SQF Quality Audit Edition 9
PREMIUM WATERS - Premium Waters - Greeneville

Summary

AUDIT DECISION
CERTIFIED

CERTIFICATION NUMBER
11277 | 149028

DECISION DATE
12/09/2021

AUDIT TYPE
UNANNOUNCED

RECERTIFICATION DATE
11/14/2022

AUDIT DATES
11/08/2021 - 11/10/2021

EXPIRATION DATE
01/28/2023

ISSUE DATE
12/16/2021

Facility & Scope

PREMIUM WATERS (40545)
Premium Waters - Greeneville
1616 Industrial Rd.
Greeneville, TN 37745
United States

Food Sector Categories:
16. Ice, Drink, and Beverage Processing

Products:
Bottled Water

Scope of Certification:
Bottled Water - Distilled, Purified, Spring, Purified with Minerals, Purified with Fluoride

Certification Body & Audit Team

NSF Certification, LLC

789 N. Dixboro Road
Ann Arbor, MI 48113
United States

Web Site: http://www.nsf.org/

CB#: CB-1-NSF
Accreditation Body: ANSI
Accreditation Number: 1181

Lead Auditor: Scher, Gregory (201094)
Technical Reviewer: Cain, Thomas (120673)

Hours Spent on Site: 19
Hours of ICT Activities: 0
Hours Spent Writing Report: 7

Non-Conforming

2.4.3 Food Quality Plan

A Food Quality Plan has been developed, implemented and maintained by the site. It is kept on file in Food Safety and Quality Manual and maintained by QA Manager. The Food Quality Plan has been prepared in accordance with the 12 steps identified in the Codex Alimentarius Commission HACCP guidelines and outlines the means by which the site controls and assures its quality. A multi-disciplinary Food Quality Team has been identified and trained, with documentation found in the QA Manager SQF and School training and he has a strong background in Quality Management and Statistics. The Plan includes a list of all products in the scope of the certification, a product description (including relevant specification information), intended product use (including target consumer group and other relevant information, such as ease of use, use instructions, tamper evidence, etc.) and flow diagrams for each process step, including those inputs and delays that impact quality. The process flow has been verified by the site per review. The Food Quality Team has analyzed all quality threats reasonably likely to occur at each process step, raw material and ingredient input. Control measures are in place to eliminate or reduce the quality threats to acceptable levels. The following Critical Quality Points have been identified: • CQP1 Microbiological results. • CQP2 Bromate As a result, the following Critical Quality Limits were identified: • CQP1 HPC >10 cfu/100ml , coliform >0 cfu/100/ml , Y&M >0 cfu/100/ml Pseudomonas >5 cfu/100ml • CQP2 >0.010 mg/l Control limit compliance is monitored and verified by the site's Food Quality Plan. Any deviation found in the monitoring of established control limits is documented and investigated, with proper disposal of involved products. The plan is verified as part of the SQF System and reviewed annually or when changes occur, by the Food Quality Team with the last review date on 8/10/2021. The following minor nonconformance was observed on the Food Quality Plan 2.4.3.8. Bromate was described as a biological hazard in the plan, it is a chemical hazard.

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

RESPONSE: MINOR

EVIDENCE: Bromate was described as a biological hazard in the plan, it is a chemical hazard.

ROOT CAUSE: While updating Food Quality plan, there was an oversight and Bromate was listed as a Biological vs. a Chemical Hazard. Human Error

CORRECTIVE ACTION: Food Quality Plan was corrected and reviewed by the Food Safety Team.

VERIFICATION OF CLOSEOUT: Sniop of the revised bromate hazard accepted. CAR closed. RS

COMPLETION DATE: 12/03/2021 **CLOSEOUT DATE:** 11/30/2021

Audit Statements

SQF Practitioner Name	Name the designated SQF Practitioner **RESPONSE:** Jeremy Haney
SQF Practitioner Email	Email of the designated SQF Practitioner **RESPONSE:** jeremy.haney@premiumwaters.com
Opening Meeting	People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Don Meyers, Plant Manager; Jeremy Haney, QA Lead; Greg Pluimer, QA Director; Greg Scher, Lead Auditor; James Gass, Shift Manager
Facility Description	Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details **RESPONSE:** The 178000 sq ft. facility was built in 1975 and an addition completed in 2021 The facility 24/7/362 and produces 2.2 million cases per month. Major equipment includes PET and HDPE bottle/jug production equipment, Gallon line, Distillers, Storage tanks (x4) and three bottling lines.
Closing Meeting	People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Don Meyers, Plant Manager; Jeremy Haney, QA Lead; Greg Pluimer, QA Director; Greg Scher, Lead Auditor
Auditor Recommendation	Auditor Recommendation **RESPONSE:** Certify

Section Responses

2.1.1 Management Responsibility

A currently dated organizational chart outlines the structure of staff having responsibility for quality at key process steps. Clear, measured, quality objectives, including Quality Complaint Trends reduced by 5% year over year. These are outlined in the Food Safety and Quality Manual. Senior management has communicated this to the organization and provides the resources for implementation of the quality systems. The QA Manager is the designated SQF Practitioner for food safety, is also the SQF Quality Practitioner. The site has a food safety and quality commitment statement, called the Food Safety and Quality Commitment, that senior management has implemented. It is signed by the Plant Manager. The Policy statement covers customer and regulatory requirements, the use of continuous improvement of the system for quality and the review of (food safety and) quality objectives. The Policy is communicated to the facility's staff by way of posting and is English, the language used in the site. The policy was observed to be posted in the break area. The site's vision and mission statement are included in the food safety and quality statement. The site is not using the SQF Quality Shield. N/A

2.1.1.1 Senior site management shall prepare and implement a policy statement that outlines the site's commitment to quality and includes at a minimum: i. Establishment and maintenance of a quality management system; ii. Compliance with customer, regulatory, and company quality requirements; iii. Identification of quality objectives and the methods used to measure them; and iv. Continuous improvement of its quality performance.

