



SQF Food Safety Audit Edition 9

El Paso Paper Box, Inc.

Summary

AUDIT DECISION

CERTIFIED

CERTIFICATION NUMBER

54141 | 650143

AUDIT RATING



Excellent

DECISION DATE

05/07/24

AUDIT TYPE

RE-CERTIFICATION

RE-CERTIFICATION DATE

03/09/25

AUDIT DATES

04/03/24 - 04/04/24

EXPIRATION DATE

05/23/25

ISSUE DATE

05/07/24

Facility & Scope

El Paso Paper Box, Inc.

24 Zane Grey
El Paso TX 79906
United States

Food Sector Categories:

27. Manufacture of Food Packaging

Products:

Folding Carton
Exclusions: None

Scope of Certification:

Folding Carton
Exclusions: None

Certification Body & Audit Team

Perry Johnson Registrars Food Safety, Inc

755 West Big Beaver Road
Suite 1340
Troy, MI 48084
United States

CB#: CB-1-PJR

Accreditation Body: ANSI

Accreditation Number: 1114

Lead Auditor: Brian Powers (132894)

Technical Reviewer: Wayne Williams (135126)

Other Members:

N/A

Hours Spent on Site: 16

Hours of ICT Activites: N/A

Hours Spent Writing Report: 8

13.4.1 Staff Engaged in Food Handling and Processing Operations

Confirmed that there are employee entrance doors. It was observed that all employees did enter through these doors. Confirmed that all doors were closed, but that they did have issues with doors in past weekly inspections. They are addressing these issues. One issue noted for evidence of eating in the production area by finding candy wrappers on the production floor. See NCR.

13.4.1.2 Personnel working in or visiting food sector packaging manufacturing, handling, or storage operations shall ensure that:

- i. Eating, drinking, smoking, or spitting is not permitted in areas where food sector packaging is manufactured, handled, stored, or exposed.
- ii. Drinking water is permitted in food sector packaging manufacturing, handling, and storage areas in a method that will not cause a food safety risk to raw and packaging materials, working-progress, food sector packaging, and equipment.

RESPONSE: MINOR

EVIDENCE: Found evidence of candy wrappers on the production floor and a piece of candy in an employee's belongings.

ROOT CAUSE: Personnel did not acknowledge correctly the GMPs rules where 1 of them is that food is not allowed at manufacturing floor at any time.

CORRECTIVE ACTION: 1. Retrain all personnel to assure GMPs are properly followed
2. Create a ppt from the GMPs alchemy training and add it to the monthly video along with monthly metrics and birthdays to be display at Cafeteria all the time to assure personnel awareness.

VERIFICATION OF CLOSEOUT: Reviewed powerpoint and GMP training records.

COMPLETION DATE: 05/02/2024 **CLOSEOUT DATE:** 05/06/2024

13.8.1 Waste Disposal

Reviewed the last pick up of used plates on 6/13/23. reviewed the pick up of waste paperboard on 12/29/23. Liquid waste removal is done on a as needed basis. The liquid waste, which is mostly oil/grease, is stored in a metal barrel . The liquid waste is pumped or dumped into the barrel. They have a local service that picks up the waste. The area surrounding the waste drum is designed to hold the oil/grease, should there be a leak. Dry waste is collected and bailed for recycling. One issue found with waste water not being properly disposed of in a timely fashion. See NCR.

13.8.1.2 Waste shall be contained in bins identified for its purpose, located in designated areas, and removed at a routine frequency that avoids build-up in food sector packaging, manufacturing, handling, and storage areas.

RESPONSE: MINOR

EVIDENCE: Found mop buckets with dirty water sitting near the printing area.

ROOT CAUSE: Cleaning personnel did not dispose properly the wastewater from mops buckets due to obstructed path to the Janitor's sink

CORRECTIVE ACTION: 1. Created a path to Janitor's Sink to avoid any obstructions
2. Add two drums to dispose mop's wastewater, these drums will be disposed into wastewater container on a weekly basis.

VERIFICATION OF CLOSEOUT: Reviewed photos and training records

COMPLETION DATE: 05/01/2024 **CLOSEOUT DATE:** 05/06/2024

Section Responses

Audit Statement	Audit
SQF Practitioner Name	Name the designated SQF Practitioner RESPONSE: JOSE CARLOS GALLEGOS
SQF Practitioner Email	Email of the designated SQF Practitioner RESPONSE: JGALLEGOS@EPPBINC.COM
Opening Meeting	People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas) RESPONSE: THE PEOPLE PRESENT AT THE OPENING MEETING ARE, BRIAN POWERS: AUDITOR, JOSE HERRERA: SQF PRACTITIONER/HR MANAGER, JOSE GALLEGOS: QUALITY MANAGER, PAUL PATRICK MALCOM: GENERAL MANAGER, DANIEL QUIFOZ: CONTINUAL IMPROVEMENT COORDINATOR, ADRIANA AVINA: QUALITY ENGINEER, JOANN RINCON: CUSTOMER SERVICE MANAGER, EVAN JURADO: SALES MANAGER, NICOLAS GONZALEZ: CUTTING SUPERVISOR, BLANCA DUARTE: PRODUCTION MANAGER, MANNY CORRAH: PRINTING MANAGER, JOE MEDINA TROAY: PRE-PRESS SUPERVISOR, ALFRED SALAS: WAREHOUSE SUPERVISOR, RUBEN RIVERA: OFFICE MANAGER.
Facility Description	Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details) RESPONSE: LOCATED IN A BUSINESS PARK, SURROUNDED BY VARIOUS TYPES OF BUSINESSES AND THE TOPOGRAPHY OR LANDSCAPE IS RELATIVELY FLAT. THE BUILDING IS AROUND 105,000 SQUARE FEET, WITH PARKING LOT AND TRAILER LOADING/UNLOADING ON TWO SIDES OF THE BUILDING. THEY HAVE ABOUT 200 EMPLOYEES, RUNNING THREE SHIFTS A WEEK. THE GENERAL LAYOUT OF THE FACILITY ENCOURAGES EFFICIENT MATERIAL AND PRODUCT FLOW AND DISCOURAGES THE POTENTIAL FOR CONTAMINATION.
Closing Meeting	People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas) RESPONSE: THE PEOPLE PRESENT AT THE CLOSING MEETING ARE, BRIAN POWERS: AUDITOR, JOSE HERRERA: SQF PRACTITIONER/HR MANAGER, JOSE GALLEGOS: QUALITY MANAGER, PAUL PATRICK MALCOM: GENERAL MANAGER, DANIEL QUIFOZ: CONTINUAL IMPROVEMENT COORDINATOR, ADRIANA AVINA: QUALITY ENGINEER, JOANN RINCON: CUSTOMER SERVICE MANAGER, EVAN JURADO: SALES MANAGER, NICOLAS GONZALEZ: CUTTING SUPERVISOR, BLANCA DUARTE: PRODUCTION MANAGER, MANNY CORRAH: PRINTING MANAGER, JOE MEDINA TROAY: PRE-PRESS SUPERVISOR, ALFRED SALAS: WAREHOUSE SUPERVISOR, RUBEN RIVERA: OFFICE MANAGER.

Auditor Recommendation

RESPONSE: RECOMMENDED FOR CERTIFICATION PENDING CLOSURE OF MINOR NONCONFORMANCES.

2.1.1 Management Responsibility

The Quality Manual and organizational chart describe the "high" level reporting structure. They drill down in the structure by the job descriptions and the individual procedures/work instructions for specific responsibilities and authorities. The SQF Practitioner had all the required training course records available review. Top management shows it's committed to making sure the system has its resources, because they dedicate many employees to completing the necessary tasks. The integrity of the system has been maintained during changes. Reviewed the safe food quality culture and found that they do two things. One is to score the weekly inspection audits. These audits are GMP focused and it gauges how well the employees abide by the food safety requirements. 2023 results were scored at 93% and 2024 (YTD) was scored at 95%. In addition, they send out an employee survey annually. The score has gone up from 2022 to 2023. The 2024 survey has not been sent out yet. Overall, this process is effective.

- 2.1.1.1** Senior site management shall prepare and implement a policy statement that outlines at a minimum the commitment of all site management to:
- i. Supply safe food sector packaging;
 - ii. Establish and maintain a food safety culture within the site;
 - iii. Establish and continually improve the site's food safety management system; and
 - iv. Comply with customer and regulatory requirements to supply safe food sector packaging.

The policy statement shall be:

- v. Signed by the senior site manager and displayed in prominent positions; and
- vi. Effectively communicated to all site personnel in language(s) understood by all site personnel.

RESPONSE: COMPLIANT

EVIDENCE:

- 2.1.1.2** Senior site management shall lead and support a food safety culture within the site that ensures at a minimum:
- i. The establishment, documentation, and communication to all relevant staff of food safety objectives and performance measures;
 - ii. Adequate resources are available to meet food safety objectives;
 - iii. Food safety practices and all applicable requirements of the SQF System are adopted and maintained;
 - iv. Staff are informed and held accountable for their food safety and regulatory responsibilities;
 - v. Staff are positively encouraged and required to notify management of actual or potential food safety issues; and
 - vi. Staff are empowered to act to resolve food safety issues within their scope of work.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.1.3 The reporting structure shall identify and describe site personnel with specific responsibilities for tasks within the food safety management system and identify backup for absence of key personnel.

Job descriptions for the key personnel shall be documented.

Site management shall ensure departments and operations are appropriately staffed and organizationally aligned to meet food safety objectives.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.1.4 Senior site management shall designate a primary and substitute SQF practitioner for each site with responsibility and authority to:

- i. Oversee the development, implementation, review, and maintenance of the SQF System;
- ii. Take appropriate action to ensure the integrity of the SQF System; and
- iii. Communicate to relevant personnel all information essential to ensure the effective implementation and maintenance of the SQF System.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.1.5 The primary and substitute SQF practitioner shall:

- i. Be employed by the site;
- ii. Hold a position of responsibility in relation to the management of the site's SQF System;
- iii. Have completed a HACCP training course;
- iv. Be competent to implement and maintain HACCP-based food safety plans; and
- v. Have an understanding of the SQF Food Safety Code: Manufacture of Food Packaging and the requirements to implement and maintain an SQF System relevant to the site's scope of certification.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.1.6 Senior site management shall ensure the training needs of the site are resourced, implemented, and meet the requirements outlined in system elements 2.9 and that site personnel meet the required competencies to carry out those functions affecting the legality and safety of food sector packaging.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.1.7 Senior site management shall ensure the integrity and continued operation of the food safety system in the event of organizational or personnel changes within the company or associated facilities.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.1.8 Senior site management shall inform their certification body of any defined blackout periods that prevent unannounced re-certification audits from occurring when the site is not operating for legitimate business reasons. The list of blackout dates and their justification shall be submitted to the certification body a minimum of one (1) month before the sixty (60) day re-certification window for the agreed-upon unannounced audit.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.2 Management Review

Verified that they conduct monthly management reviews. December and November of 2023 meetings were reviewed, along with January and February of 2024. The required topics were verified to be discussed in the meeting. The required attendees include; Quality Manager, Plant Manager, Quality Engineer, HR Manager, Office Manager, CI Manager, and General Manager. The data and talking points discussed in the meeting are detailed and include actions and decisions. The overall meeting minutes are effective.

2.1.2.1

The SQF System shall be reviewed by senior site management at least annually and include:

- i. Changes to food safety management system documentation (policies, procedures, specifications, food safety plan);
- ii. Food safety culture performance;
- iii. Food safety objectives and performance measures;
- iv. Corrective and preventative actions, and trends in findings, from internal and external audits, customer complaints, and verification and validation activities;
- v. Hazard and risk management system; and
- vi. Follow-up action items from previous management review.

Records of all management reviews and updates shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.2.2

The SQF practitioner(s) shall update senior site management on at least a monthly basis on matters impacting the implementation and maintenance of the SQF System. The updates and management responses shall be documented.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.3 Complaint Management

This process is described in procedure 2.1.4 Complaint Management. The Quality Manager walked me thru the different ways a complaint could come in, such as, RMAs, Corrective Actions, and NCRs. Some examples reviewed were RMA 2419 (2/27/24), RMA 2422 (3/7/24), and Corrective Action 2024-020 (3/21/24), They did go thru a root cause analysis for these actions. The root cause had been done correctly and thoroughly. Overall, this process is effective.

