8.1 (2.3.1.1) OPERATIONAL PLANNING AND CONTROL

The organization has planned, implemented, and controlled the processes needed to meet the requirements of products and services:

- Determining the requirements for the products and services.
- Establishing criteria for the processes and acceptance of products and services.
- Determining the resources needed to achieve conformity.
- Implementing control of the processes in accordance with criteria.
- Determining, maintaining, and retaining documented information to the extent necessary.
  - To have confidence that processes have been carried out as planned.
  - To demonstrate the conformity of products and services to their requirements.

The output of this planning is suitable for the organization's operation. The organization has control on planned changes and reviews the consequences of unintended changes, taking action to mitigate any adverse effect.

In case of any outsourced processes will be evaluated and controlled by Quality department.

8.2 REQUIREMENTS FOR PRODUCTS AND SERVICES

8.2.1 (2.3.4.1/ 2.3.4.2/ 2.3.4.3) Customer communication

Effective arrangements for communication with customers include:

- Information relating to the products and services.
- Enquiries, contracts, orders, and changes.
- Customer feedback and complaints.
- Handling and controlling customer property.
- Establishing specific requirements for contingency actions, when applicable.

A purchase order with item number and/or description, quantity, price, due date, and terms must be generated by the customer and sent to EPPB by mail, e-mail, and fax or in person. PO is confirmed to the customer by CSR in no more than 72hrs. W.8.2.1 CUSTOMER SERVICE.

The methods and responsibility for ensuring all agreements relating to food safety and customer packaging requirements and its realization and delivery are specified and agreed shall be documented and implemented.

The site shall:

- Verify compliance with the SQF Food Safety Code for Manufacture of Food Packaging and that all customer requirements are being met at all times.
- Ensure changes to contractual agreements are approved by both parties and communicated to relevant personnel.

Records of all contract reviews and changes to contractual agreements and their approvals shall be maintained.

If the customer requirements cannot be met, the customer is contacted, and new requirements are negotiated by Sales representative and/or Customer Service.

In the case that customer due dates will not be met due to internal issues or problems Customer Service Rep., or sales Rep. will immediately notify the customer by e-mail and will come to an agreement with new delivery dates. The new delivery date will be updated in the ERP Release module.

Customer feedback and/or complaints are communicated to upper management for follow-up.

Records of contract review are maintained in the main office by customer name.

8.2.2 (2.3.1.2/ 2.3.2.4) Determining the requirements for products and services.

When determining the requirements for the products and services the organization has ensured that:

- The requirements are defined, including any applicable statutory and regulatory requirements, and all considered necessary by the organization.
- The intended use of each product shall be determined and documented. This shall include requirements for further processing if applicable, and potential alternative use of the product.
- The organization can meet the claims for the products and services offered.
- Product designs, manufacturing processes and the fulfillment of product requirements shall be validated by site trials and product testing.
- The methods and responsibility for developing and approving detailed raw material and packaging specifications shall be documented.

A request for quote (RFQ) may be submitted by phone, fax, mail, e-mail or may be brought in person.

If a sample is supplied, the following information is gathered:

a. Must be approved for size, style, substrate, caliper, grade, color, and copy.

If there is no approved sample, the customer must provide the preceding information either through a specification sheet or a verbal description, including quantity and delivery information to complete the RFQ.

Samples and layout (CAD) are requested to Die Shop. These are returned to requestor and in turn to either the President or Vice president, who generate pricing and negotiate terms with the customer.

8.2.3 Review of the requirements for products and services

8.2.3.1 (2.3.1.5/ 2.3.1.7/ 2.3.5.1/ 2.3.5.2/ 2.4.6.2)

The organization has ensured that has the ability to meet the requirements for products and services offered, including the validation of Food Safety plan. The organization has conducted a review before committing to supply to a customer, which includes:

- Requirements specified by customer, including delivery and post-delivery activities.
    - Food packaging manufactured with post-consumer recycled materials shall conform to the applicable regulatory requirements.
- Requirements not stated by the customer but necessary for the intended use, when known.