RESPONSE: COMPLIANT

2.1.1.2 The policy statement shall be displayed in a prominent position and communicated to all staff. It may be included in or separate from the organization's food safety policy.

RESPONSE: COMPLIANT

2.1.1.3 Senior site management shall implement, maintain, and continuously improve the quality culture within the site that ensures at a minimum: i. Quality objectives and key performance indicators are communicated to all staff; ii. Provision of adequate resources to meet the objectives and key performance indicators; iii. Awareness by all staff of their quality responsibilities and their accountability in meeting the requirements of the SQF Quality Code; iv. Responsibility to notify management of actual or pending quality issues and empowerment to resolve quality issues within their scope of work; and v. Education of all staff to understand the importance of quality controls and deviation consequences.

RESPONSE: COMPLIANT

2.1.1.4 Senior site management shall ensure the personnel performing key process steps and responsible for achieving quality objectives and meeting customer, regulatory, and company quality requirements are identified in the reporting structure and have the required competencies to carry out these functions.

RESPONSE: COMPLIANT

2.1.1.5 Job descriptions for personnel performing key process steps and responsible for achieving quality requirements shall be documented and include provisions for coverage in the absence of key personnel.

RESPONSE: COMPLIANT

2.1.1.6 Senior site management shall designate an SQF quality practitioner for each site with responsibility and authority to: i. Oversee the development, implementation, review, and maintenance of the SQF Quality System, including quality fundamentals outlined in 2.4.2 and the quality plan outlined in 2.4.3; ii. Take appropriate action to ensure the integrity of the quality system; and iii. Communicate to relevant personnel all information essential to ensure the effective implementation and maintenance of the quality system.

RESPONSE: COMPLIANT

2.1.1.7 The SQF quality practitioner shall: i. Be competent to implement and maintain food quality plans using a risk-based methodology such as HACCP; ii. Understand the Quality Code and the requirements to implement and maintain a quality management system; and iii. Be competent, through training or experience, in process control and/or other quality tools to reduce process variation impacting quality and achieve customer requirements.

RESPONSE: COMPLIANT

2.1.1.8 Senior site management shall develop and implement a quality communication program to ensure all staff: i. Know the site's quality statement, quality objectives, and the process by which quality performance is measured; and ii. Understand the methods by which customer, regulatory, and company quality requirements, where applicable, are met.

RESPONSE: COMPLIANT

2.1.1.9 Senior site management shall establish a process to trend progress in quality performance against agreed measures. Benchmarking shall be part of this process, and the performance data shall be reported at least annually, and communicated to all staff, to demonstrate effectiveness of the quality management system.

RESPONSE: COMPLIANT

2.1.1.10 Sites that are certified to the SQF Quality Code may use the SQF Quality Shield. The use of the quality shield shall follow the requirements outlined in Appendix 4: SQF Quality Shield Rules of Use.

RESPONSE: NOT APPLICABLE

EVIDENCE: The site is not using the SQF Quality Shield. N/A

2.1.2 Management Review

Job descriptions are written for staff responsible for food safety and quality, with coverage for absenteeism assigned. Job descriptions for QA Manager, Maintenance Technician, and a Forklift Driver were reviewed and contained quality responsibilities and the provision to cover personnel during absences. A quality communication plan has been implemented, in which plant staff is informed of the site's quality objectives and quality performance trends. Personnel were aware of the site's requirement to report quality issues to management, as evidenced by interviews with the Maintenance Manager and the Plant Manager. Senior site management has processes in place to demonstrate continuous improvement, to ensure the integrity of the quality systems and to have personnel are in place with the competency and resources for achieving the quality objectives. Trending and benchmarking of the site's quality performance in comparison to other corporate goals were reviewed and found to be conducted annually and as directed.

2.1.2.1 Senior site management shall be responsible for reviewing the performance of the SQF Quality System. Reviews shall include actions required to: i. Monitor compliance to specifications; ii. Measure and reduce process and product variation; iii. Meet customer requirements; iv. Take appropriate corrective action where applicable; and v. Ensure sufficient resources are allocated to maintain and improve the performance of the quality system.

RESPONSE: COMPLIANT

2.1.2.2 The SQF quality practitioner(s) shall update senior site management monthly at a minimum on matters impacting the implementation and maintenance of the SQF Quality System. The updates and management responses shall be documented. The SQF Quality System in its entirety shall be reviewed at least annually.

RESPONSE: COMPLIANT

2.1.2.3 The quality system, including food quality plans, shall be reviewed when any changes are implemented that have an impact on the site's ability to meet customer requirements and/or corporate quality requirements where applicable.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.1.2.5 Senior site management shall document and implement a change management process that details how changes in specifications, materials, equipment, or resources are evaluated for their impact on quality, communicated to customers, and effectively implemented.