2.1.3.1

The methods and responsibility for handling, investigating, and resolving food safety complaints from commercial customers, consumers, and authorities, arising from products manufactured or handled on-site or co-manufactured, shall be documented and implemented.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.3.2

Adverse trends of customer complaint data shall be investigated and analyzed and the root cause established by personnel knowledgeable about the incidents.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.3.3 Corrective and preventative action shall be implemented based on the seriousness of the incident and the root cause analysis as outlined in 2.5.3. Records of customer complaints, their investigation, and resolution shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.2.1 Food Safety Management

Reviewed documented system with SQF Practitioner. Their system is in electronic format and the records are a combination of hard copy and electronic formats. The food safety policy and the scope were all in the manual. Changes were made over the last year and the changes are controlled in their document control software, which follows some strict rules on changing documents. Verified that the integrity of the system will be maintained with this software.

2.2.1.1 The methods and procedures the site uses to meet the requirements of the SQF Food Safety Code: Manufacture of Food Packaging shall be maintained in electronic and/or hard copy documentation. It will be made available to relevant staff and include:

- i. A summary of the organization's food safety policies and the methods it will apply to meet the requirements of this standard;
- ii. The food safety policy statement and organization chart;
- iii. The processes and products included in the scope of certification;
- iv. Food safety regulations that apply to the manufacturing site and to the country of sale (if known);
- v. Raw material, ingredient, packaging, and finished product specifications;
- vi. Food safety procedures, pre-requisite programs, and food safety plans;
- vii. Process controls that impact product safety; and
- viii. Other documentation necessary to support the development and the implementation, maintenance, and control of the SQF System.

RESPONSE: COMPLIANT

EVIDENCE:

2.2.1.2 Food safety plans, Good Manufacturing Practices, and all relevant aspects of the SQF System shall be reviewed, updated, and communicated as needed when any changes implemented have an impact on the site's ability to deliver safe food.

All changes to food safety plans, Good Manufacturing Practices, and other aspects of the SQF System shall be validated or justified prior to their implementation. The reasons for the change shall be documented.

RESPONSE: COMPLIANT

EVIDENCE:

2.2.2 Document Control

Procedure 2.2.2 talks about the process for document control. Reviewed the process for revising document with the SQF Practitioner. Found no issues with any forms or procedures sampled and their respective revision control.

2.2.2.1 The methods and responsibility for maintaining document control and ensuring staff have access to current requirements and instructions shall be documented and implemented.

Current SQF System documents and amendments to documents shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.2.3 Records

Procedure 2.2.3 describes the control in place for the record retention. The record control procedure has the retention list for all records and there were no violations. All records were legible and records were retrievable.

2.2.3.1 The methods, frequency, and responsibility for verifying, maintaining, and retaining records shall be documented and implemented.

RESPONSE: COMPLIANT

EVIDENCE:

2.2.3.2 All records that demonstrate inspections, analyses, and other essential activities have been completed shall be legible, accurate, and reviewed for correctness and completion.

RESPONSE: COMPLIANT

EVIDENCE:

2.2.3.3 Records shall be readily accessible, retrievable, and securely stored to prevent unauthorized access, loss, damage, and deterioration. Retention periods shall be in accordance with customer, legal, and regulatory requirements, at a minimum the product shelf life, or established by the site if no shelf life exists.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.1 Product Formulation and Realization

Procedure 2.3.1 details the process for product development. The SQF Practitioner reviewed the development process. They conduct a new item meeting to discuss any new product developments. Reviewed their most recent record (8/11/23) and it was for "Garlic Herb Chicken Cuts". The process includes "pre-flight" the artwork, which is always provided by the customer. They also create a CAD file to create the cut die drawing. A proof is developed for the cut die and the artwork. These proofs are reviewed internally and by the customer. Once the approvals are complete, then the part is entered into the system, purchase orders are created for the die, and production planning begins. They use a form to control the process and the form number is F.8.2.1.1 (New Item Meeting Release). They keep all design input records on this form. The process showed capability in the past. Overall, this process is effective.

2.3.1.1 The methods and responsibility for the design and development of finished products from concept to commercial realization shall be documented and implemented.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.1.2 Changes to raw material, design, process, and equipment to produce the finished product shall be validated by site trials and product testing as required to ensure product safety (refer to 2.3.1.5).

RESPONSE: COMPLIANT

EVIDENCE:

2.3.1.3 Where applicable, finished products designed with a functional effect for food safety reasons (i.e., prevent ingress of pathogens) shall have specified criteria and be referenced in the food safety plan (refer to 2.4.3).

RESPONSE: COMPLIANT

EVIDENCE:

2.3.1.4 Trials where necessary shall be conducted to establish and validate a product's:
i. Handling and storage requirements; and
ii. Customer specification including the intended use of the product.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.1.5 The site's food safety plan shall be validated and verified for each new finished product, its associated production and distribution processes, or where a change to raw material, design, manufacturing process or equipment may impact food safety.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.1.6 Where applicable, the site shall have a procedure for confirmation and approval of customer artwork for the finished product. The controls shall also describe how print run samples are approved by customers and changes to artwork are managed.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.1.7 The process flows for all new and existing manufacturing processes shall be designed to ensure that product is manufactured to approved product specifications to prevent cross-contamination and organized so there is a continuous flow of product through the process.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.1.8 Records of product design, specifications, process flows, shelf life trials (as required), and approvals for all new and existing products shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.2 Specifications (Raw Material, Packaging, Finished Product and Services)

The two samples of raw material had certificate of conformances. Confirmed that the register had both of these materials on it. Also confirmed that the raw material specifications were accurate. This process is described in Procedure 2.3.5 (Rev. B). All of their product specifications are stored on the shared drive on their server. Verified the prints for the two orders that sampled. The register of finished product specifications exists and is in the procedure book.

2.3.2.1 The methods and responsibility for developing, managing, and approving raw material and packaging specifications shall be documented.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.2.2 Specifications shall be documented and kept current for raw materials, additives, processing aids, and auxiliary packaging materials (those used in direct contact with finished products) for containment or unitization.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.2.3 Finished product labels shall be accurate, comply with the relevant legislation, and be approved by qualified company personnel. Printed materials applied to or printed directly on finished product shall be accurate, legible, and comply with customer and regulatory requirements, including information regarding ingredients, allergens, identification codes, and other requirements. They shall be approved by designated company personnel and controlled to ensure relevance and accuracy.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.2.4 All raw materials including those made with recycled material, plant-based material, or additional additives shall be suitable for the intended use, food contact compliant where applicable, and shall comply with the relevant legislation in the country of manufacture and country of destination, if known.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.2.5 Site management shall require raw materials suppliers to notify of changes in product composition where they could have an impact on finished product, design, processing, or food safety.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.2.6 Raw and auxiliary packaging materials shall be verified to ensure food safety is not compromised and the material is fit for its intended purpose. Verification of raw and packaging materials' conformance to food safety specifications shall include a letter of guarantee and a certificate of conformance, certificate of analysis, inspection, sampling, or testing.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.2.7 Description of services for contract service providers that have an impact on food safety shall be documented, current, and include relevant training requirements, where applicable, for all contract personnel.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.2.8 Finished product specifications shall be documented, current, approved by the site and their customer, if applicable, accessible to relevant staff, and may include:

- i. Physical and chemical characteristics;
- ii. Microbiological characteristics, where applicable;
- iii. Artwork and unitizing requirements;
- iv. Confirmation that the food sector packaging is suitable for the intended use by the customer; and
- v. Lists of raw materials, allergens, ingredients, identification codes, etc.

Specifications for direct food contact packaging shall list the functional characteristics to protect the food product (shelf life extension, barrier properties, etc.).

RESPONSE: COMPLIANT

EVIDENCE:

2.3.2.9 Specifications for raw materials, auxiliary packaging materials, processing aids, printed materials, finished products, and contract services shall be reviewed as changes occur that impact product safety. Records of reviews shall be maintained.

A list of all the above specifications shall be maintained and kept current.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.2.10 Where applicable, procedures shall also be in place for managing and verifying the specifications for correct printing plates, anilox rollers, and cylinders used during printing.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.3 Contract Manufacturers

Confirmed that this is not done on a regular basis, but only if there was a crisis.

2.3.3.1 The methods and responsibility for ensuring all agreements with contract manufacturers relating to food safety, customer product requirements, and their realization and delivery shall be documented and implemented.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.3.2 The site shall establish a method to determine the food safety risk level of contract manufactured product and shall document the risk. The site shall:

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

RESPONSE: COMPLIANT

EVIDENCE:

2.3.3.3 Records of verified compliance, contracts, and changes and approvals to contractual agreements for contract manufacturers shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.4 Approved Supplier Program

Reviewed the approved vendor list and that it was updated on 2/2/24. Sampled three vendors and they were on the list and also the supplier evaluation. The statement of guarantee was present for all vendors. The vendors were WestRock, Roosevelt, and Greenpaper.

2.3.4.1 The responsibility and procedure for selecting, evaluating, approving, and monitoring an approved supplier shall be documented and implemented.

A current record of approved suppliers, receiving inspections, and supplier audits shall be maintained.

Code Amendment #2

Approved supplier registers shall include supplier contact details. All approved and emergency suppliers shall be registered.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.4.2 The approved supplier program shall be based on the prior performance of a supplier and the risk level of the raw and packaging materials and services supplied. The program shall contain at a minimum:

- i. Agreed specifications (refer to 2.3.2);
- ii. Reference to the risk rating of the supplier, materials, or services supplied;
- iii. An assessment of the supplier's food safety risks and or controls to ensure that supplied materials does not pose a risk to food safety;
- iv. Methods for granting approved supplier status;
- v. Methods and frequency of monitoring approved suppliers;
- vi. Details of the certificates of analysis or conformance if required; and
- vii. Methods and frequency of reviewing approved supplier performance and status.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.4.3 Verification of raw materials shall include certificates of conformance, certificate of analysis, or sampling and testing. The verification frequency shall be identified by the site.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.4.4 Raw materials and services that impact finished product food safety shall meet the agreed specification (refer to 2.3.2.2) and be supplied by an approved supplier. The receipt of raw materials, processing aids, and packaging from non-approved suppliers shall be acceptable only in an emergency situation and provided a receiving inspection or analysis is conducted and recorded before use.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.4.5 Raw materials, auxiliary packaging, and finished product received from other sites under the same corporate ownership shall be subject to the same specification requirements (refer to 2.3.2), approved supplier requirements, and incoming inspections as all other material providers.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.4.6 Supplier audits shall be based on risk and shall be conducted by individuals knowledgeable of applicable regulatory and food safety requirements and trained in auditing techniques.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.1 Food Legislation

The SQF Practitioner and the back up are both responsible for keeping informed of relevant changes to legislation through professional organizations, publications, regulatory email updates, continuing education, webinars. SQFI and the certification body will be notified in writing (email is preferred) within 24 hours of identification of a food safety event that requires public notification. Specified in SQF 2.4.1.

2.4.1.1 The site shall ensure that, at the time of delivery to customers, finished products shall comply with food safety legislation applicable to the country of manufacture and sale. This includes compliance with legislative requirements applicable to food safety, packaging, product descriptions, any other criteria listed under food legislation, and to relevant established industry codes of practice.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.1.2 The methods and responsibility for ensuring the site is kept informed of changes to relevant legislation, scientific and technical developments, emerging food safety issues, and relevant industry codes of practice shall be documented and implemented.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.1.3 SQFI and the certification body shall be notified in writing within twenty-four (24) hours in the event of a regulatory warning. Notification to SQFI shall be by email to foodsafetycrisis@sqfi.com.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.2 Good Manufacturing Practices

The facility has made provisions for the implementation and maintenance of the GMP Program, along with the HACCP plan and pre-requisite programs which ensures that the products and the premises are maintained structurally sound and operated in a hygienic manner. The effectiveness of these programs are verified as described in 2.5.4, auditor reviewed verification records for pre-requisite programs, GMP audits, and monitoring of CCPs (None Identified) as described in the verification schedule. The schedule is a separate document and its coupled with a training schedule too. Compared the GMP program with observations during the facility review and found no issues.

