SQF Food Safety Audit Edition 9

Southern Minnesota Beet Sugar Cooperative - Renville Factory

Summary

AUDIT DECISION
CERTIFIED WITH EXTENSIONS

CERTIFICATION NUMBER
9698 | 310048

AUDIT RATING
97
Excellent

DECISION DATE
04/15/24

AUDIT TYPE
RE-CERTIFICATION

RECERTIFICATION DATE
03/31/25

AUDIT DATES
03/05/24 - 03/06/24

EXPIRATION DATE
06/14/25

ISSUE DATE
04/15/24

Facility & Scope

Southern Minnesota Beet Sugar Cooperative - Renville Factory
83350 County Rd. 21, Renville, MN 56284

Food Sector Categories:
19. Food Ingredient Manufacture

Products:
Granulated Sugar, Liquid Sugar

Scope of Certification:
Granulated Sugar, Liquid Sugar

Certification Body & Audit Team

CICS Americas Inc.
8350 Ashlane Way Suite 104,
The Woodlands, TX 77382

CB#: CB-1-CICS
Accreditation Body: ANSI
Accreditation Number: 1087

Lead Auditor: Joseph Khanona (449963)
Technical Reviewer: Luis Palacios (124403)

Hours Spent on Site: 16
Hours of ICT Activites: 0
Hours Spent Writing Report: 8

Non-Conforming

11.1.2 Building Materials

Floors are constructed of smooth and dense impact-resistant material and properly graded for effective drainage of overflow or wastewater with the exception of the concrete slab floor of the Sugar Packaging warehouse has cracks and unsealed joints. Wastewater during the audit was observed to be properly discharged. Drains were observed to be located and constructed for ease of cleaning and inspection. There are no waste traps on site. The site has a documented risk assessment for overhead ducting, pipes, or conduit on risk assessment was carried out on January 4, 2024.
The walls, ceilings, and doors are of durable construction with smooth and light-colored surfaces. These areas were observed to be relatively clean during the audit inspection. Wall to wall and wall to floor junctures were observed to be sealed and free of debris. Products are processed and handled in an enclosed system and maintained to prevent the contamination of products. Products are not exposed at any step of the process after cleaning and washing step.

Overhead cleaning was found to be part of the master cleaning schedule. There were not any overhead pipes for sanitary waste or wastewater. Doors, windows, and frames were observed to be properly constructed of materials with the same functional requirements as internal walls and partitions. The ceilings in all food processing and handling areas are constructed of wood. Drop ceilings were not used. Stairs, catwalks, and platforms were observed during facility inspection to be constructed and designed so that food contamination is avoided.

N/A 11.1.2.3 – There are no waste traps on site.
N/A 11.1.2.6 – The site does not have pipes carrying sanitary waste or wastewater that are located directly over product lines or storage areas.

Minor 11.1.2.1 – The concrete slab floor of the Sugar Packaging warehouse has cracks and unsealed joints.

11.1.2.1 Floors shall be constructed of smooth, dense, impact-resistant material that can be effectively graded, drained, impervious to liquid, and easily cleaned. Floors shall be sloped to floor drains at gradients suitable to allow the effective removal of all overflow or wastewater under normal working conditions.
Where floor drainage is not available, plumbed options to handle overflow or wastewater shall be in place.

RESPONSE: MINOR

EVIDENCE: The concrete slab floor of the Sugar Packaging warehouse has cracks and unsealed joints.

ROOT CAUSE: Floor cracks were not part of the planned maintenance and were not identified in routine inspections or audits.

CORRECTIVE ACTION: Floor cracks to be repaired and sealed. Floors will be added to routine maintenance schedules and internal inspection checklist.

VERIFICATION OF CLOSEOUT: The root cause, corrective action, and supporting evidence were reviewed. However, they will need to be verified in the next audit cycle.

COMPLETION DATE: INVALID **CLOSEOUT DATE**: 03/25/2024

2.5.4 Internal Audits and Inspections

The Internal Auditing & Facility Inspections policy, dated April 8, 2022, outlines the site's internal auditing program. Internal auditing consists of both corporate internal audits and local facility internal inspections. In addition, it defines the procedure for scheduling and conducting internal audits so the effectiveness of the SQF system is verified has been documented and implemented. Site conducts internal audits to ensure food safety, and quality programs are implemented, monitored, and verified. This program verifies compliance with regulatory requirements, the BSN standards, and food safety SQF systems. The Internal Audit Program is maintained by the SQF Practitioner. If there were any changes implemented from the internal audits that have an impact on food safety, it would trigger an SQF review. Facility and equipment inspections, internal audits of the food safety plan, and regulatory inspections are part of the internal audit programs. The frequency of the audits is communicated to management and required monthly for internal inspections and annually for the internal audits to verify the effectiveness of the SQF Food Safety Code that have been documented and implemented.

Personnel conducting audits have been properly trained and audit areas independent of their function by using teams. The Director of Technical Services (SQF Practitioner) completed PCQI training for Preventive Control for Human Food through FSPCA on August 4, 2016; Implementing SQF System through SQFI on September 24, 2014; and the inhouse Internal Auditor training on November 21, 2013. The trainer was trained on Internal Auditor principles through AIB International on November 22, 2011. The SQF backup, completed PCQI training for Preventive Control for Human Food through Food Industry Consulting on July 21, 2022, and Mastering SQF, edition 9: food Manufacturing through Register Crop on December 6, 2022. The Quality Assurance Manager completed PCQI training for Preventive Control for Human Food Online Course through AIB International on January 19, 2023; The HACCP online through AIB International on May 31, 2023; Implementing SQF System through SQFI on May 31, 2023; and the Principles of Internal Auditing through NSF International on May 30, 2023.

The site completed the internal auditing for SQF food safety code on January 4, 2024. However, the site did not maintain records for the monthly internal Good Manufacturing Practices and facilities inspection from January

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: MINOR

EVIDENCE: The site did not maintain records for the monthly internal Good Manufacturing Practices and facilities inspection from January 2023 through January 2024. Additionally, the February 2024 Internal GMP audit findings were not documented in the site's defined corrective and preventive action system for internal auditing and inspections.

ROOT CAUSE: Addition of routine items with GMP inspections caused confusion when reporting action items.

CORRECTIVE ACTION: GMP inspections were separated from routine findings to add clarity to GMP Inspection Documentation of inspections and findings.

VERIFICATION OF CLOSEOUT: The root cause, corrective action, and objective evidence were reviewed and accepted.

COMPLETION DATE: 03/15/2024 **CLOSEOUT DATE**: 03/25/2024

11.2.5 Cleaning and Sanitation

The Cleaning, Sanitation, & Waste Management, dated April 8, 2019, defines the methods and responsibility for the effective cleaning of the food handling and processing equipment and environment and storage areas. The site non-GMP areas such as factory beet ends, flat storage warehouses, staff amenities, grounds, etc. maintain these areas in a hygienic manner to the extent possible to prevent cross contamination with GMP areas, risks to product or packaging, or risks to personnel that might work in GMP areas. The cleaning of these areas is verified through routine inspection. The Moisture sensitive environments such as sugar warehouses or granulated sugar handling areas employ dry cleaning techniques to limit microbial proliferation. Dry cleaning involves a top-down approach and includes vacuuming, sweeping, and other means to keep floors, walls, and equipment surfaces clean. The site processing equipment employed for liquid sugar, medium invert, and coating syrup routinely clean tanks, piping, gaskets, and fittings to minimize the presence of microbiological spoilage organisms. The site Clean in Place (CIP) Systems flush systems with water and sanitize them employing hot water treatment. Effective sanitization occurs when the effluent water is monitored and maintained above 180° F for a minimum of 15 minutes. The site restarts cycles when temperatures drop below 180° F. CIP frequencies are determined by the Facility based on microbiological reporting. The site strives to meet National Food Processors Association (NFPA) Canners Standards and National Soft Drink Association (NSDA) Bottlers Standards. In addition, facilities sanitize tanks before initial use, after any maintenance, and after any periods greater than 24 hours without use. Facilities sanitize couplers, fittings, gaskets, reducers, and caps during the CIP process by using chlorine sanitizing solutions or clean out of place (COP) washers. Where applicable, facilities also ensure spray balls are functioning during CIP to ensure adequate coverage. The site uses sanitizing solutions for couplers, fittings, gaskets, reducers, caps, etc. use chlorine solutions between 100-200 ppm. Solutions used on food contact surfaces exceeding 200 ppm is against federal regulations; therefore, Facilities verify concentration using chlorine test strips and include results in records. Solutions older than 24 hours or solutions found outside of the 100-200 ppm range are discarded. Facilities choosing this route should implement a work instruction and training for mixing solutions. The detergents and sanitizers that have been mixed for use correctly, and according to the manufacturers' instructions, stored in containers that are suitable for use, and clearly identified. Mix concentrations are verified, and records maintained. However, the site lacks training records for staff assigned to verify the detergents and sanitizers' chemical concentrations. Moreover, during the record

11.2.5.2 Detergents and sanitizers shall be suitable for use in a food manufacturing environment, labeled according to regulatory requirements, and purchased in accordance with applicable legislation. The organization shall ensure:
i. The site maintains a list of chemicals approved for use;
ii. An inventory of all purchased and used chemicals is maintained;
iii. Detergents and sanitizers are stored as outlined in element 11.6.4;
iv. Safety Data Sheets (SDS) are provided for all detergents and sanitizers purchased; and
v. Only trained staff handle sanitizers and detergents.

RESPONSE: MINOR

EVIDENCE: The site lacks training records for staff assigned to verify the detergents and sanitizers' chemical concentrations. Moreover, during the record review process, inconsistencies were observed in reporting results. Results were reported as an absolute number and, in some cases, only as "Good," with no clear definition of what "Good" meant within the established procedure. Furthermore, the operators performed the concentration verification while the QA technician documented the results. However, this step was not reflected in the in-house procedure.

ROOT CAUSE: SOP Program was currently being updated at time of audit. New program will ensure proper adherence to updated SOP's along with proper documentation of training.

CORRECTIVE ACTION: CIP Procedure was updated to include digital documentation of sanitation chemical strength, new SOP, and currently training to these procedures.

VERIFICATION OF CLOSEOUT: The root cause, corrective action, and objective evidence were reviewed and accepted.

COMPLETION DATE: 04/01/2024 **CLOSEOUT DATE**: 02/25/2024

Section Responses

Audit Statement	Audit
SQF Practitioner Name	Name the designated SQF Practitioner **RESPONSE:** DAN DUMAS
SQF Practitioner Email	Email of the designated SQF Practitioner **RESPONSE:** DAN.DUMAS@SMBSC.COM
Opening Meeting	People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** GREG MARTIN, VP OPERATIONS, DOMINIC JOHNSON, WAREHOUSE MANAGER, GRAIG GLAESER, DIRECTOR OF SUPPLY CHAIN; AUSTIN GESSELL, FACTORY CHEMIST; MIA BURNS, QA SPECIALIST; GARY CORNELIUS, DIRECTOR OF RISK MANAGEMENT; KAITLIN CULVER KUEMPE, SQF PRACTITIONER; DAN DUMAS, DIRECTOR OF TECHNICAL SERVICES (SQF PRACTITIONER); LARRY BLUME, DIRECTOR OF ENGINEERING; KELLY SCHEFFLES, FACTORY MANAGER; PATRICK DAWN, OPERATIONS MANAGER, AND LEAD AUDITOR.
Facility Description	Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details **RESPONSE:** THE SITE IS ENCOMPASSED IN A 400,000 SQUARE FOOT PLUS FACILITY ON 1,200 ACRES OF LAND. THE SITE HAS THREE TANK FARMS FOR HEAVY SYRUP STORAGE, THE FACTORY PLANT, AND GMP COMPLIANT WAREHOUSING AREAS. THE SITE TAKES THE RAW SUGAR BEETS AND TURNS THE ROOTS THROUGH A SERIES OF CHEMICAL ACTIONS INTO GRANULATED AND LIQUID SUGAR. THE SITE LOADS OUT SUGAR IN RAIL CARS, TRUCKS, OR PACKED INTO BAGS OR TOTES. THE SITE HAS ABOUT 400 EMPLOYEES WORKING 4-12 HOUR SHIFTS 7 DAYS A WEEK. THE SITE WAS BUILT IN 1975.
Closing Meeting	People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** DOMINIC JOHNSON, WAREHOUSE MANAGER, GRAIG GLAESER, DIRECTOR OF SUPPLY CHAIN; AUSTIN GESSELL, FACTORY CHEMIST; MIA BURNS, QA SPECIALIST; GARY CORNELIUS, DIRECTOR OF RISK MANAGEMENT; KAITLIN CULVER KUEMPE, SQF PRACTITIONER; DAN DUMAS, DIRECTOR OF TECHNICAL SERVICES (SQF PRACTITIONER); LARRY BLUME, DIRECTOR OF ENGINEERING; KELLY SCHEFFLES, FACTORY MANAGER; PATRICK DAWN, OPERATIONS MANAGER, AND LEAD AUDITOR.

Auditor Recommendation	Auditor Recommendation **RESPONSE:** IT IS RECOMMENDED THE SITE BE RECERTIFIED PENDING CLOSURE OF CORRECTIVE ACTIONS
2.1.1	**Management Responsibility** The site has a food safety Policy Statement that is entitled “Food Safety and Quality Mission Statement” (dated October 16, 2023), and it was signed on January 22, 2024. This statement has been implemented by senior management and signed by the CEO. The Policy statement covers customer and regulatory requirements, establishing and maintaining a food safety culture, and the use of continuous improvement of the system. The policy communicates that the primary mission is to provide our customers quality products at competitive pricing on a national platform, and fully committed to providing appropriate resources to maintain HACCP-based and regulatory-compliant food safety and quality assurance programs. To further advance commitment, the site meets the stringent requirements of Global Food Safety Initiative (GFSI) certification standards to ensure compliance with the Federal Food, Drug and Cosmetic Act and all current requirements set forth in the Food Safety Modernization Act. The policy further conveys and reaffirm its status in the industry through established teams that have a long-standing tradition for championing continual improvement. These efforts consistently improve processes, programs, and products, which ensures fulfillment of the site’s mission and that we consistently exceed customer expectations. Part of this is to establish a food safety and quality culture with objectives that are reviewed annually. The site promotes and provide staff with training and instruction to report food safety and quality problems to personnel with the authority to initiate action to ensure continuity of our established culture. The Policy is communicated to the facility's staff by way of posting in the Main employees’ lunchroom and several offices. It’s communicated through new hire orientation, annual orientation and posted throughout the facility. The policy was written and communicated in English language. There is an annual refreshing training was carried during October and the last hiring process was carried out on January 5, 2024. A food safety culture was in place. Plant staff is required to report food safety issues to management and are empowered to make decisions regarding food safety, as evidenced by the job descriptions and interviews with employees. The training program was in place for regulatory and food safety responsibilities. Adequate resources were in place for the maintenance of the SQF system. Food safety objectives were established for employees to understand goals during internal inspections to 99.45%, food safety incidents rate 0.08%, and continuously working toward 0 substantiated foreign customer complaints. The site continually monitors food
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; 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. 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 the 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. Employees are informed and held accountable for their food safety and regulatory responsibilities;
v. Employees are positively encouraged and required to notify management about actual or potential food safety issues; and
vi. Employees 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 a backup for the 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 related 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: Food Manufacturing 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 products.

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 designate defined blackout periods that prevent unannounced re-certification audits from occurring out of season or 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

The Food Safety and Quality System Review dated June 14, 2022, outlines the site's food safety and quality assurance system review program, including local management reviews to ensure that the quality programs align with current regulations, industry best practices, and customer expectations, included food safety culture, food safety objectives, and any changes to the SQF system. Food safety fundamentals and the food safety plans are to be reviewed by management when any changes are made in products and systems. The SQF practitioner is responsible for maintaining records of all reviews, validations, and changes to the SQF System. The annual review was performed on August 15-16, 2023, and it includes elements outlined in 2.1.2.1 of the SQF system. The annual review records were reviewed during the audit, and it was found to be effectively documented and maintained by the Director of Technical Services (SQF Practitioner). The Quality Assurance hosts monthly quality meetings to discuss current internal issues, program updates, customer complaints, and customer, incidents, and internal and external audit results and/or information. Records of these reviews utilize meeting minutes that are emailed to key personnel and posted electronically. The monthly management meetings took place to ensure communication on matters impacting the SQF system from February 20, 2023, September 29, 2023, and February 28, 2024, were reviewed during the audit, and it was found to be effectively documented and maintained by the Director of Technical Services (SQF Practitioner).

