C's were raised (all of which have been closed out) and sufficient documented evidence of conformity was in place deatiled on the asociated Internal Audit report.

N/C's were recorded on the associated Correction Action Report with root-cause analysis completed and documented as part of the investigation. N/C's are required to be completed within a set timeframe, typically within 28 days. The completion of corrective action is signed off on Internal Audit Form by the Auditor.

3.6	Supplier approval and performance monitoring

System Validated: 20 April 2016
The company has a supplier approval and monitoring system in place as procedure CP 6 at issue 1, dated 10.11.15. Proposed new suppliers are identified by the Managing Director. Suppliers must complete and return a self-assessment questionnaire in the first instance and if deemed acceptable are then asked to provide evidence of certifications and are subject a trial period. The self-assessment questionnaire is split into key sections focusing on the supplier's internal quality systems and procedures. After a successful trial period the Supplier is added to the ASL. Suppliers must hold accreditation to a recognised Quality Management Standard in order to supply.
Suppliers are monitored by the Company Secretary or Operations Manager through non-conformances, technical performance, delivery performance and price and results are retained on site.
There is an approved Supplier list in place. Suppliers are not used that are not on the approved suppliers list, but if an exception needed to be made this would be done on a batch or delivery basis and may take the form of a Certificate of Analysis or Declaration of Compliance.

Challenged at this Audit: 2016-SM

1. Plastirol – Polysterene Film Supplier. Certified to BRC Packaging by DNV valid until 20.12.16 under Cert Ref 81551-2010-ABRC IOP-NLD-SINCERT. Questionnaire completed on the 07.02.14.
2. A & K Ecofilm – rPET Supplier. Certified to BRC Packaging by NSF Knight valid until 26.05.16 under Cert Ref 9155.

3.7	Management of subcontracted processes

System Validated: 20 April 2016
No sub-contracted operations

Challenged at this Audit: 2016-SM
No sub-contracted operations

3.8	Management of suppliers of services

System Validated: 20 April 2016
The company use several suppliers of services e.g. pest control, transport and Waste Management. The management of these suppliers is covered by procedure CP7 at issue 1, dated 20.11.15. Service specifications for suppliers of services are in place.

Challenged at this Audit: 2016-SM
Examples of suppliers of services: -

1. Rentokill – Signed Service Specification dated 24.08.00.
2. B & M Waste Management – Signed Service Specification dated 17.12.15.
3. L E Jones Transport – Signed Service Specification dated 28.11.05.

3.9	Traceability

System Validated: 20 April 2016
The company has thorough and robust traceability procedures in place to identify its products through all stages of the manufacturing processes from the intake of Raw Materials to the dispatch of Finished Goods. Defined as Control Procedure CP 8 at issue 1, dated 10.11.15. The Company identifies raw material by Batch Number, Reel Number and Purchase Order No. Unique Job Numbers are allocated to each production run and are then maintained on all documentation through the manufacturing process to ensure full traceability. Any product found to be defective would be identified and segregated from similar conforming product. The company identifies W.I.P., finished products and quarantined items with labels.
The Customer can identify the product from the box or pallet label and the delivery note. This information can be traced back to the original material used in the production of the product. Labels carry Customer Name, Product No., Batch No., Pallet Qty., Box Qty., Pallet No. and Date of Production.

Challenged at this Audit: 2016-SM
A raw material to finished goods trace was test performed on 25.09.15 for Clear aPET 340 micron x 620mm wide supplied by TDX on 09.09.14 against PO No. 210815/GD. The material went into the composition of numerous works orders for Blue Earth Foods example being W/O 7408 Clear 160g Tray manufactured on the 10th and 11th of Sept 2015 & delivered to the Customer over three deliveries on the 11th, 16th & 18th of Sept 2015 on delivery notes 7115, 7123 and 7127. All material was accounted for as part of the test.

A finished goods to raw material trace test was undertaken on the 25.09.15 for Job No. 7412 Clear Cress Punnet for Ingle's Dawn Dew Salads Ltd manufactured on the 14.09.15. All raw material was consolidated as part of the test and found to be Clear aPET supplied by TDX on the 10.06.15 against PO No. 290515-GD. The test was reviewed during the assessment and found to be effective.