2.4.2.1 The site shall ensure the applicable Good Manufacturing Practices described in Module 13 of this Food Safety Code are applied or exempted according to a written risk analysis outlining the justification for exemption or evidence of the effectiveness of alternative control measures to ensure that food safety is not compromised.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.2.2 The Good Manufacturing Practices applicable to the scope of certification that outline how food safety is controlled and assured shall be documented and implemented.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3 Food Safety Plan

The food safety plan has been developed following the 12-step HACCP method and has been effectively implemented. The food safety team consists of corporate and plant specific employees. The hazard analysis has been conducted on the products made and includes all processes identified in the flow chart. There are 1 HACCP plan and no CCPs are identified. The last review was done on 3/28/24. Finally, the HACCP team is in place and training records exist for each member. Overall, this is effective.

2.4.3.1 A food safety plan shall be prepared in accordance with the twelve steps identified in the Codex Alimentarius Commission HACCP guidelines. The food safety plan shall be effectively implemented, maintained, and outline the means by which the site controls and assures food safety of the products or product groups included in the scope of the SQF certification and their associated processes. More than one HACCP food safety plan may be required to cover all products included in the scope of certification.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.2 The food safety plan or plans shall be developed and maintained by a multidisciplinary team that includes the SQF practitioner and those site personnel with technical, production, and engineering knowledge of the relevant products and associated processes. Where the relevant expertise is not available on-site, advice may be obtained from other sources to assist the food safety team.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.3 The scope of each food safety plan shall be developed and documented including the start and endpoint of the processes under consideration and all relevant inputs and outputs.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.4 Product descriptions shall be developed and documented for all food sector packaging included in the scope of the food safety plans. This shall reference the finished product specifications (refer to 2.3.2.8) plus any additional information relevant to product safety such as water vapor transmission rate and gas permeability and the intended and potential alternative uses of each. This shall include requirements for further processing, if applicable.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.5 The food safety team shall develop and document a flow diagram covering the scope of each food safety plan. The flow diagram shall include every step in the process, all raw material, packaging material, service inputs (e.g., water, steam, gasses as appropriate), scheduled process delays, and all process outputs including waste and rework. Each flow diagram shall be confirmed by the food safety team to cover all stages and hours of operation.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.6 The food safety team shall identify and document all food safety hazards that can reasonably be expected to occur at each step in the processes, including raw materials and other inputs.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.7 The food safety team shall conduct a hazard analysis for every identified hazard to identify which hazards are significant, i.e., their elimination or reduction to an acceptable level is necessary to ensure food safety. The methodology for determining hazard significance shall be documented and used consistently to assess all potential hazards.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.8 The food safety team shall determine and document the control measures that must be applied to all significant hazards. More than one control measure may be required to control an identified hazard, and more than one significant hazard may be controlled by a specific control measure.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.9 Based on the results of the hazard analysis (refer to 2.4.3.7), the food safety team shall identify the steps in the process where control must be applied to eliminate a significant hazard or reduce it to an acceptable level (i.e., a critical control point, or CCP). In instances where a significant hazard has been identified at a step in the process, but no control measure exists, the food safety team shall modify the process to include an appropriate control measure.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.10 For each identified CCP, the food safety team shall identify and document the limits that separate safe from unsafe product (critical limits). The food safety team shall validate the critical limits to ensure the designated level of control of the identified food safety hazard(s), and that all critical limits and control measures individually or in combination effectively provide the level of control required (refer to 2.5.1.1).

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.11 The food safety team shall develop and document procedures to monitor CCPs to ensure they remain within the established limits (refer to 2.4.3.11). Monitoring procedures shall identify the personnel assigned to conduct monitoring, the sampling and test methods, and the test frequency.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.12 The food safety team shall develop and document deviation procedures that identify the disposition of affected food sector packaging material when monitoring indicates a loss of control at a CCP. The procedures shall also prescribe actions to correct the process step to prevent recurrence of the food safety failure.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.13 The documented and approved food safety plan(s) shall be implemented in full. The effective implementation shall be monitored by the food safety team, and a full review of the documented and implemented plans shall be conducted at least annually or when changes to the process, equipment, inputs, or other changes affecting product safety occur.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.14 Procedures shall be in place to verify that critical control points are effectively monitored and appropriate corrective actions are applied. Implemented food safety plans shall be verified as part of SQF System verification (refer to 2.5).

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.15 Critical control point monitoring, corrective action, and verification records shall be maintained and appropriately used.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.16 Where food safety regulations in the country of production and destination (if known) prescribe a food safety control methodology other than the Codex Alimentarius Commission HACCP guidelines, the food safety team shall implement food safety plans that meet both Codex and food regulatory requirements.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.4 Product Sampling, Inspection, and Analysis

Reviewed a sample of inspection records from a randomly chosen lot number. The inspector initials the inspection record. This is done consistently throughout all the inspection records reviewed. The two samples were SO-39462 and SO-36785. Records were complete and easily retrievable.

2.4.4.1 The methods, responsibility, and criteria for sampling, inspecting, and/or analyzing raw materials, work-in-progress, and finished product shall be documented and implemented.

The methods applied shall ensure that inspections and analyses are completed at regular intervals as required and to agreed specification and legal requirements.

Sampling and testing shall be representative of the process batch and ensure that process controls are maintained to meet specification and formulation.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.4.2 Product analyses shall be conducted to nationally recognized methods, company requirements, or alternative methods that are validated as equivalent to the nationally recognized methods.

Where internal laboratories are used to conduct input, environmental, or product analysis, sampling and testing methods shall be in accordance with the applicable requirements of ISO/IEC 17025, including annual proficiency testing for staff conducting analyses.

External laboratories shall be accredited to ISO/IEC 17025 or equivalent international standard and included on the site's contract service specifications list (refer to 2.3.2.7).

RESPONSE: COMPLIANT

EVIDENCE:

2.4.4.3 On-site laboratories conducting chemical and microbiological analysis that may pose a risk to product safety, shall be located separate from any processing or handling activity and designed to limit access only to authorized personnel.

Signage shall be displayed identifying the laboratory area as a restricted area, accessible only by authorized personnel.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.4.4 Provisions shall be made to isolate and contain all hazardous laboratory waste held on the premises and manage it separately from food waste. Laboratory waste outlets shall at a minimum be downstream of drains that service processing and handling areas.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.4.5 Raw materials and finished product obtained for sampling and/or inspection shall be properly destroyed to prevent re-entry into the production process or sale to the customer.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.4.6 Records of all inspections and analyses shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.5 Non-conforming Materials and Product

Non-conforming & Rework Control (2.4.6) outlines the methods and responsibilities for handling non-conforming products. Any facility management team member can place products on hold due to non-conformity issues. Non-conforming products are put on hold in the electronic inventory system, segregated and cannot be shipped. Documentation of non-conformances are stored electronically. QA management members perform final release on all hold products. Auditor reviewed 2023 and 2024 hold logs.

2.4.5.1 The responsibility and methods outlining how non-conforming raw material, work-in-progress, finished product, or equipment detected during receipt, storage, manufacturing, or delivery is handled shall be documented and implemented. The methods applied shall ensure:

- i. Non-conforming product is quarantined, identified, handled, and disposed of in a manner that minimizes the risk of inadvertent use, improper use, or risk to the integrity of finished product; and
- ii. All relevant staff is aware of the organization’s quarantine and release requirements applicable to equipment or product placed under quarantine status.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.5.2 Finished product returned from a customer shall be quarantined until authorized for release for use or re-shipment.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.5.3 Quarantine records and records of the handling, corrective action, or disposal of nonconforming materials or product shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.6 Product Rework

Rework consists of sorting in most situations. Due to the type of product they make, if the product is nonconforming, then rework consists of sorting and in some cases gluing the box back together. Once the product is returned, the pallet is labeled and placed on hold. QC is notified that the material has arrived and they will schedule a sort order. Trained personnel will begin to sort the product and record the results on a form. Lot traceability is maintained in the system. They did not have any recent returns to review, but past records show they have the capability.

- 2.4.6.1** The responsibility and methods outlining how raw materials or food sector packaging product are reworked and recouped shall be documented and implemented. Rework shall be processed in a manner that does not contaminate raw materials or food sector packaging. The methods applied shall ensure:
- i. Reworking and recouping operations are supervised by qualified personnel;
 - ii. Reworked and recouped product is clearly identified and traceable;
 - iii. Each lot of reworked or recouped product is inspected or analyzed as required before release;
 - iv. Inspections and analyses shall conform to the requirements outlined in element 2.4.4.1;
 - v. Release of reworked and recouped product shall conform to element 2.4.7; and
 - vi. Records of all reworking operations shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

- 2.4.6.2** Food sector packaging that contains printed information shall be handled in a manner that prevents mixed or intermingled product.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.7 Product Release

Procedure 2.4.7 describes the processes involved in the product release. All products are approved and released. All production checks are documented prior to product release. Daily production packets must be signed by the QA prior to release for shipment. The packet includes all finished product quality checks, pre-op inspection, cleaning and label verification then the product is released for shipping using the electronic inventory system. Auditor reviewed completed production records from 2023 and 2024.

- 2.4.7.1** The responsibility and methods for releasing finished product shall be documented and implemented. Methods shall ensure product is released by designated personnel only after disposition activities show that product is acceptable for release and to verify legislative and food safety compliance have been met.

RESPONSE: COMPLIANT

EVIDENCE:

- 2.4.7.2** In the event that the site uses positive release based on product pathogen or chemical testing, a procedure shall be in place to ensure that product is not released until acceptable results have been received.

In the event that off-site or contract warehouses are used, these requirements shall be effectively communicated and verified as being followed.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.8 Environmental Monitoring

Verified that they conduct a swab test on the air quality every quarter and every month they conduct a swab test any surface that touches the product. They have a calendar of events and confirmed that the quarterly air test was done on 1/12/24 and the monthly surface test was done on 2/29/24 and 3/28/24. The results are recorded by taking a picture of the test tube and the color of the results. All results were good. Also verified that they test different areas at each interval.

2.4.8.1 A risk assessment for all processes shall be conducted against known or expected concerns to identify if an environmental monitoring program is necessary. If the program is required, all requirements of environmental monitoring shall be applied (2.4.8.2, 2.4.8.3, 2.4.8.4).

RESPONSE: COMPLIANT

EVIDENCE:

2.4.8.2 The responsibility and methods for the environmental monitoring program shall be documented and implemented.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.8.3 An environmental sampling and testing schedule shall be prepared, detailing any applicable pathogens or indicator organisms to test for that industry (i.e., Bacillus spp. in paper or paper products), the number of samples to be taken, and the frequency of sampling.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.8.4 Environmental testing results shall be monitored and corrective actions (refer to 2.5.3.1) implemented where unsatisfactory trends are observed.

RESPONSE: COMPLIANT

EVIDENCE:

2.5.1 Validation and Effectiveness (Mandatory)

Reviewed the monthly GMP audits/inspections that take place. Records indicate that they are done monthly. Reviewed the records from February and March, 2024.

2.5.1.1 The methods, responsibility, and criteria for ensuring the effectiveness of all applicable elements of the SQF Program shall be documented and implemented. The methods applied shall validate that:

- i. Good Manufacturing Practices are confirmed to ensure they achieve the required results;
- ii. Critical food safety limits are reviewed annually and re-validated or justified by regulatory standards when changes occur; and
- iii. Changes to the processes or procedures are assessed to ensure the controls are still effective.

Records of all validation activities shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.5.2 Verification Activities (Mandatory)

They have three different verification levels for the HACCP verification activities, and external audits. The verification schedule is in the procedure and records are complete.

2.5.2.1 The methods, responsibility, and criteria for verifying monitoring of Good Manufacturing Practices, critical control points and other food safety controls, and the legality of certified products shall be documented and implemented. The methods applied shall ensure that personnel with responsibility for verifying monitoring activities authorize each verified record.

RESPONSE: COMPLIANT

EVIDENCE:

2.5.2.2 A verification schedule outlining the verification activities, their frequency of completion, and the person responsible for each activity shall be prepared and implemented. Records of verification of activities shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.5.3 Corrective and Preventative Action

Procedure 2.5.3 details the requirements for corrective/preventive action. Corrective Action Procedure details root cause analysis and resolution of non-conforming products and the responsibility is of the Plant Manager. The facility documents their corrective actions as part of the audits. The auditor reviewed corrective actions (Corrective Action Response forms) from 2024 for internal audits and non-conforming product disposal. Reviewed the following corrective action; 2024-020. This action was created on 3/21/24. The form was completely filled out and verified that the root cause was completely effectively. Overall, the corrective action was verified to be accurate and complete. They also conduct continuous improvement projects. They use a continual improvement form to complete these activities. Reviewed continual improvement records 3280 and 3308. This is an effective process.