- Requirements specified by the organization.
- Statutory and regulatory requirements applicable to the products and services.
- Contract or order requirements differing from those previously expressed.

Customer requirements are reviewed F.8.2.1.1 NEW ITEM MEETING RELEASE and confirmed before acceptance, when the customer does not provide a documented statement of their requirements *(i.e):*

Physical and chemical characteristics.

- Microbiological, where appropriate.
- Artwork and unitizing requirements; and
- Confirmation that the packaging product is suitable for the intended use of the customer.
- Product ingredient list(s), allergens, identification codes, etc.

A register of finished product specifications shall be maintained (ERP unique ID#).

Where product requirements differ from previous version, it is ensured that relevant documents are amended and that relevant personnel are made aware of the changed requirements F.8.2.1.1 NEW ITEM MEETING RELEASE.

If the price is accepted, the customer must provide a signed sample approved for size, style, substrate, caliper, grade, color, and copy.

Without an existing sample, sales or customer service requests plain samples from the Die Shop department, a minimum of two. A tag showing "approved for size, style and substrate" must be on each sample.

1. Color proofs, a minimum of two are generated by pre-press and submitted for approval of Process colors and copy W.8.6.1 PRE-PRESS AREA.

2. Ink drawdowns, a minimum of two showing light, standard and dark ranges are generated for PMS or Match colors.

3. Proofs, Drawdowns and Case Label samples (or PDF file) must be sent by Customer Service to customer in order to get them signed and return one of each for inspection procedures.

8.2.3.2 (2.3.1.6)

The organization retains documented information, as applicable:

- Based on the result of the review and/or any new requirements for the product and services.
- Of all product design, process development, approvals and records of validated storage conditions shall be maintained.

8.2.4 (2.4.1.2) **Changes to requirements for products and services**

The organization ensures it that relevant documented information is amended and that relevant persons are made aware of the changed requirements, when requirements of products, services and/or relevant legislation, scientific and technical developments, emerging food safety issues are changed.

W 8.2.4 SAMPLE RUN - ECN.

8.3 DESIGN AND DEVELOPMENT OF PRODUCTS AND SERVICES

Design is not part of the scope of the business, reason to consider this chapter not applicable.

8.4 CONTROL OF EXTERNALLY PROVIDED PROCESSES, PRODUCTS AND SERVICES

8.4.1 (2.3.2.3/ 2.4.4.1/ 2.4.4.2/ 2.4.4.3/ 2.4.4.7/ 2.4.4.8/ 2.4.4.9/ 2.4.4.10) General

The organization ensures that externally provided processes, products that impact finished product safety and services conform to requirements. Determines the controls to be applied when:

- Products and services from external providers are intended for incorporation into the organization’s own products and services.
- Product and services are provided directly to the customer(s) by external providers on behalf of the organization.
- A process, or part of the process is provided by an external provider as a result of a decision by the organization.

The organization determines and applies the criteria for evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. Documented information of these activities and any necessary actions arising from the evaluation must be retained.

Suppliers are evaluated and selected based on their ability to supply products in accordance with requirements. Criteria for selection, evaluation and re-evaluation and any necessary actions arising from the evaluation are maintained.

Suppliers are selected based upon a balance of product quality, on time delivery, and best price.

The Quality Manager and / or Accounting Department maintain an F.8.4.1.1 APPROVED SUPPLIER LIST for major suppliers of Board, Ink, Glue, Corrugated Boxes, Film, Cutting Dies and supplies, Printing Plates, Coating, UV, Calibration Services, and Major Maintenance Services. All raw materials shall comply with the relevant legislation in the country of manufacture and country of destination, if known.

Purchasing will notify the Quality department if a new material will be tested F 8.4.1.3 PRODUCT QUALITY VERIFICATION or new potential supplier will be evaluated. Material will be evaluated, and feedback will be given to new potential vendor. Only if material passed the test, it will be purchased.

Purchasing will be responsible for sending F.8.4.1.2 NEW SUPPLIER QUESTIONNAIRE to new potential supplier.