3.10	Customer focus and contract review

System Validated: 20 April 2016

Customer Related Processes & Contract review is fully defined in section 3.10 of the Quality Manual as is substantiated by the Order Processing Procedure CP9 at issue 1, dated 02.12.15. The documentation details who, within the company, who is responsible for ensuring Customer requirements are met and expectations delivered, examples being the M.D., Company Secretary, Operations Manager and Internal Administrator. Customer related processes include Enquiries, Quotations and Order Processing, Manufacture, Inspection and Positive Release.
How meeting Customer's expectations is met is measured through Customer Feedback, N/C's, complaints and ongoing Customer retention. All N/C's and complaints are recorded and acted upon immediately. Ongoing contact with Customers is driven primarily via the Sales and Operations functions and feedback from Customers is continually fed back to the site and reported on at the annual Management Review meeting.

Challenged at this Audit: 2016-SM
The process from initial brief from customer through to delivery of finished product to customer was reviewed in full during the assessment for Product Code 20700B Clear rPET Tray for Nice Pack International Ltd., ordered on the 24.03.16 on Customer Purchase Order PO187828. The order confirmation was sent back to the Customer on the 29.03.16. The order was for 182,000 trays, manufactured on the 13th and 14th March 2016 and delivered on the 15.03.15.

3.11	Complaint handling

System Validated: 20 April 2016
Customer Complaints form part of the "Non-conformance" procedure CP21 at issue 1, dated 12.11.15. Customer complaints come in to the business primarily via phone or email and are logged on the "Non-conformance Register" Doc. Ref. Appendix 10(B) at issue 1, dated 02.12.15. Complaints are investigated using root cause by the Operations Manager, relevant actions assigned to designated company personnel and the complaint is then closed out through customer liaison. There have been 1 Customer complaint so far this year against a target of 0. Complaints are trended where they can be (although difficult with the consistent low complaint volumes the site experiences) with the results forming part of the annual management Review meetings.

Challenged at this Audit: 2016-SM
ID NO. 72 – Complaint raised on the 01.02.16 by Mailway Packaging for faulty slots on trays supplied. Closed out satisfactorily on the 09.02.16 with evidence of investigation & corrective action in place on the Non-conformance Report.

3.12	Management of product withdrawals, and incidents and product recalls

System Validated: 20 April 2016
Product Withdrawals, Recall & Incident Management is documented as procedure CP10 at issue 1, dated 10.11.15, dated 10.11.15 and is compliant with the requirements of the standard. The Incident Management Procedure Doc. Ref. CP11 at issue 1, dated 10.11.15 lists the type of event that would constitute an incident e.g. glass breakage or chemical spillage as well as contaminated items being sent to the Customer. Investigations following a decision to withdraw a product incorporate root cause analysis, corrective action & preventative action. The incident management team is defined as the Company Secretary, Operations Manager and the M.D. All incidents are recorded and acted upon immediately. The procedure is capable of being put into operation at any time. The M.D. in collaboration with the Customer is ultimately responsible for withdrawal decisions. Contact lists for Customers are in place. Customer and regulatory body communications are the remit of the M.D.

Challenged at this Audit: 2016-SM
The site has tested and documented the procedure on the 09.02.16. The finished product selected was Job No 7640 Clear rPET Whiskey Blister Packs supplied to Mailway Packaging Solutions Ltd on 18.12.15. The test was reviewed during the assessment and found to be effective and undertaken in collaboration with the Customer who was able to successfully identify the product at their premises. The test of the procedure was real and the stock was uplifted and brought back to site, inspected, sent for recycling and a credit was sent to the Customer.

Non-applicable clauses	3.4.4 & 3.7

4. Site Standards

4.1 External standards

System Validated: 20 April 2016
External site standards were observed to be appropriately maintained.