2.5.3.1 The responsibility and methods outlining how corrective and preventative actions are determined, implemented, and verified, including the identification of the root cause and resolution of non-compliance of critical food safety limits and deviations from food safety requirements, shall be documented and implemented.

Deviations from food safety requirements may include customer complaints, nonconformances raised at internal or external audits and inspections, non-conforming product and equipment, withdrawals and recalls, as appropriate.

RESPONSE: COMPLIANT

EVIDENCE:

2.5.3.2 Records of all investigation, root cause analysis, and resolution of non-conformities, their corrections and implementation of preventative actions shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.5.4 Internal Audits and Inspections

Reviewed the monthly GMP inspections for February (2024) and March (2024). They audited the entire system and use a checklist to accomplish this act. There were some findings and action items from these audits. Actions are taken and it looks effective. The auditors are trained to conduct the audits based on the experience of the SQF Practitioner. Evidence of the successful completion of the audits and the quality of the audit records shows competency. In addition, they have a audit schedule. This is current for 2024 and the schedule is on revision F.

2.5.4.1 An internal audit program shall be established to verify the implementation and effectiveness of all applicable requirements of the SQF Food Safety System. Internal audits shall be conducted in full and at least annually. The methods applied shall ensure:

- i. All applicable requirements of The SQF Food Safety Code: Manufacture of Food Packaging are audited;
- ii. Corrective and preventative action of deficiencies identified during the internal audits are undertaken; and
- iii. Audit results are communicated to relevant management personnel and staff responsible for implementing and verifying corrective actions.

RESPONSE: COMPLIANT

EVIDENCE:

2.5.4.2 Staff conducting internal audits shall be trained and competent in internal audit procedures. Where practical staff conducting internal audits shall be independent of the function being audited.

RESPONSE: COMPLIANT

EVIDENCE:

2.5.4.3 Regular inspections of the site and equipment shall be planned and carried out to verify Good Manufacturing Practices and facilities and equipment maintenance is compliant to the SQF Food Safety Code: the Manufacturing of Food Packaging. The site shall:

- i. Take corrections or corrective and preventative action; and
- ii. Maintain records of inspections and any corrective action taken.

RESPONSE: COMPLIANT

EVIDENCE:

2.5.4.4 Records of internal audits and inspections and any corrective and preventative actions taken as a result of internal audits shall be recorded as per 2.5.3.

Changes implemented from internal audits that have an impact on the site's ability to deliver safe food shall require a review of applicable aspects of the SQF System (refer to 2.3.1.3).

RESPONSE: COMPLIANT

EVIDENCE:

2.6.1 Product Identification

Procedure 2.6.1 details the method for identifying raw material, packaging materials, etc. They use a batch code from the vendors of raw material. This is recorded on the production run and gives full traceability back to the purchase order. In process material or work in progress is identified by a production date and the batch code. Finished products are identified by label, size, batch code and production date. This was verified by sampling some production records during my trace exercise.

2.6.1.1 The methods and responsibility for identifying raw materials, packaging, and finished products during all stages of production and storage shall be documented and implemented. The identification system shall be implemented to ensure:

- i. Raw and packaging materials, work-in-progress, process inputs, recycled materials, and finished products are clearly identified during all stages of receipt, production, storage, and dispatch; and
- ii. Finished product is labeled to the customer specification, where applicable, and/or regulatory requirements.

RESPONSE: COMPLIANT

EVIDENCE:

2.6.1.2 Product start-up and changeover procedures during manufacture of food sector packaging shall be documented and implemented to ensure that the correct product information is applied or labeled and that the changeover is inspected and approved by an authorized person.

Product identification records shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.6.2 Product Trace

They have a full product history in the ERP system. The records produced will use the serial numbers of the raw materials, or the part numbers and dates of the production run, to track down any product from any point in its life cycle. The Quality Manager pulled some production records for a traceability exercise. The sample consisted of two orders and all the inspection records met requirements. We also did a forward trace of a shipment of paper rolls and all records were retrieved.

2.6.2.1 The responsibility and methods used to trace product shall be documented and implemented to ensure:

- i. Finished product is traceable to the customer (minimum one step forward) and provides traceability through the process to the supplier and date of receipt of raw materials, auxiliary packaging, processing aids, and other inputs (minimum one step back);
- ii. Traceability is maintained where product is reworked (refer to 2.4.6); and
- iii. The effectiveness of the product trace system is tested and documented at least annually as part of the product recall and withdrawal review (refer to 2.6.3.1).

Records of raw and auxiliary packaging material receipt and use and finished product dispatch and destination shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.6.3 Product Withdrawal and Recall (Mandatory)

Verified that the last mock recall was done on 5/23/23. It only took them 15 minutes to perform this exercise. Verified this to be true during this audit by conducting my own trace exercise. They utilize a software package that keeps all records available. They also have a hard copy of each record and it was retrieved quickly. They were able to retrieve 100% of all the records.

2.6.3.1 The responsibility and methods used to withdraw or recall product shall be documented and implemented. The procedure shall:

- i. Identify those responsible for coordinating, managing, and investigating a product withdrawal or recall with customers;
- ii. Describe the procedures to be implemented by site management, including sources of legal, regulatory, and expert advice;
- iii. Outline a communication plan to inform customers, consumers, authorities, and other essential bodies in a timely manner appropriate to the nature of the incident; and
- iv. Ensure that SQFI, the certification body, and the appropriate regulatory authority are listed as an essential body and notified in instances of a food safety incident of a public nature or product recall for any reason.

RESPONSE: COMPLIANT

EVIDENCE:

2.6.3.2 The withdrawal and recall system shall be reviewed, tested, and verified as effective at least annually. Testing shall include incoming materials (minimum one step back) and finished product (minimum one step forward).

Testing shall be carried out on products from different shifts and for materials (including bulk materials) that are used across a range of products and/or products that are shipped to a wide range of customers.

RESPONSE: COMPLIANT

EVIDENCE:

2.6.3.3 Records shall be maintained of withdrawal and recall tests, root cause investigations into actual withdrawals and recalls, and corrective and preventative actions applied.

RESPONSE: COMPLIANT

EVIDENCE:

2.6.3.4 SQFI and the certification body shall be notified in writing within twenty-four (24) hours upon identification of a food safety event that requires public notification. SQFI shall be notified at foodsafetycrisis@sqfi.com.

RESPONSE: COMPLIANT

EVIDENCE:

2.6.4 Crisis Management Planning

Reviewed the crisis incident log and the last test conducted on the crisis management program was conducted on 2/1/24. Records indicate that it was a successful exercise. Lessons learned were included in the notes of the exercise.

2.6.4.1 A crisis management plan that is based on the understanding of known potential dangers (e.g. flood, drought, fire, tsunami, pandemic, or other severe weather or regional events such as warfare, civil unrest, or pandemic) that can impact the site's ability to deliver safe food sector packaging shall be documented by senior management outlining the methods and responsibility the site shall implement to cope with such a business crisis. The crisis management plan shall include as a minimum:

- i. A senior manager responsible for decision making, oversight, and initiating actions arising from a crisis management incident;
- ii. The nomination and training of a crisis management team;
- iii. The controls implemented to ensure a response does not compromise product safety;
- iv. The measures to isolate and identify product affected by a response to a crisis;
- v. The measures taken to verify the acceptability of food sector packaging prior to release;
- vi. The preparation and maintenance of a current crisis alert contact list, including supply chain customers;
- vii. Sources of legal and expert advice; and
- viii. The responsibility for internal communications and communicating with authorities, external organizations, and media.

RESPONSE: COMPLIANT

EVIDENCE:

2.6.4.2 The crisis management plan shall be reviewed, tested, and verified at least annually. Records of reviews of the crisis management plan shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.7.1 Food Defense Plan

Reviewed the vulnerability assessment conducted on 3/28/24. They concluded that all aspects of their site security plan are under control. Reviewed each required input and they did cover it. Monthly reviews indicate that they have consistent issues with doors being damaged or open. They are addressing these issues and actions are being taken. This process is effective because they are working through these problems.

2.7.1.1 A food defense threat assessment shall be conducted to identify potential threats that can be caused by a deliberate act of sabotage or terrorist-like incident.

RESPONSE: COMPLIANT

EVIDENCE:

2.7.1.2 A food defense plan shall be documented, implemented and maintained based on the threat assessment (refer to 2.7.1.1). The food defense plan shall meet legislative requirements as applicable and shall include at a minimum:

- i. The methods, responsibility, and criteria for preventing food adulteration caused by a deliberate act of sabotage or terrorist-like incident
- ii. The name of the senior site management person responsible for food defense;
- iii. The methods implemented to ensure only authorized personnel have access to production equipment and vehicles, manufacturing, and storage areas through designated access points;
- iv. The methods implemented to protect sensitive processing points from intentional adulteration;
- v. The measures taken to ensure the secure receipt and storage of raw and packaging materials, equipment, and hazardous chemicals;
- vi. The measures implemented to ensure raw and packaging materials, labels, process inputs, work-in-progress, and finished products are held under secure storage and transportation conditions; and
- vii. The methods implemented to record and control access to the premises by employees, contractors, and visitors.

RESPONSE: COMPLIANT

EVIDENCE:

2.7.1.3 Instruction shall be provided to all relevant staff on the effective implementation of the food defense plan (refer to 2.9.2.1).

RESPONSE: COMPLIANT

EVIDENCE:

2.7.1.4 The food defense threat assessment and prevention plan shall be reviewed and tested at least annually or when the threat level, as defined in the threat assessment, changes. Records of reviews of the food defense plan shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.7.2 Food Fraud

Reviewed the food fraud assessment dated 3/28/24 and the weekly site inspections. This is a self assessment of the vulnerability to fraud in this industry. They concluded that the risk is very low for this type of industry. This is done through the hazardous analysis in the HACCP program.

2.7.2.1 The methods, responsibility, and criteria for identifying the site’s vulnerability to food fraud shall be implemented and maintained. A food fraud vulnerability assessment shall be conducted to identify the site’s susceptibility to substitution, mislabeling, and counterfeiting of raw materials and finished product that may adversely impact the food safety of the product.

RESPONSE: COMPLIANT

EVIDENCE:

2.7.2.2 A food fraud mitigation plan shall be developed and implemented that specifies the methods by which the identified food fraud vulnerabilities shall be controlled, including identified food safety vulnerabilities of ingredients and materials.

RESPONSE: COMPLIANT

EVIDENCE:

2.7.2.3 Instruction shall be provided to all relevant staff on the effective implementation of the food fraud mitigation plan (refer to 2.9.2.1).

RESPONSE: COMPLIANT

EVIDENCE:

2.7.2.4 The food fraud vulnerability assessment and mitigation plan shall be reviewed and verified at least annually with gaps and corrective actions documented. Records of reviews shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.8.1 Allergen Management

The only allergens that could be introduced into the production would be through employees, cafeteria, outside visitors, etc. The products and materials do not contain any allergens. The GMP program is the main way to control the potential for allergens to be introduced into the product. The finished goods are packaged and wrapped, so human contact is minimal.

2.8.1.1 The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating food sector packaging shall be documented and implemented. The allergen management program shall include:

- i. A detailed risk analysis and assessment of workplace-related food allergens, raw materials, printed packaging, and/or processing aids, including food grade lubricants, that may contain food allergens or food allergen statements;
- ii. A list of allergens that is applicable in the country of manufacture and the country(ies) of destination if known;
- iii. A list of allergens that is accessible by relevant staff;
- iv. The food safety hazards associated with allergens and their control incorporated into the food packaging safety plan;
- v. A management plan for control of identified allergens;
- vi. Cleaning and sanitation of product contact surfaces between line changeovers is effective, appropriate to the risk and legal requirements, and sufficient to remove all potential target allergens from product contact surfaces; and
- vii. Based on the risk assessment, procedures for validation and verification of the effectiveness of the cleaning and sanitation of areas and equipment in which allergens are used is effectively implemented.