RESPONSE: COMPLIANT

2.1.2.6 Records of all quality system reviews, reasons for amending documents, and changes to the SQF Quality System shall be maintained. Records shall include decisions for actions related to the improvement of the quality system and process effectiveness.

RESPONSE: COMPLIANT

2.1.3 Complaint Management

The site's written Complaint policy is found in the document 100-SOP-QA-1032. It defines the methods and responsibilities for handling customer quality complaints. The investigation of quality complaints is handled by the QA Manager, with corrective actions and records kept of each quality complaint and its resolution. Records of quality complaints and their resolution were reviewed for crooked bottle that showed that investigation and corrective actions of the complaints had been put into place. Trending graphs of complaints for quality issues during the time period 6/1/2021 through 6/30/2021 were also reviewed.

2.1.3.1 The methods and responsibilities for the complaint management process shall be documented and implemented. They shall include: i. A mechanism to collect and record all quality complaints resulting from activities at the site; and ii. Communication processes for reporting and follow-up with senior management and customers.

RESPONSE: COMPLIANT

2.1.3.2 Trends from quality complaints shall be included in the performance measures established for the quality system.

RESPONSE: COMPLIANT

2.1.3.3 Corrective and preventative action shall be implemented based on the seriousness of the incident and identified trends and shall be completed as outlined in 2.5.3.

RESPONSE: COMPLIANT

2.1.3.4 Records of quality complaints, their investigation and resolution, if applicable, shall be maintained.

RESPONSE: COMPLIANT

2.2.1 Quality Management System

A Quality Manual has been developed and is maintained in hard copy and electronic form called the Quality Assurance Procedures. 112-POL-QA-002 is dated 9/3/2021 and maintained by Quality Manager. The Quality manual contains the scope of the certification, a list of products in the scope, finished product specifications, the organizational chart; and the food safety and quality policies, programs and procedures, including quality tools the site uses to reduce process variation that are part of the site's SQF Quality System. It is made available to all relevant staff in the QA Office.

2.2.1.1 Electronic and/or hard copy documentation that outlines the methods and procedures the site shall use to meet the requirements of the SQF Quality Code shall be current and maintained. It shall be made available to staff and include: i. A summary of the organization's quality policies and the methods it will apply to meet the requirements of the SQF Quality Code; ii. The policy statement and site organization chart; iii. A list of the products covered under the scope of certification; iv. Finished product specifications that agree with customers' requirements and/or meet the site's corporate quality requirements, where applicable; and v. A description of the applications of process control methods and other quality tools that are used to control and reduce process variation and meet customer specifications. The quality system manual may be incorporated into or be independent of the food safety system manual.

RESPONSE: COMPLIANT

2.2.2 Document Control

The site has implemented its Document Control Policy, defining the methods and responsibilities for document control of quality records. Records were found during the audit to be readily accessible and properly stored. A current list of all SQF documents, including quality documents, is maintained and documents were observed to be stored securely and are accessible. Controls for quality documents were included and were seen to be equivalent to those applied to food safety documents.

2.2.2.1 The methods and responsibility for maintenance, storage, and distribution of quality documents shall be documented and implemented.

RESPONSE: COMPLIANT

2.2.2.2 A register of current SQF Quality System documents and amendments to documents shall be maintained. Documents shall be safely stored and readily accessible.

RESPONSE: COMPLIANT

2.2.3 Records

The site has implemented its policy for verifying and retaining quality records found in a Corporate SOP called 100-SOP-QA-2311. The facility has documented procedures for authorization of documents, accessibility and retention of quality records, and record retention, the same as the record procedures used for food safety records. Quality records were observed to be readily accessible, legibly filled out, securely stored to prevent damage and have documented retention times. Quality records are retained for five years in the Plant.

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.2.3.3 Records shall be readily accessible, retrievable, and securely stored to prevent unauthorized access, loss, damage, and deterioration. Records shall be retained in accordance with periods specified by customers or regulations or, at a minimum, no less than the product shelf- life.

RESPONSE: COMPLIANT

2.3.1 Product Formulation and Realization

Product was not developed on site

2.3.1.1 The methods for designing, developing, and converting product concepts to commercial realization shall include a comparison of process controls with specification limits (i.e., process capability analysis) to ensure that processes can consistently supply products that meet customer specifications.

RESPONSE: NOT APPLICABLE

EVIDENCE: Product was not developed on site

2.3.1.2 Product formulation, manufacturing processes, and the fulfillment of product quality requirements shall be validated by facility trials and product testing.

RESPONSE: NOT APPLICABLE

EVIDENCE: Product was not developed on site

2.3.1.3 Shelf life trials shall be conducted for new products, or when there are changes in materials, ingredients, or equipment, to establish and validate a product's packaging, handling, storage, and customer-use requirements through the end of its commercial life and consumer use.

RESPONSE: NOT APPLICABLE

EVIDENCE: Product was not developed on site

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

Specifications for raw materials, packaging, ingredients, additives, chemicals, and processing aids that have an impact on product quality have been documented. Current registers were reviewed for raw materials, packaging materials, and labels. Specifications for apackaging film and a processing aid were reviewed and found to be current. All applicable raw and packaging materials are verified to ensure product quality and regulatory requirements are met, and the material is fit for its intended purpose. Product labels that are designed or specified by customers are approved have been approved by those customers. There is an electronic register of raw material, ingredients, and packaging specifications affecting product quality called the "Specification Register" that was found to be correct.