Problematic suppliers are reviewed during Management Review Meetings. If it is determined that a problematic subcontractor no longer can meet El Paso Paper Box, Inc.'s requirements, purchasing of materials from the subcontractor will cease.

If a subcontractor used by El Paso Paper Box supplies an exclusive material and, therefore, El Paso Paper Box must utilize their services regardless if they do not meet all specified requirements, all products received by this subcontractor are subject to a more complete receiving inspection.

In the event of an emergency situation when prior evaluation is not possible, products can be ordered on a one-time and/or emergency basis. Products and/or services received on these occasions may be more thoroughly inspected at receiving depending on the nature of the products and or services. A subsequent evaluation and history of quality product and service must be conducted prior to the supplier achieving approved status.

The Purchasing Manager, Inventory Control, Quality Control, or designee is made aware of incoming goods/services from new suppliers and, as appropriate may inspect these goods/services at any time after they are received.

Major suppliers are evaluated per Supplier Monthly Evaluation Form. The Quality Manager, Customer Service, or a designee maintains records of approved suppliers.

Raw materials shall comply with the relevant legislation in the country of manufacture and country of destination, if known.

8.4.2 (2.3.2.1) Type and extent of control

The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers.

The organization:

- Ensures that externally provided processes remain within the control of its quality management system.
- defines both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output.
- Ensures that all specifications for all raw materials, including, but not limited to additives, hazardous chemicals and processing aids that impact food safety of the product shall be documented and kept current.

Take into consideration:

- the potential impact of the externally provided processes, products, and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements.
- the effectiveness of the controls applied by the external provider.
- determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

8.4.3 (2.3.3.1/ 2.3.3.2) Information for external providers

The organization shall ensure the adequacy of requirements prior to their communication to the

External provider.

The organization shall communicate to external providers its requirements for:

- the processes, products, and services to be provided.
- the approval of:
  - products and services.
  - methods, processes, and equipment.
  - the release of products and services.
- competence, including any required qualification of persons.
- the external providers' interactions with the organization.
- control and monitoring of the external providers' performance to be applied by the organization.
- verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.

A purchase order is required for production materials to be ordered. This requisition is completed by the department Manager or designated.

Specifics of the order may include but not limited to; quantity of product, cost, physical description, supplier, purchase order number, required date to be received, the date the product was ordered, part number and special instructions as necessary. And the requestor should notify the purchasing person when the good or service is needed. A register of all contract service specifications shall be maintained.

The purchase requisition form F.8.4.3.1 PURCHASE ORDER REQUISITION is turned to Head for approval. If the Department head is not available, he is notified by phone for verbal approval of the purchase or as required.

Accounts ~~receivable~~ Payable Department receives and reviews the purchase order requisition and then generates a purchase order number from the information on the purchase order requisition.

The person who is in charge to place the PO via e-mail, phone, fax and or way, will see the opportunity to quote further the item in order to obtain the best price. If it is a unique supplier, he will go ahead and place the PO. This person will notify back to the requestor of any information regarding the item intended to purchase.

No new articles can be added to the submitted requisition and/or Purchase order, in case an extra article and or quantities are needed, a new requisition/PO is necessary.

In emergency cases, the requestor will have an emergency P.O. # to get out of the problem at that time; however, immediate notification should be made to the person in charge to review and verify the P.O. # for prompt control and analysis.

8.5 PRODUCTION AND SERVICES PROVISION

8.5.1 (2.3.1.4) Control of production and services provision

The organization implements production and service provision under controlled conditions.

Controlled conditions include, as applicable:

a) The availability of documented information that defines:
   1. the characteristics of the products to be produced, the services to be provided, or the activities to be performed. ERP Item Specification Sheet.
   2. the results to be achieved.

b) The availability and use of suitable monitoring and measuring resources.

c) The implementation of monitoring and measurement activities at appropriate stages to verify that:
   1. Criteria for control of processes or outputs, and acceptance criteria for products and services, have been met; W.8.5.1 MONITORING AND MEASUREMENT OF PRODUCT

d) The use of suitable infrastructure and environment for the operation of processes.

e) The appointment of competent people, including any required qualification.

f) The validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement.

g) the implementation of actions to prevent human error.

h) the implementation of release, delivery, and post-delivery activities

8.5.2 (2.3.2.2/ 2.6.1.1/ 2.6.2.1/ 2.6.2.2) Identification and traceability

ERP management system allows the organization to register records of raw and packaging material receipt and use, and finished product dispatch and destination inputs, as well as outputs when it is necessary to ensure the conformity of products and services.