RESPONSE: COMPLIANT

EVIDENCE:

2.8.1.2 Instructions shall be provided to all relevant staff involved in the receipt or handling of raw materials, work-in progress, rework, or finished product on the identification, handling, storage, and segregation of materials containing allergens.

RESPONSE: COMPLIANT

EVIDENCE:

2.8.1.3 Sites that do not handle allergenic materials shall document, implement, and maintain an allergen management program that addresses at a minimum the mitigation of introduced unintended allergens through supplier, contract manufacturer, employee, and visitor activities.

RESPONSE: COMPLIANT

EVIDENCE:

2.9.1 Training Requirements

Established through the training skills matrix and job descriptions. Verified that they have both established.

2.9.1.1 The responsibility for establishing and implementing the training needs of the site's personnel to ensure they have the required competencies to carry out functions affecting the manufacture of safe food sector packaging and regulatory compliance shall be defined and documented (refer to 2.1.1.6).

RESPONSE: COMPLIANT

EVIDENCE:

2.9.1.2 Appropriate training shall be provided for personnel carrying out the tasks essential to the effective implementation of the SQF System and the maintenance of food safety and regulatory requirements.

RESPONSE: COMPLIANT

EVIDENCE:

2.9.2 Training Program

Reviewed the training program for a sample of employees in production and maintenance. Their training program is controlled thru a spreadsheet. They have core training for different positions, as it relates to SQF program. Verified that all training had been completed in a timely fashion.

2.9.2.1

A training program shall be documented and implemented that outlines at a minimum the necessary competencies for specific duties and the training methods to be applied for personnel carrying out tasks associated with:

- i. Implementing HACCP for staff involved in developing and maintaining food safety plans;
- ii. Monitoring and corrective action procedures for all staff engaged in monitoring critical control points (CCPs);
- iii. Personal hygiene;
- iv. Good Manufacturing Practices and work instructions for all staff engaged in the handling, storage, and manufacturing of food sector packaging and equipment;
- v. Applying food safety regulatory requirements;
- vi. Sampling and test methods for all staff involved in sampling and testing of raw materials, packaging, work-in-progress, and finished products;
- vii. Environmental monitoring for relevant staff;
- viii. Allergen management, food defense, and food fraud for all relevant staff; and
- ix. Tasks identified as critical to meeting effective implementation and maintenance of the SQF Code.

The training program shall include provision for identifying and implementing the refresher training needs of the site.

RESPONSE: COMPLIANT

EVIDENCE:

2.9.2.2

Training materials, the delivery of training, and procedures on all tasks critical to meeting regulatory compliance and the maintenance of food safety shall be provided in languages understood by staff.

RESPONSE: COMPLIANT

EVIDENCE:

2.9.2.3

Training records shall be maintained and include:

- i. Participant name;
- ii. Skills description;
- iii. Description of the training provided;
- iv. Date training completed;
- v. Trainer or training provider; and
- vi. Verification that the trainee is competent to complete the required tasks.

RESPONSE: COMPLIANT

EVIDENCE:

13.1.1 Premises Location and Approval

Business license verified and it is current.

13.1.1.1 The site shall assess local activities and the site environment to identify any risks that may have an adverse impact on product safety and implement controls for any identified risks. The assessment shall be reviewed in response to any changes in the local environment or activities.

The construction and ongoing operation of the premises on the site shall be approved by the relevant authority.

RESPONSE: COMPLIANT

EVIDENCE:

13.1.2 Building Materials

Product and non-product contact surfaces are constructed of materials that do not pose a product safety risk. Floors are constructed of smooth, dense impact resistant materials, are properly graded, drained and are impervious to liquid. Walls, ceilings and doors are properly constructed. The wall junctions are designed to be easily cleaned. They are sealed to avoid accumulation of debris. Pipes are designed for easy cleaning. Doors and windows are in good condition. Windows are made of shatterproof glass (lexan). The condition of the walls is free from damage or tears/rips.

13.1.2.1 Floors shall be constructed of smooth, dense, impact-resistant material that can be effectively graded, drained, are impervious to liquid, and easily cleaned.

RESPONSE: COMPLIANT

EVIDENCE:

13.1.2.2 Drains shall be constructed and located so they can be easily cleaned and do not present a food safety hazard.

RESPONSE: COMPLIANT

EVIDENCE:

13.1.2.3 Waste trap system shall be located sufficiently far away from any food sector packaging handling area or entrance to the premises to prevent contamination.

RESPONSE: COMPLIANT

EVIDENCE:

13.1.2.4 Walls, partitions, ceilings, and doors shall be of durable construction.

RESPONSE: COMPLIANT

EVIDENCE:

13.1.2.5 In food sector packaging manufacturing, handling, and storage areas, wall-to-wall and wall-to-floor junctions shall be designed to be easily cleaned and sealed to prevent the accumulation of debris.

RESPONSE: COMPLIANT

EVIDENCE:

13.1.2.6 In food sector packaging manufacturing, handling, and storage areas, doors shall be of solid construction and windows shall be of shatterproof glass or similar material.

RESPONSE: COMPLIANT

EVIDENCE:

13.1.3 Lightings and Light Fittings

The lights are hung from the ceiling by a chain and there is a surface that needs to be cleaned. They have it on semi annual cleaning report. At the time of this audit, the surfaces looked clean. The lighting is not and appears to not require a cover. It is a string of LED, which are shatter proof. They do have some fluorescent lighting still mixed with the LEDs, but the fluorescents are shatter proof. No threat to the product. The intensity of the light is appropriate for the operations.

13.1.3.1 Lighting in food sector packaging manufacturing, handling, and storage areas shall be of appropriate intensity to enable the staff to carry out their tasks efficiently and effectively.

RESPONSE: COMPLIANT

EVIDENCE:

13.1.3.2 Light fittings in food sector packaging manufacturing, handling, and storage areas shall be shatterproof, manufactured with a shatterproof covering, or fitted with protective covers and recessed into or fitted flush with the ceiling.

Where fixtures cannot be recessed, structures shall be protected from accidental breakage, manufactured from cleanable materials, and included in the cleaning and sanitation program.

RESPONSE: COMPLIANT

EVIDENCE:

13.1.3.3 Light fittings in areas where the product is stored shall be designed to prevent product contamination.

RESPONSE: COMPLIANT

EVIDENCE:

13.1.4 Dust, Insect, and Pest Proofing

All doors and windows are adequately sealed to protect against dust and pest contamination. Rodent traps are located away from the processing areas and do not pose a risk to the products. Bait stations are located along the exterior perimeters only. Rodent and Bait stations are monitored by outside source and are in great condition. Overall, this process is effective.

13.1.4.1 All external windows, ventilation openings, doors, and other openings shall be effectively sealed when closed and proofed against dust, vermin, and other pests.

External personnel access doors shall be effectively insect-proofed and fitted with a self-closing device and proper seals to protect against entry of dust, vermin, and other pests.

RESPONSE: COMPLIANT

EVIDENCE:

13.1.4.2 Methods shall be in place to adequately control dust that may result from the manufacturing process.

RESPONSE: COMPLIANT

EVIDENCE:

13.1.4.3 External access doors and overhead dock doors used for product, material, pedestrian, or vehicle access shall be effectively designed, maintained, and fitted with proper seals to protect against entry of dust, vermin, and other pests.

RESPONSE: COMPLIANT

EVIDENCE:

13.1.4.4 Electric insect control devices, pheromone, or other traps and baits shall be located so as not to present a contamination risk to food sector packaging or manufacturing equipment. Poison rodenticide bait shall not be used inside food sector packaging manufacturing, handling, or storage areas.

RESPONSE: COMPLIANT

EVIDENCE:

13.1.5 Ventilation

Auditor observed that the air ventilation is adequate for the type of facility and process. They have "localized" air duct work and larger duct work for the overall facility. Filters are changed on a schedule. Confirmed that this process is effective.

13.1.5.1 Adequate ventilation shall be provided in enclosed packaging manufacture and handling areas.

RESPONSE: COMPLIANT

EVIDENCE:

13.1.6 Equipment and Utensils

Reviewed the process for the control of Equipment, Utensils and Protective Clothing. Equipment that is stored are done so in a controlled manner. Upon using the stored equipment, maintenance personnel will prepare the equipment and perform a cleaning. There is no need to for protective clothing and they require utensils to be in good repair. Verified that this is effectively implemented.

13.1.6.1 Specifications for new equipment and procedures for purchasing equipment to ensure it is appropriate for the task shall be documented and implemented.

RESPONSE: COMPLIANT

EVIDENCE:

13.1.6.2 Equipment shall be designed, constructed, installed, operated, and maintained so as not to pose a contamination threat to food sector packaging and to allow for cleaning beneath and behind it. Tools, utensils, and containers used for handling raw materials or packaging, work-in-progress, and food sector packaging shall be made of food safe materials.

RESPONSE: COMPLIANT

EVIDENCE:

13.1.6.3 Vehicles used in food sector packaging manufacturing, handling, or storage areas shall be designed and operated so as not to present a food safety hazard.

RESPONSE: COMPLIANT

EVIDENCE:

13.1.6.4 Non-conforming equipment shall be identified, tagged, and segregated for repair or disposal in a manner that minimizes the risk of inadvertent use, improper use, or risk to the integrity of finished product. Records of the handling, corrective action, and/or disposal of non-conforming equipment shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

13.1.6.5 In sites where food sector packaging is manufactured, product contact surfaces shall be constructed of materials that will not contribute to a food safety risk to the manufacture of packaging materials.

RESPONSE: COMPLIANT

EVIDENCE:

13.1.7 Grounds and Roadways

During the tour of the facility, confirmed that the surrounding outside area was clean and free from debris. The parking lot was free from debris and in good condition. Observed no excessive amounts of debris in and around the trash receptacles. Overall, the outside perimeter was in good condition.

13.1.7.1 The external grounds and areas surrounding the premises, including external storage buildings, machinery, and equipment shall be maintained to prevent accumulated debris and waste and control vegetation. These areas shall be inspected routinely to ensure they will not attract pests and vermin or present a food safety hazard to the sanitary operation of the site.

RESPONSE: COMPLIANT

EVIDENCE:

13.1.7.2 Paths, roadways, and loading and unloading areas shall be maintained so as not to present a food safety hazard to the operation of the premises. They shall be adequately drained to prevent pooling of water. Drains shall be separate from the site drainage system and regularly cleared of debris.

RESPONSE: COMPLIANT

EVIDENCE:

13.2.1 Repairs and Maintenance

Interviewed the Maintenance Manager for this area. They use a software system called MP9. Every morning, the manager reviews a list of maintenance activities. Reviewed the maintenance history of two of the machines and the history was complete. The work order tells you who did the maintenance activity. Temporary repairs are handled by the production staff sending an email to maintenance and then a work order is created. They use food grade grease on all equipment above any type of conveyors or moving product. Sampled two work orders (2398 and 2399), which were completely filled out and accurate. The work order has an instruction to make sure all instruments and tools had been cleaned up and the machine they worked on is clear for production.

13.2.1.1 The methods and responsibility for the maintenance and repair of the facility, equipment, and buildings shall be documented, planned, and implemented in a manner that minimizes the risk of contamination of food sector packaging material or equipment.

RESPONSE: COMPLIANT

EVIDENCE:

13.2.1.2 Routine maintenance of the equipment in any food sector packaging manufacturing, handling, or storage area shall be performed according to a maintenance control schedule and recorded. The maintenance schedule shall include the building, equipment, vehicles, and other areas of the premises critical to the maintenance of food safety.

RESPONSE: COMPLIANT

EVIDENCE:

13.2.1.3 Equipment failures shall be documented, and repair activities shall be incorporated into the maintenance schedule.

RESPONSE: COMPLIANT

EVIDENCE:

13.2.1.4 Site supervisors shall be notified when maintenance or repairs are to be undertaken in any food sector packaging manufacturing, handling, or storage area.

RESPONSE: COMPLIANT

EVIDENCE:

13.2.1.5 The maintenance supervisor and the site supervisor shall be informed if any repairs or maintenance pose a potential threat to food safety from foreign objects or contaminants (e.g., pieces of electrical wire, damaged light fittings, and loose overhead fittings). When possible, maintenance is to be conducted outside manufacturing times.

RESPONSE: COMPLIANT

EVIDENCE:

13.2.1.6 Temporary repairs, where required, shall not pose a food safety risk and shall be included in routine inspections (refer to 2.5.4.3) and in the cleaning program. There shall be a plan in place to address completion of temporary repairs to ensure they do not become permanent solutions.