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 reviews.
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

The customer complaint management procedure, dated September 2, 2021, defines the methods and responsibilities for handling customer complaints, and effective complaint handling to drive root cause analysis and continuous improvement. Complaints may be received by multiple parties, including Account Support Department representatives, the National Sugar Marketing (NSM) Quality Assurance, Partner Quality Assurance, and local warehouses. Receiving parties communicate complaint information to NSM Quality Assurance as complaints are received. NSM strives to initiate customer communication within 24 hours for food safety/security complaints and five (5) business days for quality complaints that do not affect customer production. NSM Quality Assurance submits complaint information promptly by emailing pertinent complaint information within 48 hours.

The NSM Quality Assurance classifies customer complaints during the receipt and communication process. Classification can be described as Low: Customer has noted an issue with the product, but the issue has not resulted in a product rejection nor a customer hold of their products. Moderate: Customer has noted an issue with the product that has resulted in a rejection or hold of sugar products. High: Customer has noted an issue with the product that has subsequently resulted in the customer holding their finished products or retrieving their products from commerce.
The intercompany warehouses communicate product/shipment issues using the electronic complaint management system. The site handles intercompany complaints in the same manner as customer complaints.

The customer complaints records from 2023 and 2024 YTD, were reviewed during the audit, and there were Six customer complaints in total received at the site, of which five were quality issue, and one of foreign material. The foreign material complaint was C23057, the customer reported discovering a screw and washer while processing the product on their line. RCA was completed. To resolve the design issue, the site hired a third-party contractor to weld a bead ring around the loading spout. The site quality team also reviewed a new return service form to ensure that when new work is completed equipment is properly inspected before use. Furthermore, the site will install loadout covers to prevent foreign material during the loading process. Th complaint was closed on June 28, 2023. Response was sent to customer on June 26, 2023. Records of customer

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** A food safety manual has been developed and is maintained electronically. Policies and procedures are documented in the manual and outline how the SQF Code is met. The food safety manual contains the scope of the certification, a list of products and processes in the scope, the organizational chart, all food safety policies, and procedures that make up the SQF System, reference to the raw material, packaging and finished product specifications, process controls that impact food safety and the food safety regulations that apply to the manufacturing site. It is made available to all relevant staff by means of access to the quality department or electronic read only. Changes to the system were to be validated or justified. There had not been any changes implemented that had an impact on the site's ability to deliver safe food.
2.2.1.1	The methods and procedures the site uses to meet the requirements of the SQF Food Safety Code: Food Manufacturing shall be maintained in electronic and/or hard copy documentation. They 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 the country(ies) of sale (if known); v. Raw material, ingredient, packaging, and finished product specifications; vi. Food safety procedures, prerequisite programs, food safety plans; vii. Process controls that impact product safety; and viii. Other documentation necessary to support the development, 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** The document control policy, dated April 8, 2019, defines the establish guidelines, methods, and responsibility for maintaining document control and ensuring staff have access to current requirements and instructions for document control. The procedure ensures that the site controls the creation, approval, and distribution of documents. This practice ensures that personnel only have access to current documents and that document history is maintained. The site has based its established document tier system on the principles outlined in ISO 9001 standard approach to documentation, which includes policies, procedures (SOP's), work instruction, and records. Records were found during the audit to be readily accessible and properly stored. No issues were noted with randomly selected documents throughout the audit.
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

The document control policy, dated April 8, 2019, defines the methods, and responsibility for verifying, maintaining, and retaining records. The facility has documented procedures for recording production and quality monitoring as well as the proper correcting and initialing of errors. These are based on company and regulatory requirements. Records were observed to be readily accessible, legibly filled out, securely stored to prevent damage, and have documented retention times. The records completion and retention policy, dated October 30, 2023, defines the requirements for establishing, completing, and retaining records. Records are used to ensure and prove that personnel complete activities required by the site's food safety and quality programs. Additionally, records may be used as a legal document or shared with customers. The site's quality assurance team is responsible for implementing this policy and ensuring employees are trained on it, and for furnishing records for customer complaints and corrective action requests. The retention time for records was past the determining shelf life of the product (two years).

The foreman report/QA Log sheet (includes MD CCP records), QA, and Lot Assignment for Bulk Rail loading (MD CCP record, screen and Magnet inspection records, 50 lbs. bagging metal detector check, from April 2, 2023, June 23, 2023, and December 5, 2023, were reviewed during the audit. The prospective departments kept records and followed defined processes to ensure completion.

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 shall be legible and confirmed by those undertaking monitoring activities that demonstrate inspections, analyses, and other essential activities that have been completed.

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 minimum the product shelf-life or established by the site if no shelf-life exists.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.1 Specification, Formulation, and Realization

The specification management policy, dated April 8, 2019, defines, and communicate the responsibilities and methods for specification management. Specifications include final product specifications, customer-specific specifications, ingredient/process aid specifications, packaging specifications, contract manufacturers' specifications/agreements, and specifications for contract services relating to food safety and quality assurance or conducted in GMP areas. The site does not participate in product development or commercial realization. Additionally, no new products are developed. In case of new products, the food safety team is in charge of validate, verify, and update the food safety and HACCP Plans, where a change to ingredients, process, or packaging occurs that may impact food safety. The process flows for all new and existing manufacturing processes are designed to ensure that product is manufactured according to approved product formulations and to prevent cross-contamination. Records were properly maintained by the Director of Technical Services (SQF Practitioner).

2.3.1.1 The methods and responsibility for designing and developing new product formulations and converting product concepts to commercial realization shall be documented and implemented.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.1.2 New product formulations, manufacturing processes, and the fulfillment of product requirements shall be established, validated, and verified by site trials and product testing as required to ensure product safety.

Product formulations shall be developed by authorized persons to ensure that they meet the intended use. Where necessary, shelf life trials shall be conducted to validate and verify a new product's:
i. Pre-consumer handling and storage requirements, including the establishment of "use by," "best before dates," or equivalent terminology;
ii. Microbiological criteria, where applicable; and
iii. Consumer preparation, where applicable, and storage and handling requirements.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.1.3 A food safety plan shall be validated and verified by the site food safety team for each new product and its associated process through conversion to commercial production and distribution or where a change to ingredients, process, or packaging occurs that may impact food safety.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.1.4 Product formulations and manufacturing processes for products included in the scope of certification shall be reviewed when there are changes in materials, ingredients, or equipment.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.1.5 The process flows for all new and existing manufacturing processes shall be designed to ensure that product is manufactured according to approved product formulations and to prevent cross-contamination.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.1.6 Records of product design, formulations, label compliance, process flows, shelf life trials, 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 specification management policy, dated April 8, 2019, defines the methods and responsibility for developing, managing, and approving raw material, finished product, and packaging specifications. The site ensures that specifications for products, packaging, ingredients/process aids, and contracted service providers are documented and current. Specifications define products or services and ensure they do not negatively impact product safety or quality and are approved by relevant parties prior to implementation. Specifications for raw materials, packaging, and ingredients have been documented. There are current registers in place for raw materials, packaging materials, and labels. Specifications for the bag, sugar beet, and bisulfite, were reviewed and found to be current. A policy defining the methods and responsibilities for developing and maintaining specifications has been documented and implemented, which noted the use of the supplier specifications. Addressed the requirement that raw material suppliers notify the site of any changes to product composition. Raw and packaging materials are validated to ensure product safety, regulatory requirements, and quality are met by means of the receipt of the Letters of Guarantee. Product labels are approved by corporate and were noted in the development procedures. Records of specification reviews were on file in the event of changes that could impact product safety. Finished product specifications are available for the finished products the site produces. The specifications were in the electronic database for all of the quality attributes. The storage requirements, composition to meet label claims, packaging, and shelf life were noted on the specification for each product. Finished product specifications for granulated sugar were reviewed. The Contract Service Providers were on a master list that had specifications for descriptions of service. A list of current contract service providers is maintained and found to include providers of services including Labs, and pest control. Contract arrangements for pest control were reviewed during the audit and found to be satisfactory. The contractors were required to undergo training on their first visit to the site as noted on the master list. The contract service registry dated September 28, 2023, was reviewed during the audit, and it includes a full description of the services to be provided, and detail relevant training requirements of all contract personnel. The finished product specification for granulated sugar, and liquid sucrose beet 67.5 degree were reviewed during the audit and were found to be effectively documented and maintained by the quality assurance team.
2.3.2.1	The methods and responsibility for developing, managing, and approving raw material, finished product, and packaging specifications shall be documented. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.3.2.2	Specifications for all raw materials and packaging, including, but not limited to, ingredients, additives, hazardous chemicals, processing aids, and packaging that impact finished product safety shall be documented and kept current. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.3.2.3	All raw materials, packaging, and ingredients, including those received from other sites under the same corporate ownership, shall comply with specifications and with the relevant legislation in the country of manufacture and country(ies) of destination if known. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.3.2.4	Raw materials, packaging, and ingredients shall be validated to ensure product safety is not compromised and the material is fit for its intended purpose. **RESPONSE:** COMPLIANT

EVIDENCE:

2.3.2.5	Site management shall require approved raw materials suppliers to notify the site of changes in product composition that could have an impact on product formulation (e.g., protein content, moisture, amino acid profiles, contaminant levels, allergens, and/or other parameters that may vary by crop or by season). **RESPONSE:** COMPLIANT **EVIDENCE:**
2.3.2.6	Verification of packaging shall include a certification of all packaging that comes into direct contact with food meets either regulatory acceptance or approval criteria. Documentation shall either be in the form of a declaration of continued guarantee of compliance, a certificate of conformance, or a certificate from the applicable regulatory agency. In the absence of a certificate of conformance, certificate of analysis, or letter of guarantee, analyses to confirm the absence of potential chemical migration from the packaging to the food contents shall be conducted and records maintained. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.3.2.7	Finished product labels shall be accurate, comply with the relevant legislation, and be approved by qualified company personnel. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.3.2.8	Description of services for contract service providers that have an impact on product safety shall be documented, current, include a full description of the services to be provided, and detail relevant training requirements of all contract personnel. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.3.2.9	Finished product specifications shall be documented, current, approved by the site and its customer, accessible to relevant staff, and shall include, where applicable: i. Microbiological, chemical, and physical limits; ii. Composition to meet label claims; iii. Labeling and packaging requirements; and iv. Storage conditions. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.3.2.10	Specifications for raw materials and packaging, chemicals, processing aids, contract services, and finished products 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:

2.3.3 Contract Manufacturers

NA 2.3.3.1 -4 - The site does not have contract manufacturers.

2.3.4 Approved Supplier Program

The Approved Supplier policy, dated April 21, 2021, defines the requirements for supplier approval programs relating to sugar products, ingredients, processing aids (final product), packaging, and equipment. These requirements ensure that incoming materials are of appropriate quality and conform to agreed specifications. The policy includes specifications, the level of risk to the facility and how approved supplier status is granted, and the food fraud assessment and mitigation plan. Also included are methods to review the approved supplier performance and status. Emergency suppliers were allowed with upper management approval; however, none had been used in the past year. A register is maintained of all current approved suppliers, which was reviewed during the audit and found to be complete. Raw materials found in the storage warehouse (sugar beet, bag, and bisulfite) were verified to have come from suppliers on the Approved Supplier List and supplier contact details. Third-party audits were on file for the approved suppliers of these same ingredients and packaging materials with a summary of food safety controls for the beets. Raw materials from sister facilities were allowed as they were under the same corporate approval requirements but had not occurred in the past year. When sugar beet arrives, every receiving is taken and tested for weight, the example was reviewed dated April 2, 2023. When materials arrive at this facility, they are verified using a certificate of analysis and testing. The Quality Assurance team is responsible for evaluating and approving suppliers that influence finished product safety and quality. The purchasing manager is responsible for ingredient, packaging, processing aid, and equipment. In general, all ingredients and process aids employed for use in final product require a documented risk assessment with consideration to FDA warning letters and/or supplier recalls and may not be sourced from China. In addition, ingredient and final product processing aids undergo a more detailed risk assessment that includes additional information such as food fraud vulnerability. Based on the risk assessments, raw materials do not require food fraud mitigation plans. Risk assessment updates are emailed and/or posted to Basicsafe software, document management system. The Sodium Carbonate risk/Vulnerability Assessment Ingredient/Raw Material for Soda Ash performed on February 22, 2024, were reviewed. Risk type evaluated were, Allergen Contamination, Physical Contamination Microbiology, Chemical Risk, including radiological, Economic Adulteration, BCCGS 5.4.3 and 21 CFR 117.130, and summary section for the risks. No gaps were identified, and the report was reviewed and signed by the Director of Quality. The Magna Enzyme dextrose approved supplier records approved on January 12, 2024, the records included the SDS sheet, Kosher, Letter of continuing Guarantee, Technical Data

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 past performance of a supplier and the risk level of the raw materials, ingredients, processing aids, packaging, and services supplied, and shall contain at a minimum:
i. Agreed specifications (refer to 2.3.2);
ii. Reference to the level of risk applied to raw materials, ingredients, packaging, and services from the approved supplier;
iii. A summary of the food safety controls implemented by the approved supplier;
iv. Methods for granting approved supplier status;
v. Methods and frequency of monitoring approved suppliers;
vi. Details of the certificates of 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, certificates of analysis, or sampling, and testing. The verification frequency shall be identified by the site.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.4.4 The receipt of raw materials, ingredients, processing aids, and packaging from nonapproved 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, ingredients, and packaging 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 receiving inspections as all other material providers.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.4.6 Supplier audits shall be based on risk (as determined in 2.3.4.2) 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 FDA Registration & Regulatory Compliance, dated November 22, 2019, defines the site's requirements to register to process, pack, or hold food as well as to outline the methods for handling regulatory facility inspections The NSM Quality Group is responsible for the management of the program. The site operates under the jurisdiction of the FDA. The site keeps updated about changes in relevant legislation, technical developments, and industry codes of practice in their specific industry, by means of business circulars. The FDA Registration & Regulatory Compliance, dated November 22, 2019, defines 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. The site has a written provision that the certification body, and SQFI will be notified within 24 hours if a food safety event requiring public notification occurs.

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 in the country of manufacture and sale. This includes compliance with legislative requirements applicable to maximum residue limits, food safety, packaging, product description, net weights, nutritional, allergen, and additive labeling, labeling of identity preserved foods, 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 as a result of a regulatory warning or event. Notification to SQFI shall be by email to foodsafetycrisis@sqfi.com.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.2 Good Production Practices

The Good Manufacturing Practices & Prerequisite Programs, dated June 14, 2022, describes the site's prerequisite programs employed to meet FDA requirements for Current Good Manufacturing Practices (GMP) as described in the Code of Federal Regulations 21 part 117 and to support facilities Hazard Analysis and Critical Control Point (HACCP) programs. Additional requirements from SQF Module 11 that are included in the SQF good manufacturing practices that are applicable to the scope of this certification. The site's prerequisite programs are developed for the HACCP program and to meet GMP requirements. Programs consist of Employee Training, Personnel Practices, Integrated Pest Management, Equipment Calibration, Facility & Equipment Maintenance, Cleaning & Sanitation, Water & Air Programs, Physical Contaminant Prevention & Control, Product Storage & Warehousing, Sanitary Transportation, Allergens & Sensitizing Agents, Chemical Control & Approval, Supplier Approval, Visitors management program. The Hazard Analysis and Risk-Based Preventive Controls, these requirements are communicated through the food safety plans. These food safety pre-requisite programs are found in the manual. The effectiveness of the pre- requisite programs was to be verified based on a schedule.

2.4.2.1 The site shall ensure the applicable Good Manufacturing Practices described in Module 11 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 that ensure food safety is not compromised.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.2.2 The Good Manufacturing Practices applicable to the scope of certification outlining 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, dated April 8, 2019, defines the requirements for food safety plans. The site maintains an active food safety plan based on the guidelines provided by the National Advisory Committee for the Microbiological Criteria for Foods (NACMCF), the Codex Alimentarius Commission (CAC), and FDA regulations (21 CFR 117.126). Food Safety Plans are specific to each location but might share hazard analyses conducted by the Preventive Control Qualified Individual (PCQI) team. The PCQI Team prepares and oversees the food safety plans. The site has two HACCP plans, the Food Safety Plan is documented "Granulated Sugar HACCP Plan "dated May 17, 2023, and Liquid Sucrose HACCP Plan, dated May 17, 2023. The Food Safety Plan has been prepared following the 12 steps of the Codex Alimentarius Commission HACCP guidelines. The site has a multi-disciplinary Food Safety Team composed of 6 people. The team has been trained in the HACCP preliminary steps and the seven principle steps. The Plan includes a list of 2 products within the scope of the certification, a complete product description, intended product use, and process flow diagram including all input and output steps in the process. The process flow has been verified by the food safety team.