Challenged at this Audit: 2016-SM
The site is situated on an Industrial Estate in Hyde, Greater Manchester and local activities do not pose any risks to the product. The site comprises 2 units inclusive of warehousing, production facilities and office and welfare areas. There is also a small off-site storage facility utilised for storage of raw materials. All grounds within the site were seen to be controlled, managed and maintained to a high standard at the time of the assessment. The site is gated and has a steel fence perimeter on all sides. The building fabric is steel cladding over brick construction and is maintained to a high standard. There is a clean and unobstructed area along the external walls of buildings. External traffic routes are suitably surfaced. External pipe work or other access points for product and/or raw materials are appropriately sealed so as to prevent pest entry with the exception of gaps noted to the top of the roller shutter doors. Drains are trapped / protected. Natural drainage is deemed adequate. There is no external storage of raw material.

A non-conformance has been raised against clause 4.1.3 of the standard. External pipe work or other access points for product and/or raw materials are appropriately sealed so as to prevent pest entry with the exception of gaps noted to the top of the roller shutter doors. See minor 2.

4.2 Building fabric and interiors

System Validated: 20 April 2016
Building fabric and interior areas were observed to be well maintained.

Challenged at this Audit: 2016-SM
All walls floors and ceilings were observed to be adequate and in an acceptable condition. Floors are sealed, painted concrete and there are designated route ways in production and storage areas. Internal drains are protected with suitable gratings in place. Lighting in production was observed to be adequate and is subject to shatterproof and/or protective tubing or bulbs. There are no windows in the production areas that could pose a risk to the product. Suitable ventilation of natural provision was in observed to be in place. There are no suspended ceilings.

4.3 Utilities

System Validated: 20 April 2016
Potable water is supplied to site by United Utilities and does not come into contact with the product, therefore water testing is deemed unnecessary.

Compressed air used in operations is filtered; oil separated and dried but also does not come into direct contact with the product. There are 3 compressors on site subject to scheduled servicing by Airmatic Compressors Ltd.

Challenged at this Audit: 2016-SM
Water reports from the supplier's website are held on site. Latest report dated 18.03.16 with acceptable results. Compressors were last serviced on the 14.01.16.

4.4 Security

System Validated: 20 April 2016
The site is secure and has systems in place to ensure the integrity of products and processes.

Challenged at this Audit: 2016-SM
Site security arrangements are in place documented in procedure CP12 at issue 1, dated 11.11.15 along with a documented risk assessment Doc. Ref. CP12 at issue 1, dated 20.04.16. Visitors are required to sign-in with name, company, time and date and complete a Health Questionnaire which is then checked by the company host prior to entry into the production areas.
The unit is standalone and totally secure. There are keypad entry systems at the entrance to the plant. There are strategically placed CCTV cameras at various locations around the site, both internally and externally along with security lighting and a sophisticated alarm system. All entrances are locked outside production hours. Staff are encouraged to challenge unknown/unidentified visitors.

4.5	Layout and product flow

System Validated: 20 April 2016
The factory layout is appropriate and prevents the risk of product contamination where necessary.

Challenged at this Audit: 2016-SM
There is a plan of the site in place which shows all access points for personnel, staff facilities, storage areas & people & product flow. The layout of the site is logical and linier and has not changed significantly since the company's inception. The manufacturing flow from receipt of raw materials to the despatch of finished goods has considered the risk of any potential contamination. Sorting and re-working is undertaken in a designated area of the warehouse. There are line clearance and QC procedures in place on job changes. Segregation in production consists via departmental layout, e.g. manufacturing, raw material and finished goods storage.

4.6	Equipment

System Validated: 20 April 2016
All equipment is suitably designed for the purpose of thermoforming reels of film into trays punnets and blister packs for the food and non-food industry.

Challenged at this Audit: 2016-SM
Machinery is designed to minimise any risk of contamination to the product. On site there is one Keifel and two Illig thermoforming machine in operation at the site. A new machine has recently been purchased and is currently being commissioned. All machinery is designed to facilitate cleaning and maintenance programs. Notices on equipment were seen to be laminated and secure. All new equipment is thoroughly specified before use.

4.7	Maintenance

System Validated: 20 April 2016
There is a PPMP in place defined under section 4.7 of the Quality Manual. PPM is performed to a schedule which is managed by the M.D. & the Operations Manager. All equipment on site is subject to six-monthly PPM by the manufacturer and records are retained by the Operations Manager.
Temporary modifications are allowed in emergencies and must be recorded and scheduled for a permanent repair as soon as possible.
The small workshop area was observed to be tidy and well maintained and is away from the production area.

Challenged at this Audit: 2016-SM
Specific maintenance was reviewed for maintenance undertaken on all the 2 Illig Thermoforming lines on the 26.02.16. Typical checks include checking the pneumatics, vacuum equipment, forward feed mechanism, lower mould station and punch station as examples. Only food grade lubricants are used e.g. Interflon Fin Lube TF.

Following maintenance work the engineer must sign the "Post Maintenance Hygiene Clearance Checklist" at issue 1, dated 09.11.15 to declare the line is clear to resume production. Records challenged and line clearance was observed completed for the above sampled maintenance.

4.8	Housekeeping and cleaning

System Validated: 20 April 2016
Production staff are responsible for cleaning their own machines and surrounding areas. Staff facilities and all welfare areas are also cleaned by Propac personnel.

Challenged at this Audit: 2016-SM
The housekeeping and cleaning procedure is defined in in the Cleaning Procedure Doc. Ref. CP13 at issue 1, dated 11.11.15. There is a clean as you go policy in place. In addition to the clean as you go policy there are numerous cleaning schedules are in place for production and storage areas that are compliant with the requirements of the standard. Cleaning schedules were reviewed for all office areas, staff facilities and production areas and were observed completed for W/E 18.04.16.
Verification of cleaning is undertaken by the Operations Manager. There is a designated locked storage cupboard cleaning equipment and materials located on the ground floor. Toilet cleaning equipment is colour coded red & is segregated. No strongly scented chemicals were notes during the assessment.

4.9	Product contamination control
4.9.1	Glass, brittle plastics, ceramics and similar materials control

System Validated: 20 April 2016
The site has put into effect processes and procedures to minimise foreign body contamination.

Challenged at this Audit: 2016-SM
The "Contamination Control" policy is defined in Doc. Ref. CP15 at issue 1, dated 11.11.15. Glass is kept to a minimum in production and storage areas.
There is a site wide glass register in place which is completed on a quarterly basis and is administered by the Office Administrator. Results are recorded onto the numerous site wide registers. Registers were reviewed during the assessment and observed to be up to date. Registers include low risk items such as clock faces and all non-production glass and similar material.
There is a glass breakage procedure in place and forms part of the "Contamination Control" policy. Glass breakages are recorded on an incident report and there have been no instances recorded during the last 12 months.

4.9.2	Sharps control

System Validated: 20 April 2016
Systems and procedures are in place to control sharp objects on site.

Challenged at this Audit: 2016-SM
There are sharps procedures in place at the site defined in the "Contamination Control" policy Doc. Ref. CP15 at issue 1, dated 11.11.15. Knifes and blades are not used scissors only, which are allocated to each line and identified accordingly and inspected regularly by the Operations Manager for any damage.

4.9.3	Chemical and biological control

System Validated: 20 April 2016

There is a formal control system in place for chemicals. The site maintains a list of approved chemicals and MSDS's are maintained on site. The company have assessed the controls in place using the hazard analysis system. These controls have been designed to prevent chemical & microbiological contamination. Cleaning chemicals were observed to be controlled, labelled, stored in closed capped containers with manufacturers' instructions available and stored away from production in secure designated locations at the time of the assessment.

Challenged at this Audit: 2016-SM
MSDS reviewed for Amberklene FG Cleaner supplied by Ambersil.

4.10	Waste and waste disposal

System Validated: 20 April 2016
General waste is collected in wheelie bins and transferred to external skips that are removed by licensed waste merchants. Process skeletal trim is sent back to the film suppliers for recycling.

Challenged at this Audit: 2016-SM
There are formal controls in place for the waste disposal which is managed by the Company Secretary in accordance with legislative requirements. There are 2 waste streams at the site; general waste and dry mixed recycling waste. Contractor information as follows: - B&M take general waste away from site and Suppliers of film take all process waste away from site for recycling. Trademarked waste is not generated.

4.11	Pest control

System Validated: 20 April 2016
The site has an effective Pest Control program in place and has minimised any potential risk of infestation. This a Pest Control Procedure in place defined under section 4.11 of the Quality Manual.

Challenged at this Audit: 2016-SM
There is a Contract Agreement in place with Rentokil covering rodents and insects, both internal and external baits are used along with EFK's. Rentokil is a member of the BPCA, membership No. M15/035 valid until 28.02.17. There are 8 routine visits, 4 EFK inspections and 2 biologist visits per year. The EFK contract includes catch analysis each visit and an annual tube change. The last routine visit took place on and 18.04.16 and no activity was recorded. The last recorded EFK inspection and catch analysis also took place on 11.12.15 with low counts recorded in all 6 units. The last biologist visit was undertaken on the 06.10.16. One minor recommendation was made which has been closed out. Training records are in place for Siobhan O Mahoney and Colin Clarke who both hold relevant training certificates. A register of pesticides along with safety data sheets is in place, example being Bromatrol Bait Blocks. There is an up to date site plan in place displaying all pest control devices which has been authorised by the contractor and is dated 18.04.16.

Non-applicable clauses	4.1.5, 4.2.2, 4.10.4, 4.10.5 & 4.11.3

5. Product and process control

5.1	Product development

System Validated: 20 April 2016
Product development is undertaken on site and is documented in the "Product Development" procedure CP16 at issue 1, dated 11.11.15. New enquiries typically come in via the sales contact and the brief is then drawn up in a CAD program and the drawing is sent to the customer for approval. Resin prototypes are created. Once the resin prototype sample has been approved by the Customer, the aluminium tool is then created and the production run is scheduled into the factory. Product specification sheets are created for all products. Production trials do occasionally take place

and are documented. Samples and kept in storage for the life of the product. All product containing recycled materials are correctly specified on the associated works instructions. All products manufactured at site comply with EU10/2011 regulations.

Challenged at this Audit: 2016-SM
The process was reviewed during the assessment for Product Code 903287 Stoddards Icon Clam Pack for Alexir Packaging Ltd. The approval for the new product was given by the Customer 17.11.15.

5.2	Graphic design and artwork control

System Validated: 20 April 2016
No graphic design undertaken at the site.

Challenged at this Audit: 2016-SM
No graphic design undertaken at the site.

5.3	Packaging print control

System Validated: 20 April 2016
No printing undertaken at the site.

Challenged at this Audit: 2016-SM
No printing undertaken at the site.

5.4	Process control

System Validated: 20 April 2016
The site has procedures in place to ensure effective control of all operations relating to critical product defects. It was observed that the operations on site were controlled through effective Process procedures, Quality Assurance procedures and Works Instructions to continually achieve correct manufacture of safe and legal products.
Senior members of the Management Team continually review on site processes to ensure consistency of product is maintained. Established controls are in place to ensure product integrity with corresponding manufacturing SOP's and a robust control of non-conforming product procedure. PRP's maintain standards of hygiene.
Production specifications and machine settings are available for all products. Specifications are approved internally before a quotation is raised to the customer. Procedures, SOP's and prerequisites programmes are in place to ensure production of safe and legal products that meet customer requirements. There are various processes in operation on site and examples of typical machine settings would include top, bottom and outer heater temperatures, mould time, cutter dwell time, eject speed and cycle time.
The Works Order defines the product specification and process set up of the production machinery. The W/O also contains the BOM and any tolerances applicable to the product. There are first off inspection regimes in place. All first off samples must be signed off by the experienced setter/operators. Following first off sample sign off, there are in-process inspections defined through SOP's and recorded at least 3 times per pallet on the Job Sheet. Viewed completed inspection results for the jobs in production during the assessment.
Line clearance is in the form Appendix 9 at issue 1, dated 08.12.15 which is completed at the start of every run by the setter/operator & declares the line clean and clear to resume production following the completion of individual runs.
New jobs are re-specified through customer liaison and formal documented approval procedures.

Challenged at this Audit: 2016-SM
Prod Code 21952 collation tray for Nice Pak International
Prod Code 20068 collation tray for Nice Pak International

5.5	Calibration and control of measuring devices

System Validated: 20 April 2016
No calibrated equipment is used or required to monitor product quality, safety or legality.

Challenged at this Audit: 2016-SM
No calibrated equipment is used or required to monitor product quality, safety or legality.

5.6	Product inspection, testing and measuring

System Validated: 20 April 2016
Setter/Operators undertake Quality checks throughout the production run and record the results on the "Propac Job Spec Sheet". The Operator checks 1 stack of finished product every roll change. Quality checks are visual and include webs, cavities not Formed, scratches/lines, tooling marks, excessive material on forming, splitting, de-nests flanges, crushing, trim, general form quality and contamination. Quality checks were challenged during the assessment and found to have been completed for jobs in production during the site production tour.
There is no in-line product testing in place but hazard and risk analysis has not been used to determine this.
Migration testing is undertaken by suppliers as and when necessary.

Challenged at this Audit: 2016-SM
Prod Code 21952 collation tray for Nice Pak International
Prod Code 20068 collation tray for Nice Pak International

A non-conformance has been raised against clause 5.6.2 of the standard. There is no in-line product testing in place but hazard and risk analysis has not been used to determine this. See minor 3.

5.7	Control of non-conforming product

System Validated: 20 April 2016
Control of Non-conforming product is covered by Control Procedure CP21 at issue 1, dated 12.11.15. The procedure details controls required for out of specification product, including labelling and quarantining. A decision is made to "hold" or "reject" and corrective and preventative actions are then implemented. Internal N/C's are brought to the attention of the Operations Manager immediately who then oversees the subsequent investigation using root cause analysis.

Challenged at this Audit: 2016-SM
There is a non-conformance log in place. The non-conformance log was challenged and observed completed, closed out and signed off for non-conforming product identified internally on the 14.12.15. The Job Number was 7640 where there were rough cuts and nicks were found running through the sheet. Corrective action, root cause analysis and preventative action implementation was in place and recorded.

5.8	Incoming goods

System Validated: 20 April 2016
All incoming goods are visually checked by Warehouse Operatives for taint, odour, contamination & damage in accordance with procedure CP19 at issue 1, dated 12.11.15. The vehicle is also checked for overall hygiene and if acceptable the delivery note is signed and the material is unloaded and put to stock & used in conjunction with FIFO principles.

Challenged at this Audit: 2016-SM
Reviewed for an incoming delivery of 17 pallets of rPET sheet from A&K Eco film Ltd on the 19.04.16 against PO Nos. 080416/GD & 040416/GD. Product and vehicle checks were undertaken by Mark Artingstall – Warehouse Manager.

5.9	Storage of all materials and intermediate and finished products

System Validated: 20 April 2016
Storage of materials are undertaken in accordance with procedure IPMPR-021 at issue 4, dated 14.03.16. The procedure covers, receiving goods, loading outgoing goods, storage, return handling, internal product movement, order picking, stock taking, stock rotation, warehouse security & warehouse hygiene. All raw materials and finished goods are suitably identified with labels & wrapped to avoid contamination where necessary and stored in controlled environments which includes an off-site warehouse ½ mile away which was also visited during the assessment and found to meet with the requirements of the standard. During the assessment it was observed that raw materials and finished product were kept segregated. There are no hazardous chemicals on site.

5.10	Dispatch and transport

System Validated: 20 April 2016
All finished goods are checked along with the vehicle before loading and must be signed off on the Delivery Note before the vehicle leaves the site in accordance with procedure CP 20 at issue 1, dated 12.11.15. Any damaged pallets that arrive from suppliers are brought to the attention of the Warehouse Manager and appropriate actions taken. Agreed terms of business are in place with numerous transport organisations. Delivery drivers are supervised whilst on site and must abide by the company hygiene rules. There is one company transport vehicle used to shunt raw materials from the off-site warehouse to the site and is subject to documented cleaning schedules.

Challenged at this Audit: 2016-SM
Reviewed for a delivery of 26 pallets of multiple Product Codes to Blue Earth Foods Ltd on the 18.04.16 on delivery note 7529. The transport company used was MPF and vehicle hygiene checks were undertaken and documented by Mark Artingstall – Warehouse Manager
Transport contracts reviewed for L E Jones Transport – Signed Service Specification dated 28.11.05.

Non-applicable clauses	5.2, 5.3, 5.6.3, 5.6.6

6. Personnel

6.1	Training and competence

System Validated: 20 April 2016
There are formal training procedures in place at the site managed under the stewardship of the Company Secretary. All new employees are subject to an induction program comprising site safety, quality and hygiene issues amongst other subject matter.
Each employee has their own training file. All training undertaken by employee's is recorded and signed off on the Training Record.
Training requirements are reviewed every on an annual basis by the Senior Management Team and also when there are any changes to site procedures.
Each employee is subject to refresher training programs and records of this are documented. Examples of refresher training undertaken at the site are Hygiene refresher training, fire refresher training, PPE refresher training and BRC awareness refresher training.

Challenged at this Audit: 2016-SM
Training records reviewed during the assessment as follows: -

1. Robert Pringle – Machine Setter/Operator
2. Daniel Wheeler – Machine Setter/Operator
3. David Campbell – Machine Operator

Training records define the course taken, name and role of employee, and the trainer. Records are signed off by both trainee and trainer.

6.2	Personal hygiene

System Validated: 20 April 2016
Personal hygiene is covered in the by procedure QP22 at issue 1, dated 12.11.15

Challenged at this Audit: 2016-SM
The company has a formal documented Jewellery Policy and allows one wedding band to be worn in production areas. Watches, bracelets or necklaces are not permitted. False nails, nail polish and any aftershave or perfume is not permitted. Hands must be washed every time any employee enters the Production area.
Documented procedures are in place for personal medicines.
No mobile phones are allowed in the Production Areas. Blue nitrile gloves are available as and when requested.
Cuts and grazes are covered with a blue plaster and issued via the First Aiders.

6.3	Staff facilities

System Validated: 20 April 2016
The company has provided adequate facilities that were observed in good order at the time of the assessment.

Challenged at this Audit: 2016-SM
The company has implemented controls to ensure that access to locker rooms meet the requirements of the standard. Locker rooms are clean and tidy & provide adequate segregation of workwear and personnel items with three suitably sized lockers provided for all production employees. No evidence was found during the assessment of staff, eating, drinking or smoking in locker rooms.
The company has provided facilities which address the provision of hand washing and include warm water, unscented soap, suitable hand drying and advisory signs in all units. Hand washing facilities are available at the entrance to production areas. Toilet facilities were found to be maintained in a clean and hygienic condition in all units.
There is 1 canteen on site which provides suitable amenities including food storage facilities. The canteen is clean and tidy and provides clearly marked waste containers. There are drinking water facilities in place in designated areas of production with the provision of conical cups. Drinks must be taken next to the fountain. Eating is strictly limited to the canteen. There is 1 external smoking area with suitable facilities in place for the disposal of smokers' waste.

6.4	Medical screening

System Validated: 20 April 2016
All staff are required to complete a Heath Questionnaire upon employment. If any staff are feeling unwell they must report immediately to their Line Manager. Staff are sent home if necessary and are then subject to return-to-work protocols. All visitors and contractors are required to complete health questionnaire and which is checked by the host on entry.

Challenged at this Audit: 2016-SM
Practices in evidence at the site.

6.5	Protective clothing

System Validated: 20 April 2016
Protective clothing is worn across the site in accordance with procedure CP24 at issue 2, dated 23.03.16 Company issued protective garments that are suitable & sufficient are provided to employees. All company protective clothing is

laundered by employees with written instructions and laundry bags provided. Issues consist of jackets, polo-shirts, sweatshirts, trousers, safety shoes, safety glasses & disposable hair nets. Beard snoods are provided if required. Clothing is permitted to be worn between departments but not off-site. Personnel change into and out of company clothing on site. The process is monitored for compliance by the Senior Management. **Challenged at this Audit: 2016-SM** PPE was seen to be worn by all employees during the assessment.	
Non-applicable clauses	