RESPONSE: COMPLIANT

EVIDENCE:

13.2.1.7 Equipment located over raw or packaging materials, food sector packaging, or product conveyors shall be lubricated with food grade lubricants and their use controlled to minimize the contamination of the product. Machinery lubricant controls shall be in place to prevent contamination of food sector packaging from gear box oils, bearing lubricants, hydraulics, or any other source.

RESPONSE: COMPLIANT

EVIDENCE:

13.2.1.8 Paint used in food sector packaging manufacturing, handling, and storage areas and product contact zones shall be suitable for use, intact, and free of chips and shall not be used on any food contact surfaces.

RESPONSE: COMPLIANT

EVIDENCE:

13.2.2 Maintenance Staff and Contractors

Upon arrival at the facility, you are required to sign a visitor log to enter the facility. Entry into the production and storage areas is done through the common employee entrance. The visitor is guided by the employee visited. They have a separate form the visitor must fill out for the GMP requirements at the facility. Verified that all past contractors/visitors have filled out the visitor log and signed the GMP instructions.

13.2.2.1 Maintenance staff and contractors shall comply with the site's personnel hygiene requirements (refer to 13.3.4).

RESPONSE: COMPLIANT

EVIDENCE:

13.2.2.2 All maintenance and other engineering contractors required to work on-site shall be trained in the site's food safety and hygiene procedures or shall be escorted at all times until their work is completed.

RESPONSE: COMPLIANT

EVIDENCE:

13.2.2.3 Maintenance staff and contractors shall remove all tools, parts, and debris from areas where maintenance and repairs were conducted once it has been completed. They shall inform the appropriate supervisor so that hygiene and sanitation actions and a pre-operational inspection can be conducted prior to the restarting of operations.

RESPONSE: COMPLIANT

EVIDENCE:

13.2.3 Calibration

ISample of inspection records from the production sample reviewed and asked for the calibration records for the instruments used in the inspection process. The two instruments are scale and micrometer. They perform an annual calibration by an outside source and they perform a daily check/verification of the scales. Reviewed the two calibration certificates and they had passed the "as received" process. Reviewed the calibration log (Rev. B) and compared it to other devices checked. All calibration instruments are in a state of calibration.

13.2.3.1 The methods and responsibility for calibration and re-calibration of measuring, testing, and inspection equipment used for monitoring activities outlined in prerequisite programs, food safety plans and other process controls, or to demonstrate compliance with customer specifications shall be documented and implemented. Software used for such activities shall be validated as appropriate.

RESPONSE: COMPLIANT

EVIDENCE:

13.2.3.2 Procedures shall be documented and implemented to address the resolution of potentially affected food sector packaging should measuring, testing, and inspection equipment be found to be out of calibration state.

RESPONSE: COMPLIANT

EVIDENCE:

13.2.3.3 Calibrated measuring, testing, and inspection equipment shall be protected from damage and unauthorized adjustment.

RESPONSE: COMPLIANT

EVIDENCE:

13.2.3.4 Equipment shall be calibrated against national or international reference standards and methods or to an accuracy appropriate to its use. In cases where standards are not available, the site shall provide evidence to support the calibration reference method applied.

RESPONSE: COMPLIANT

EVIDENCE:

13.2.3.5 Calibration shall be performed according to regulatory requirements and/or to the equipment manufacturers' recommended schedule.

RESPONSE: COMPLIANT

EVIDENCE:

13.2.3.6 A directory of measuring, testing, and inspection equipment requiring calibration and records of calibration tests shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

13.2.4 Pest Prevention

Reviewed the pest control program, which consists of a pest control log that keeps track of flying insects and other pests. The log showed little activity and most of that was in the cafeteria. The vendor they use is Waves Pest Control Co. and reviewed their certificate of insurance and the technician's applicators license, which expires on 7/31/24. Also reviewed the pest technicians license, which doesn't expire until 7/31/24. Reviewed the pest control map. During my tour of the facility, confirmed all the traps were accurate on the map. Overall, this process is effective.

- 13.2.4.1** A documented pest prevention program shall be effectively implemented. It shall:
- i. Describe the methods and responsibility for the development, implementation, and maintenance of the pest prevention program;
 - ii. Record pest sightings and trend the frequency of pest activity to target pesticide applications;
 - iii. Outline the methods used to prevent pest problems;
 - iv. Outline the pest elimination methods and the appropriate documentation for each inspection;
 - v. Outline the frequency with which pest status is to be checked;
 - vi. Include on a site map the identification, location, number, and type of applied pest control/ monitoring devices;
 - vii. List the chemicals used. The chemicals are required to be approved by the relevant authority and their Safety Data Sheets (SDS) made available;
 - viii. Outline the methods used to make staff aware of the bait control program and the measures to take when they come into contact with a bait station;
 - ix. Outline the requirements for staff awareness and training in the use of pest and vermin control chemicals and baits; and
 - x. Measure the effectiveness of the program to verify the elimination of applicable pests and identify trends.

RESPONSE: COMPLIANT

EVIDENCE:

- 13.2.4.2** Pest contractors and/or internal pest controllers shall:
- i. Be licensed and approved by the local relevant authority;
 - ii. Use only trained and qualified operators who comply with regulatory requirements;
 - iii. Use only approved chemicals;
 - iv. Provide a pest prevention plan (refer to 2.3.2.7) that includes a site map indicating the location of bait stations, traps, and other applicable pest control monitoring devices;
 - v. Report to a responsible authorized person on entering the premises and after the completion of inspections or treatments;
 - vi. Provide regular inspections for pest activity with appropriate action taken if pests are present; and
 - vii. Provide a written report of their findings and the inspections and treatments applied.

RESPONSE: COMPLIANT

EVIDENCE:

- 13.2.4.3** Pest activity risks shall be analyzed and recorded. Inspections for pest activity shall be undertaken on a regular basis by trained site personnel and the appropriate action taken if pests are present. Identified pest activity shall not present a risk of contamination to raw materials or food sector packaging.

Records of all pest control inspections and applications shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

- 13.2.4.4** Raw materials or packaging, processing aids, work-in-progress, or food sector packaging that is found to be contaminated by pest activity shall be effectively disposed of and the source of pest infestation investigated and resolved.

RESPONSE: COMPLIANT

EVIDENCE:

- 13.2.4.5** Pesticides shall be clearly labeled and stored per 13.6.2 if kept on-site.

RESPONSE: COMPLIANT

EVIDENCE:

13.2.4.6 No animals shall be permitted on-site in food sector packaging manufacturing, handling, or storage areas.

RESPONSE: COMPLIANT

EVIDENCE:

13.2.5 Cleaning and Sanitation

The SQF Practitioner retrieved a sample of sanitation checklists for the exterior and shipping/receiving. These inspections were done on 3/25-31/24. Reviewed last months cleaning records and they are all filled out completely. Verified that people handling the soap had awareness training.

13.2.5.1 The methods and responsibility for the effective cleaning of food sector packaging manufacturing, handling and storage areas, and staff amenities shall be documented and implemented.

RESPONSE: COMPLIANT

EVIDENCE:

13.2.5.2 Cleaning equipment, tools, racks, and other items used in support of the cleaning and sanitizing program shall be clearly identified, stored, and maintained in a manner that prevents contamination of food sector packaging manufacturing, handling, and storage areas and equipment.

RESPONSE: COMPLIANT

EVIDENCE:

13.2.5.3 Adjacent production equipment shall be covered or shut down and raw and packaging materials, work-in-progress, and food sector packaging shall be moved from the vicinity if using compressed air hoses to clean.

RESPONSE: COMPLIANT

EVIDENCE:

13.2.5.4 Pre-operational inspections shall be conducted following cleaning and sanitation operations to ensure manufacturing areas, product contact surfaces, equipment, staff amenities, and other essential areas are clean before the start of production. Inspections shall be conducted by qualified personnel to ensure the areas are cleaned at a defined frequency.

RESPONSE: COMPLIANT

EVIDENCE:

13.2.5.5 The responsibility and methods used to verify the effectiveness of the cleaning procedures shall be documented and implemented. A verification schedule shall be prepared.

A record of pre-operational hygiene inspections, cleaning and sanitation activities, and verification activities shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

13.2.5.6 Appropriate cleaning agents shall be purchased in accordance with applicable legislation and suitable for use. The site shall ensure that only trained staff handle cleaning agents and that it is according to manufacturer instructions. Documentation, storage, usage, and disposal of cleaning agents shall comply with 13.6.2.

RESPONSE: COMPLIANT

EVIDENCE:

13.3.1 Personnel Welfare

Employees are trained on infectious disease concerns in their GMP refresher training and during their new hire training. Employees are also trained on exposed cuts and lesions in their GMP refresher training and during their new hire training. Use of tobacco, eating, drinking or smoking is not allowed in the production areas. A lunch room is available to employees for eating and drinking.

13.3.1.1 Personnel who are known to be carriers of infectious diseases that present a health risk to others on-site shall not engage in the manufacture of food sector packaging or enter areas where food sector packaging is exposed.

Code Amendment #1

A medical screening procedure shall be in place for all employees, visitors and contractors who handle exposed product or food contact surfaces.

RESPONSE: COMPLIANT

EVIDENCE:

13.3.1.2 The site shall have measures in place to prevent contact of raw and packaging materials, work-in-progress, food sector packaging, and product contact surfaces from any bodily fluids, open wounds, coughing, sneezing, spitting, or any other means.

In the event of an injury that causes spillage of bodily fluid, a properly trained employee shall ensure that all affected areas have been adequately cleaned and that all affected materials have been quarantined and/or disposed of.

RESPONSE: COMPLIANT

EVIDENCE:

13.3.1.3 Personnel with exposed cuts, sores, or lesions shall not engage in handling raw and packaging materials, work-in-progress, food sector packaging, and product contact surfaces. Minor cuts or abrasions on exposed parts of the body shall be covered with a colored bandage containing a metal-detectable strip or an alternative suitable waterproof and colored dressing.

RESPONSE: COMPLIANT

EVIDENCE:

13.3.2 Handwashing

Employees are instructed to wash their hands before starting and/or returning to work. Observation of employees during the audit noted adherence to the facility hand wash policy. Hand wash sinks are located at the employee entrances, in the bath rooms and break rooms. All hand wash basins are constructed of stainless steel or non-corrodible materials. All wash basins are supplied with water at appropriate temperatures, liquid soap, paper towels and a waste container. Signs are available at all wash stations which are legible and prominently displayed in English. The soap containers are fixed to the wall near the sinks.

13.3.2.1 Personnel shall have clean hands, and hands shall be washed by all personnel, including staff, contractors, and visitors:

- i. On entering production areas;
- ii. After each visit to a toilet;
- iii. After using a handkerchief;
- iv. After smoking, eating, or drinking; and
- v. After handling waste or chemicals.

RESPONSE: COMPLIANT

EVIDENCE:

13.3.2.2 Handwash stations shall be provided in appropriate areas that support the capability of site personnel and visitors to wash their hands as outlined in 13.3.2.3.

RESPONSE: COMPLIANT

EVIDENCE:

13.3.2.3 Handwash stations shall have:

- i. Basins constructed of stainless steel or similar non-corrosive material;
- ii. A potable water supply at an appropriate temperature;
- iii. Liquid hand soap within a fixed dispenser;
- iv. Paper towels or effective hand dryer; and
- v. A means of containing used paper towels.

RESPONSE: COMPLIANT

EVIDENCE:

13.3.2.4 Signage in appropriate languages instructing people to wash their hands before entering the food sector packaging manufacturing, handling, and storage areas shall be provided in a prominent position in break rooms, at break rooms exits, toilet rooms, and in outside eating areas if applicable.

RESPONSE: COMPLIANT

EVIDENCE:

13.3.2.5 When gloves are used, personnel shall maintain the handwashing practices outlined above.

RESPONSE: COMPLIANT

EVIDENCE:

13.3.3 Clothing and Personal Effects

During my tour of the facility, confirmed that clothing worn by staff is properly maintained, clean and did not pose a risk to the product. Disposable gloves are used over clean hands. During my tour of the interior facility, noticed that no employees had on jewelry or other loose objects in the production department. Reviewed their GMP program and their employees appeared to be in compliance with the program.