The program includes hazards analysis following the process flow diagram which includes the physical, chemical, and microbiological hazards for each process step, ingredient, and packaging. The site routinely challenges detectors and reject mechanisms as part of HACCP monitoring. The site ensures that metal detectors are monitored at least once per shift and pass metal detector checks before permitting the product's entrance into interstate commerce. The metal detection limits are 1.5 mm for ferrous, 1.8 for nonferrous, 2.0 mm for stainless, and 2.0 mm for aluminum. Screens are employed to remove product lumps and monitor systems for foreign material contamination from the liquid sugars' finished products. The screen size is set at 100 microns maximum, and socks are checked once per shift for integrity and continuously monitored for differential pressure.

The site ensures that CCP monitoring is documented accurately, legibly, and concurrently with the monitoring as outlined in the document control, dated April 8, 2019. In addition, metal detector monitoring records includes downtime/non-scheduled line operation notations during scheduled monitoring so that periods of time where lines are not running is documented. If the site experience deviations during routine CCP monitoring, immediate

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 and maintained and shall outline how 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 raw materials, packaging, processing aids, 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 endpoints 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 products included in the scope of the food safety plans. The descriptions shall reference the finished product specifications (refer to 2.3.2.9) plus any additional information relevant to product safety, such as pH, water activity, composition, and/or storage conditions.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.5 The intended use of each product shall be determined and documented by the food safety team. This shall include target consumer groups, the potential for consumption by vulnerable groups of the population, requirements for further processing if applicable, and potential alternative uses of the product.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.6 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 materials, packaging, service inputs (e.g., water, steam, gasses as applicable), 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:

2.4.3.7 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:

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

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.9	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:**
2.4.3.10	Based on the results of the hazard analysis (refer to 2.4.3.8), 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:**
2.4.3.11	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 all of the critical limits to ensure the 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 2.5.2.1). **RESPONSE:** COMPLIANT **EVIDENCE:**
2.4.3.12	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:**
2.4.3.13	The food safety team shall develop and document deviation procedures that identify the disposition of affected product 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 safety failure. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.4.3.14	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:**

2.4.3.15 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:

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

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.17 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

The Product Sampling & Retain Requirements, dated April 22, 2021, describes the methods, responsibility, and criteria for sampling, inspecting, and/or analyzing raw materials, work-in- progress, and finished product. The policy further defines the requirements for collecting samples for laboratory analysis and outline retain sample holding requirements. This policy ensures that shipped products are sampled in a hygienic manner, analyzed to agreed specifications, and that retains are available if reanalysis is deemed necessary. The employees collecting samples ensure that the collected samples represent the product being shipped and that labs complete analyses before releasing product for shipment.

The site also holds retain samples for lots shipped and ensures that shipped products meet agreed specifications. The Granulated Sugar is sampled at point of use a minimum for Moisture, SO2, and Sediment. The site analyzes the granulated sugar once per shift. Color, Ash, Visual Specks, and Granulation is at a minimum, sampled/analyzed every 2,000 cwt for bulk and every four hours for bagged product. The granulated sugar samples are collected from a sample port or by using a clean, food-contact designated utensil. The sample utensil must be handled and stored in a sanitary manner. The liquid sugar products are sampled from sample ports (petcock valve) or by directly sampling the tanker via ladle. Employees collecting samples, must ensure the samples are collected aseptically in sterile containers unless otherwise noted in writing by the customer. The site requires micro analyses to be conducted on a 2,000 CWT dry-weight basis for liquid sucrose. NSM utilizes trending of these samples for customer inquiries, complaints, etc. The site ship liquid samples in sterile containers overnight to Central Laboratory, ISO 17025 Accredited Laboratory for Microbiology Testing, between Mondays and Thursdays for Total Coliform Testing. Also, the technician/sampler complete the form liquid Sugar Request for Chemical Analysis to accompany the sample shipment.

The Certificates of Analysis are required for food ingredients and finished products. All policies and procedures are in place and matched up to ensure testing is completed according to the policy. All tests conducted are to a nationally recognized standard or equivalent. Proficiency testing is not needed because there are no critical tests being completed on site. The site retains for granulated sugar are collected as one per daily lot number at a minimum. Granulated sugars retain are held for the shelf life (2 years) of the product. Liquid Sucrose hold

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 specifications 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 or 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 analyses, 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 an equivalent international standard, and included on the site's contract service specifications list (refer to 2.3.2.11).

RESPONSE: COMPLIANT

EVIDENCE:

2.4.4.3 On-site laboratories conducting chemical and microbiological analyses that may pose a risk to product safety shall be located separate from any food 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 food processing and handling areas.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.4.5 Retention samples, if required by customers or regulations, shall be stored according to the typical storage conditions for the product and maintained for the stated shelflife of the product.

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

The Nonconforming Product and Materials, dated August 2, 2022, defines the responsibility and methods outlining how to handle non-conforming product, raw material, ingredient, work-in-progress, or packaging, which is detected during receipt, storage, processing, handling, or delivery from approved suppliers to to prevent inadvertent use or distribution.
The Nonconforming Products includes products that are not suitable for direct sale without further processing or reclassification. These products are considered downgraded products but should not be allowed to be further contaminated with the intent of removal. Methods to segregate, identify, handle, and dispose of the product include placing it in the holding area, use of hold tags, and use of status electronically. Nonconforming products or equipment is required to be identified, segregated, or disposed of.

The hold records for 219,700 lbs. of Bulk Fine Cran., Lot number SR24064R3, placed on hold due to Heavy Metal Fines, were reviewed during the audit. The hold records identify, product name, date, by whom and when, lot number, quantity placed on hold. Relevant staff is aware of the Hold policy, as evidenced by interviews with QA, warehouse and production employees. The Quality Assurance team is responsible for interpretation of FDA law, certification standards, and their application to Company policies. Responsible for verifying GMP and prerequisite program compliance.

The Warehouse/General Managers is responsible for determining nonconforming product identification and ensuring that warehouses label and segregate non-conforming products. The site employees are responsible for identifying and reporting nonconforming products and materials. The Director of Technical Services (SQF Practitioner) maintains records of the nonconforming product.

2.4.5.1 The responsibility and methods outlining how to handle non-conforming product, raw material, ingredient, work-in-progress, or packaging, which is detected during receipt, storage, processing, handling, or delivery, shall be documented and implemented. The methods applied shall ensure:
i. Non-conforming product is quarantined, identified, handled, and/or 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 personnel are aware of the organization's quarantine and release requirements applicable to product placed under quarantine status.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.5.2 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

The Nonconforming Product and Materials, dated August 2, 2022, defines the responsibility and methods outlining how ingredients, packaging, or products are reworked to ensure the rework process is overseen by qualified personnel; It is clearly identified and traceable; is processed in accordance with the site's food safety plan; and the reworked product is inspected or analyzed as required per site's published food safety procedures and policies before release for distribution with impact on the safety or integrity of the finished product. The site defines the nonconforming products requiring rework it consists of sugar that does not meet quality specifications or contains contamination that the site remove by dissolving, thermal processing, filtering, and recrystallizing. This is rejected sugar from bulk, bags or totes, sugar produced outside of quality specifications, overs from lump screening, product vacuumed from clean surfaces, brown and powdered sugar, sugar that has been outside of the site's control, sugar from bulk car cleaning, and any sugar that can be handled as liquid only can also be remelted. The rework process is documented, traceable, and records are maintained the Director of Technical Services (SQF Practitioner).

2.4.6.1 The responsibility and methods outlining how ingredients, packaging, or products are reworked shall be documented and implemented. The methods applied shall ensure:
i. Reworking operations are overseen by qualified personnel;
ii. Reworked product is clearly identified and traceable;
iii. Reworked product is processed in accordance with the site's food safety plan;
iv. Each batch of reworked product is inspected or analyzed as required before release;
v. Inspections and analyses conform to the requirements outlined in element 2.4.4.1;
vi. Release of reworked product conforms to element 2.4.7; and
vii. Reworked product does not affect the safety or integrity of the finished product.
Records of all reworking operations shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.7 Product Release

The product hold and release, dated April 8, 2019, outline the methods and responsibilities for holds relating to products, ingredients, packaging material, and equipment. The product labelling and Palletizing products policy, dated June 14, 2022, defines the requirements for label compliance with food legislation in the country of manufacture and countries of use or sale. The site does not perform pathogen testing on finished product. However, the site implemented and maintained hold programs that include positive release mechanisms and incident-driven hold procedures to ensure that defined testing and monitoring passes acceptance criteria before releasing product to commerce and incident-driven holds evaluate risk before determining disposition. The site considers all packaged or loaded production to be on quality hold until appropriate monitoring and analyses occur. Appropriate monitoring includes commencement and documentation of quality testing per the Product Sampling and Retain Requirements, dated April 22, 2021, and HACCP monitoring per Food Safety Plan policy, dated April 8, 2021. Off-site or contract warehouses are not used before releasing product to commerce.

A review of records for product releases from April 2, 2023, June 23, 2023, and December 5, 2023, were reviewed during the audit, and it was noted they had been conducted per defined procedures. The product was granulated sugar. Records were maintained within the site database system for lot management and records are maintained the Director of Technical Services (SQF Practitioner).

2.4.7.1 The responsibility and methods for releasing products shall be documented and implemented. The methods applied shall ensure the product is released by authorized personnel, and only after all inspections and analyses are successfully completed and documented to verify legislative and other established food safety controls have been met.
Records of all product releases shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.7.2 Product release shall include a procedure to confirm that product labels comply with the food legislation that applies in the country of manufacture and the country(ies) of use or sale if known (refer to 2.4.1.1).
If product is packaged and distributed in bulk or unlabeled, product information shall be made available to inform customers and/or consumers of the requirements for its safe use.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.7.3 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

The site performed a Risk/Vulnerability Assessment General for Environmental Monitoring program on February 24, 2023, to formally document and evaluate risks associated with environmental pathogens. It was concluded through testing and peer reviewed journals that environmental pathogen testing is not required for sugar products. Records were maintained by the Director of Technical Services (SQF Practitioner).

2.5.1 Validation and Effectiveness (Mandatory)

The Validation policy, dated April 8, 2019, outlines the validation program applicable to critical control points, critical limits, and prerequisite programs. The site's food safety and quality program utilize validation techniques for food safety controls. Validation techniques are based on publications by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) and the Codex Alimentarius Commission (CAC). The Quality Assurance Team under the direction of the Quality Assurance Specialist performs this process annually and when significant changes prompt the need for validation. This process includes an examination of regulatory requirements, customer needs/expectations, peer-reviewed literature, and empirical data.

The validations were required to be completed annually or in the event of changes. The annual validation and/or assessment for the metal detector, liquid sugar filter, magnet, and PPRs were performed on January 2, 2024. The site validate process included a review of applicable regulatory requirements, customer specifications, a review of customer complaints, and scientific reference to address the specific CCP's or CP points. Records of all verification of effectiveness and validation are maintained by the Director of Technical Services (SQF Practitioner).

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)**

The verification policy dated April 9, 2022, outline and define verification items of the site's Verification Program. Verification is segmented into corporate and site-specific verification activities to ensure that personnel and facilities follow programs according to policies and certification standards, and to ensure that the criteria for verifying the effectiveness of monitoring prerequisite programs critical control points and other food safety controls identified shall be documented and implemented. The Quality Assurance team performs food safety and quality verifications in addition to the verifications outlined in a site's HACCP plan. Verifications take the form of visual observations, record reviews, facility inspections, and internal auditing by personnel with responsibility for verifying monitoring activities authorize each record verified.

The site established a registry that define the verification activities and schedule, titles "Local Verification and the Verification Schedule". The schedule outlines the items that will be verified, description of the activity, frequency of the task, assign the responsibility to specific individual and/or a team, and identifies the records that will require to be completed and maintained. The verifications of CCP's, the Metal Detector, and Liquid Sugar Filter, were performed on March 4, 2024. Records of all verification of effectiveness and validation are maintained by the Director of Technical Services (SQF Practitioner).

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

The corrective Actions and Root Cause Analysis policy, dated June 14, 2022, outlines the responsibility and methods for investigating, resolving, and managing corrective actions. The identification of root causes and resolutions to deviations of critical control limits are required to be documented. The site utilizes corrective and preventive action methodology for incidents and non-conformances. Corrective action processes identify root causes, document investigations, declare preventive measures, and allows tracking for future effectiveness validation. The Quality Assurance team determine the need for corrective actions and manage the process. Corrective actions can address issues noted from customer complaints, audit results, incidents, and internal discoveries. The Quality Assurance team initiate and document corrective actions for nonconformances arising from various sources: internal audits, facility inspections, customer complaints, internal incidents, and implement preventive measures to prevent recurrence.

The site incorporates corrective actions into management review programs. All corrective actions are reviewed upon completion and reviewed during the annual management review. Records of investigations and corrective actions were reviewed during the audit for internal holds and internal inspections. Corrective actions were maintained in each specific program. These were found to have proper reviews, investigations, corrective and preventative actions, and resolutions documented. Records are maintained by the Director of Technical Services (SQF Practitioner).

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 the implementation of preventative actions shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.5.4 Internal Audits and Inspections

The Internal Auditing & Facility Inspections policy, dated April 8, 2022, outlines the site's internal auditing program. Internal auditing consists of both corporate internal audits and local facility internal inspections. In addition, it defines the procedure for scheduling and conducting internal audits so the effectiveness of the SQF system is verified has been documented and implemented. Site conducts internal audits to ensure food safety, and quality programs are implemented, monitored, and verified. This program verifies compliance with regulatory requirements, the BSN standards, and food safety SQF systems. The Internal Audit Program is maintained by the SQF Practitioner. If there were any changes implemented from the internal audits that have an impact on food safety, it would trigger an SQF review. Facility and equipment inspections, internal audits of the food safety plan, and regulatory inspections are part of the internal audit programs. The frequency of the audits is communicated to management and required monthly for internal inspections and annually for the internal audits to verify the effectiveness of the SQF Food Safety Code that have been documented and implemented.

Personnel conducting audits have been properly trained and audit areas independent of their function by using teams. The Director of Technical Services (SQF Practitioner) completed PCQI training for Preventive Control for Human Food through FSPCA on August 4, 2016; Implementing SQF System through SQFI on September 24, 2014; and the inhouse Internal Auditor training on November 21, 2013. The trainer was trained on Internal Auditor principles through AIB International on November 22, 2011. The SQF backup, completed PCQI training for Preventive Control for Human Food through Food Industry Consulting on July 21, 2022, and Mastering SQF, edition 9: food Manufacturing through Register Crop on December 6, 2022. The Quality Assurance Manager completed PCQI training for Preventive Control for Human Food Online Course through AIB International on January 19, 2023; The HACCP online through AIB International on May 31, 2023; Implementing SQF System through SQFI on May 31, 2023; and the Principles of Internal Auditing through NSF International on May 30, 2023.

The site completed the internal auditing for SQF food safety code on January 4, 2024. However, the site did not maintain records for the monthly internal Good Manufacturing Practices and facilities inspection from January

2.5.4.1 The methods and responsibility for scheduling and conducting internal audits to verify the effectiveness of the SQF System shall be documented and implemented. 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: Food Manufacturing are audited per the SQF audit checklist or a similar tool;
ii. Objective evidence is recorded to verify compliance and/or non-compliance;
iii. Corrective and preventative actions of deficiencies identified during the internal audits are undertaken; and
iv. Audit results are communicated to relevant management personnel and staff responsible for implementing and verifying corrective and preventative 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 facility and equipment maintenance are compliant to the SQF Food Safety Code: Food Manufacturing. The site shall:
i. Take corrections or corrective and preventative action; and
ii. Maintain records of inspections and any corrective actions 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: MINOR

EVIDENCE: The site did not maintain records for the monthly internal Good Manufacturing Practices and facilities inspection from January 2023 through January 2024. Additionally, the February 2024 Internal GMP audit findings were not documented in the site's defined corrective and preventive action system for internal auditing and inspections.

ROOT CAUSE: Addition of routine items with GMP inspections caused confusion when reporting action items.

CORRECTIVE ACTION: GMP inspections were separated from routine findings to add clarity to GMP Inspection Documentation of inspections and findings.

VERIFICATION OF CLOSEOUT: The root cause, corrective action, and objective evidence were reviewed and accepted.

COMPLETION DATE: 03/15/2024 **CLOSEOUT DATE**: 03/25/2024

2.6.1 **Product Identification and Traceability**
The product lot numbers policy, dated July 11, 2022, defines the methods and responsibility for identifying raw materials, ingredients, packaging, work-in-progress, process inputs, and finished products during all stages of production and storage process. All products packaged and shipped are identified by unique lot number codes to facilitate traceability. Lot numbers and manufacturing dates are assigned as granulated sugar is packaged or products are made and packaged/loaded, e.g., liquid sucrose into a tanker. Sugar that is reprocessed such as work in process, reconditioned, or conversion sugar (bulk rail to bulk truck) will be assigned a new lot number at the time of processing. The site ensures all packaged products are labeled with legible, accurate lot numbers and that all bulk products are identified via accompanying paperwork, such as, Bills of Lading, and Certificates of Analysis.

Product identification records were reviewed during the audit for sugar dated June 23, 2023, and demonstrated the products were properly identified throughout the process. Records of a changeover to ensure correct product and packaging were reviewed on the same days. Changeovers were documented on lot reconciliation and records were reviewed for June 23, 2023. There had not been any label inconsistencies that needed investigation. The Quality Assurance team is responsible for defining lot structure, ensuring products are identified with lot numbers and correcting any related lot number coding issues, and maintain appropriate records.

2.6.1.1 The methods and responsibility for identifying raw materials, ingredients, packaging, work-in-progress, process inputs, and finished products during all stages of production and storage shall be documented and implemented to ensure:
i. Raw materials, ingredients, packaging, work-in-progress, process inputs, 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 and/or regulatory requirements.

RESPONSE: COMPLIANT

EVIDENCE:

2.6.1.2 Product start-up, product changeover, and packaging changeover (including label changes) procedures shall be documented and implemented to ensure that the correct product is in the correct package and with the correct label and that the changeover is inspected and approved by an authorized person.
Procedures shall be implemented to ensure that label use is reconciled and any inconsistencies investigated and resolved.
Product changeover and label reconciliation records shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.6.2 Product Trace

The Traceability policy, dated November 13, 2023, defines the standards for facilities to maintain traceability programs and to outline traceability requirements for finished product, ingredients, and packaging materials. The site performs product traces once per year per product type, e.g., liquid products, or granulated products. Trace procedures ensure that the site randomly select a manufacturing/Julian date and account for all products packaged, including bulk, and packaged. The site defines a successful product trace will account for at least 99% of a given lot number in four hours. The following items must be discoverable in a product trace, Information about the trace (person conducting, date, timeline, etc.); Product type(s) traced; Quantities (produced, shipped, on-hand, etc.); Raw material lot numbers; Consignee/customers; and Processing documentation (CCP records, BoL, and CoA's).

The Quality Assurance team is responsible for overseeing traceability requirements for their respective facility, including performing trace exercises, training personnel in trace procedures, and implementing corrective actions when trace exercises do not meet success requirements. The Warehouse Managers and General Managers are the individual's given authority over warehouses and may work with Quality team during trace exercises. Warehouse managers and general managers assume trace oversight for the site without a dedicated quality assurance staff member. Receipt dates were recorded and used to help trace the raw the effectiveness of the trace system is required to be conducted at least annually. Records of the receipt, use, and dispatch of products are maintained. Rework is commonly used and recorded on the hold log.

The backward and forward trace and recall exercise was completed on January 16, 2024, for the bagged granulated sugar. Product receiving records indicated receiving 20,606 CWT under lot number SR2008, of which all was shipped to multiple shipping locations under specific BoL as indicated in the annual mock recall exercise records. The product was traced at 99.99% within a 1 hour and 27 minutes. The Annual Mock Recall Exercise was properly documented, and all supporting records were maintained by the Director of Technical Services (SQF Practitioner).

2.6.2.1 The responsibility and methods used to trace product shall be documented and implemented to ensure:
i. Finished product is traceable at least one step forward to the customer and at least one step back from the process to the manufacturing supplier;
ii. The receipt dates of raw materials, ingredients, food contact packaging and materials, and other inputs are recorded (refer to 2.8.1.8 for traceback of allergen containing food products.);
iii. Traceability is maintained where product is reworked (refer to 2.4.6); and
iv. The effectiveness of the product trace system is reviewed at least annually, as part of the product recall and withdrawal review (refer to 2.6.3.2).
Records of raw and 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)

The Recall Program and Testing, dated September 22, 2022, defines the responsibility and methods used to define the requirements for developing recall procedures, conducting recalls, and performing recall testing exercises.
National Sugar Marketing (NSM) and the site jointly generate and maintain a documented recall program that complies with current regulations. The program assigns responsibility and ensures that, if necessary, mechanisms are in place to effectively remove products from commerce promptly to protect customers and reduce the cost impacts of a recall. The plan is tested each calendar year against standards for success, and NSM and the site jointly implements corrective actions when testing reveals opportunities for improvement. Recalls are only initiated with approval of the NSM Board. If initiated, the NSM Director of Quality Assurance has oversight for the procedure.

The NSM and the site jointly conducts recall test exercises a minimum of once each calendar year. Recall testing must include a full lot across multiple product types and production shifts. Criteria for success when testing is ≥ 98% product identification and recall strategy development within 24 hours of notification. Recall testing may involve participation from NSM Quality Assurance, NSM Logistics, Account Support, Partner Quality Assurance, and Partner Warehousing. During testing, responsible parties test all aspects of a product recall plan except for customer notification/letters, and effectiveness checks. These items are omitted from testing because they require customer contact. When performing testing. The SQFI and the certification body require to be notified in writing within twenty-four (24) hours upon identification of a food safety event that requires public notification.

The withdrawal policy includes the requirement to investigate a recall and determine the root cause of a recall/withdrawal with corrective action. The backward and forward trace and recall exercise was completed on January 16, 2024, for the bagged granulated sugar. Product receiving records indicated receiving 20,606 CWT under lot number SR2008, of which all was shipped to multiple shipping locations under specific BoL as indicated in the annual mock recall exercise records. The product was traced at 99.99% within a 1 hour and 27 minutes. The Annual Mock Recall Exercise was properly documented, and all supporting records were

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 initiating, managing, and investigating a product withdrawal or recall;
ii. Describe the management procedures to be implemented, including sources of legal, regulatory, and expert advice, and essential traceability information;
iii. Outline a communication plan to inform site personnel, customers, consumers, authorities, and other essential bodies in a timely manner appropriate about the nature of the incident; and
iv. Ensure that SQFI, the certification body, and the appropriate regulatory authority are listed as essential organizations 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 product withdrawal and recall system shall be reviewed, tested, and verified as effective at least annually. Testing shall include incoming materials (minimum traceability one step back) and finished product (minimum traceability 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**

The Crisis Management & Contingency Planning, dated January 27, 2022, outlines the business processes for preventing service disruptions during a crisis. The site implements crisis management teams and plans to ensure that crises are handled promptly, and that affected product is not inadvertently released into commerce. Crisis management plans also attempt to ensure that shipments to customers are not disrupted and that any affected product is held and verified prior to release. The plan noted the senior management in charge of crisis including the nomination of a team leader who has oversight of the plan. The local crisis management team identified and trained on February 8, 2024. The plan includes responses to an extended business interruption, isolating and identifying affected products, and a current crisis alert list. The crisis plan includes internal/external communications and sources of legal and expert advice. The NSM maintains a 24-hour emergency contact list. This list is made available under NSM Emergency Contacts posted to the website and is updated as needed to remain current. The site's establish local crisis management teams and train those teams on local crisis management procedures. The crisis management teams consist of senior management. Crisis Management Plans are often jointly managed between Site Management, Safety Departments, and Quality Assurance.

The mock exercise was completed on February 9, 2024, using a spring crop pesticide application fly over, an equipment caused the plane to suddenly lose control and crash into the side of silo 1. During this tabletop exercise all actions are hypothetical. No gaps were identified during the exercise. Records were maintained by the Director of Technical Services (SQF Practitioner).

2.6.4.1 A crisis management plan based on the understanding of known potential dangers (e.g., flood, drought, fire, tsunami, or other severe weather events, warfare or civil unrest, computer outage, pandemic, loss of electricity or refrigeration, ammonia leak, labor strike) that can impact the site's ability to deliver safe food 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 at 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 any responses do 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 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 with gaps and appropriate corrective actions documented. Records of reviews of the crisis management plan shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.7.1 **Food Defense Plan**

The Food Defense policy, dated November 15, 2023, outlines the methods in place to communicate the food defense program. This program ensures compliance with certification standards, customer expectations, and regulatory requirements outlined in 21 CFR 121: Mitigation Strategies to Protect Food Against Intentional Adulteration. A food defense protocol includes the title of the senior management responsible for food defense. This program complied with legislative requirements. The program outlined the access of only authorized personnel, designated access points, the secured storage of materials and hazardous chemicals, and the control of access to contractors and visitors.

The Defense Challenge assessment was performed on February 8, 2024. The challenge was to be trying to get to the top of the silos without being stopped and/or being on camera. Two gaps were identified during the challenge assessment, where three doors were found unlocked and the potential intruder was not spotted on the site's security cameras. The site issued work orders (115550, 115549, and 115548) to address and fix the doors and plan to add additional security cameras within the next 4 to 6 months. Food defense training was carried out on February 22, 2024. Records were maintained by the Director of Technical Services (SQF Practitioner).

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 materials, ingredients, packaging, equipment, and hazardous chemicals to protect them from deliberate acts of sabotage or terrorist-like incidents;
vi. The measures implemented to ensure raw materials, ingredients, packaging (including labels), work-in-progress, process inputs, 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 site personnel, 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 and tests of the food defense plan shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.7.2 Food Fraud

The Food Fraud policy, dated April 8, 2019, outlines the site's programs for evaluating, monitoring, and preventing food fraud or deliberate introduction of substances or hazards introduced for economic gain. The food fraud program builds on the principles of Hazard Analysis and Critical Control Point (HACCP). Food fraud programs demonstrate compliance with 21 CFR 117.130(a)(2)(iii). The Food Fraud Program covers the sale of unfit and potentially harmful food, deliberate mislabeling of products, and formulation substitution. The site does not engage in economically motivated adulteration. Such practices deprive the consumers of the products they intend to purchase and may have implications on consumer health. NSM performs vulnerability assessments that consider economic adulteration for all products marketed and all raw materials that may negatively affect sellable products. Such evaluations include historical evidence, substitution factors, and applicable testing. Risk assessments of this nature evaluate food safety and food quality hazards. The site has developed a review schedule for elements of the food fraud program. Review records can take the form of revising a review date or meeting minutes, which are documented and maintained by the Director of Technical Services (SQF Practitioner). The schedule identifies the vulnerability assessments, Hazard analysis, and food fraud customer statements, assign the responsibility to perform the task, and frequency.

There was a re-assessment summary that was completed on February 8, 2024. There were not any gaps in this risk assessment that needed corrective actions. The risk assessment showed that there were not any high-risk materials and mitigation controls were not required. Training on food fraud was carried out on February 22, 2024. Records were maintained by the Director of Technical Services (SQF Practitioner).

2.7.2.1 The methods, responsibility, and criteria for identifying the site's vulnerability to food fraud, including susceptibility to raw material or ingredient substitution, finished product mislabeling, dilution, or counterfeiting, shall be documented, implemented, and maintained.

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 Allergens and Sensitizing Agents policy, dated April 21, 2022, defines the site's allergen exclusion and awareness program. This program also includes sensitizing agent monitoring and control. The site ensures that all sugar products distributed to customers are compliant with the Food Allergen Labeling and Consumer Protection Act. Products are free of known allergens and contain sulfur dioxide levels less than labeling requirements. The site does not process or handle known allergens.

This policy was developed to clearly explain the general procedures and guidelines of allergen management. This policy is communicated to relevant employees, and all employees are expected to adhere to the standards set forth in this policy. Last Allergen training was carried out during the year on February 22, 2024. Records were maintained by the Director of Technical Services (SQF Practitioner). Despite facilities not processing allergens, allergens may be present onsite through lunches and vending. In a case where allergenic contamination is suspected through unintended introduction from suppliers, employees, or visitors, standard product hold processes will be implemented.

The National Sugar Marketing's (NSM) sugar products are protein-free carbohydrates manufactured in facilities that do not process known allergens. The site ensures an allergen-free product through verifying the allergen-free status of processing aids and maintenance chemicals, maintaining allergen awareness training, and enforcing eating exclusion programs. The site performed risk assessment on February 24, 2023. Records were maintained by the Director of Technical Services (SQF Practitioner).

2.8.1.1 The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented. The allergen management program shall include:
i. A risk analysis of those raw materials, ingredients, and processing aids, including food grade lubricants, that contain food allergens;
ii. An assessment of workplace-related food allergens that may originate from locker rooms, vending machines, lunchrooms, and visitors;
iii. A list of allergens that is applicable in the country of manufacture and the country(ies) of destination, if known;
iv. A list of allergens that is accessible to relevant staff;
v. The control of hazards associated with allergens and incorporated into the food safety plan, and
vi. Management plans for control of the identified allergens.

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 how to identify, handle, store, and segregate raw materials and products containing allergens.

RESPONSE: COMPLIANT

EVIDENCE:

2.8.1.3 Provisions shall be made to clearly identify and segregate foods that contain allergens. Segregation procedures shall be implemented and continually monitored.

RESPONSE: COMPLIANT

EVIDENCE:

2.8.1.4 Where allergenic material may be intentionally or unintentionally present cleaning and sanitation of product contact surfaces between line changeovers shall be effective, appropriate to the risk and legal requirements, and sufficient to remove all potential target allergens from product contact surfaces, including aerosols as appropriate, to prevent cross-contact.
Separate handling and production equipment shall be provided, where satisfactory line hygiene and clean-up or segregation are not possible.

RESPONSE: COMPLIANT

EVIDENCE:

2.8.1.5 Based on risk assessment, procedures for validation and verification of the effectiveness of the cleaning and sanitation of areas and equipment in which allergens are used shall be documented and effectively implemented.

RESPONSE: COMPLIANT

EVIDENCE:

2.8.1.6 Where allergenic material may be present, product changeover procedures shall be documented and implemented to eliminate the risk of cross-contact.

RESPONSE: COMPLIANT

EVIDENCE:

2.8.1.7 The product identification system (refer to 2.6.1.1) shall make provision for clear identification and labeling, in accordance with the regulatory requirements of those products produced on production lines and equipment on which foods containing allergens are manufactured.

RESPONSE: COMPLIANT

EVIDENCE:

2.8.1.8 The product trace system (refer to 2.6.2) shall take into consideration the conditions under which allergen-containing foods are manufactured and ensure full traceback of all ingredients and processing aids used.

RESPONSE: COMPLIANT

EVIDENCE:

2.8.1.9 The site shall document and implement methods to control the accuracy of finished product labels (or consumer information where applicable) and assure work-in progress and finished product are true to label with regard to allergens. Measures may include label approvals at receipt, label reconciliations during production, destruction of obsolete labels, verification of labels on finished product as appropriate, and product change over procedures.

RESPONSE: COMPLIANT

EVIDENCE:

2.8.1.10 Re-working of product (refer to 2.4.6) containing food allergens shall be conducted under conditions that ensure product safety and integrity are maintained. Re-worked product containing allergens shall be clearly identified and traceable.

RESPONSE: COMPLIANT

EVIDENCE:

2.8.1.11 Sites that do not handle allergenic materials or produce allergenic products shall document, implement and maintain an allergen management program addressing at a minimum the mitigation of introduced or unintended allergens through supplier, contract manufacturer, site personnel, and visitor activities.

RESPONSE: COMPLIANT

EVIDENCE:

2.9.1 Training Requirements

The Employee Food Safety and Quality Training Policy, dated June 14, 2022, defines the requirements for assessing and implementing a training program with an emphasis on food safety and quality assurance. Training is required by food regulation and critical to all food safety and quality programs, including refreshing training program. The Director of Technical Services (SQF Practitioner) completed a HACCP training course through the HACCP international alliance on August 14-15, 2014; PCQI training for Preventive Control for Human Food through FSPCA on August 4, 2016; Implementing SQF System through SQFI on September 24, 2014; and the inhouse Internal Auditor training on November 21, 2013. The trainer was trained on Internal Auditor principles through AIB International on November 22, 2011. The SQF backup has completed a HACCP training course through NSF International on June 15, 2021; PCQI training for Preventive Control for Human Food through Food Industry Consulting on July 21, 2022, and Mastering SQF, edition 9: food Manufacturing through Register Crop on December 6, 2022. The Quality Assurance Manager completed PCQI training for Preventive Control for Human Food Online Course through AIB International on January 19, 2023; The HACCP online through AIB International on May 31, 2023; Implementing SQF System through SQFI on May 31, 2023; and the Principles of Internal Auditing through NSF International on May 30, 2023.

2.9.1.1 The responsibility for establishing and implementing the training needs of the organization's personnel to ensure they have the required competencies to carry out those functions affecting products, legality, and safety 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

The Employee Food Safety and Quality Training Policy, dated June 14, 2022, defines the requirements for assessing and implementing a training program with an emphasis on food safety and quality assurance, which covers the necessary competencies for plant personnel. This program requires training to be conducted for new hires and refresher training to ensure regulatory, food safety, and all other requirements of the SQF System are met. This training program is administered by a QA department and HR. Work instructions have been written explaining how tasks critical to maintaining food safety are performed. Records of work instruction training were reviewed for sanitation. The SQF Practitioner was the only person who sampled for environmental and received training from the third-party lab. HACCP training for personnel involved in the development and maintaining the food safety plan is administered. The team members had training on file. The training language and materials are in English, which is the language used in the operation and understood by all plant personnel. Periodic refresher training needs have been identified in the Training program that noted which programs were required. The training program was in place for personnel hygiene, allergen, HACCP, food defense food fraud, and quality. Refresher training is completed on an annual basis. A training skills register is maintained by the SQF Practitioner and includes a listing of the trainee, trainer, the description of the training, the date of training, and verification by supervision that the training was completed. The facility verifies the effectiveness of training by quizzes and visual observation for certain programs. Plant employees interviewed in quality, production, and maintenance were found to have current training records on the register. The Matrix training program dated February 22, 2024, for Color coding, food defense, food safety roles, allergen, GMP, and handwashing trainings were reviewed during the meeting, and appropriate records were maintained by the Director of Technical Services (SQF Practitioner).

2.9.2.1 A training program shall be documented and implemented that at a minimum outlines the necessary competencies for specific duties and the training methods to be applied to 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 for all staff involved in the handling of food products and food contact surfaces;
iv. Good Manufacturing Practices and work instructions for all staff engaged in food handling, food processing, and equipment;
v. Sampling and test methods for all staff involved in sampling and testing of raw materials, packaging, work-in-progress, and finished products;
vi. Environmental monitoring for relevant staff;
vii. Allergen management, food defense, and food fraud for all relevant staff; and
viii. Tasks identified as critical to meeting the effective implementation and maintenance of the SQF code.
The training program shall include provisions for identifying and implementing the refresher training needs of the organization.

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 language(s) 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:

11.1.1 **Premises Location and Approval**
The sites buildings, property and surroundings were observed during the audit to not pose a risk to food safety. There was an on-going risk assessment for the local activities. If there were any changes to local activities, it was recorded on this log. The site maintains the required approvals by relevant authorities, as evidenced by FDA registration, current State Food Processing License, for their ongoing operations. The site FDA registration for the site XXXXXXX4978 was valid through December 31, 2024, and the Minnesota Department of Agriculture, License 20000548 was valid through December 31, 2024.

The site performed risk assessment on March 4, 2024, to assess local activities and the site environment to identify any risk that may have an adverse impact of product safety and implements controls for any identified risks. No risk was identified, and records were maintained by the Director of Technical Services (SQF Practitioner).

11.1.1.1 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:

11.1.2 Building Materials

Floors are constructed of smooth and dense impact-resistant material and properly graded for effective drainage of overflow or wastewater with the exception of the concrete slab floor of the Sugar Packaging warehouse has cracks and unsealed joints. Wastewater during the audit was observed to be properly discharged. Drains were observed to be located and constructed for ease of cleaning and inspection. There are no waste traps on site. The site has a documented risk assessment for overhead ducting, pipes, or conduit on risk assessment was carried out on January 4, 2024.
The walls, ceilings, and doors are of durable construction with smooth and light-colored surfaces. These areas were observed to be relatively clean during the audit inspection. Wall to wall and wall to floor junctures were observed to be sealed and free of debris. Products are processed and handled in an enclosed system and maintained to prevent the contamination of products. Products are not exposed at any step of the process after cleaning and washing step.

Overhead cleaning was found to be part of the master cleaning schedule. There were not any overhead pipes for sanitary waste or wastewater. Doors, windows, and frames were observed to be properly constructed of materials with the same functional requirements as internal walls and partitions. The ceilings in all food processing and handling areas are constructed of wood. Drop ceilings were not used. Stairs, catwalks, and platforms were observed during facility inspection to be constructed and designed so that food contamination is avoided.

N/A 11.1.2.3 – There are no waste traps on site.
N/A 11.1.2.6 – The site does not have pipes carrying sanitary waste or wastewater that are located directly over product lines or storage areas.

Minor 11.1.2.1 – The concrete slab floor of the Sugar Packaging warehouse has cracks and unsealed joints.

11.1.2.1 Floors shall be constructed of smooth, dense, impact-resistant material that can be effectively graded, drained, impervious to liquid, and easily cleaned. Floors shall be sloped to floor drains at gradients suitable to allow the effective removal of all overflow or wastewater under normal working conditions.
Where floor drainage is not available, plumbed options to handle overflow or wastewater shall be in place.

RESPONSE: MINOR

EVIDENCE: The concrete slab floor of the Sugar Packaging warehouse has cracks and unsealed joints.

ROOT CAUSE: Floor cracks were not part of the planned maintenance and were not identified in routine inspections or audits.

CORRECTIVE ACTION: Floor cracks to be repaired and sealed. Floors will be added to routine maintenance schedules and internal inspection checklist.

VERIFICATION OF CLOSEOUT: The root cause, corrective action, and supporting evidence were reviewed. However, they will need to be verified in the next audit cycle.

COMPLETION DATE: INVALID **CLOSEOUT DATE**: 03/25/2024

11.1.2.2 Drains shall be constructed and located so they can be easily cleaned and not present a hazard.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.2.4 Walls, partitions, ceilings, and doors shall be of durable construction. Internal surfaces shall have an even and regular surface and be impervious with a light-colored finish and shall be kept clean (refer to 11.2.5). Wall-to-wall and wall-to-floor junctions shall be designed to be easily cleaned and sealed to prevent the accumulation of food debris.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.2.5 Ducting, conduit, and pipes that convey ingredients, products, or services, such as steam or water, shall be designed and constructed to prevent the contamination of food, ingredients, and food contact surfaces and allow ease of cleaning.
A risk analysis shall be conducted to ensure food contamination risks are mitigated.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.2.7 Doors, hatches, and windows and their frames in food processing, handling, or storage areas shall be of a material and construction that meets the same functional requirements as for internal walls and partitions. Doors and hatches shall be of solid construction, and windows shall be made of shatterproof glass or similar material.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.2.8 Product shall be processed and handled in areas that are fitted with a ceiling or other acceptable structure that is constructed and maintained to prevent the contamination of products. Drop ceilings, where present, shall be constructed to enable monitoring for pest activity, facilitate cleaning, and provide access to utilities.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.2.9 Stairs, catwalks, and platforms in food processing and handling areas shall be designed and constructed so they do not present a product-contamination risk and with no open grates directly above exposed food product surfaces. They shall be kept clean (refer to 11.2.5).

RESPONSE: COMPLIANT

EVIDENCE:

11.1.3 Lightings and Light Fittings

All lighting is either constructed of non-glass material, e.g., LED or shielded, including dock lighting, forklift lighting, and insect light trap bulbs. Facilities discard replaced overhead light bulbs in trash receptacles located outside of the GMP areas. Lighting was of the appropriate intensity for employees to carry out their tasks efficiently. There were not any light intensity regulations, and the lighting was adequate for the industry.

11.1.3.1 Lighting in food processing and handling areas and at inspection stations shall be of appropriate intensity to enable the staff to carry out their tasks efficiently and effectively and shall comply with local light-intensity regulations or industry standards.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.3.2 Light fixtures in processing areas, inspection stations, ingredient and packaging storage areas, and all areas where the product is exposed 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 must be protected from accidental breakage, manufactured from cleanable materials, and addressed in the cleaning and sanitation program.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.3.3 Light fixtures in the warehouse or other areas where product is covered or otherwise protected shall be designed to prevent breakage and product contamination.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.4 Inspection/ Quality Control Area

The areas are located within the facility are provided and suitable for product inspections. There are appropriate hand washing facilities and the areas were observed to be well lit. A waste disposal bin was located within the inspection area and the area was found to be kept clean. The inspection area was located near each roaster and at a midway point for the packaging lines.

11.1.4.1 If online inspection is required, a suitable area close to the processing line shall be provided for the inspection of product (refer to 2.4.4). The inspection/quality control area shall be provided with facilities that are suitable for examination and testing of the type of product being handled/processed. The inspection area shall:
i. Have easy access to handwashing facilities;
ii. Have appropriate waste handling and removal; and
iii. Be kept clean to prevent product contamination.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.5 Dust, Insect, and Pest Proofing

Windows, doors, and other openings were observed during facility tours to be properly sealed to prevent any pest infestation or dust coming into the facility. Personnel access doors are self-closing and sealed to prevent any pest infestation. External doors and dock doors were sealed to prevent infestation. Electric insect devices, interior and exterior rodent stations are located so product is not at risk for contamination. Bait was not used on site.

11.1.5.1 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:

11.1.5.2 External doors, including overhead dock doors in food handling areas used for product, pedestrian, or truck access, shall be designed and maintained to prevent pest ingress by at least one or a combination of the following methods:
i. A self-closing device;
ii. An effective air curtain;
iii. A pest-proof screen;
iv. A pest-proof annex; and
v. Adequate sealing around trucks in docking areas.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.5.3 Electric insect control devices, pheromone, or other traps and baits shall be located and operated so they do not present a contamination risk to the product, packaging, containers, or processing equipment. Poison rodenticide bait shall not be used inside ingredients or product storage areas or processing areas where ingredients, packaging, and products are handled, processed, or exposed.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.6 Ventilation

The building structure is a closed building with no windows. The oven was used in well-ventilated areas with fume extraction devices which were included in the master cleaning schedule. Condensation was not seen. Adequate ventilation was observed throughout. Positive air pressure was not required. Fans and exhaust vents are insect-proofed and located so they do not pose a contamination risk and shall be kept clean.

11.1.6.1 Adequate ventilation shall be provided in enclosed processing and food handling areas.
Where appropriate, positive air-pressure systems shall be installed to prevent airborne contamination.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.6.2 All ventilation equipment and devices in product storage and handling areas shall be adequately cleaned as per 11.2.5 to prevent unsanitary conditions.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.6.3 Extractor fans and canopies shall be provided in areas where open cooking operations are carried out or a large amount of steam is generated. Capture velocities shall be sufficient to prevent condensation build-up and to evacuate all heat, fumes, and other aerosols to the exterior via an exhaust hood positioned over the cooker(s).

RESPONSE: COMPLIANT

EVIDENCE:

11.1.6.4 Fans and exhaust vents shall be insect-proofed and located so they do not pose a contamination risk and shall be kept clean.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.7 Equipment and Utensils

The site has the specifications for equipment, utensils and protective clothing written in the Manual of GMP. All equipment and utensils are designed, constructed, installed, operated, and maintained to meet regulatory requirements and they not to pose a contamination threat to products. Equipment is made of stainless steel and approved materials for food contact and non-food contact. Equipment is installed in such a way it is easy cleanable. Benches, tables, conveyors, tanks, pipes, and metal detectors are hygienically designed and located for appropriate cleaning. Equipment surfaces were observed smooth, impervious, and free from cracks and crevices. Product containers, tubs, bins for edible and inedible material are made of materials that are non-toxic, they are smooth, impervious, and readily cleaned. Bins used for inedible material are clearly identified. Waste and overflow water from tubs, tanks and molds washing machine are discharged direct to the floor drainage system, and they meet local regulatory requirements. Protective clothing used in plant does not contribute to contamination of materials and products. Equipment, utensils, and protective clothing are cleaned after use to control contamination and stored in a clean and serviceable condition to prevent microbiological contamination. Non-conforming equipment is defined in section 7.2.2.4, dated August 2, 2022, the site repair inoperative equipment in a manner that protects food safety and quality. The site follows lockout tagout procedures to address failed equipment. Maintenance personnel tag or tape off equipment that management anticipates as being out of service for prolonged periods. Records of the handling, corrective action, and/or disposal of non-conforming equipment is maintained by the Maintenance Director.

11.1.7.1 Specifications for equipment and utensils and procedures for purchasing equipment shall be documented and implemented.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.7.2 Equipment and utensils shall be designed, constructed, installed, operated, and maintained to meet any applicable regulatory requirements and to not pose a contamination threat to products.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.7.3 Equipment storage rooms shall be designed and constructed to allow for the hygienic and efficient storage of equipment and containers. Where possible, food contact equipment shall be segregated from non-food contact equipment.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.7.4 Product contact surfaces and those surfaces not in direct contact with food in food handling areas, raw material storage, packaging storage, and cold storage areas shall be constructed of materials that will not contribute to a food safety risk.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.7.5 Benches, tables, conveyors, mixers, mincers, graders, and other mechanical processing equipment shall be hygienically designed and located for appropriate cleaning. Equipment surfaces shall be smooth, impervious, and free from cracks or crevices.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.7.6 Product containers, tubs, and bins used for edible and inedible material shall be constructed of materials that are non-toxic, smooth, impervious, and readily cleaned as per 11.2.5.1. Bins used for inedible material shall be clearly identified.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.7.7 All equipment and utensils shall be cleaned after use (refer to 11.2.5.1) or at a set and validated frequency to control contamination and be stored in a clean and serviceable condition to prevent microbiological or cross-contact allergen contamination.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.7.8 Vehicles used in food contact, handling, or processing zones or cold storage rooms shall be designed and operated so as not to present a food safety hazard.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.7.9 Non-conforming equipment shall be identified, tagged, and/or 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:

11.1.8 Grounds and Roadways

The immediate grounds and surrounding areas were observed to be free of dust and waste, so pests are not attracted. The outside grounds were included in the annual internal inspections. Vegetation was controlled so as not to attract pests and vermin. Paths, roadways, and dock areas were well maintained. Pathways from amenities (smoking area and outside eating area) were sealed. Standing water was not seen.

11.1.8.1 A suitable external environment shall be established, and the effectiveness of the measures shall be monitored and periodically reviewed. The premises, its surrounding areas, storage facilities, machinery, and equipment shall be kept free of waste or accumulated debris, and vegetation shall be controlled so as not to attract pests and vermin or present a food safety hazard to the sanitary operation of the site.

RESPONSE: COMPLIANT

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

11.1.8.3 Paths from amenities leading to site entrances shall be effectively sealed.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.1 Repairs and Maintenance

The facility and equipment maintenance, dated April 8, 2019, defines the quality-related requirements pertaining to equipment maintenance. These are designed to prevent or minimize equipment failures and to ensure that maintenance and repair activities will be carried out in a manner that reduces risk of product, packaging, or equipment contamination. The site takes appropriate measures to prevent equipment and maintenance activities from becoming potential sources of contamination. Based on risk, quality requirements for maintenance are implemented in GMP-designated areas. The site utilizes the Maintenance Connection Software, to manage all preventive maintenance activities. It includes using food-grade materials. The maintenance system requires a task list, at the end of the task it is verified. At the beginning and end of every shift, there is another global verification. Samples were taken: In this record evidence is available: Screws/Boks must be acct after job done, ensure tools accounted after repair done. There are two cabinets to keep food-grade lubricants and allergen-free. The preventative maintenance program includes in Renville plant areas: sugar conservation, sugar conservation n2, production corn silos, unit 1, unit 2, etc. For each area, there is a maintenance plan: mechanical and electrical. There are work orders, the department is working, there is a new system and some pending information to upload to the system / for improvement projects there are outsourcing maintenance suppliers. Alon & CRC Lubricated are food grade and allergen-free and their use is controlled to minimize the contamination of the product.
Maintenance managers incorporates all equipment in GMP-designated areas into a preventive maintenance program. Preventive maintenance is predetermined and documented on a schedule or routine inspection. In addition, they are given the responsibility for determining and overseeing maintenance activities.

Failures of plant equipment are documented in facility records and, if deemed necessary by maintenance managers, incorporated into preventive maintenance schedules. The site identifies non-functioning equipment by using LOTO or caution tape while not in use. Temporary repairs include repairs with materials such as wood, duct tape, cardboard, and string or twine. Temporary repairs are not permitted during normal operations. If a temporary repair is needed for emergency cases, the repair is documented, and facilities submit work orders to make the repairs permanent. The site do not permit loose objects or tools to be stored on equipment. The site-designated personnel clean affected areas after maintenance to remove potential contaminants, tools, loose

11.2.1.1 The methods and responsibility for the maintenance and repair of plant, equipment, and buildings shall be documented, planned, and implemented in a manner that minimizes the risk of product, packaging, or equipment contamination.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.1.2 Routine maintenance of plant and equipment in any food processing, handling, or storage areas shall be performed according to a maintenance control schedule and recorded.
The maintenance schedule shall be prepared to include buildings, equipment, and other areas of the premises critical to the maintenance of product safety.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.1.3 Failures of plant and equipment in any food processing, handling, or storage areas shall be documented and reviewed, and their repair(s) incorporated into the maintenance control schedule.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.1.4 Site supervisors shall be notified when maintenance or repairs are to be undertaken in any processing, handling, or storage areas.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.1.5 The maintenance supervisor and the site supervisor shall be informed if any repairs or maintenance activities pose a potential threat to product safety (e.g., pieces of electrical wire, damaged light fittings, and loose overhead fittings). When possible, maintenance is to be conducted outside operating times.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.1.6 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 the cleaning program. There shall be a plan in place to address the completion of temporary repairs to ensure they do
not become permanent solutions.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.1.7 Food contact equipment and equipment located over food contact equipment shall be lubricated with food-grade lubricant, and its use shall be controlled to minimize the contamination of the product.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.1.8 Paint used in a food handling or processing area shall be suitable for use, in good condition, and not be used on any product contact surfaces.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.2	**Maintenance Staff and Contractors** Maintenance personnel and contractors are trained on GMPs and follow established GMPs when working in GMP-designated areas. Mechanics are included in annual GMP training as outlined in policy 5.2 Employee Food Safety & Quality Training, dated June 14, 2022. Mechanics are instructed to report and document when performing maintenance in GMP areas and when maintenance activities present risks to food safety and/or quality. In addition, personnel performing maintenance on equipment in GMP areas maintain clean tools suitable for product contact equipment. The site provides a form of contractor orientation/training for all contractors prior to the commencement of work. Contractor access and requirements are determined locally; however, contractors entering GMP areas must review and sign a hygiene acknowledgement form or sticker. Contractors are restricted to their assigned service areas and designated personnel oversee their work. Overseeing personnel ensure services do not pose risks to food and that contractors follow hygiene practices when in GMP areas. When repairs are completed, personnel are required to document the accounting of tools and cleanliness of the work areas which is then followed by an inspection and release. This documentation found on file in completed work orders that included certified start-up which included cleaning and inspection. There had not been any non- routine repairs in the last year on food contact surfaces. The contractor Orientation document was dated May 26, 2022.
11.2.2.1	Maintenance staff and contractors shall comply with the site's personnel and process hygiene requirements (refer to 11.3). **RESPONSE:** COMPLIANT **EVIDENCE:**
11.2.2.2	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:**
11.2.2.3	Maintenance staff and contractors shall remove all tools and debris from any maintenance activity once it has been completed, and inform the area supervisor and maintenance supervisor, so appropriate hygiene and sanitation can be conducted and a pre-operational inspection completed prior to the restarting of site operations. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.2.3	**Calibration** The Equipment Calibration, dated April 8, 2019, defines the calibration program for equipment relating to food safety and' Hazard Analysis and Critical Control Point (HACCP) programs. Related items include metal detectors. The policy outlines the methods and responsibilities for calibrating measuring, testing, and inspection equipment. There was a master list of calibrated equipment that included all of the scales, magnets, moisture and pH meter, and metal detectors. The calibration schedule was noted in the procedure. The frequency of inspections is based on the manufacturer's recommendations and customer requirements. A review of the third-party calibration records for scales confirms the schedule is being followed. Inspection and testing equipment is protected from damage or unauthorized use by being kept at the place of use. Equipment is calibrated against national or international standards. Magnets pull calibration was carried out on January 16, 2024, through Magnetic Product using NIST standards, and the metal detectors where calibration was carried out by Metro Toledo on June 26, 2023 (valid through June 26, 2024). 108764, C042262955, and 125759. Records were maintained by the Director of Technical Services (SQF Practitioner).

11.2.3.1	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:**
11.2.3.2	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:**
11.2.3.3	Calibration shall be performed according to regulatory requirements and/or to the equipment manufacturers' recommended schedule. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.2.3.4	Procedures shall be documented and implemented to address the resolution of potentially affected products when measuring, testing, or inspection equipment is found to be out of calibration. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.2.3.5	Calibrated measuring, testing, and inspection equipment shall be protected from damage and unauthorized adjustment or use. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.2.3.6	A directory of measuring, testing, and inspection equipment that require calibration and records of the calibration tests shall be maintained. **RESPONSE:** COMPLIANT **EVIDENCE:**

11.2.4 **Pest Prevention**

The Integrated Pest Management policy, dated April 22, 2021, defines the requirements for a contracted pest control program and outline the proactive measures that the site takes to prevent and control pests. No pest activity was identified or noted during tours, that presented a risk for product contamination and corrective action and record-keeping procedures are in place should this occur dated April 22, 2021, annual risk assessment was carried out on January 4, 2024. This included handling any pest infestation in packaging, raw materials, or finished products including requirements for records of any incidents. Live animals were not found nor allowed inside the facility. The site hired Terminix Commercial to perform pest management activities at the site, the updated scope of service was dated March 4, 2024, defines the methods of pest control, frequency of interior and exterior inspections, and targeted pests. The service is weekly. A current site map dated March 1, 2024, is accurate in showing the location of external and internal devices. A pesticide application log gives details of the chemical usage which had not occurred in the past year. The technician provided reports of the service completed. Licenses of the Pest Control Operator from local authorities are current and indicate employees are trained and competent, licenses 20220268 was valid through December 31, 2024, Liability insurances was valid through October 1, 2024. A list of chemicals used by the Pest Control Operator is found in the approved pesticide list and includes SDS information, the approved chemical list dated January 12, 2023. The pest control operator removes empty chemical containers from the site however no pesticides had been used in the past year. Pesticides were not stored on site. Inspection activity reports are signed by a management representative after visits and were reviewed and found to be completed as scheduled. Any observations or issues highlighted by the Pest Control Operator are addressed and documented by the facility. Trending was found in the pest control program and completed quarterly. The site does not permit storage of pesticide chemicals on site. Terminix Commercial service reports from March 8, 2023, June 14, 2023, and August 27, 2023, were reviewed during the audit. Activities were properly documented and maintained by the Director of Technical Services (SQF Practitioner).

NA 11.2.4.5—The site does not store pesticides, as the pest contract service provider handles and stores all pesticides off-site.

11.2.4.1 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 the identification, location, number, and type of applied pest control/monitoring devices on a site map;
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 to identify trends.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.4.2 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 2.3.2.8), which 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:

11.2.4.3 Pest activity risks shall be analyzed and recorded. Inspections for pest activity shall be conducted 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 food products, raw materials, or packaging.
Records of all pest control inspections and applications shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.4.4 Food products, raw materials, or packaging that are found to be contaminated by pest activity shall be effectively disposed of, and the source of pest infestation shall be investigated and resolved. Records shall be kept of the disposal, investigation, and resolution.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.4.6 No animals shall be permitted on-site in food handling and storage areas.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.5 Cleaning and Sanitation

The Cleaning, Sanitation, & Waste Management, dated April 8, 2019, defines the methods and responsibility for the effective cleaning of the food handling and processing equipment and environment and storage areas. The site non-GMP areas such as factory beet ends, flat storage warehouses, staff amenities, grounds, etc. maintain these areas in a hygienic manner to the extent possible to prevent cross contamination with GMP areas, risks to product or packaging, or risks to personnel that might work in GMP areas. The cleaning of these areas is verified through routine inspection. The Moisture sensitive environments such as sugar warehouses or granulated sugar handling areas employ dry cleaning techniques to limit microbial proliferation. Dry cleaning involves a top-down approach and includes vacuuming, sweeping, and other means to keep floors, walls, and equipment surfaces clean. The site processing equipment employed for liquid sugar, medium invert, and coating syrup routinely clean tanks, piping, gaskets, and fittings to minimize the presence of microbiological spoilage organisms. The site Clean in Place (CIP) Systems flush systems with water and sanitize them employing hot water treatment. Effective sanitization occurs when the effluent water is monitored and maintained above 180° F for a minimum of 15 minutes. The site restarts cycles when temperatures drop below 180° F. CIP frequencies are determined by the Facility based on microbiological reporting. The site strives to meet National Food Processors Association (NFPA) Canners Standards and National Soft Drink Association (NSDA) Bottlers Standards. In addition, facilities sanitize tanks before initial use, after any maintenance, and after any periods greater than 24 hours without use. Facilities sanitize couplers, fittings, gaskets, reducers, and caps during the CIP process by using chlorine sanitizing solutions or clean out of place (COP) washers. Where applicable, facilities also ensure spray balls are functioning during CIP to ensure adequate coverage. The site uses sanitizing solutions for couplers, fittings, gaskets, reducers, caps, etc. use chlorine solutions between 100-200 ppm. Solutions used on food contact surfaces exceeding 200 ppm is against federal regulations; therefore, Facilities verify concentration using chlorine test strips and include results in records. Solutions older than 24 hours or solutions found outside of the 100-200 ppm range are discarded. Facilities choosing this route should implement a work instruction and training for mixing solutions. The detergents and sanitizers that have been mixed for use correctly, and according to the manufacturers' instructions, stored in containers that are suitable for use, and clearly identified. Mix concentrations are verified, and records maintained. However, the site lacks training records for staff assigned to verify the detergents and sanitizers' chemical concentrations. Moreover, during the record

11.2.5.1 The methods and responsibility for the effective cleaning of the food handling and processing equipment and environment and storage areas shall be documented and implemented. Consideration shall be given to:
i. What is to be cleaned;
ii. How it is to be cleaned;
iii. When it is to be cleaned;
iv. Who is responsible for the cleaning;
v. Validation of the cleaning procedures for food contact surfaces (including CIP);
vi. Methods used to confirm the correct concentrations of detergents and sanitizers; and
vii. The responsibility and methods used to verify the effectiveness of the cleaning and sanitation program.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.5.2 Detergents and sanitizers shall be suitable for use in a food manufacturing environment, labeled according to regulatory requirements, and purchased in accordance with applicable legislation. The organization shall ensure:
i. The site maintains a list of chemicals approved for use;
ii. An inventory of all purchased and used chemicals is maintained;
iii. Detergents and sanitizers are stored as outlined in element 11.6.4;
iv. Safety Data Sheets (SDS) are provided for all detergents and sanitizers purchased; and
v. Only trained staff handle sanitizers and detergents.

RESPONSE: MINOR

EVIDENCE: The site lacks training records for staff assigned to verify the detergents and sanitizers' chemical concentrations. Moreover, during the record review process, inconsistencies were observed in reporting results. Results were reported as an absolute number and, in some cases, only as "Good," with no clear definition of what "Good" meant within the established procedure. Furthermore, the operators performed the concentration verification while the QA technician documented the results. However, this step was not reflected in the in-house procedure.

ROOT CAUSE: SOP Program was currently being updated at time of audit. New program will ensure proper adherence to updated SOP's along with proper documentation of training.

CORRECTIVE ACTION: CIP Procedure was updated to include digital documentation of sanitation chemical strength, new SOP, and currently training to these procedures.

VERIFICATION OF CLOSEOUT: The root cause, corrective action, and objective evidence were reviewed and accepted.

COMPLETION DATE: 04/01/2024 **CLOSEOUT DATE**: 02/25/2024

11.2.5.3 Detergents and sanitizers that have been mixed for use shall be correctly mixed according to the manufacturers' instructions, stored in containers that are suitable for use, and clearly identified. Mix concentrations shall be verified and records maintained.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.5.4 Cleaning-in-place (CIP) systems, where used, shall not pose a chemical contamination risk to raw materials, ingredients, or product. CIP parameters critical to assuring effective cleaning shall be defined, monitored, and recorded (e.g., chemical and concentration used, contact time, and temperature). CIP equipment, including spray balls, shall be maintained, and any modifications to CIP equipment shall be validated. Personnel engaged in CIP activities shall be effectively trained.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.5.5 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 processing areas, product handling equipment, and storage areas as well as the tools themselves.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.5.6 Suitably equipped areas shall be designated for cleaning product containers, knives, cutting boards, and other utensils used by staff. The areas for these cleaning operations shall be controlled so they do not interfere with manufacturing operations,
equipment, or product. Racks and containers for storing cleaned utensils shall be provided as required.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.5.7 Pre-operational inspections shall be conducted following cleaning and sanitation operations to ensure food processing areas, product contact surfaces, equipment, staff amenities, sanitary facilities, and other essential areas are clean before the start
of production. Pre-operational inspections shall be conducted by qualified personnel.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.5.8 Staff amenities, sanitary facilities, and other essential areas shall be inspected by qualified personnel at a defined frequency to ensure the areas are clean.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.5.9 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:

11.3.1 **Personnel Welfare**

The personnel practices policy, dated October 30, 2023, outlines the health and hygiene-related requirements for personnel working in designated GMP areas. These practices ensure compliance with SQF food safety code, federal food regulations, and customer expectations. Full implementation of this policy ensures that employees interfacing with product, packaging, or food contact surfaces do not become a source of contamination.

The site restricts personnel suffering from communicable illness, infectious diseases, or who are carriers of infectious diseases from handling finished products or working in direct contact positions in GMP-designated areas. Facilities instruct personnel to report such conditions. The site grants supervisory personnel the authority to move employees with known signs of foodborne illness to non-GMP areas. Signs of foodborne illness are defined by the FDA, such as, Diarrhea, Vomiting, Fever, Sore throat with fever, visibly infected skin (boils, cuts, rash, etc.), and Discharge from the ear, eye, or nose are prohibited from working in food handling areas.

Personnel cover minor cuts on exposed parts of the body with facility-supplied, metal-detectable bandages. If there is a risk where employees could bleed through the bandage, Management will move employees to an area where they will not contact product, packaging, or food contact surfaces. If there is an event involving release of blood or bodily fluids, the site's blood borne pathogen response plan is followed. If the release affects product or packaging material, then these are dispositioned as landfill. Affected equipment is cleaned, sanitized, and verified by supervisory personnel prior to commissioning back into service. Employee interviews confirmed that employees are trained in good manufacturing practices and are knowledgeable of the requirements.

11.3.1.1 Personnel who are known to be carriers of infectious diseases that present a health risk to others through the packing or storage processes shall not engage in the processing or packing of food or enter storage areas where food 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:

11.3.1.2 The site shall have measures in place to prevent contact of materials, ingredients, food packaging, food, or food contact surfaces from any bodily fluids, open wounds, coughing, sneezing, spitting, or any other means.
In the event of an injury that causes the spillage of bodily fluid, a properly trained staff member shall ensure that all affected areas, including handling and processing areas, have been adequately cleaned, and that all materials and products have been quarantined and/or disposed of.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.1.3 Personnel with exposed cuts, sores, or lesions shall not engage in handling or processing exposed products or handling primary (food contact) packaging or touching food contact surfaces. Minor cuts or abrasions on exposed parts of the body shall be covered with a colored, metal-detectable bandage or an alternative suitable waterproof and colored dressing.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.2 Handwashing

A policy covering hand washing requirements has been documented and implemented. Personnel entering GMP-designated areas wash their hands thoroughly. Personnel are instructed to wash their hands after lunches, breaks, restroom use, tobacco use (if applicable), using wash down hoses, handling contaminated material, after using a handkerchief or tissues, and any other times necessary to keep them clean. The site provides appropriate signage to ensure that employees are aware of hand washing requirements, including entry to GMP areas and breakroom exits.
The wash bay area has adequate hand wash station(s), which include warm water, antibacterial hand soap and a means of drying hands. Hand washing signs are posted at hand wash station(s) that instruct employees, visitors, and contractors to wash their hands. Hand wash basins are located at appropriate employee access points to processing areas. Hand wash sinks are made of non- corrosive materials and supplied with tempered potable water and liquid soap. Disposable towels were used with waste container nearby. Signs are posted reminding employees to wash their hands before returning to work. Signs are posted at hand wash stations and in bathrooms. Employees are required to wash hands when wearing gloves. Interviews conducted with employees during the audit demonstrated that employees understand the hand washing requirements. Employees were observed to wash their hands properly during the audit. There were not any high-risk areas.

NA 11.3.2.4 - The site does not have high-risk areas.

11.3.2.1 All personnel shall have clean hands, and hands shall be washed by all staff, contractors, and visitors:
i. On entering food handling or processing areas;
ii. After each visit to a toilet;
iii. After using a handkerchief;
iv. After smoking, eating, or drinking; and
v. After handling wash down hoses, cleaning materials, dropped product, or contaminated material.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.2.2 Handwashing stations shall be provided adjacent to all personnel access points and in accessible locations throughout food handling and processing areas as required.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.2.3 Handwashing stations shall be constructed of stainless steel or similar non-corrosive material and at a minimum supplied with:
i. A potable water supply at an appropriate temperature;
ii. Liquid soap contained within a fixed dispenser;
iii. Paper towels in a hands-free cleanable dispenser; and
iv. A means of containing used paper towels.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.2.5 Signage in appropriate languages instructing people to wash their hands before entering the food processing areas shall be provided in a prominent position in break rooms, at break room exits, toilet rooms, and in outside eating areas, as applicable.

RESPONSE: COMPLIANT

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

11.3.3	**Clothing and Personal Effects** The personnel practices policy, dated October 30, 2023, outlines the health and hygiene-related requirements for personnel working in designated GMP areas. Risk assessment for hair and clothing is addressed within this policy. The site determined that aprons, gloves, hair nets and beard nets were required. These did depend on work area. A policy defining clothing requirements has been documented and implemented. Clothing including shoes are required to be clean at the commencement of the shift and changed if excessively soiled. Clothing was required to be street clothes covered by an apron if handling product. The protective clothing was either cleaned after use or disposable. Racks were used for the aprons. Disposable gloves are to be changed when soiled or damaged. Employees were observed to be in compliance with the clothing requirements of the facility except for a glove issue. There were not any high-risk areas at the site. A policy defining jewelry has been written and implemented. Jewelry and other loose objects are prohibited in food processing and handling areas. Employees were observed to be in compliance with the jewelry policy during the audit tours. Medic alert and plain wedding bands were allowed. There were not any exceptions to the jewelry policy.
11.3.3.1	The site shall undertake a risk analysis to ensure that the clothing and hair policy protects materials, food, and food contact surfaces from unintentional microbiological or physical contamination. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.3.3.2	Clothing worn by staff engaged in handling food shall be maintained, stored, laundered, and worn so it does not present a contamination risk to products. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.3.3.3	Clothing, including shoes, shall be clean at the start of each shift and maintained in a serviceable condition. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.3.3.4	Excessively soiled uniforms shall be changed or replaced when they present a product contamination risk. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.3.3.5	Disposable gloves and aprons shall be changed after each break, upon re-entry into the processing area, and when damaged. Non-disposable aprons and gloves shall be cleaned and sanitized as required and when not in use stored on racks provided in the processing area or in designated sealed containers in personnel lockers. They should not be placed or stored on packaging, ingredients, product, or equipment. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.3.3.6	Protective clothing shall be manufactured from material that will not pose a food safety threat and is easily cleaned. All protective clothing shall be cleaned after use, or at a frequency to control contamination, and stored in a clean and serviceable condition to prevent microbiological or cross-contact allergen contamination.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.3.7	Racks shall be provided for the temporary storage of protective clothing when staff leave the processing area and shall be provided nearby or adjacent to the personnel access doorways and handwashing facilities. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.3.3.8	Jewelry and other loose objects shall not be worn or taken into a food handling or processing operation or into any area where food is exposed. Wearing plain bands with no stones, prescribed medical alert bracelets, or jewelry accepted for religious or cultural reasons can be permitted, provided these items are properly covered and do not pose a food safety risk. 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:**
11.3.4	**Visitors** The Visitors policy, dated April 22, 2019, defines the requirements for onsite visitors. These requirements ensure that visitors are tracked, informed, and monitored to ensure their protection and to safeguard our products. This was a specific sign in agreement for the GMPs. Visitors are required to follow the facility rules including using proper access points, comply with hand wash requirements, use of suitable protective clothing and footwear, removal of jewelry and other loose objects and there was an illness advisement.
11.3.4.1	All visitors shall be trained in the site's food safety and hygiene procedures before entering any food processing and handling areas or shall be escorted at all times in food processing, handling, and storage areas. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.3.4.2	All visitors, including management staff, shall be required to remove jewelry and other loose objects in accordance with the facilities Good Manufacturing Practices and 11.3.3.8. All visitors shall wear suitable clothing and footwear when entering any food processing and handling area. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.3.4.3	Visitors exhibiting visible signs of illness shall be prevented from entering areas in which food is handled and processed. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.3.4.4	Visitors shall enter and exit food handling areas through the proper staff entrance points and comply with all handwashing and personnel practice requirements.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.5 Staff Amenities (change rooms, toilet, break rooms)

Employee bathrooms and break rooms were observed to be appropriately lit and ventilated and available for all personnel at the site. These were included in the master cleaning schedule. There are facilities for employees to change into and out of the hair nets and aprons. Clothing racks of clean aprons or uniforms was segregated from other storage. Provisions have been made for storage of street clothing and personal items and are separate from processing and storage areas. Showers were not required. Rest rooms and washrooms were observed to be constructed so they are separate from food processing and handling areas and accessed via a separate room. They were observed to be sufficient in number for all employees and were found to be cleaned and maintained on a scheduled basis. Site indicated that the sanitary drainage is separated from plant drainage. The sanitary facilities have hand wash sinks and comply with requirements in 11.3.2.2. There were designated tools for cleaning the toilet rooms. Lunchrooms properly separate from production are available, well lit, properly ventilated and are appropriately sized for the number of facility employees. Lunchrooms include hot and cold potable water, food storage areas, refrigerators with utensil washing capabilities. Lunchrooms were observed to be clean and well-maintained during the audit tours. The outside eating area was adequate.

NA 11.3.5.3 -The site does not have high-risk products, ingredients, or operations.
NA 11.3.5.4 - The site does not change from street clothes.
NA 11.3.5.5 - The site does not have showers for employee use.
NA 11.3.5.10 -The site does not have outside eating areas.

11.3.5.1 Staff amenities shall have documented cleaning procedures, be supplied with appropriate lighting and ventilation, and shall be made available for use by all persons engaged in the handling and processing of product.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.5.2 Change rooms shall be provided to enable staff and visitors to change into and out of protective clothing as required. Change rooms shall be kept clean.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.5.6 Toilet rooms shall be:
i. Designed and constructed so that they are accessible to staff and separate from any processing and food handling operations;
ii. Accessed from the processing area via an airlock vented to the exterior or through an adjoining room;
iii. Sufficient in number for the maximum number of staff;
iv. Constructed so that they can be easily cleaned and maintained;
v. Located inside or nearby areas for storing protective clothing, outer garments, and other items while using the facilities; and
vi. Kept clean and tidy.
Tools/equipment used for cleaning toilet rooms shall not be used to clean processing areas.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.5.7 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:

11.3.5.8 Handwashing basins shall be provided immediately outside or inside the toilet room and designed as outlined in 11.3.2.3.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.5.9 Separate break rooms shall be provided away from food contact/handling zones.
Break rooms shall be:
i. Ventilated and well lit;
ii. Provided with adequate tables and seating to cater for the maximum number of staff at one sitting;
iii. Equipped with a sink serviced with hot and cold potable water for washing utensils;
iv. Equipped with refrigeration and heating facilities, enabling staff to store or heat food and to prepare non-alcoholic beverages if required; and
v. Kept clean and free from waste materials and pests.

RESPONSE: COMPLIANT

EVIDENCE:

11.4.1 **Staff Engaged in Food Haldning and Processing Operations**
Food handling procedures for all employees are documented and implemented. Personnel are required to access the processing areas through personnel doors only and doors were observed closed. False fingernails or fingernail polish is prohibited, and no violations were noted with the exception of the employee with holes in gloves as noted in 11.3.3.5. Hair nets and beard nets were required in the processing areas. Ingredients were appropriately, labeled containers and most kept off the floor. Sensory evaluations were conducted in designated areas that were well lit and appropriately equipped for that purpose and personnel conducting sensory evaluations are trained and maintain high hygienic standards. Drinking water was available to employees with clear enclosed bottles at workstations. Smoking was allowed in designated outside areas that included electronic cigarettes. Wash down hoses were observed to be properly stored on racks when not in use. The GMP policy prohibits smoking, eating, drinking, or spitting in the facility.

N/A 11.4.1.4 – Sensory evaluations are prohibited in a food handling/contact zone. There is no sensory evaluation on site.

11.4.1.1 All personnel engaged in any food handling, preparation, or processing operations shall ensure that products and materials are handled and stored in such a way as to prevent damage or product contamination. They shall comply with the following processing practices:
i. Personnel entry to processing areas shall be through the personnel access doors only;
ii. All doors are to be kept closed. Doors shall not be open for extended periods when access is required for waste removal or receiving of product/ingredient/packaging;
iii. Packaging, product, and ingredients shall be kept in appropriate containers as required and off the floor;
iv. Waste shall be contained in the bins identified for this purpose and removed from the processing area on a regular basis and not left to accumulate; and
v. All wash down and compressed air hoses shall be stored on hose racks after use and not left on the floor.

RESPONSE: COMPLIANT

EVIDENCE:

11.4.1.2 Personnel working in or visiting food handling or processing operations shall ensure that:
i. Staff shall not eat or taste any product being processed in the food handling/contact zones, except as noted in element 11.4.1.4;
ii. The wearing of false fingernails, false eyelashes, eyelash extensions, long nails, or fingernail polish is not permitted when handling exposed food;
iii. Hair restraints and beard covers, where applicable, shall be used in areas where product is exposed.
iv. Smoking, chewing, eating, or spitting is not permitted in areas where product is produced, stored, or otherwise exposed.
v. Drinking water is permissible only under conditions that prevent contamination or other food safety risks from occurring. Drinking water containers in production and storage areas shall be stored in clear, covered containers, and in designated areas away from raw materials, packaging, tools, or equipment storage.

RESPONSE: COMPLIANT

EVIDENCE:

11.4.1.3 The flow of personnel in food processing and handling areas shall be managed such that the potential for contamination is minimized.

RESPONSE: COMPLIANT

EVIDENCE:

11.5.1 **Water Supply**
Potable water is sourced for use in the facility for processing, handwashing, rinsing process, and cleaning the premises and equipment. Potable water is supplied from the onsite four wells water quality report on file. It was determined that there was adequate hot and cold water for cleaning and processing. The water used at the site is potable and appropriately filtered through filtration/RO, softening, and carbon filtration. The site installs 5-micron filters for incoming water and monitor the filters by manual inspection or pressure monitoring. Softeners are installed when water hardness exceeds 200 ppm of CaCo3. All piping is constructed from stainless steel after an in-line filter and up to and including the spinner or spray ball. The system is maintained internally by the maintenance team, and the filter is changed every 90 days through a 3rd party contractor, complete water solution. Records are maintained by the Director of Engineering. Backflow devices are installed on water lines. Non- potable water is not used at the facility although backflow devices were on hose taps to ensure nonportable water was not accidentally used and is tested annually. Water is not stored on-site. There was a written water contingency plan noted in FDA Guidance in “Guidance for Industry: Use of Water by Food Manufactures in Areas Subject to a Boil-Water Advisory”. A third-part analysis was carried out on February 29, 2024. There are three backflow prevention devices were calibrated on July 26, 2023, by a third-party certified company, the plumbing and Heating of Willmar, Inc. License number BT090547. The three devices were successfully calibrated, and records were maintained by the Director of Technical Services (SQF Practitioner).

N/A 11.5.1.6 – water is not stored on-site.

11.5.1.1 Adequate supplies of potable water drawn from a known clean source shall be provided for water used as an ingredient during processing operations and for cleaning the premises and equipment. The source of potable water shall be identified as well as on-site storage (if applicable) and reticulation within the facility.

RESPONSE: COMPLIANT

EVIDENCE:

11.5.1.2 Contingency plans shall be in place for instances when the potable water supply is deemed to be contaminated or otherwise inappropriate for use.

RESPONSE: COMPLIANT

EVIDENCE:

11.5.1.3 Supplies of hot and cold water shall be provided, as required, to enable the effective cleaning of the premises and equipment.

RESPONSE: COMPLIANT

EVIDENCE:

11.5.1.4 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:

11.5.1.5 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 backflow or back-siphonage.

RESPONSE: COMPLIANT

EVIDENCE:

11.5.2 Water Treatment

N/A 11.5.2.1-3 – There is no water treatment on-site.

11.5.3 Water Quality

The site water complies with local, and national potable water microbiological and quality standards. Water used at the site for processing, handwashing, rinsing process, and cleaning the premises and equipment. Potable water is supplied from the onsite four wells water quality report on file. Water samples are monitored and analyzed for Total Coliforms and Nitrate annually. The annual analysis was performed February 29, 2024, at UC Laboratory, a third-party accredited laboratory by the state on Minnesota, the MN certification Number 027-161-186 EPA ID # MN00068 was reviewed during the audit. Results were negative for Total Coliforms and were maintained by the Director of Technical Services (SQF Practitioner).

11.5.3.1 Water shall comply with local, national, or internationally recognized potable water microbiological and quality standards, as required when used for:
i. Washing, thawing, and treating food;
ii. Handwashing;
iii. Conveying food;
iv. An ingredient or food processing aid;
v. Cleaning food contact surfaces and equipment;
vi. The manufacture of ice; or
vii. The manufacture of steam that will come into contact with food or be used to heat water that will come into contact with food.

RESPONSE: COMPLIANT

EVIDENCE:

11.5.3.2 Microbiological analysis of the water and ice 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 at sources supplying water for the process or cleaning or from within the site. The frequency of analysis shall be risk-based and at a minimum annually.

RESPONSE: COMPLIANT

EVIDENCE:

11.5.3.3 Water and ice shall be analyzed using reference standards and methods.

RESPONSE: COMPLIANT

EVIDENCE:

11.5.4 Ice Supply

NA 11.5.4.1 - 3 - The site does not use or produce ice.

11.5.5 Air and Other Gasses

NA 11.5.5.1-2 - The site does not have nor use Air and any other gases such as nitrogen or carbon Dioxide that contact food or food contact surfaces.

11.6.1 Receipt, Storage and Handling of Goods

The Product Storage and Warehousing, dated April 8, 2019, defines the requirements for ambient warehouse storage facilities employed to house packaged product to ensure that product is protected from all sources of contamination during storage and warehousing. The site does not use alternate warehousing facilities or overflow storages. The policy outlines the requirements for stock rotation which is based on FIFO system to ensure that all ingredients, materials, work- in-progress, rework, and finished product are utilized within their designated shelf-life. Storage rooms for raw materials, finished goods, containers, and equipment were observed to be well designed and constructed. Temporary or alternative storage was not used.

The shipment to warehouse schedule, Bill of Lading, Incoming weight ticket, Liquid trailer loading checklist, truck loading order, Wash inspection form, assistant sugar warehouse foreman checklist, liquid & dry bulk truck cleaning inspection certificate, sugar coop-pellets, pellet truck inspection & loading report, Sugar Coop-Molasses, Liquid Sugar CIP sheet, certificate of analysis for incoming load, Shipments matrix for a specific day, which indicates lot, quantity, and location, Contractor Traffic Log, Traffic Log, daily car release report, daily car release report, bulk fine gran, carrier, shipping ticket, warehouse shipping authorization, and truck weight ticket for shipping and receiving records from April 2, 2023, June 23, 2023, and December 5, 2023, were reviewed during the audit. Records were maintained by the Director of Operations and Director of Technical Services (SQF Practitioner).

N/A 11.6.1.5 – 6 – The site does not have or use temporary storage for materials, packaging, finished products, or ingredients.

11.6.1.1 The site shall document and implement an effective storage plan that allows for the safe, hygienic receipt and storage of raw materials (i.e., frozen, chilled, and ambient), ingredients, packaging, equipment, and chemicals.

RESPONSE: COMPLIANT

EVIDENCE:

11.6.1.2 Controls shall be in place to ensure all ingredients, raw materials, processing aids, and packaging are received and stored properly to prevent cross-contamination risks. Unprocessed raw materials shall be received and stored separately from processed raw materials to avoid cross-contamination risk.

RESPONSE: COMPLIANT

EVIDENCE:

11.6.1.3 The responsibility and methods for ensuring effective stock rotation principles shall be documented and implemented.

RESPONSE: COMPLIANT

EVIDENCE:

11.6.1.4 Procedures shall be in place to ensure that all ingredients, materials, work- in-progress, rework, and finished product are utilized within their designated shelf-life.

RESPONSE: COMPLIANT

EVIDENCE:

11.6.2 Cold Storage, Freezing and Chilling of Foods

NA 11.6.2.1 - 4 - The site does not have any cold storage operations.

11.6.3 Storage of Dry Ingredients, Packaging, and Shelf Stable Packaged Goods

The Product Storage and Warehousing, dated April 8, 2019, defines the requirements for ambient warehouse storage facilities employed to house packaged product to ensure that product is protected from all sources of contamination during storage and warehousing. Storage areas for raw materials, packaging and finished goods were observed to be located away from any wet areas, clean and well maintained. Product is protected from contamination and deterioration. Racking is designed and constructed from impervious materials and located so storage areas can be cleaned and inspected.

11.6.3.1 Rooms used for the storage of product ingredients, packaging, and other dry goods shall be located away from wet areas and constructed to protect the product from contamination and deterioration and prevent packaging from becoming a harborage for pests or vermin.

RESPONSE: COMPLIANT

EVIDENCE:

11.6.3.2 Racks provided for the storage of packaging shall be constructed of impervious materials and designed to enable cleaning and inspection of the floors and behind the racks. Storage areas shall be cleaned at a pre-determined frequency.

RESPONSE: COMPLIANT

EVIDENCE:

11.6.4 Storage of Hazardous Chemicals and Toxic Substances

The Chemical Control and Approval policy dated April 22, 2021, outlines chemical-related requirements to meet regulation and certification standard compliance, and to ensure that chemical handling does not adversely affect finished product quality or safety. The site approves, purchase, and use chemicals in accordance with chemical labeling recommendations, intended usage, and all applicable regulatory requirements, including but not limited to State, EPA, FDA, and OSHA. The site ensure that all chemicals stored and utilized onsite do not present food safety and quality risks to products, packaging, or food contact surfaces. Chemical storage areas were observed to be locked and had instructions on handling hazardous chemicals, an up-to-date inventory of all chemicals, available first aid and spill containment equipment. Daily supplies of chemicals were stored properly.

All stored chemicals have current SDS information on file at the facility. Most chemicals were either in original containers or properly labeled secondary containers. Training was in place for employees that handle chemicals. Spillage instructions were outlined in the training materials which referenced the SDS. Spillage cleanup kits were in place. There were not any issues noted with disposal of chemicals containers. Chemical training was carried out during the year. The Matrix training program dated February 22, 2024, for Color coding, food defense, Sanitation and cleaning, food safety roles, allergen, GMP, and handwashing trainings were reviewed during the meeting, and appropriate records were maintained by the Director of Technical Services (SQF Practitioner).

11.6.4.1 Hazardous chemicals and toxic substances with the potential for food contamination shall be:
i. Clearly labeled, identifying and matching the contents of their containers;
ii. Included in a current register of all hazardous chemicals and toxic substances that are stored on-site; and
iii. Supplemented with current Safety Data Sheets (SDS) made available to all staff.

RESPONSE: COMPLIANT

EVIDENCE:

11.6.4.2 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 pesticides, rodenticides, fumigants, and insecticides are stored separately from sanitizers and detergents; and
vi. Stored in a manner that prevents a hazard to finished product or product contact surfaces.
Processing utensils and packaging shall not be stored in areas used to store hazardous chemicals and toxic substances.

RESPONSE: COMPLIANT

EVIDENCE:

11.6.4.3 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-inprogress, finished product, or product contact surfaces;
iii. Returned to the appropriate storage areas after use; and
iv. Be compliant with national and local legislation.

RESPONSE: COMPLIANT

EVIDENCE:

11.6.4.4	Daily supplies of chemicals used for continuous sanitizing of water, as a processing aid, or for emergency cleaning of food processing equipment and surfaces in food contact zones may be stored within or in close proximity to a processing area, provided that access to the chemical storage facility is restricted to only authorized personnel. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.6.4.5	Personnel who handle hazardous chemicals and toxic substances, including pesticides and cleaning chemicals,: i. Shall be fully trained in the purpose of the hazardous chemicals and toxic substances, their storage, handling, and use; ii. Be provided first aid equipment and personnel protective equipment (PPE); and iii. Ensure compliance with the proper identification, storage, usage, disposal, and clean-up requirements. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.6.4.6	The site shall dispose of empty, obsolete, and unused chemicals, pesticides, toxic substances, and containers in accordance with requirements and ensure that primary containers are: i. Not reused; ii. Segregated and securely stored prior to collection; and iii. Disposed through an approved vendor. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.6.4.7	In the event of a hazardous spill, the site shall: i. Have spillage clean-up instructions to ensure that the spill is properly contained; and ii. Be equipped with PPE, spillage kits, and cleaning equipment. **RESPONSE:** COMPLIANT **EVIDENCE:**

11.6.5	**Loading, Transport, and Unloading Practices** The dry van trailers and container standards, dated April 8, 2019, defines the guidelines for formalizing operational practices for properly and consistently conducting all warehousing, shipping, and receiving activities. These practices influence the quality, safety, and stability of the raw materials, ingredients, and finished products. It was observed during the audit inspection that food was unloaded, stored, and loaded under conditions that prevented cross-contamination. Seals were placed on each outbound load and noted on the BOL. The site policy requires that all trailers be inspected for cleanliness, infestation, odors, damage, etc. before loading. All shipping is ambient. Warehouse interviews revealed that employees are aware of the proper procedures and follow them. It was observed that unloading practices are designed to prevent product contamination. All receiving is ambient. Dry ingredients and packaging were observed to be stored separately from unprocessed raw materials. The Bulk Rail loading from April 5, 2023, June 8, 2023, and November 12, 2023, were reviewed during the audit. Loading records for liquid truck, dated November 12, 2023, and October 5, 2023, were reviewed during the audit. The records were effectively documented, and records were maintained by the Director of Quality (SQF Practitioner). NA 11.6.5.2 - The site does not transfer materials or products between sites. NA 11.6.5.5 - 7 - All materials and finished products are shipped at ambient temperatures.
11.6.5.1	The practices applied during loading, transport, and unloading of food shall be documented, implemented, and designed to maintain appropriate storage conditions and product integrity. Foods shall be loaded, transported, and unloaded under conditions suitable to prevent cross-contamination. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.6.5.3	Vehicles (e.g., trucks/vans/containers) shall be secured from tampering using seals or other agreed-upon and acceptable devices or systems. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.6.5.4	Loading and unloading docks shall be designed to protect the product during loading and unloading. Loading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining product and package integrity during loading and transport. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.6.5.8	Unloading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining product and package integrity. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.7.1	**High-Risk Processes** NA 11.7.1.1 - 5 - The site does not have any high-risk ingredients or Processes.

11.7.2 Thawing of Food

NA 11.7.2.1 - 3 - The site does not thaw ingredients for use in products.

11.7.3 Control of Foreign Matter Contamination

The Physical Contaminant Control, dated September 12, 2019, defines the responsibility and methods used to prevent foreign matter contamination of the product. Inspections are performed to ensure plant and equipment remain in good condition and equipment has not become detached or deteriorated and is free from potential contaminants. The site prerequisite programs aid in preventing foreign matter contamination, including programs such as facility and equipment maintenance, cleaning and sanitation, integrated pest management, and sanitary transport. Additional methods specifically targeting prevention for foreign matter include: The Glass, brittle plastic, and ceramic is virtually undetectable in non-liquid products. Therefore, to mitigate risk of glass contamination, facilities implement exclusion, monitoring, and reaction techniques. The site implemented reasonable precautions to exclude glass from sensitive, GMP areas, including lab glassware, glass containers, glass equipment gauges, thermometers. Additionally, the site has created a glass and brittle plastic register/master list, which defines the location and quantity of glass, brittle plastic, and ceramic items. The site inspects and document all items on the register monthly basis. In circumstances where glass or similar material breakage occurs, the site document breakage procedure and train personnel on reporting and cleanup requirements. The work instruction includes supervisor notification, incident documentation, area segregation, product hold for products within 20 feet of breakage, use of disposable shoe coverings during cleanup, and cleanup inspection and verification. After cleanup, the site discards all products, tools and items used to clean up glass.

The site limit wood in GMP areas with exceptions for key items such as pallets, storage rack material, facility construction, which are dedicated for that purpose, clean, and maintained in good order. The site prohibits the use of cutting instruments in GMP areas with disposable blades. Where applicable, warehouses require the use of scissors or non-disposable blade cutting instruments. In cases where this is not possible, utility knives may be used provided they are attached to equipment by cables and are monitored. Employees maintain cutting instruments in a sanitary manner. The site takes precautions by removing or attaching loose objects found on equipment or overhead structures so as not to present a hazard. The metal and rubber gaskets, rubber impellers, and other equipment made of materials that can wear or deteriorate over time are inspected on a regular frequency during the preventive maintenance program in accordance with the facility & equipment

11.7.3.1 The responsibility and methods used to prevent foreign matter contamination of the product shall be documented, implemented, and communicated to all staff.
Inspections shall be performed (refer to 2.5.4.3) to ensure plant and equipment remain in good condition and equipment has not become detached or deteriorated and is free from potential contaminants.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.3.2 Containers, equipment, and other utensils made of glass, porcelain, ceramics, laboratory glassware, or other similar materials shall not be permitted in food processing /contact zones (except where the product is contained in packaging made from these materials, or measurement instruments with glass dial covers are used, or MIG thermometers are required under regulation).
Where glass objects or similar material are required in food handling/contact zones, they shall be listed in a glass inventory, including details of their location and condition.

RESPONSE: COMPLIANT

EVIDENCE:

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

RESPONSE: COMPLIANT

EVIDENCE:

11.7.3.4 Glass instrument dial covers on processing equipment and MIG thermometers shall be inspected at the start of each shift to confirm they have not been damaged.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.3.5 In circumstances where glass or similar material breakage occurs, the affected area shall be isolated, cleaned, thoroughly inspected (including cleaning equipment and footwear), and cleared by a suitably responsible person prior to the start of operations.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.3.6 Wooden pallets and other wooden utensils used in food processing and handling areas shall be dedicated for that purpose, clean, and maintained in good order. Their condition shall be subject to regular inspection.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.3.7 Loose metal objects on equipment, equipment covers, and overhead structures shall be removed or tightly fixed so as not to present a hazard.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.3.8 Knives and cutting instruments used in processing and packaging operations shall be controlled, kept clean, and well maintained. Snap-off blades shall not be used in manufacturing or storage areas.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.3.9 Gaskets, rubber impellers, and other equipment made of materials that can wear or deteriorate over time shall be inspected on a regular frequency (refer to 2.5.4.3).

RESPONSE: COMPLIANT

EVIDENCE:

11.7.4 Detection of Foreign Objects

The Physical Contaminant Control, dated September 12, 2019, defines the responsibility, methods, and frequency for monitoring, maintaining, calibrating, and using screens, magnets, and metal detection devices to remove or detect foreign. The inline magnets are installed and inspected to monitor sugar handling equipment. The site generates monitoring schedules with a minimum frequency of once per shift while in use. Monitoring includes documenting date, time, findings, person monitoring, and reporting abnormal findings to supervisory personnel. Based on findings, supervisory personnel may implement product hold procedures. The site ensures that granulated sugar passes through a functioning metal detector incorporated in the site's Food Safety/HACCP plan. Metal detectors are equipped with reject mechanisms to ensure the product is metal-free. The site routinely challenges detectors and reject mechanisms as part of HACCP monitoring. The site ensures that metal detectors are monitored at least once per shift and pass metal detector checks before permitting the product's entrance into interstate commerce. The metal detection limits are 1.5 mm for ferrous, 1.8 for nonferrous, 2.0 mm for stainless, and 2.0 mm for aluminum. Screens are employed to remove product lumps and monitor systems for foreign material contamination from the liquid sugars' finished products. The screen size is set at 100 microns maximum, and socks are checked once per shift for integrity and continuously monitored for differential pressure.

In all cases of foreign matter contamination, the policy instructs and trains employees to report foreign matter contamination or potential foreign matter contamination to supervisory and quality personnel. All cases of potential foreign matter are documented in a food safety and quality incident report or similar mechanism. The affected lot number (s) or item (s) are isolated, inspected, reworked, or disposed of. The site maintains records of the inspection of foreign object detection devices, any products rejected or removed by them, and corrective and preventative actions resulting from the inspections.

Metal Analysis records for Trucks, Rail, bagging 5s, and bagging super sacks from January 2, 2024, September 18, 2024, and February were reviewed during the audit. Records were completed correctly and maintained. A review of hold records observed that the lot numbers SR24002R3 and SR24003R2 were placed on hold on January 2, 2024, due to metal contamination. The SQF Practitioner conducted a review and had the onsite

11.7.4.1 The responsibility, methods, and frequency for monitoring, maintaining, calibrating, and using screens, sieves, filters, or other technologies to remove or detect foreign matter shall be documented and implemented.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.4.2 Where detection and/or removal systems are used, the site shall establish limits for detection, based on a risk assessment of the product and its packaging, and identify the location(s) of the detector(s) in the process.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.4.3 Metal detectors or other physical contaminant detection technologies shall be routinely monitored, validated, and verified for operational effectiveness. The equipment shall be designed to isolate defective product and indicate when it is rejected.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.4.4 Records shall be maintained of the inspection of foreign object detection devices, of any products rejected or removed by them, and of corrective and preventative actions resulting from the inspections.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.4.5 In all cases of foreign matter contamination, the affected batch or item shall be isolated, inspected, reworked, or disposed of. Records shall be maintained of the disposition.

RESPONSE: COMPLIANT

EVIDENCE:

11.8.1 Waste Disposal

The Cleaning, Sanitation, & Waste Management, dated April 8, 2019, defines the responsibility and methods used to collect and handle dry, wet, and liquid waste and how to store it prior to removal from the premises. The site control and monitor waste to ensure waste is conveyed, stored, and discarded in such a way to minimize the development of odor, pest attractant, harborage, and to protect against contamination of product, product contact surfaces, water supplies, and ground surfaces. Waste bins are only used for the intended purpose. The site ensures that waste bins are made of impermeable material and that they are covered and labeled. The site does not require covers for outside containers 10 cubic yards or larger provided waste is contained in tied liners to prevent harborage. Additionally, the site prohibits the use of packaging material for waste containment or storage.

The site dispose of sugar found to be unfit for reprocessing as standard waste, for landfill. Liquid waste is handled according to local state and federal requirements by either disposing via drains or having environmental staff oversee disposal. Where possible, the site recycles waste materials and/or packaging and ensure these activities and do not present risks for inadvertent use. The site incorporates waste removal into local waste management system. Contractors removing waste are subject to the site's Supplier Approval program to ensure that contractors meet local regulations for disposal. Trademarked materials were sent to a landfill with certificate of destruction according to the same policy. The site does not permit inedible waste for animal feed, and it is handled discharged and is used to irrigate the local fields. The site reviews the effectiveness of waste management, and the results of these inspections includes waste removal into facility inspections and/or the daily hygiene inspections.

NA 11.8.1.7 - The site does not create any inedible food for animal feed.

11.8.1.1 The responsibility and methods used to collect and handle dry, wet, and liquid waste and how to store it prior to removal from the premises shall be documented and implemented.

RESPONSE: COMPLIANT

EVIDENCE:

11.8.1.2 Waste shall be removed on a regular basis and not allowed to build up in food handling or processing areas. Designated waste accumulation areas shall be maintained in a clean and tidy condition until external waste collection is undertaken.

RESPONSE: COMPLIANT

EVIDENCE:

11.8.1.3 Waste and overflow water from tubs, tanks, and other equipment shall be discharged directly to the floor drainage system or by an alternative method that meets local regulatory requirements.

RESPONSE: COMPLIANT

EVIDENCE:

11.8.1.4	Trolleys, vehicle waste disposal equipment, collection bins, and storage areas shall be maintained in a serviceable condition, cleaned, and sanitized regularly to prevent the attraction of pests and other vermin. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.8.1.5	Adequate provision shall be made for the disposal of all solid processing waste, including trimmings, inedible material, and used packaging. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.8.1.6	Where applicable, a documented procedure shall be in place for the controlled disposal of trademarked materials waste considered high-risk for handling or other reasons. Where a contracted disposal service is used, the disposal process shall be reviewed regularly to confirm compliance. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.8.1.8	Waste held on-site prior to disposal shall be stored in a separate storage facility that is suitably insect proofed and located where it does not present any hazards. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.8.1.9	Adequate provision shall be made for the disposal of all liquid waste from processing and food handling areas. Liquid waste shall either be removed from the processing environment continuously or held in a designated storage area in lidded containers prior to disposal where it does not present any hazards. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.8.1.10	Reviews of the effectiveness of waste management shall form part of regular site inspections (refer to 2.5.4.3), and the results of these inspections shall be included in the relevant inspection reports. **RESPONSE:** COMPLIANT **EVIDENCE:**