The organization controls through ERP management system the unique identification of the outputs for traceability purposes and the documented information is saved in the company server.

If requested by the customer a Certificate of F 8.5.2.2 CERTIFICATE OF COMPLIANCE

Product is identified, where appropriate, by suitable means throughout production F 8.5.2.1 WIP TAG.

Parts labeled with a part number or customer name are considered as conforming unless identified with a “Reject” tag or sticker. Finished product labels shall be accurate, comply with the relevant legislation and be approved by qualified company personnel.

Nonconforming products, or products on hold at any stage of receiving, in-stock, or final inspection is identified with a “Reject” tag or stamp. These products are quarantined while the situation is discussed with the supplier or while a disposition is being decided.

8.5.3 Property belonging to customers or external providers.

Care is exercised with customer property while it is under control or being used. Customer property provided for use or incorporation into product is identified, verified, protected, and safeguarded. Any customer property that is lost, damaged, or otherwise found to be unsuitable for use is recorded and reported to customers. Customer property at El Paso Paper Box, Inc. can consist of dies.

Customer-supplied property undergoes receiving verification upon arrival to El Paso Paper Box, Inc. to ensure required materials are received. Dies are logged in ERP.

In some event Customer pays for Dies. In this case, it is stated in the quote or sales contract. Customer at any time can take out the die (s). Die(s) belonging to EPPB or customers are identified with unique number. There is no special identification for Customer Property Dies.

All customer property is stored safely to prevent damage.

If at any time customer-supplied property is found to be lost, damaged or unsuitable for use, the personnel noticing the problem informs the Sales Representative who contacts the customer (owner of the material) to determine the disposition of the property. Customer Service records the problem with the property and the customer’s disposition.

8.5.4 (2.3.1.3) Preservation

Conformity of product during internal processing and delivery to the intended destination is preserved. This includes identification, handling, packaging, storage, and protection. Preservation also applies to the constituent parts of a product W.8.6.4 RECEIVING/SHIPPING/HANDLING.

8.5.5 Post-delivery activities

The organization shall meet requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, the organization shall consider:

a) statutory and regulatory requirements.
b) the potential undesired consequences associated with its products and services.
c) the nature, use and intended lifetime of its products and services.
d) customer requirements.
e) customer feedback.

8.5.6 Control of changes

The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review F.8.2.1.1 NEW ITEM MEETING RELEASE **or** W 8.2.4 SAMPLE RUN ECN**.**

8.6 (2.3.2.6/ 2.4.7.1/ 2.4.7.2/ 2.6.1.2/ 2.6.1.3) RELEASE OF PRODUCTS AND SERVICES

The organization has implemented planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

- W.8.6.1 PRE-PRESS AREA.
- W.8.6.2 DIE SHOP AREA
- W.8.6.3 MANUFACTURING
- W.8.6.4 RECEIVING/SHIPPING/HANDLING
- W.8.6.5 PRINTING MAKEREADY

The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer, the organization shall retain documented information on the release of products and services (A register of current raw materials and packaging material specifications shall be maintained - ERP). The documented information shall include:

a) evidence of conformity with the acceptance criteria.
b) traceability to the person(s) authorizing the release.

8.7 CONTROL OF NONCONFORMING OUTPUTS

8.7.1 (2.4.1.3/ 2.4.5.1/ 2.4.5.2/ 2.4.5.3/ 2.4.6.1/ 2.4.6.4)

The organization deals with nonconforming outputs in one or more of the following ways:

a) Correction.
b) Segregation, containment, return or suspension of provision of products and services.
c) Informing the customer.
d) Obtaining authorization for acceptance under concession.

1. Nonconforming material/ product may be identified with red paint, a reject tag, or clearly labeled as waste or scrap. Other nonconforming material is identified with a “reject” tag or sticker F 10.2.1.1 REJECTED MATERIAL
2. When the supplier is the originator of the nonconformity then a F 10.2.1.2 DEFECTIVE MATERIAL REPORT (DMR) is completed, and disposition is determined for non-conforming raw material.
3. If finished material or material in process does not pass inspection, Quality personnel are consulted and the nonconformance is corrected if possible. Actions are taken to eliminate the cause of the nonconformity. If the nonconformance cannot be corrected, Quality determines disposition of product.
4. ~~All internal quality issues shall be monitored and analyzed thru pareto tool at least twice a year and implement corrective actions for main problems~~.
5. Product identified as waste is discarded. The Quality Manager will keep records of waste. This data will be used to improve results.
6. When product is at the customer, a F 10 2.1.3 RMA (RETURN MATERIAL AUTHORIZATION) will be sent to the customer to return or scrap non-conformant product; following with Quality Department investigation and a Corrective Action Report F 10 2.1.5 CORRECTIVE

AND PREVENTIVE ACTION is completed.

7. *Following the implementation of corrective actions in response to identified non-conformities, a review is conducted to assess the effectiveness of the actions taken. The evaluation considered whether the root causes of the issues were accurately identified, and if the corrective actions have successfully mitigated the risks based on no further occurrences of non-conformity notified by the specific customer in the following 3 months of the initial notification.*
8. Records are maintained when Quality Department authorizes product use, release, or acceptance under concession by the original customer, or any El Paso Paper Box, Inc. customer.
9. Non-conformances trends (waste) or results are discussed at Management Review Meetings as appropriate.
10. Any employee that identifies material that does not fulfill El Paso Paper Box requirements will notify Quality personnel to identify the material as nonconforming material.
11. Non-conforming (waste) material from Printing and Cutting departments shall be sent to the recycling area.
12. The disposition for the nonconforming material might be scrap, rework, use as is, or return to vendor.
13. The disposition shall be given by the appropriate personnel (operators, supervisors, quality personnel, VP or President).
14. All reworked or sorted material shall be re-inspected / re audited in the normal process.
15. Records of all reworking operations shall be maintained.
16. The Quality Manager/ Practitioner is the main responsible to notify customers if a nonconforming material was shipped, and SQFI in the event of a food packaging safety event that requires public notification within 24hrs, at foodsafetycrisis@sqfi.com.
17. EPPB must receive approval to make / ship products that do not comply with previously approved requirements. Deviation qty and expiration date shall be kept.

8.7.2

The organization retains documented information that:

a) Describes the nonconformity.
b) Describes the actions taken.
c) Describes any concessions obtained.
d) Identifies the authority deciding the action in respect of the nonconformity.

REFERENCE OF DOCUMENTED INFORMATION

- W 8.2.1 CUSTOMER SERVICE
- F 8.2.1.1 NEW ITEM MEETING RELEASE
- W 8.2.4 SAMPLE RUN - ECN
- F 8.4.1.1 APPROVED SUPPLIER LIST
- F 8.4.1.2 NEW SUPPLIER QUESTIONNAIRE
- F 8.4.1.3 PRODUCT QUALITY VERIFICATION
- F 8.4.3.1 PURCHASE ORDER REQUISITION

- W 8.5.1 MONITORING AND MEASUREMENT OF PRODUCT
- F 8.5.2.2 CERTIFICATE OF COMPLIANCE
- W 8.6.1 PRE-PRESS AREA
- W 8.6.2 DIE SHOP AREA
- W 8.6.3 MANUFACTURING
- W 8.6.4 RECEIVING/SHIPPING/HANDLING
- W.8.6.5 PRINTING MAKEREADY
- F 10.2.1.1 REJECTED MATERIAL
- F 10.2.1.2 DEFECTIVE MATERIAL REPORT (DMR)
- F 10 2.1.3 RMA (RETURN MATERIAL AUTHORIZATION)
- F 10 2.1.5 CORRECTIVE AND PREVENTIVE ACTION