13.3.3.1 The site shall have a clothing and hair policy that protects raw and packaging materials, work-in-progress, food sector packaging, and product contact surfaces from unintentional contamination.

RESPONSE: COMPLIANT

EVIDENCE:

13.3.3.2 Clothing worn by staff engaged in handling food sector packaging shall be maintained, stored, laundered, and worn so as not to present a contamination risk to products.

RESPONSE: COMPLIANT

EVIDENCE:

13.3.3.3 Clothing worn by staff engaged in manufacturing and warehouse processes shall be made from materials that will not contaminate raw and packaging materials, working-progress, and food sector packaging. Clothing and shoes shall be clean at the commencement of each shift, maintained in a serviceable condition, and changed where they present a product contamination risk.

RESPONSE: COMPLIANT

EVIDENCE:

13.3.3.4 When protective clothing (e.g. frocks, smocks, aprons, boots, gloves, face shields, etc.) is used, hooks racks, cabinets, or other forms of off the floor storage shall be provided for temporary storage when staff leave the manufacturing area and shall be provided in close proximity or adjacent to the personnel access doors and handwashing stations. All clothing stored on-site shall be maintained and stored so as not to present a contamination risk to raw or packaging materials, work-in-progress, and food sector packaging.

RESPONSE: COMPLIANT

EVIDENCE:

13.3.3.5 Gloves used when handling food sector packaging material shall be clean and replaced when needed.

RESPONSE: COMPLIANT

EVIDENCE:

13.3.3.6 Jewelry and other loose objects shall not be worn or taken into any area where raw and packaging materials, work-in-progress, or food sector packaging is exposed. Wearing plain bands with no stones and medical alert bracelets that cannot be removed can be permitted; however, the site will need to consider their customer requirements and the applicable food legislation.

RESPONSE: COMPLIANT

EVIDENCE:

13.3.3.7 All exceptions shall meet regulatory and customer requirements and shall be subject to a risk assessment and evidence of ongoing risk management.

RESPONSE: COMPLIANT

EVIDENCE:

13.3.4 Visitors

Upon arrival at the facility, visitors are subjected to read the GMP program and that if you are experiencing a high temperature or illness, then you should not enter the building. You are then required to sign a visitor log to enter the facility. Entry into the production and storage areas is done through the common employee entrance. The visitor is guided by the employee visited.

- 13.3.4.1** All visitors shall be trained in, and comply with, applicable food safety and hygiene procedures before entering food sector packaging manufacturing, handling, or storage areas. Visitors shall be trained in, and comply with, additional food safety policies, such as maintenance and cleaning procedures, as appropriate to the purpose of the visit. Where applicable, policies shall define exceptions for visitors when they are escorted at all times.

RESPONSE: COMPLIANT

EVIDENCE:

- 13.3.4.2** All visitors shall wear suitable clothing and footwear when entering any food sector packaging manufacturing, handling, or storage areas.

RESPONSE: COMPLIANT

EVIDENCE:

- 13.3.4.3** Visitors shall enter and exit food sector packaging manufacturing, handling, and storage areas through the designated entrance points.

RESPONSE: COMPLIANT

EVIDENCE:

- 13.3.4.4** Visitors exhibiting visible signs of illness shall be prevented from entering areas in which food sector packaging is handled or processed.

RESPONSE: COMPLIANT

EVIDENCE:

13.3.5 Staff Amenities (change rooms, toilets, break rooms)

During the interior tour, confirmed that the lighting and ventilation of the staff amenities are acceptable. The ventilation is confirmed to exit the building. Lockers are provided to employees. There are no protective clothing requirements and the lockers are not private, which is appropriate. The lockers are assigned to employees. The condition of the lockers is acceptable and the surrounding area is clean. Reviewed various bathrooms in the facility and confirmed that they are constructed of material that is easy to clean. Records show that the cleaning of the bathrooms are conducted on a daily basis. The facility is nearly 105,000 square feet and the bathrooms are located at key locations. They have one lunch room in this facility and they are separate from the production areas. This lunch room are enclosed and were observed to be clean and organized. During my tour of the facility, it was observed that an employee regularly cleans the lunch rooms. Confirmed that signage is posted just before you exit the lunch room to wash your hands. Hand wash stations are in each lunch room. It was also observed that pest stations were positioned within the lunch room.

13.3.5.1 Staff amenities shall have documented cleaning procedures, be supplied with appropriate lighting and ventilation, and shall be made available for the use of all persons engaged in the handling and storage of food sector packaging.

RESPONSE: COMPLIANT

EVIDENCE:

13.3.5.2 Where applicable, facilities shall be provided to enable staff to change into and out of protective clothing as required. Provision shall be made for staff to store their street clothing and personal items separate from food sector packaging manufacturing, handling, or storage areas.

RESPONSE: COMPLIANT

EVIDENCE:

13.3.5.3 Toilet rooms shall be:

- i. ~~D~~esigned and constructed so that they are separate from any food sector packaging manufacturing, handling, or storage areas;
- ii. ~~A~~ccessed from operations via an airlock vented to the exterior or through an adjoining room;
- iii. ~~S~~ufficient in number for the maximum number of staff;
- iv. ~~C~~onstructed so that they can be easily cleaned and maintained;
- v. ~~I~~nclude an area inside or nearby for storing protective clothing, outer garments, and other items while using the facilities; and
- vi. ~~K~~ept clean and tidy.

Tools/equipment used for cleaning toilet rooms shall not be used to clean food sector packaging manufacturing areas.

RESPONSE: COMPLIANT

EVIDENCE:

13.3.5.4 Sanitary drainage shall not be connected to any other drains within the premises and shall be directed to a septic tank or a sewerage system in accordance with regulations.

RESPONSE: COMPLIANT

EVIDENCE:

13.3.5.5 A procedure shall document how to minimize the potential for contamination to the premises, personnel, raw and packaging materials, work-in-progress, and food sector packaging in the event of a sewage backup.

RESPONSE: COMPLIANT

EVIDENCE:

13.3.5.6 Handwash stations shall be provided immediately outside or inside the toilet room and designed as outlined in 13.3.2.3.

RESPONSE: COMPLIANT

EVIDENCE:

13.3.5.7 Separate break room facilities shall be provided away from food sector packaging manufacturing, handling, or storage areas. Break rooms shall be kept clean and tidy and free from waste materials and pests.

RESPONSE: COMPLIANT

EVIDENCE:

13.3.5.8 Where outside eating areas are provided, they should be kept clean and free from waste materials and maintained in a manner that minimizes the potential for introduction of contamination including pests to the site.

RESPONSE: COMPLIANT

EVIDENCE:

13.4.1 Staff Engaged in Food Handling and Processing Operations

Confirmed that there are employee entrance doors. It was observed that all employees did enter through these doors. Confirmed that all doors were closed, but that they did have issues with doors in past weekly inspections. They are addressing these issues. One issue noted for evidence of eating in the production area by finding candy wrappers on the production floor. See NCR.

13.4.1.1 All personnel engaged in food sector packaging manufacture, handling, and storage operations shall comply with the following practices:

- i. Personnel entry to production areas shall be through designated access doors only;
- ii. All doors are to be kept closed. Doors shall not be left open for extended periods when access is required for waste removal or receiving of product/ingredient/packaging;
- iii. Raw and packaging materials, work-in-progress, and food sector packaging shall be maintained appropriately, kept off the floor when applicable, and handled and stored in a manner to prevent damage and contamination; and
- iv. Waste shall be contained in the bins identified for this purpose and removed from the manufacturing area on a regular basis and not left to accumulate.

RESPONSE: COMPLIANT

EVIDENCE:

13.4.1.2 Personnel working in or visiting food sector packaging manufacturing, handling, or storage operations shall ensure that:

- i. Eating, drinking, smoking, or spitting is not permitted in areas where food sector packaging is manufactured, handled, stored, or exposed.
- ii. Drinking water is permitted in food sector packaging manufacturing, handling, and storage areas in a method that will not cause a food safety risk to raw and packaging materials, working-progress, food sector packaging, and equipment.

RESPONSE: MINOR

EVIDENCE: Found evidence of candy wrappers on the production floor and a piece of candy in an employee's belongings.

ROOT CAUSE: Personnel did not acknowledge correctly the GMPs rules where 1 of them is that food is not allowed at manufacturing floor at any time.

CORRECTIVE ACTION: 1. Retrain all personnel to assure GMPs are properly followed
2. Create a ppt from the GMPs alchemy training and add it to the monthly video along with monthly metrics and birthdays to be display at Cafeteria all the time to assure personnel awareness.

VERIFICATION OF CLOSEOUT: Reviewed powerpoint and GMP training records.

COMPLETION DATE: 05/02/2024 **CLOSEOUT DATE:** 05/06/2024

13.4.1.3 The manufacturing process shall be controlled such that food sector packaging is safe and free from contamination. Procedures shall be in place to prevent cross-contamination of food sector packaging from contaminated materials, cleaning agents, or chemicals.

RESPONSE: COMPLIANT

EVIDENCE:

13.4.1.4 The flow of personnel in food sector packaging manufacturing, storage, and handling areas shall be managed such that the potential for contamination is minimized.

RESPONSE: COMPLIANT

EVIDENCE:

13.5.1 Water Supply

During my tour of the facility, confirmed that supplies of water were adequate and available. Hot water was available for cleaning applications. They do have a reverse osmosis system and storage of water. They have an outside contractor maintain this system. Reviewed the last maintenance report for this system and it was acceptable. No water actually touches or comes in contact with the product.

13.5.1.1 Adequate supplies of hot and cold clean water shall be provided for use during manufacturing operations as needed and to enable effective cleaning of the premises and equipment.

RESPONSE: COMPLIANT

EVIDENCE:

13.5.1.2 The delivery of water within the premises shall ensure potable water is not contaminated. Testing of the backflow system, where possible, shall be conducted at least annually and records shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

13.5.1.3 The use of non-potable water shall be controlled such that:

- i. There is no cross-contamination between potable and non-potable water lines;
- ii. Non-potable water piping and outlets are clearly identified; and
- iii. Hoses, taps, and other similar sources of possible contamination are designed to prevent back flow or back siphonage.

RESPONSE: COMPLIANT

EVIDENCE:

13.5.1.4 Where water is stored on-site, storage facilities shall be adequately designed, constructed, and maintained to prevent contamination.

RESPONSE: COMPLIANT

EVIDENCE:

13.5.2 Water Quality

Reviewed the El Paso City Water report from 2022 and it was published in middle of 2023. SQF Practitioner said they will review 2023 report in a few months, when the city publishes the latest report. The city report stated that there were no violations of drinking water regulations.

- 13.5.2.1** Water shall comply with local, national, or internationally recognized potable water microbiological and quality standards as required when used for:
- i. Handwashing;
 - ii. As a raw material or processing aid;
 - iii. Cleaning of product contact surfaces and equipment; or
 - iv. The manufacture of steam that will come into contact with food sector packaging or used to heat water that will come into contact with food sector packaging.

RESPONSE: COMPLIANT

EVIDENCE:

- 13.5.2.2** Microbiological analysis of the water supply shall be conducted to verify the cleanliness of the supply, the monitoring activities, and the effectiveness of the treatment measures implemented. Samples for analysis shall be taken on-site at sources supplying water for the process, handwashing, and/or cleaning, or from within the site. The frequency of analysis shall be risk-based and at a minimum annually.

RESPONSE: COMPLIANT

EVIDENCE:

- 13.5.2.3** Water shall be analyzed using reference standards and methods.

RESPONSE: COMPLIANT

EVIDENCE:

13.5.3 Air and Other Gases

They conduct a quarterly test of any surfaces that could or are being touched by compressed air. They conduct a swab test of the area. The last test was on 1/28/24 and the results were good. These are kits purchased to do the swab test. Reviewed the kit and test to be effective.

- 13.5.3.1** Dry ice, compressed air, and other gasses (e.g., nitrogen, carbon dioxide) that contact food sector packaging or product contact surfaces shall be food-grade, clean, and present no risk to food safety.

RESPONSE: COMPLIANT

EVIDENCE:

- 13.5.3.2** Compressed air and other systems used to store or dispense gases that come into contact with food sector packaging or product contact surfaces shall be maintained and regularly monitored for quality and potential food safety hazards. The frequency of analysis shall be risk-based and at a minimum annually.