2.3.2.1 Specifications for all raw materials and packaging, including but not limited to ingredients, additives, agricultural inputs (where applicable), hazardous chemicals, and processing aids that impact finished product quality shall be documented and kept current.

RESPONSE: COMPLIANT

2.3.2.2 Raw and packaging quality parameters shall be verified upon receipt to ensure they meet specifications.

RESPONSE: COMPLIANT

2.3.2.3 Product labels that are designed or specified by customers shall be approved by those customers. Records shall be maintained of customer approvals.

RESPONSE: COMPLIANT

2.3.2.4 The register of current raw material and packaging specifications shall include those raw material and packaging materials that impact product quality and customer labels.

RESPONSE: COMPLIANT

2.3.2.5 Finished product specifications shall be documented, current, approved by the site and its customers when required, and accessible to relevant staff. The specifications shall include product quality attributes, service delivery requirements, and labeling and packaging requirements.

RESPONSE: COMPLIANT

2.3.2.6 Customer product specifications and delivery requirements shall be communicated to appropriate departments and staff within the site.

RESPONSE: COMPLIANT

2.3.2.7 Specifications for contract services that have an impact on in-process or finished product quality shall be documented, current, include a full description of the service to be provided, and detail relevant training requirements of contract personnel. The register of contract service specifications shall list those services impacting product quality

RESPONSE: COMPLIANT

2.3.3 Contract Manufacturers

Contract manufacturers were not utilized

2.3.3.1 The methods and responsibility for ensuring all agreements with contract manufacturers relating to quality, site/customer product requirements, their realization, and delivery shall be specified, documented, agreed upon, and implemented.

RESPONSE: COMPLIANT

EVIDENCE: Contract manufacturers were not utilized

2.3.3.2 The site shall: i. Ensure that the processes in place at the contract manufacturer are capable of consistently meeting customer and/or corporate quality requirements, where applicable; ii. Verify compliance with the SQF Quality Code and that all customer requirements are being met; iii. Audit the contract manufacturer annually, at a minimum, to verify compliance to the SQF Quality Code and with agreed arrangements, or accept the manufacturer's certification to the SQF Quality Code or equivalent; and iv. Ensure changes to contractual agreements are approved by both parties, agreed with customers when necessary, and communicated to relevant personnel.

RESPONSE: NOT APPLICABLE

EVIDENCE: Contract manufacturers were not utilized

2.3.3.3 Records of audits, contracts, and changes to contractual agreements and their approvals shall be maintained.

RESPONSE: NOT APPLICABLE

EVIDENCE: Contract manufacturers were not utilized

2.3.4 Approved Supplier Program

The site has a written supplier approval policy was implimented with the procedures for granting and monitoring of approved suppliers of raw materials, ingredients, packaging, and services that impact product quality. Material supplies are only accepted into the facility based on either certificate of analysis for every lot received, or inspection at receipt to ensure materials comply with the specification. The approved supplier program contains an agreement with suppliers for the return or disposal of materials that fail to meet specifications or are damaged or contaminated. The policy includes a review of products and testing applicable to each supplier. Approval requires material suppliers to maintain controlled and current specifications for the site and to have a quality complaint corrective action program in place.

2.3.4.1 Raw materials, ingredients, packaging materials, processing aids, and services, including co-manufactured products, that impact finished product quality shall be supplied by an approved supplier.

RESPONSE: COMPLIANT

2.3.4.2 Material suppliers shall be selected and approved based on their ability to supply materials that meet quality specifications. The evaluation program shall require suppliers to: i. Maintain controlled and current copies of specifications; ii. Have processes that are capable of consistently supplying materials that meet specification and other defined quality metrics (e.g., delivery, service, etc.); iii. Provide evidence that the supplied product meets agreed specifications and metrics; and iv. Have a complaint management system in place that includes corrective actions processes.

RESPONSE: COMPLIANT

2.3.4.3 Materials supplied shall only be accepted by the site based on either a certificate of analysis for each lot received, or inspection of the lot at receipt, to ensure materials comply with specifications. All receipts shall be visually inspected for damage and product integrity.

RESPONSE: COMPLIANT

2.3.4.4 The approved supplier program shall include an agreement with suppliers for the return or disposal of materials that fail to meet specifications or are damaged or contaminated.

RESPONSE: COMPLIANT

2.3.4.5 Any supplier audits performed shall be conducted by individuals knowledgeable of applicable regulatory and food quality requirements and trained in auditing techniques.

RESPONSE: COMPLIANT

2.4.1 Customer Requirements

As a large ingredient supplier and retail/wholsale product supplier, the SQFP reviews the requirements and expectations of its customers and final consumers on a timeframe decided upon in multiple contracts. The accuracy of specifications and the ability to supply to customer needs are part of this review including alternate facilities in the Crisis Management Plans. Primary responsibility for ensuring that the site is up to date on the requirements of customers and consumers and for notifying essential customers of temporary quality issues is held by Corporate Account Managers. Procedures are in place to safeguard and control customer property used by the site as observed with the locked trash bins for branded items (labels).

2.4.1.1 The methods and responsibilities for managing customer requirements and/or consumer expectations shall be documented and implemented. They shall include at a minimum: i. A review and approval process for all new or updated customer requirements, as they occur; ii. A process for collection and analysis of data for product quality attributes to ensure specifications continue to meet consumer expectations; and iii. A communication process to notify identified customers when the ability to supply compliant products is temporarily halted.

RESPONSE: COMPLIANT

2.4.1.2 Where customer products, materials, or equipment are used within the facility, the site shall have measures in place to safeguard customer property and ensure its correct and proper use.

RESPONSE: COMPLIANT

2.4.2 Quality Fundamentals

The property, buildings, and equipment are located, constructed, and designed to ensure food meets specifications and is manufactured, stored, and transported to meet customer and corporate quality requirements. Calibration of measuring, inspection, and test equipment used to monitor compliance to customer specifications is documented in the Calibration Policy.

2.4.2.1 The buildings and equipment shall be constructed, designed, and maintained to facilitate the manufacture, handling, storage, and/or delivery of food that meets customer specifications, regulatory requirements, and/or company quality requirements.

RESPONSE: COMPLIANT

2.4.2.2 The methods and responsibility for the calibration of measuring, test, and inspection equipment used for quality testing of raw materials, work-in-progress, and finished product, for food quality 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

2.4.2.3 Storage and transport of raw materials, work-in-progress, and finished product shall be suitable to maintain the integrity of the product without loss, waste, or damage and to meet customer requirements for inventory management and transportation, where applicable.

RESPONSE: COMPLIANT

2.4.3 Food Quality Plan

A Food Quality Plan has been developed, implemented and maintained by the site. It is kept on file in Food Safety and Quality Manual and maintained by QA Manager. The Food Quality Plan has been prepared in accordance with the 12 steps identified in the Codex Alimentarius Commission HACCP guidelines and outlines the means by which the site controls and assures its quality. A multi-disciplinary Food Quality Team has been identified and trained, with documentation found in the QA Manager SQF and School training and he has a strong background in Quality Management and Statistics. The Plan includes a list of all products in the scope of the certification, a product description (including relevant specification information), intended product use (including target consumer group and other relevant information, such as ease of use, use instructions, tamper evidence, etc.) and flow diagrams for each process step, including those inputs and delays that impact quality. The process flow has been verified by the site per review. The Food Quality Team has analyzed all quality threats reasonably likely to occur at each process step, raw material and ingredient input. Control measures are in place to eliminate or reduce the quality threats to acceptable levels. The following Critical Quality Points have been identified: • CQP1 Microbiological results. • CQP2 Bromate As a result, the following Critical Quality Limits were identified: • CQP1 HPC >10 cfu/100ml , coliform >0 cfu/100/ml , Y&M >0 cfu/100/ml Pseudomonas >5 cfu/100ml • CQP2 >0.010 mg/l Control limit compliance is monitored and verified by the site's Food Quality Plan. Any deviation found in the monitoring of established control limits is documented and investigated, with proper disposal of involved products. The plan is verified as part of the SQF System and reviewed annually or when changes occur, by the Food Quality Team with the last review date on 8/10/2021. The following minor nonconformance was observed on the Food Quality Plan 2.4.3.8. Bromate was described as a biological hazard in the plan, it is a chemical hazard.

2.4.3.1 A food quality plan shall be developed, effectively implemented, and maintained in accordance with a risk-based method such as HACCP. The food quality plan may be combined with or independent from the food safety plan, but either way it must identify quality threats and critical quality points and their controls.

RESPONSE: COMPLIANT

2.4.3.2 The food quality plan shall outline how the site controls and assures the quality attributes of the products or product groups and their associated processes.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.3.4 The scope of the food quality plan shall be developed and documented, including the start and endpoints of the processes under consideration and all relevant inputs and outputs.

RESPONSE: COMPLIANT

2.4.3.5 Product descriptions shall be developed and documented for all products included in the scope of the food quality plan. This shall include information in the finished product specifications (refer to 2.3.2.1) plus any additional quality or service attributes established by agreement with the customers.

RESPONSE: COMPLIANT

2.4.3.6 The intended use of each product shall be determined and documented. This shall include, as appropriate, target consumer groups, ease of use by consumers, consumer instructions, evidence of tampering , and other applicable information affecting product quality.

RESPONSE: COMPLIANT

2.4.3.7 The food quality team shall review the flow diagrams developed as part of the food safety plan and confirm and ensure process steps, process delays, and inputs and outputs that impact product quality are included.

RESPONSE: COMPLIANT

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

RESPONSE: MINOR

EVIDENCE: Bromate was described as a biological hazard in the plan, it is a chemical hazard.

ROOT CAUSE: While updating Food Quality plan, there was an oversight and Bromate was listed as a Biological vs. a Chemical Hazard. Human Error

CORRECTIVE ACTION: Food Quality Plan was corrected and reviewed by the Food Safety Team.

VERIFICATION OF CLOSEOUT: Sniop of the revised bromate hazard accepted. CAR closed. RS

COMPLETION DATE: 12/03/2021 **CLOSEOUT DATE:** 11/30/2021

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.3.11 Based on the results of the threat analysis (refer to 2.4.3.9), the food quality team shall identify the steps in the processes where control must be applied to eliminate a significant threat or reduce it to an acceptable level. These steps shall be identified as Critical Quality Points or CQPs.

RESPONSE: COMPLIANT

2.4.3.12 For each identified CQP, the food quality team shall identify and document the quality limits that separate acceptable from unacceptable product. The food quality team shall validate the critical quality limits to ensure the designated level of control of the identified quality threat (s), and that all critical quality limits and control measures individually or in combination effectively provide the level of control required.

RESPONSE: COMPLIANT

2.4.3.13 The food quality team shall develop and document procedures to monitor CQPs to ensure they remain within the established limits (refer to 2.4.3.12). Monitoring procedures shall identify the personnel assigned to conduct testing, the sampling and test methods, and the test frequency.

RESPONSE: COMPLIANT

2.4.3.14 The food quality team shall develop and document deviation procedures that identify the disposition of affected product when monitoring indicates a loss of control at a CQP. The procedures shall also prescribe actions to correct the process step to prevent recurrence of the quality failure.

RESPONSE: COMPLIANT

2.4.3.15 The documented and approved food quality plan shall be fully implemented. The effective implementation shall be monitored by the food quality team, and a full review of the documented and implemented plans shall be conducted at least annually, or when changes to the process, equipment, specifications or inputs occur which may affect product quality.

RESPONSE: COMPLIANT

2.4.3.16 Implemented food quality plans shall be verified as part of SQF Quality System verification (refer to 2.5).

RESPONSE: COMPLIANT

2.4.4 Product Sampling, Inspection, and Analysis

The Food Safety and Quality Manual contained a summary of the site's procedures and criteria for sampling, inspecting and analyzing programs for quality attributes of raw materials, work-in-progress and finished product have and implemented in the water processing and bottling. The program includes sensory evaluations and scheduled verifications of process parameters, or scheduled in-process measurement at suitably equipped locations, to ensure compliance with customer requirements. Process control methods are in use to effectively control and optimize production processes that improve process efficiency, product quality and reduce waste For example, Control Charts for Spring Water ozonation covering the date range 6/01/2021 to 6/7/2021 were reviewed. Control charts were reviewed for Spring water ozonation and the specification and approved process had upper and lower process control limits. Product sensory testing records were reviewed for caffeine joe water production during the audit and found to be conducted to ensure customer expectations and specifications were met.

2.4.4.1 Processing parameters or in-process measurements shall be established, validated, and verified at a determined frequency to meet all customer, regulatory, and/or company requirements.

RESPONSE: COMPLIANT

2.4.4.2 On-site laboratories and inspection stations shall be equipped and resourced to enable testing of in-process and finished products to meet customer, regulatory, and/ or company requirements and meet quality objectives. 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 2.3.2.7).

RESPONSE: COMPLIANT

2.4.4.3 Process control methods shall be used to effectively control and optimize production processes to improve process efficiency, product quality, and reduce waste. Control charts and/or other quality tools shall be used for control of key processes

RESPONSE: COMPLIANT

2.4.4.4 A sensory evaluation program shall be in place to ensure alignment with agreed customer and/or company requirements. Sensory evaluation results shall be communicated with relevant staff and with customers where appropriate.

RESPONSE: COMPLIANT

2.4.4.5 Records of all quality inspections and analyses and statistical analyses shall be maintained.

RESPONSE: COMPLIANT

2.4.5 Non-conforming Product or Equipment

The site has written procedures for withholding non-conforming products for quality reasons, including raw materials, work-in-progress, ingredients, packaging, product returns and equipment in the Food Safety and Quality Manual, which were found to be properly implemented in the facility. The site has written procedures to accept products returned by customers that do not meet finished product specifications. Methods to segregate, identify, handle and dispose of non-conforming and returned product include tagging and crushing/recycling, and were observed to minimize any inadvertent use.

2.4.5.1 Non-conforming product shall include products that fail to meet in-process or product requirements for quality. Non-conforming product shall be suitably identified, segregated, and appropriately dispositioned with records maintained.

RESPONSE: COMPLIANT

2.4.5.2 Non-conforming equipment shall include equipment that is not suitable for use and/ or is not capable of producing products that meet in-process or product requirements for quality. Non-conforming equipment shall be identified and segregated from production areas, if possible, with appropriate documentation maintained.

RESPONSE: COMPLIANT

2.4.5.3 The site shall document and implement a procedure to accept returned product that does not meet finished product specifications. The procedure shall include identification, handling, and disposition of returned goods to prevent redistribution or contamination of other products.

RESPONSE: COMPLIANT

2.4.6 Product Rework

Rework was not done

2.4.6.1 Procedures shall be documented and implemented to ensure product quality or formulation is not compromised by the rework process. Material to be reworked shall be identified and traceable. Rework operations shall be overseen by qualified personnel.

RESPONSE: NOT APPLICABLE

EVIDENCE: Rework was not done

2.4.7 Product Release

The site has written procedures in multiple SOPs that are implemented for the positive release of finished products. These positive release procedures include ensuring that all product inspections and analyses have been verified and documented by authorized personnel to show that all food safety and quality controls, packaging integrity, sensory analysis, product specifications and service requirements have been met. A review of records for product releases of spring water and alkhaline water during the audit showed they had been conducted per procedures.

2.4.7.1 The site shall document and implement a positive product release procedure to ensure that, at the time of delivery to its customer, the food supplied complies with all agreed customer, regulatory, and/or company requirements, including but not limited to product specifications, sensory attributes, packaging and package integrity, labeling, delivery, and service requirements.

RESPONSE: COMPLIANT

2.4.7.2 Records of all product release or disposition shall be maintained

RESPONSE: COMPLIANT

2.5.1 Validation and Effectiveness

The site has written validation activities that authenticate critical quality limits, process controls, and other quality tests to ensure customer requirements are met. These methods are located in Food Safety and Quality Manual and were found to ensure that each has been implemented effectively. Methods to ensure that procedure or process changes are still effective in controlling quality requirements are in place and documented in the Quality Plan. Critical quality limits are re-validated at least annually by the Corporate QA Director. Records of all verifications of effectiveness and validations are maintained by the SQF Practitioner.

2.5.1.1 Validation activities shall include those necessary to authenticate critical quality limits, process controls, and other quality tests established to meet customer requirements.

RESPONSE: COMPLIANT

2.5.1.2 Records of validation of quality criteria shall be maintained.

RESPONSE: COMPLIANT

2.5.2 Verification Activities

The site has established a verification schedule outlining the verification steps, procedures, and responsibilities for each verification activity. The schedule is found electronically within the facility's cloudbased system and is maintained by the SQF Practioner. The procedures for verifying Critical Control Points, Quality Points, process controls, and other quality tests include utilizing authorized personnel to verify all monitoring activities. Records of verification of monitoring activities including Shred Head Inspection, Harp Wire Inspection, and weight verification were reviewed and found to meet requirements.

2.5.2.1 The verification schedule shall include activities designed to ensure the effectiveness of process controls and quality tests.

RESPONSE: COMPLIANT

2.5.2.2 The methods, responsibility, and criteria for verifying the effectiveness of monitoring critical quality points and other process and quality controls shall be documented and implemented. The methods applied shall ensure that personnel with responsibility for verifying monitoring activities authorize each record.

RESPONSE: COMPLIANT

2.5.2.3 Verification activities shall include a comparison between process control limits and specification limits to ensure alignment and appropriate process control corrections.

RESPONSE: COMPLIANT

2.5.2.4 Records of the verification of quality activities shall be maintained.

RESPONSE: COMPLIANT

2.5.3 Corrective and Preventative Action

The site's Corrective and Preventative Action program is written in the Food Quality Plan. It describes the methods and responsibilities for investigating, resolving and managing corrective actions, including the identification of root causes and resolutions to deviations of critical limits and deviation from quality requirements. Records of investigations and corrective actions were reviewed for 06/01/2021 through 06/7/2021. These were found to have reviews, investigations, corrective and preventative actions and resolutions documented. Quality-related verification activities were found to include continuously monitored parameters that when exceeded rejected product for further inspection.

2.5.3.1 Corrective and preventative action methods shall include the identification of the root cause(s) and the resolution of non-compliance of critical quality limits and deviations from quality requirements.

RESPONSE: COMPLIANT

2.5.4 Internal Audits

The site's procedure for scheduling and conducting internal audits to assess the effectiveness of the SQF Quality system has been documented and implemented per the document the Internal Plant Audit Procedure. The Internal Audit Program is maintained by the SQF Practitioner. Process controls, quality plans, quality tests, and all applicable SQF Quality Code requirements, are part of the internal audit program. Personnel auditing quality functions, e.g. SQF Practitioner and QA Team Leader, were seen to have knowledge of the quality process and process control methods for the activities audited.

2.5.4.1 Internal audit plans and methods shall include assessments of food quality plans, process controls, quality tests, and other activities implemented to meet finished product specifications as well as customer and company requirements.

RESPONSE: COMPLIANT

2.5.4.2 Staff conducting the quality internal audits shall be trained and competent in internal audit procedures and have knowledge and experience in quality processes and process control methods as they relate to the scope of certification. Where practical, staff conducting internal audits shall be independent of the function being audited.

RESPONSE: COMPLIANT

2.6.1 Product Identification and Traceability

A policy defining how finished product are labeled to the agreed customer, company or corporate requirements is found in the Food Safety and Quality Manual. Product changeover procedures are written to include quality attributes required to meet finished product specifications and customer requirements. Product startup/changeover procedures include those quality attributes required to meet customer requirements as well as finished product specifications. Product identification records, Raw material receiving reports, work order/batch sheets, and shipping BOLs were reviewed during the audit for 6/01/2021 through 6/07/2021.

2.6.1.1 Finished product shall be labeled to the agreed customer, regulatory, and/or company requirements.

RESPONSE: COMPLIANT

2.6.1.2 Product changeover procedures shall include verification of quality attributes required to meet finished product specifications and customer requirements.

RESPONSE: COMPLIANT

2.6.1.3 Finished product shall be traceable forward to the customer, such as the retailer, distributor, or manufacturer (one forward).

RESPONSE: COMPLIANT

2.6.1.4 All raw materials, ingredients, and packaging materials used in manufacturing a finished product and processing aids associated with the product shall be identified with the finished product lot number and traceable back to the supplier (one back).

RESPONSE: COMPLIANT

2.6.2 Product Withdrawal and Recall

The site has a Recall Plan that includes recall and withdrawal procedures for products recalled or withdrawn from the marketplace due to failure to meet customer specifications or corporate quality requirements.

2.6.2.1 The site's recall and withdrawal procedures shall apply to product recalled or withdrawn due to failure to meet customer specifications or corporate quality requirements. Records shall be maintained and meet customer, regulatory, and company requirements, as applicable.

RESPONSE: COMPLIANT

2.6.3 Crisis Management

A Crisis Management Plan has been prepared by Senior Management and is found in the Food Safety and Quality Manual. The Plan has been implemented and addresses serious disaster threats that could impact on the site's ability to meet customer requirements of product quality and service levels. Plant Manager has oversight of the Crisis Management Plan, and it contains a provision to contact customers when a crisis occurs that affects the site's ability to supply quality products.

2.6.3.1 The crisis management plan prepared by senior site management shall include the methods by which the site shall, in the event of a crisis, maintain continuity of supply that meets customer, regulatory, and/or company product and service quality requirements.

RESPONSE: COMPLIANT

2.6.3.2 The site shall contact its customers in the event of a crisis that impacts its ability to supply quality product.

RESPONSE: COMPLIANT

2.7.1 Food Fraud

The site has conducted a Food Fraud Vulnerability Assessment, found in the document Food Defense and Food Fraud, which includes the site's susceptibility to fraudulent economic gain, including product substitution, mislabeling, counterfeiting, and dilution that could impact product quality. The site has developed a Food Fraud Mitigation Plan, called Food Fraud and Vulnerability Assessment & Mitigation Plan, to address the control of the identified food fraud vulnerabilities to product quality, which is tested at least annually.

2.7.1.1 The food fraud vulnerability assessment shall include the site's susceptibility to ingredient or product substitution, mislabeling, dilution, and counterfeiting that could adversely impact food quality. This assessment may address both food safety and quality.

RESPONSE: COMPLIANT

2.7.1.2 A food fraud mitigation plan shall be developed and implemented that specifies the methods to be used for controlling identified food fraud vulnerability that could adversely impact food quality.

RESPONSE: COMPLIANT

2.8.1 General Requirements for Identity Preserved Foods

The site's policy for the identification and processing of products requiring preservation of their status is 112-POL-QA-002. Identity Preserved Foods produced by this site include: Spring Water and Distilled. The identification methods used by the site, based on inputs and controls for Spring Water packed on 06/1/2021 showed that procedures adequately address the status of all ingredients, preservatives, processing aids and flavorings; that specifications include handling, transport, storage and delivery of inputs prior to use, and agreements with the suppliers of relevant input materials. : • Physical separation from incompatible materials during storage • Processing in separate locations • Scheduling and cleaning controls to prevent cross contamination of materials • Implementation of customer-specific requirements.

2.8.1.1 The methods and responsibility for the identification, label approval, and processing of food and other products requiring the preservation of their identity preserved status (e.g., Kosher, Halal, organic, GMO free, regional provenance, free from, free trade, etc.) shall be documented and implemented.

RESPONSE: COMPLIANT

2.8.1.2 Identification shall include a statement of the product's identity preserved status of all ingredients, including additives, preservatives, processing aids, and flavorings.

RESPONSE: COMPLIANT

2.8.1.3 Raw material and ingredient specifications for identity preserved foods shall include requirements for their handling, transport, storage, and delivery prior to use.

RESPONSE: COMPLIANT

2.8.1.4 Assurances concerning the raw material or ingredient's identity preserved status shall be by agreement with the supplier of the material.

RESPONSE: COMPLIANT

2.8.1.5 The process description shall allow for a product's identity preserved status to be maintained during manufacturing.

RESPONSE: COMPLIANT

2.8.1.6 The processing of identity preserved foods shall be conducted under controlled conditions such that: i. Ingredients are physically separated from ingredients identified as incompatible with the identity preserved food; ii. Processing is completed in separate rooms, scheduled as the first production run, or carried out after completion of thorough sanitation of the processing area and equipment; and iii. Finished product is stored and transported in separate units or isolated by a physical barrier from the non-specialty product.

RESPONSE: COMPLIANT

2.8.1.7 The identity preserved status shall be declared in accordance with regulatory requirements.

RESPONSE: COMPLIANT

2.8.1.8 Additional customer-specific requirements for identity preserved foods shall be included in the finished product specification, as described in 2.3.2.5, or the label register and implemented by the site.

RESPONSE: COMPLIANT

2.9.1 Training Requirements

Appropriate training is provided for all plant personnel for all tasks to ensure the effective implementation of the SQF Quality system and the maintenance and improvement of quality requirements. This training program is administered by the QA Team Lead. Detailed proprietary quality inspection SOPs with detailed forms were reveiewed for 6/2021.

2.9.1.1 Appropriate training shall be provided for personnel carrying out the tasks critical to the effective implementation of the SQF Quality System and the maintenance and improvement of quality requirements.

RESPONSE: COMPLIANT

2.9.1.2 Instructions shall be available explaining how all tasks critical to meeting customer and company specifications and quality and process efficiency are to be performed.

RESPONSE: COMPLIANT

2.9.2 Training Program

The site has implemented a training program, entitled Training, which covers competencies including process control, monitoring of quality points, steps identified as critical to effective implementation and maintenance of the food quality plan, and product inspection and testing. This training was evidenced in the facility by interviews with three plant employees GP, DM, and CB.

2.9.2.1 The employee training program shall include the necessary competencies for specific duties and the training methods to be applied for those staff carrying out tasks associated with: i. Process control and monitoring of critical quality points (CQPs); ii. Steps identified as critical to effective implementation of the food quality plan and the maintenance of food quality; and iii. Product inspection and testing.

RESPONSE: COMPLIANT

2.9.2.2 The employee training program shall include: i. Applicable process control and quality tools training for those responsible for operating, inspecting, and overseeing key manufacturing processes; ii. Training, calibration, and proficiency testing of internal laboratory personnel; iii. Training of personnel responsible for sensory evaluations; iv. Training in the application of risk-based principles, such as HACCP, used for the identification and control of quality threats for staff involved in developing and maintaining the food quality plan; and v. Provision for identifying and implementing the refresher training needs of site personnel.

RESPONSE: COMPLIANT

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