RESPONSE: COMPLIANT

EVIDENCE:

13.6.1 Storage of Materials and Product

Procedure 13.6.1 describes the process for storing and handling material, food packaging equipment. Overall, the procedure is simple, which is fine based on the type of food packaging they produce. The raw materials are enclosed or wrapped in shrink wrap and remain so until it is ready for use. The forklifts that are used to move the material around the facility are clean and regularly maintained. The finished goods are packaged in corrugated boxes and sealed with tape. In addition, the finished goods are placed on skids and wrapped with plastic. Unlikely that any contamination could occur, but they do have a pest control program that is effective.

13.6.1.1 The site shall document and implement a storage plan that allows for the safe, hygienic storage of raw and packaging materials, work-in-progress, food sector packaging, finished product returns, production equipment, processing aids, and chemicals that impact food safety.

RESPONSE: COMPLIANT

EVIDENCE:

13.6.1.2 The responsibility and methods for ensuring effective stock rotation principles are applied shall be documented and implemented to ensure that all raw materials, work-in-progress, rework, and food sector packaging are utilized within their designated shelf life, where applicable.

RESPONSE: COMPLIANT

EVIDENCE:

13.6.1.3 Equipment storage rooms shall be designed and constructed to allow equipment to be stored in a hygienic manner.

RESPONSE: COMPLIANT

EVIDENCE:

13.6.1.4 Where raw and packaging materials, work-in-progress, and food sector packaging are held under temporary or overflow conditions that are not designed for the safe storage of those goods, a risk analysis shall be performed to ensure the integrity of those goods is maintained, they are not at risk of contamination, and there are no other food safety concerns.

RESPONSE: COMPLIANT

EVIDENCE:

13.6.1.5 Rooms and equipment used for the storage of raw and packaging materials, work-in-progress, and food sector packaging shall be constructed to protect the product from contamination and deterioration.

RESPONSE: COMPLIANT

EVIDENCE:

13.6.1.6 Where required, procedures shall be in place for effective storage of printing plates, cylinders, and print blankets.

RESPONSE: COMPLIANT

EVIDENCE:

13.6.2 Storage and Use of Hazardous Chemicals and Toxic Substances

Confirmed that they have a designated area to store their bulk chemicals. Smaller containers are stored near the workstations and in storage cabinets. They do use secondary containers for chemicals and observed them having the proper GHS labeling. Took a sample of chemicals during my tour of the facility and compared it to the chemical list and the SDS sheet. All records and documents were accurate.

13.6.2.1 Hazardous chemicals and toxic substances, including solvents and agents with the potential for contamination of food sector packaging, shall be:

- i. Clearly labelled, identifying and matching the contents with their containers;
- ii. Included in a current list of all chemicals and toxic substances that are stored on-site; and
- iii. Supplemented with a current Safety Data Sheet (SDS) that is made available to all staff.

RESPONSE: COMPLIANT

EVIDENCE:

13.6.2.2 Storage of hazardous chemicals and toxic substances shall be:

- i. Located in an area with appropriate signage indicating that the area is for hazardous storage;
- ii. Controlled, lockable, and accessible only by personnel trained in the storage and use of chemicals;
- iii. Adequately ventilated;
- iv. Stored where intended and not comingled (e.g., food versus non-food grade);
- v. Designed such that there is no cross-contamination between chemicals; and
- vi. Stored in a manner that prevents hazards to raw and packaging materials, work-in-progress, food sector packaging, and product contact surfaces.

RESPONSE: COMPLIANT

EVIDENCE:

13.6.2.3 Hazardous chemicals and toxic substances shall be correctly labeled and:

- i. Used only according to manufacturers' instructions;
- ii. Controlled to prevent contamination or a hazard to raw and packaging material, work-in-progress, food sector packaging, or finished product contact surfaces;
- iii. Returned to the appropriate storage areas after use; and
- iv. Be compliant with national and local legislation.

RESPONSE: COMPLIANT

EVIDENCE:

13.6.2.4 Employees who handle hazardous chemicals and toxic substances, including pesticides and cleaning chemicals, shall:

- i. Be properly trained on handling and usage;
- ii. Be provided with first aid equipment and personnel protective equipment; and
- iii. Ensure compliance to the proper identification, storage, usage, disposal, and clean-up requirements as defined.

RESPONSE: COMPLIANT

EVIDENCE:

- 13.6.2.5** The site shall dispose of obsolete inventory and empty containers of chemicals, pesticides, and toxic substances in accordance with site and regulatory requirements and ensure that:
- i. Single-use containers are not reused;
 - ii. Containers are segregated and securely stored prior to collection; and
 - iii. Containers are disposed through an appropriate vendor.

RESPONSE: COMPLIANT

EVIDENCE:

- 13.6.2.6** In the event of a hazardous chemical or toxic substance spill, the site shall:
- i. Have spillage clean-up instructions to ensure that the spill is properly contained; and
 - ii. Be equipped with spillage kits and cleaning equipment.

RESPONSE: COMPLIANT

EVIDENCE:

13.6.3 Loading, Transport, and Unloading Practices

Reviewed records of trailer inspections from a sample of two orders, both incoming and outgoing. Records indicate that the trailers are inspected for odor, pest, and overall condition of the trailer. There were no failures observed. Reviewed records of receiving and shipping and they have a place on the bill of lading to record the trailer inspection. Sampled two orders and they had completed this task.

- 13.6.3.1** The practices applied during transport, loading, and unloading of raw and packaging materials and food sector packaging shall be documented and implemented. Practices shall be conducted to prevent cross-contamination, maintain appropriate storage conditions, and ensure product integrity.

RESPONSE: COMPLIANT

EVIDENCE:

- 13.6.3.2** Vehicles (e.g., semi-trucks, trailers, vans, containers) used for transporting food sector packaging shall be inspected prior to loading to ensure they are clean, in good repair, suitable for the purpose, and free from odors or other conditions that may impact negatively on the food sector packaging.

RESPONSE: COMPLIANT

EVIDENCE:

- 13.6.3.3** Vehicles (e.g. semi-trucks, trailers, vans, containers) used for transporting food sector packaging from the site shall be secured from tampering using a seal or other acceptable device or system as agreed upon by the carrier and customer.

RESPONSE: COMPLIANT

EVIDENCE:

13.7.1 Control of Foreign Matter Contamination

During my tour of the facility, reviewed the glass and brittle plastic list. Compared that list to what was observed and found nothing missing. They had it separated by location and it appeared to be complete. Last time it was audited was on 3/17/24 and they did find one incident of damage, which they wrote up a work order to have it corrected. The broken covers did not have any pieces missing, but had visual damage, so they are going to replace it. They conduct these inspections monthly, which is a good frequency based on risk.

13.7.1.1 The responsibility and methods used to prevent foreign matter contamination of raw and packaging materials, work-in-progress, food sector packaging, and product contact surfaces shall be documented, implemented, and communicated to all staff.

RESPONSE: COMPLIANT

EVIDENCE:

13.7.1.2 Inspections shall be performed to ensure that the site and equipment remain in good condition and equipment has not become detached or deteriorated and is free from potential contaminants.

RESPONSE: COMPLIANT

EVIDENCE:

13.7.1.3 Containers, storage and transport vessels, equipment, utensils, and tools made of glass, porcelain, ceramics, and brittle plastics shall not be permitted in food sector packaging manufacturing, handling, and storage areas.

Exceptions shall include product made from, or packaged in these materials, measurement instruments with glass dial covers or MIG thermometers required under regulation or part of the processing equipment, and other essential items shielded with shatterproof coverings.

RESPONSE: COMPLIANT

EVIDENCE:

13.7.1.4 Glass, porcelain, ceramics, and brittle plastics that are permitted in manufacturing areas shall be listed on a glass inventory and inspected at a frequency based on risk to confirm that they have not been damaged or to monitor for further damage prior to repair or replacement.

Regular inspections of product handling/contact zones shall be conducted (refer to 2.5.4.3) to ensure they are free of glass or similar material and to establish changes to the condition of objects listed in the glass inventory.

RESPONSE: COMPLIANT

EVIDENCE:

13.7.1.5 Wooden pallets and other wooden objects used in food sector packaging manufacturing, handling, and storage areas shall be dedicated for that purpose, clean, and maintained in good order. Their condition shall be subject to regular inspection.

RESPONSE: COMPLIANT

EVIDENCE:

13.7.1.6 Wooden pallets, wooden top frames, and wooden utensils used in food sector packaging, manufacturing, handling, and storage areas shall be dedicated for that purpose, clean, maintained in good order, and subject to regular inspection.

RESPONSE: COMPLIANT

EVIDENCE:

13.7.1.7 Loose, deteriorated, or damaged objects on and above structures and equipment in food sector packaging manufacturing, handling, and storage areas shall be controlled, repaired, or replaced to prevent foreign object contamination and other food safety hazards affecting raw and packaging materials, work-in-progress, and food sector packaging.

RESPONSE: COMPLIANT

EVIDENCE:

13.7.1.8 Knives and cutting tools used in manufacturing operations shall be controlled, kept clean, and well maintained so as not to present a hazard to raw materials, work-in progress, or food sector packaging. Snap-off blades shall not be used in food sector packaging manufacturing, handling, or storage areas.

RESPONSE: COMPLIANT

EVIDENCE:

13.7.2 Managing Foreign Matter Contamination Incidents

SQF Practitioner reviewed with me the process by which they go through in case there was an incident. The process is controlled by identifying the incident and writing up a repair work order. They show the capacity to handle a situation, through the last glass/plastic inspection activity, which occurred on 3/17/24.

13.7.2.1 In circumstances where glass or similar brittle material breakage occurs, the affected area and equipment shall be isolated, cleaned, and thoroughly inspected prior to restarting operations. Utensils and equipment used for clean-up and footwear of those walking in the vicinity shall be inspected and cleaned if necessary.

RESPONSE: COMPLIANT

EVIDENCE:

13.8.1 Waste Disposal

Reviewed the last pick up of used plates on 6/13/23. reviewed the pick up of waste paperboard on 12/29/23. Liquid waste removal is done on a as needed basis. The liquid waste, which is mostly oil/grease, is stored in a metal barrel . The liquid waste is pumped or dumped into the barrel. They have a local service that picks up the waste. The area surrounding the waste drum is designed to hold the oil/grease, should there be a leak. Dry waste is collected and bailed for recycling. One issue found with waste water not being properly disposed of in a timely fashion. See NCR.

13.8.1.1 The responsibility and methods used to collect, handle, and store waste prior to removal from the premises shall be documented and implemented. This shall include consideration of the path of waste removal to prevent cross contamination in food sector packaging manufacturing, handling, and storage areas. Disposal of hazardous chemicals and toxic substances shall comply with 13.6.2.5.

RESPONSE: COMPLIANT

EVIDENCE:

13.8.1.2 Waste shall be contained in bins identified for its purpose, located in designated areas, and removed at a routine frequency that avoids build-up in food sector packaging, manufacturing, handling, and storage areas.

RESPONSE: MINOR

EVIDENCE: Found mop buckets with dirty water sitting near the printing area.

ROOT CAUSE: Cleaning personnel did not dispose properly the wastewater from mops buckets due to obstructed path to the Janitor's sink

CORRECTIVE ACTION: 1. Created a path to Janitor's Sink to avoid any obstructions
2. Add two drums to dispose mop's wastewater, these drums will be disposed into wastewater container on a weekly basis.

VERIFICATION OF CLOSEOUT: Reviewed photos and training records

COMPLETION DATE: 05/01/2024 **CLOSEOUT DATE:** 05/06/2024

13.8.1.3 Waste disposal equipment, trolleys, vehicles, and collection bins shall be maintained in a serviceable condition and cleaned regularly so as not to attract pests and other vermin. Designated waste accumulation and storage areas shall be well-maintained while awaiting external collection.

RESPONSE: COMPLIANT

EVIDENCE:

13.8.1.4 Reviews of the effectiveness of waste management shall form part of regular site inspections (refer to 2.5.4.3), and the results of the inspections shall be included in the relevant inspection reports.

RESPONSE: COMPLIANT

EVIDENCE:

13.8.1.5 Where applicable, a documented procedure shall be in place for the controlled disposal of trademarked or printed packaging materials and finished products. Where a contracted disposal service is used, the disposal process shall be reviewed regularly to confirm compliance.

RESPONSE: COMPLIANT

EVIDENCE: