Waiakea Bottling Inc. d.b.a

Waiakea Hawaiian Volcanic Water

447 Kalanianaole Avenue
Hilo, HI 14825

FOOD SAFETY PLAN & SYSTEM

Version 2.1 – August 29, 2019
Reviewed & Approval

This plan is reviewed annually and revised as necessary when personnel, procedures, processes, suppliers, or as other significant factors change. The Plan will also be reviewed after any Company Recall.

Overseen by:

Jay Malloe — August 29, 2019

Jay Malloe, Quality Control — Date Reviewed
PCQI# d6c1b14b

Owner, operator or agent in charge of the facility:

Jerry Clark — August 29, 2019

Jerry Clark, Plant Manager — Date Reviewed
PCQI# be1a6464

Version Update/Review History

Ver	Name	Title	Date Completed	Purpose	PCQI Review by
1.0	Crystal Casas	Quality Manager	8/1/2018	Initial Plan built upon existing HACCP Plan	NA
2.0	Jay Malloe	Quality Manager	5/13/19	Update of plan	Jerry Clark
2.1	Jay Malloe	Quality Manager	8/29/19	Update of content	Jerry Clark

PRELIMINARY STEPS

Company Overview

The Waiakea Hawaiian Volcanic Water Co. was founded by Ryan Emmons in 2015.

The Company has one major line of business: a) Bottled Water. The Hilo facility is only in the bottled water line of business. It markets bottled water directly to wholesale and retail customers.

Bottled water is produced on-site in a range of sizes and containers. Initial production is under one "Standard of Identity" as the FDA refers to them: 1) Well water (drawn from a deep well). In the future the plant may expand offerings to include a Sparkling version (well water infused with carbon dioxide).

For on-site production, the primary ingredient is water from Kai Source which travels by dedicated tanker from the source to the production facility. The water is subject to minimal treatment designed to protect its purity and attributes of the source water.

We test each finished product batch in-house for Total Coliform and E.coli. Once a week we send samples to an outside laboratory. Source waters are also routinely tested.

We have adopted a comprehensive Food Safety Plan compliant with the FDA's Preventive Controls for Human Food. This includes integrated pest control and other programs which insure our facility and source meet all regulatory requirements.

While not currently members, we follow the Model Code of the International Bottled Water Association. We contract annually for an outside audit conducted by NSF International, a qualified 3rd party auditing company. We maintain one or more Preventive Controls Qualified Individuals (PCQI) on staff or retainer.

Management Commitment

It is the policy of the management of our company to fully supports the Food Safety Plan developed and implemented at this facility.

As senior management, we will request and review periodic progress reports on the status of the Food Safety Plan. We will provide human and financial resources to support our food safety systems and are committed to the continuous improvement of our system. We are committed to supply safe bottled water, using all necessary and appropriate methods to comply with its customers and regulatory requirements.

Our Food Safety Plan and System incorporates our Hazard Analysis, Risk Analysis and Preventive Controls plan that follows the principles in accordance with CODEX Alimentarius and the US FDA's Final Rule for Preventative Controls for Human Food. We have also incorporated other controls, prerequisite programs, good manufacturing practices, work instructions including sanitary standard operating procedures, standard operating procedures, checklists and logs that affirm our commitment to doing everything necessary to produce safe, quality products.

We have vested management and staff with responsibility and authority to oversee the development, implementation, review and maintenance of our Food Safety plan and to also communicate to relevant personnel all information essential to ensure the effective implementation and maintenance.

A copy of the complete Food Safety Plan and System document is kept in the office and is available on request for those needing to review any portion and also for regulatory compliance or 3rd party audits.

JLD

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Ryan Emmons
CEO & Co-Founder
Waiakea, Inc.
5800 Hannum Ave, #135
Culver City, CA 90230

JC

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Jerry Clark
Plant Manager
Waiakea, Inc.
447 Kalanianaole
Hilo, HI 96720

Scope of this Food Safety Plan

The **SCOPE** of this Food Safety Plan includes the facility known as Waiakea Hawaiian Volcanic Water of Hilo, HI and the products produced on the premises under the standards of identity of well water in a variety of sizes.

This plan does cover the water source site which is located about 10 miles from the bottling plant.

The facility does not purchase any additional packages of bottled water from any supplier.

The Food Safety Plan and System covers the process from receiving of source water (from natural source) through the treatment and bottling of finished product and warehouse storage onsite. Distribution and transportation is only within scope of the plan as it relates to the first point of sale. Hazards assessed include known or reasonably foreseeable microbiological, chemical, radiological and physical hazards related to the water, raw materials and processing.

Facility Information

Corporate Name:	Waiakea Hawaiian Volcanic Water, Hilo, HI.	
Corporate Office: ☑ Standalone ☐ Part of Bottling Facility	**Ryan Emmons, President & CEO** (805) 450-0981, ryanemmons@waiakeasprings.com **Crystal Casas, Quality Control Manager** (805) 827-5507, ccasas@waiakeasprings.com 5800 Hannum Avenue, Suite 135 Culver City, CA 90230 Office: (424) 228-4234 Customer Service: 808-491-6998	# of Employees in total company: 40 Hours: M-F, 9AM – 4:30 PM No food production at this location.
Bottling Facility:	**Jerry Clark, Plant Manager** (209) 550-1070 jClark@waiakeasprings.com 447 Kalanianaole Avenue Hilo, HI 96720 Main Phone: 808-491-6980 No Fax	NYSHD Cert. # # of Employees: 24 FT, 0 PT Square Footage of Plant: 8,500 Acreage of Property: 24,772 sf Office: M-F, 8:00 AM – 4:30 PM Production: M-F, 7:00 AM – 3:00 PM Seasonal: Production based on demand; during slower periods may produce less frequently; Saturday shift based on demand
Water Source: ☑ Standalone ☐ Part of Bottling Facility Property	Kai Well **16-329 Shipman Road, Kea'au, Hawaii 96749** Owned by Ke'aloha'lani LLC (The founder and Chairman of Waiakea has a controlling ownership interest in the source and the property it is located on.) State Well No B-3802-012, Benchmark Elevation 242.29 feet above sea level.	
Public Water Source:	PWSID: HI0000101 DWS HILO 345 Kekuanaoa Street, Suite 20, Hilo, HI 96720 (808) 961-8050 Source of water: Ground The facility is connected to the public water system of Hilo for purposes of Operations water (for toilets, handwashing sinks, etc.). It is also used at the Kai well site to wash down the back of the tanker if there is visible dirt.	
Company Description:	Waiakea Hawaiian Volcanic Water of Hilo, HI is a bottled water manufacturing company producing bottled water in sealed containers. It is located in an environment that is largely rural and is located in the city limits of Hilo, HI. The property and building are leased. There is a single bottling line fed by two blow molders located inside the facility.	

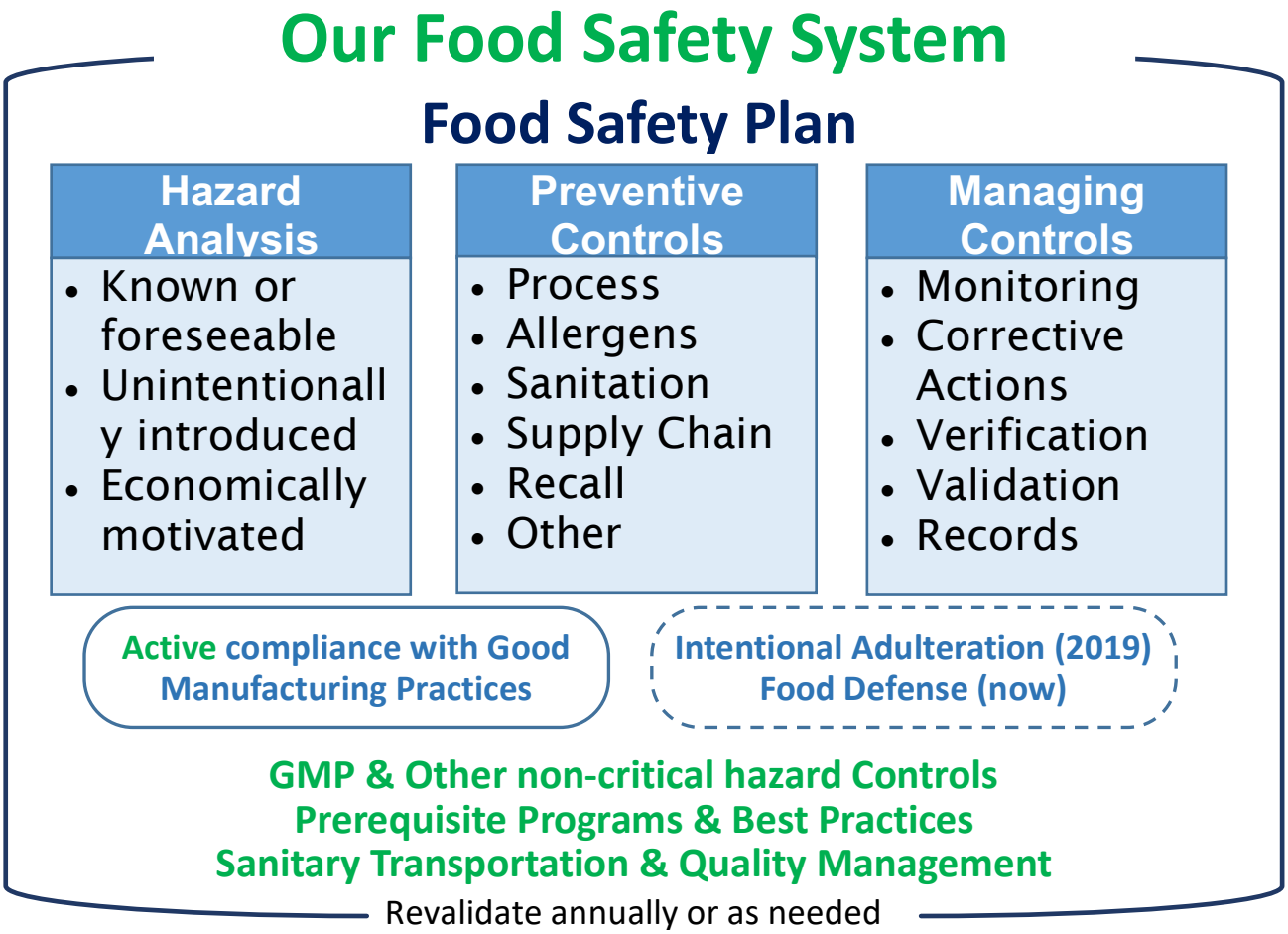
Qualified Individuals

We are compliant with new FSMA rules that call out the requirement that management and employees to be trained and qualified for the role they serve in food safety. Curriculum vitae are available on request for individuals we have designated as qualified. Our HR department also has written job descriptions to help define scope of duties of employees.

§117.4 (1) and (2) sets forth the requirements for owners and management:	
The owner, operator, or agent in charge of a facility must ensure that all individuals who manufacture, process, pack, or hold food subject to subpart C, D, E, F, or G of this part are qualified to perform their assigned duties. The management of an establishment must ensure that all individuals who manufacture, process, pack, or hold food subject to subparts B and F of this part are qualified to perform their assigned duties.	**Ryan Emmons, Chairman** **Jerry Clark, Plant Manager** PCQI# be1a6464
§117.155 requires that each food facility must have a "Preventative Controls qualified individual:	
Qualified individual means a person who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.	**Jerry Clark -** PCQI# be1a6464 **Joel Cook** - PCQI# e3f65963 **Jay Malloe** - PCQI# d6c1b14b **Michele Cadaoas** - PCQI# 76dedb13
§117.4 (c) sets minimum requirements for qualified supervisors:	
Additional qualifications of supervisory personnel. Responsibility for ensuring compliance by individuals with the requirements of this part must be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe food.	**Jerry Clark** - PCQI# be1a6464
§117.4 (b) sets minimum requirements for everyone else:	
Qualifications of all individuals engaged in manufacturing, processing, packing, or holding food. Each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must: (1) Be a qualified individual as that term is defined in § 117.3—i.e., have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties; and (2) Receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties.	**All other Staff**

Food Safety System

Our HACCP, PRPs, GMPs and other food safety and quality documents have been incorporated into this plan.



Although the Preventive Controls for Human Food (PCHF) does not specifically require preliminary steps similar to those in HACCP be included in a Food Safety Plan, we have followed the FDA Industry Guidance document published August 2016 for PCHF which recommends first a company overview, then the five preliminary steps articulated by HACCP followed by a 6th step that provides a process narrative. We have also chosen to make our Food Safety System inclusive of quality management.

Record Retention Policy

We maintain all our records related to Food Safety for at least the past two calendar years plus the current calendar year. This includes any records related to changes in equipment, our food safety plan or validation. We keep annual tests for at least five years. Other records may be kept longer than the minimum two years if we feel there is benefit that might accrue from historical review and/or analysis.

Our general guidelines that apply to the records are that they must be kept as original records, true copies, or electronic records. They should contain actual values and observations. They should be accurate, indelible, and legible. Whenever possible, they should be created concurrently with performance of the activity documented (done in real time).

We acknowledge under FSMA, the FDA has the legal right to request any records associated with the manufacturing, processing, packing, or holding of our bottled water products. This includes all records generated under Part 117. All records must be made promptly available to a duly authorized representative of the FDA for official review and copying upon oral or written request

Preliminary Step 1 – Food Safety Team

We are utilizing the members of our previous HACCP team to serve the broader role of being our Food Safety Team. The team is multi-disciplinary, including representatives that deal with receiving, shipping, Q/C, sanitation, processing and maintenance. It can also call upon independent outside expertise to support the team or if necessary, provide a temporary back up for our Qualified Individual in case of absence or temporary vacancy.

Due to the size of the organization along with the many hats each manager wears, we have given our Food Safety Team the broader mandate of also being responsible for Quality Management and Food Defense.

Member	Department	Position	Date Joined (4)	Training Courses
Jerry Clark (1)(2)(3)	Production	Plant Manager	1/2017	PCQI
Joel Cook (3)	Engineering	Chief Engineer	7/2016	PCQI
Jerry Malloe (3)	Quality	Quality Assurance Manager	5/2018	PCQI
Michele Cadaoas (3)	Administration	Office Manager	7/2017	PCQI
Crystal Casas	Corporate Quality	Quality Control Mgr	4/2017	

(1) – This is the individual who approves the plan and requisite documents on the authority of the Company. He/she also can serve as the back-up reviewing authority for any food safety records requiring management review and/or approval.

(2) – This is the individual who is primarily responsible for the plan being kept up-to-date and supervises the day-to-day operations and general execution of the Food Safety Plan. This individual serves as the primary reviewing authority for any food safety records requiring management review and/or approval.

(3) – This individual is a Preventative Controls Qualified Individual aka "PCQI" who assist in overseeing the development and execution of our Plan.

(4) – Year Team Member joined the Company as employee.

Team Meeting Agenda & Record Keeping

The Plant Manager or their designee has the responsibility to conduct Food Safety Meetings to ensures the Food Safety system performance is being implemented and communicated within the organization. Team Meetings are held periodically; often in connection with management or operations meeting. Topics discussed are marked below.

- Results of any internal and external audits or inspections.
- Review of any completed corrective actions and action plan status reports.
- Review of any customer or consumer complaints.
- Proposed or pending modifications to Food Safety Plan or System.
- Proposed or pending changes impacting treatment, production, bottling or warehousing.
- Changes to authorized raw material suppliers or specifications.
- Review of documents related to any Preventive Controls.
- Changes/updates to Work Instructions (SOPs, SSOPs, Checklists, Logs, etc.).
- Other topics as may be appropriate to insure safe and quality product is produced.

Written Records of meetings are the Team Leader's responsibility. Minutes of the meeting are documented by a member of the team and available upon request for review. Meeting records are kept for a minimum of 2 years and longer if they are relevant to the current plan operations, structure, configuration or equipment utilization.

Preliminary Step 2 - Product Description

Element	Details			
1a. Product type and name(s) produced on-site.	***Brand***	Material	Size	Type
	Waiakea Hawaiian Volcanic Water	PET Bottle	330ml	Deep Well Water
	Waiakea Hawaiian Volcanic Water	PET Bottle	500ml	Deep Well Water
	Waiakea Hawaiian Volcanic Water	PET Bottle	700ml	Deep Well Water
	Waiakea Hawaiian Volcanic Water	PET Bottle	1 Liter	Deep Well Water
	Waiakea Hawaiian Volcanic Water	PET Bottle	1.5 Liter	Deep Well Water
1b. Products sourced from other locations	Not Applicable			
2. Product Description, including Important Food Safety Characteristics	*Attribute*	Kai Well Water		
	Conductivity (+/- 15)	<1 NTU		
	TDS (+/-15) ppm	96		
	pH (+/- 0.5)	< 8.5		
	Cap Color	Clear		
3. Ingredients	Refer to Step 3 Form - Product Ingredients & Incoming Materials			
4. Preforms, Bottles and Caps used for primary packaging	**One-Way 330 ml**			
	25 gram bottles made of PET			
	One-Way 500 ml			
	25 gram bottles made of PET			
	One-Way 700 ml			
	44 gram bottles made of PET			
	One-Way 1 Liter			
	44 gram bottles made of PET			
	One-Way 1.5 Liter			
	48 gram bottles made of PET			
	High Density Polypropylene (HDPE) Cap			
	2.9 gram - 28 mm cap of HDPE (HDPE) for PET bottles			
5. What is the intended use and end user	The product is ready for immediate consumption. The intended user is the general public. The product has no specific age demographic. Individuals with suppressed immunity and children under 12 may consume product but they are not the target audience.			
6. Intended Consumer	Retail sales based out of bottling facility & 3rd party distributors.			
7. Shelf Life	Shelf stable All packages - The individual bottle shows date of production. See Traceability section for information on batch/date coding Shelf life/expiration date for Hilo produced product is 2 years when asked (subject to storage conditions). Best Used By date is printed on bottom shoulder.			
8. Labeling Instructions	Compliance with the US FDA Food Labeling Guide published by the US Food and Drug Administration.			
9. Storage & Distribution	Raw Materials stored at plant warehouse. Finished Product distributed to customers at ambient temperature. Warehouse managed to insure inside temperature does not exceed 120 degrees F.			

Preliminary Step 3a - Product Ingredients & Incoming Materials

The FDA's PCHF Draft Guidance of August 2016 shows this as part of Step 2 form.

Category	HA	Item	Details (#)
Primary Ingredients	**A**	Kai Well	Well is located on separate property. Licensed by the State of Hawaii
Food Contact Substances (FCS) - includes packaging	**B**	25 gram for 330ml & 500ml 44 gram for 700ml & 1-Liter 48 gram for 1.5 Liter All are PET (polyethylene terephthalate)	Preforms Purchased from Koksan Packaging Company 21 CFR 177.1590 – Indirect Food Additive – PET Polymer PET also complies with 1907/2006/EC
	C	28mm Closures (HDPE) for PET (Tamper-evident)	FDA approved in 21 CFR 177.1600 - Indirect Food Additive – Polyethylene resin 21 CFR 177.1520 "Olefins Polymers" 21 CFR 178.3297, "Colorants for Polymers" and CONEG Model legislation regarding heavy metal content.
	D	Labels with adhesive Film, water flexo printing & adhesive	Applied to blown bottles PET: Mylar (biaxially oriented PET) applied on bottle surface. 21 CFR 177.1590 – Indirect Food Additive - PET PC: BOPP (Polypropylene) applied to surface & also used to 21 CFR 177.1600 – Indirect Food Additive – Polyethylene resin Film, water flexo printing and adhesive also complies with 21 CFR 175.105 and 21 CFR 170 to 199
	E	Cardboard boxes for each size: 330 ml, 500ml, 700 ml, 1Liter, 1.5 Liter	Full depth Kraft box made by Wood pulp from reclaimed fiber is used for boxes; FDA 21 CFR Par 176.20 Linerboard, Ink and Adhesive – Complies with 21 CFR 176.170, 21 CFR 176.180, CFR 176.260
	F	LHDPE Stretch Film for wrapping pallets 0.5 mil/48 gauge thickness made of LLDPE	FDA approved in 21 CFR 177.1600 - Indirect Food Additive – Polyethylene resin
	G	Wood Pallets – Domestic	Domestic grocery grade specifications – standard wood - No Preservatives – Grade A or better
	H	Wood Pallets - International	International grocery grade specifications – standard wood - No Preservatives – Heat Treated
Processing Aids - used for water treatment, and disinfection	**I**	Ozone (generated onsite)	21 CFR 101.100(a)(3) Antimicrobial disinfection for rinsing blown bottles and/or routine sanitation. Antimicrobial agent for bottle rinsing & CIP.
	J	Filter Cartridges & Membranes	Each with manufacturer's documentation confirming approved use for potable water treatment.
Chemical Cleaners & Sanitizers that have direct and indirect contact with food surfaces	**K**	Clorox® Sodium hypochlorite (5.25%) is the active ingredient; also contains water, sodium chloride, sodium carbonate, sodium chlorate, sodium hydroxide & sodium polyacrylate.	Sanitizer used for hose and pipe fittings as well as food contact surfaces – diluted to range of 50 to 100 ppm with no rinse. Higher concentrations require rinse. FDA Approved 21 CFR 178.1010(b)
	L	Clorox® - Wipes Sanitizing wipes used for general cleaning	Ethylene glycol monohexyl ether (CAS 112-25-4) 1 – 5% n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride (CAS 85409-23-0) 0.1 - 0.2%; n-Alkyl (5% C12, 60% C14, 30% C16, 5% C18) dimethyl benzyl ammonium chloride (CAS 53516-76-0) 0.1 - 0.2% FDA approved per 21 CFR 178.1010(b)(16)
	M	Isopropyl Alcohol – 71% to 99%	Isopropyl Alcohol – substance + distilled water FDA 21CFR Part 173.240; secondary direct food additive
	N	Peroxide (Food Grade)	Sanitizing solution used at 1% to 6% depending on application. For disinfection of inside of water storage tanks. FDA approved per 21 CFR 178.1005
	O	ZEP FS AMINE-Z® No rinse Quaternary ammonium sanitizer (Prod #1700) Use on food contact surfaces	Medium pH (6.0 – 8.0) General purpose sanitizer topically applied to food contact surfaces. USDA –D2; Sanitizers for all surfaces not always requiring a rinse. FDA approved per 21 CFR 178.1010(b)(16)
	P	EcoLab's Drysan Duo	Isopropanol (CAS 67-63-0) 10.89% [Part 178.1010]; Hydrogen Peroxide (CAS 7722-84-1) 0.045% [Part 184.1366] Alkyl dimethyl benzyl ammonium chloride (CAS 68424-85-1) 0.016% … [Part 172.165] Octyl decyl dimethyl ammonium chloride (CAS 32426-11-2) 0.012% [Part 172.165] Didecyl Dimethyl Ammonium Chloride (CAS 7173-51-5) 0.007% [Part 172.165] Dioctyl dimethyl ammonium chloride (CAS 5538-94-3) 0.005% [Part 172.165]

Product Ingredients & Incoming Materials (Continued)

	Q	Eco-Wipe Duo	Isopropanol (CAS 67-63-0) 10.89% [Part 178.1010]; Ethanol (CAS 64-17-5) [Didecyl Dimethyl Ammonium Chloride (CAS 7173-51-5) 0.023% [Part 172.165] Alkyl dimethyl benzyl ammonium chloride (CAS 68424-85-1) 0.015% … [Part 172.165]
	R	Ecolab's Soil-Off II	poly(oxy-1,2-ethanediyl), .alpha-isotridecyl-omega-hydroxy (CAS 9043-30-5) 5-10% [FDA Substance Registry] 2-butoxyethanol (CAS 111-76-2) 1-5% [FDA Substance Registry] trisodium phosphate (CAS 7601-54-9) 1-5% [FDA GRAS food additive]
	S	EcoLab's Vortexx	Acetic acid (CAS 64-19-7) 10-30% … FDA GRAS per Sec. 184.1005 Acetic Acid Hydrogen Peroxide (CAS 7722-84-1) 6.9% [Part 184.1366] Peroxyacetic acid (CAS 79-21-0) 4.4% [Part 178.1010] Secondary Alkanesulphonates (CAS 5324-84-5) 1-5% Octanoic acid (CAS 124-07-2) 3.3% [Part 178.1010]
	T	EcoLab's Quorum Clear V (quaternary ammonium sanitizer)	Alkyl dimethyl benzyl ammonium chloride (CAS 68424-85-1) 0.016% … [Part 172.165] Octyl decyl dimethyl ammonium chloride (CAS 32426-11-2) 0.012% [Part 172.165] Didecyl Dimethyl Ammonium Chloride (CAS 7173-51-5) 0.007% [Part 172.165] Dioctyl dimethyl ammonium chloride (CAS 5538-94-3) 0.005% [Part 172.165]
	U	Softsoap Antibacterial Liquid Soap	Cetrimonium Chloride (CAS 112-02-7) - cationic quaternary ammonium salt - FDA approved as topical Glycerin (CAS 56-81-5) - FDA GRAS per Sec 182.1320
	V	Vinegar (Acetic Acid – active ingredient @ 4 – 8%)	FDA GRAS per Sec. 184.1005 Acetic Acid Allowable use includes as chelating agent, binding metals by making them soluble.
	W	Sanitary Spray Lubricant	NSF Nonfoods Compounds as H1
OTHER (No direct or indirect contact with source or finished product)	**X**	Activated Carbon NOTE: This carbon is used to dechlorinate water originating from CIP of the well where we dose with chorine for sanitation. It is routed to a dry well away from the source.	Letter of Continuing Guarantee, COA or Warrantee confirming no tree nut antigens each batch FDA 21 CFR GRAS as food processing aid when it is acid washed and meets USP food grade status (Brudock, 1997).

(#) Where applicable, a current ***Letter of Continuing Warrantee*** or ***Certificate of Analysis*** or other appropriate documentation from the manufacturer is kept on file as part of our Supplier Assurance program.

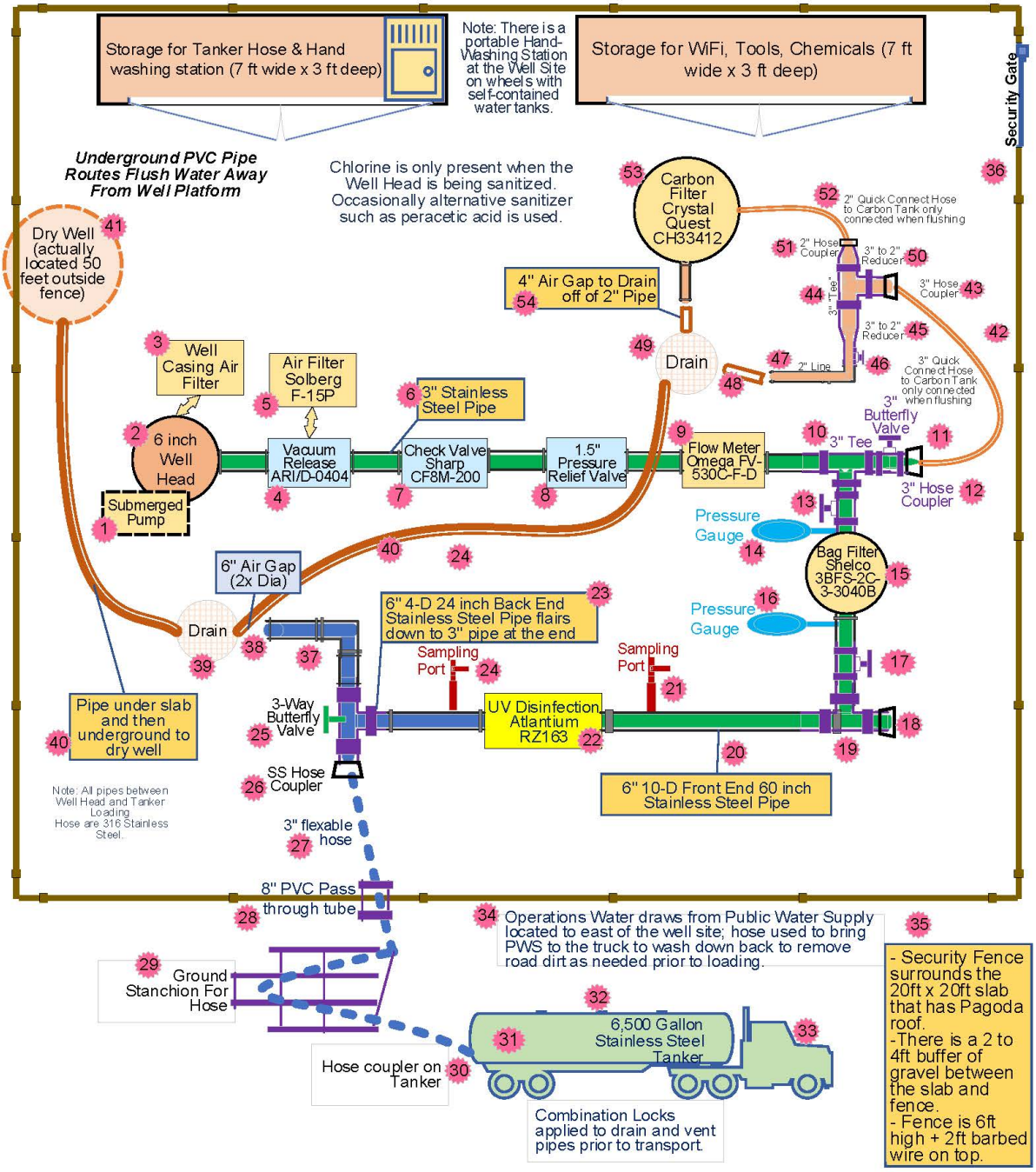
Preliminary Step 3b – Significant Equipment

This form is meant for internal use only and may exclude some non-essential pieces of equipment.

Category	#	Item	Details
Equipment		***See individual pages behind respective Flow Diagram***	

Preliminary Step 4a - Process Flow Diagram

Waiakea Hawaiian Volcanic Water	DIAGRAM – Process Flow Diagram – Well Source Water		
	Completed by: Jay Malloe	Date: May 14, 2019	Rev # 2.0
	Approved by: Jerry Clark	Supersedes: August 1, 2018	Doc # DIAG-01
	Waiakea Hawaiian Volcanic Water	Hilo, HI	

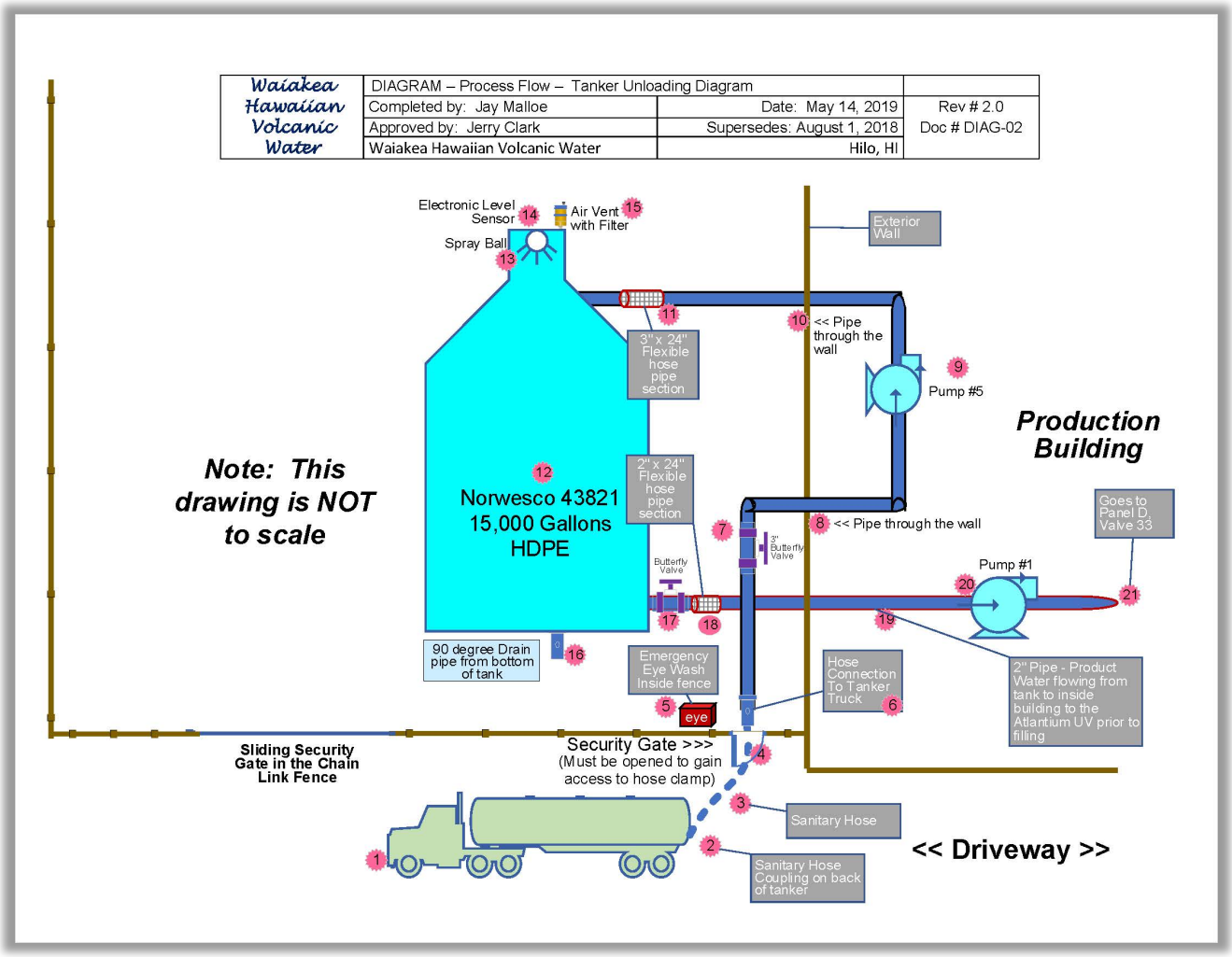


6,500 Gallon Stainless Steel Tanker dedicated to transporting Waiakea Deep Well Water to Bottling Facility approximately 10 miles/20 minutes away.

#	Item	Make	Model
1	Submerged Pump	Grundfos	230S500-16
2	6" well head	NA	
3	Well casing air filter	Solberg	F-15P-75
4	Vacuum release	ARI	D-040
5	Air filter	Solberg	F-15P-100
6	3" stainless steel piping	McMaster-Carr	Part# 4813K221
7	Check valve	Sharpe	CF8M-200
8	1.5" Pressure Relief Valve	Alpha Laval	D60RTHMP
9	Flow meter (vortex)	Omega	FV-530C-F-D
10	3" stainless steel (304) tee	McMaster-Carr	316-4464K142
11	3" Stainless Steel Butterfly Valve	Sharpe	50M76
12	3" Hose Coupler	Dixon	RE300SE
13	3" Valve	Sharpe	50M76
14	Pressure gauge	Winters	PFP824R1
15	Bag filter	Shelco	3BFS-2C-3-3040B
16	Pressure gauge	Winters	PFP824R1
17	3" Stainless Steel Butterfly Valve	apollo	76-100-01
18	3" Hose Coupler	Dixon	RE300SE
19	3" stainless steel tee	McMaster-Carr	316-4464K142
20	3" expander to 6" stainless steel piping for 10D (60") into UV	McMaster-Carr	P#4322K241
21	Stainless Steel Sampling port	Optimum	Sanitary Sampling
22	UV Disinfection - See Appendix 25	Atlantium	RZ163
23	6" 5D pipe post UV tapering down to 3" after sampling valve	McMaster-Carr	P#4322K241
24	Stainless Steel Sampling port	Optimum	Sanitary Sampling
25	3 Way Diverter Valve [controlled by UV]	Assured Automation	J30DAXF8S2C3B
26	3" Hose Coupler	Dixon	RE300SE
27	3" Flexable Hose	McMaster-Carr	5544K17 - 3"
28	PVC Pass Through	No Sheet	
29	Ground Stanchion for Hose to rest as it stretches to Tanker	McMaster-Carr	316-4464K142
30	Hose Coupler on Tanker - See Appendix 23	See Appendix 23	
31	Stainless Steel Tanker - See Appendix 23	See Appendix 24	
32	Tank Air Vent - See Appendix 23	See Appendix 25	
33	Tractor for Tanker - See Appendix 23	See Appendix 26	
34	Spigot fed by Public Water System	PWS	
35	Security Fence	6 ft High + 2 ft Barbed Wire	
36	Security Gate	6 ft High + 2 ft Barbed Wire Swing Gate	
37	3" Pipe to Drain	McMaster-Carr	P#4322K241
38	6" air Gap	No Equipment - just open gap	
39	Drain	PVC	
40	Pipe to Drywell	PVC	
41	Dry Well	NA	
42	3" Flexible Hose	McMaster-Carr	5544K17 - 3"
43	Hose Coupler	McMaster-Carr	2084T27
44	3" Stainless Steel Tee	McMaster-Carr	316-4464K142
45	3" to 2" Bushing	McMaster-Carr	4322K237
46	2" Butterfly Valve	Top-Line	38-S-20-E
47	2" Line to drain	McMaster-Carr	3120656-7TL
48	4" air gap	No Equipment - just open gap	
49	Drain	PVC	
50	3" to 2" reducer	McMaster-Carr	4322K237
51	2" hose coupler	McMaster-Carr	2084T15
52	2" hose	McMaster-Carr	5544K15
53	Carbon filter (only used on discharge water to dry well)	Crystal Quest	CH33412
54	4" air gap between 2" pipe and drain	No Equipment - just open gap	
*	There is also a portable hand-washing station on the well platform.		

APPENDIX 14

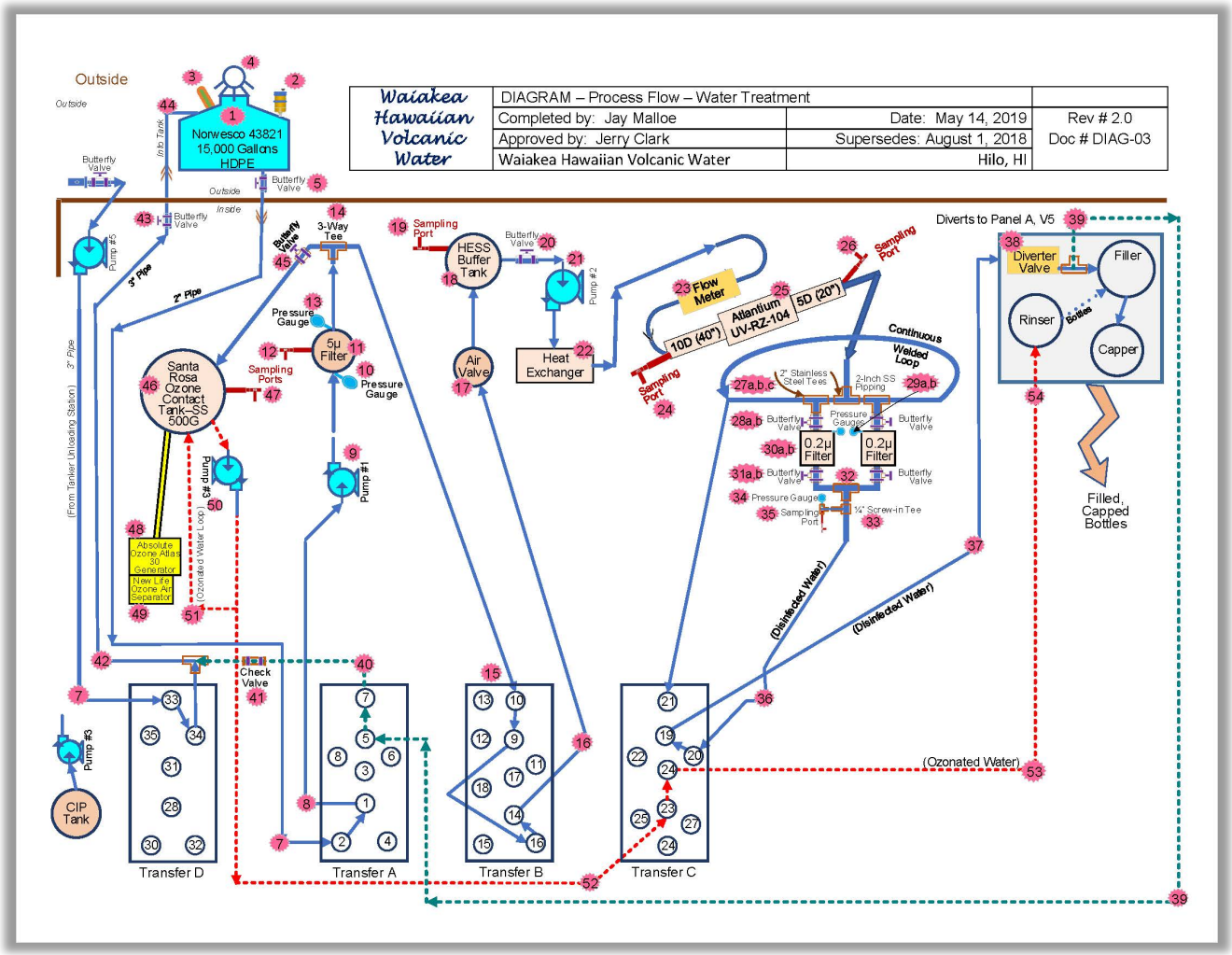
[Microsoft Excel Worksheet Object]


Waiakea Hawaiian Volcanic Water
DIAGRAM – Process Flow – Tanker Unloading Diagram
Completed by: Jay Malloe
Date: May 14, 2019
Rev # 2.0
Approved by: Jerry Clark
Supersedes: August 1, 2018
Doc # DIAG-02
Waiakea Hawaiian Volcanic Water
Hilo, HI
Electronic Level Sensor 14
Air Vent with Filter 15
Spray Ball 13
Exterior Wall
11
3" x 24" Flexible hose pipe section
10 << Pipe through the wall
9 Pump #5
Production Building
Note: This drawing is NOT to scale
12
Norwesco 43821
15,000 Gallons
HDPE
2" x 24" Flexible hose pipe section
7
3" Butterfly Valve
8 << Pipe through the wall
Goes to Panel D Valve 33
Butterfly Valve
Pump #1
20
21
17
18
19
90 degree Drain pipe from bottom of tank
16
Emergency Eye Wash Inside fence
5
eye
Hose Connection To Tanker Truck
6
2" Pipe - Product Water flowing from tank to inside building to the Atlantium UV prior to filling
Sliding Security Gate in the Chain Link Fence
Security Gate >>>
(Must be opened to gain access to hose clamp)
4
3
Sanitary Hose
1
2
Sanitary Hose Coupling on back of tanker
<< Driveway >>

#	Item	Make	Model
1	6500 gallon stainless steel tanker		
2	Sanitary Hose Coupling on Tanker Truck	Camlock	
3	3" PVC hose with 316 stainless steel fittings - 3A certified	McMaster-Carr	5544K17
4a	6' security fence with 3 rows of straight barbed wire on top.	NA	
4	Security Gate with Combination lock	Bulldog	
5	Emergency Eye Wash Station	ULINE	H6697
6	3" stainless steel hose coupling	Dixon	
7	3" stainless steel butterfly valve	Top-Line	3830130EPM12
8	3" stainless steel pipe goes through the wall into Production Area	Top-Line	3130656-7TL
9	Pump #5	Top-Flow	TF-C328-M-D- 2hp
10	3" stainless steel pipe goes through the wall from Production Area	Dixon	
11	3" x 24" Flexible Hose pipe section	McMaster-Carr	5544K17
11B	3" Hose adopter	McMaster-Carr	4322K777
12	Well Water Storage Tank (15,000 gallons - HDPE)	Norwesco	43821
13	Spray Ball for CIP	Spraying Solutions	PD28910-000
14	Electronic Sensor (tank level - sonar)	Echo Pulse	LR15
15A	Air Vent Housing	Pure Aqua	BBH-101
15B	Air Vent Media		
16	90 degree Drain pipe from bottom of tank	McMaster-Carr	4322K111
17	2" stainless steel butterfly valve	Top-Line	3830120EPM12
18	2" x 36" flexible hose pipe section - 3A certified	McMaster-Carr	5544K15
18B	Hose Adopter	McMaster-Carr	4322K775
19	2" product pipe	Top-Line	3120656-7TL
20	Pump #1	Top-Flow	TF-C328-M-D- 2hp
21	2" Pipe to panel D valve 33	Top-Line	3120656-7TL

APPENDIX 26

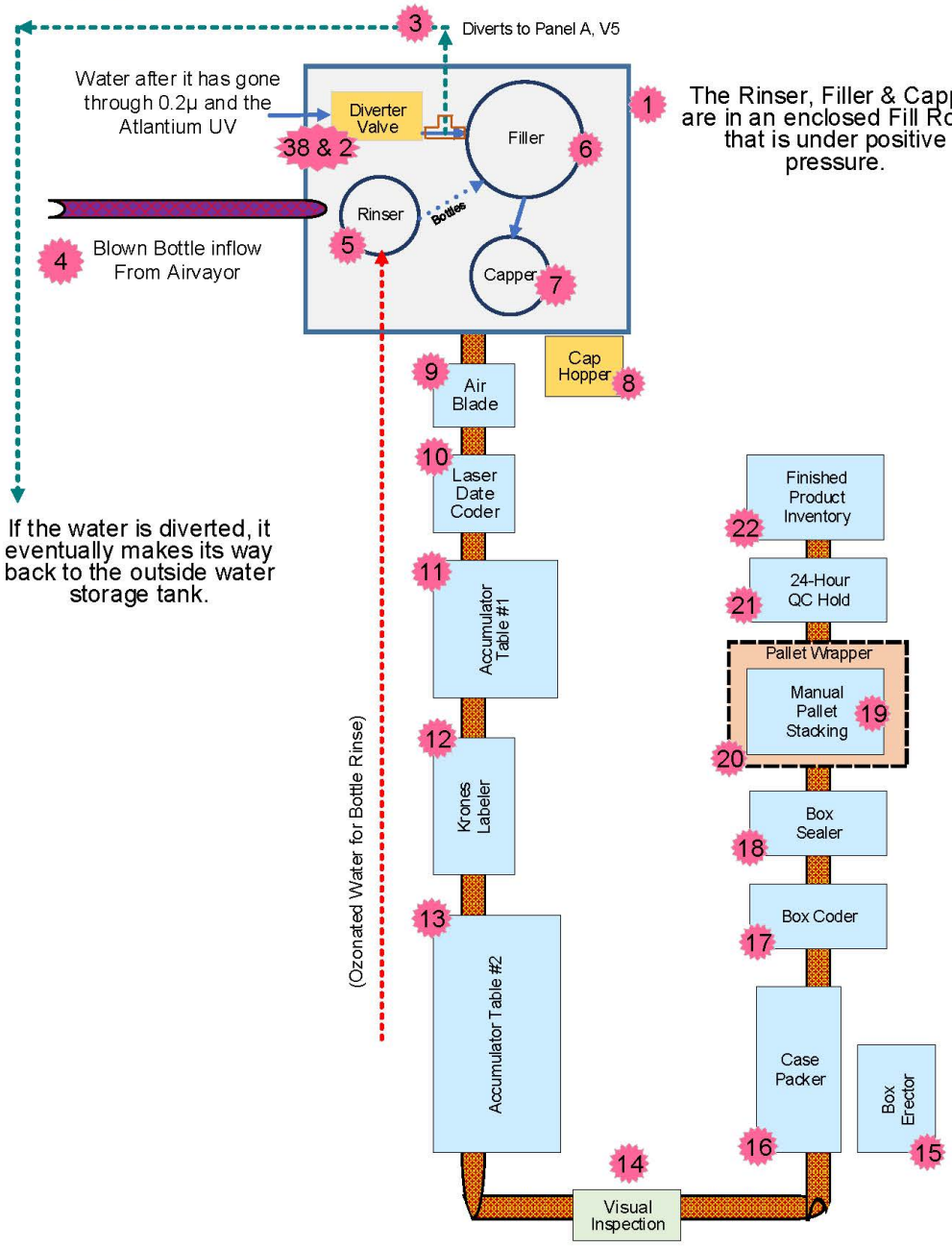
[Microsoft Excel Worksheet Object]


Waiakea Hawaiian Volcanic Water
DIAGRAM – Process Flow – Water Treatment
Completed by: Jay Malloe
Date: May 14, 2019
Rev # 2.0
Approved by: Jerry Clark
Supersedes: August 1, 2018
Doc # DIAG-03
Waiakea Hawaiian Volcanic Water
Hilo, HI
Outside
Norwesco 43821 15,000 Gallons HDPE
Butterfly Valve
Pump #5
3" Pipe
2" Pipe
(From Tanker Unloading Station)
3-Way Tee
Pressure Gauge
5µ Filter
Sampling Ports
Pressure Gauge
Santa Rosa Ozone Contact Tank–SS 500G
Pump #3
Pump #1
Absolute Ozone Atlas 50 Generator
New Life Ozone Air Separator
(Ozonated Water Loop)
Check Valve
CIP Tank
Transfer D
Transfer A
Transfer B
Transfer C
HESS Buffer Tank
Air Valve
Pump #2
Heat Exchanger
Sampling Port
Flow Meter
10D (40")
Atlantium UV-RZ-104
5D (20")
Continuous Welded Loop
2" Stainless Steel Tees
2-inch SS Piping
0.2µ Filter
0.2µ Filter
Pressure Gauges
¼" Screw-in Tee
(Disinfected Water)
(Ozonated Water)
Diverts to Panel A, V5
Diverter Valve
Filler
Rinser
Bottles
Capper
Filled, Capped Bottles

#	Item	Make	Model
1	Well Water Storage Tank (15,000 gallons - HDPE)	Norwesco	43821
2	Air Vent for tank		
3	Tank Level Sensor	Echo Pulse	LR15
4	Spray Ball for CIP	Spraying Systems Co	PD28910-000
5	3in Stainless Steel Butterfly Valve	Top-Line	38-S-30-E
6	2" Suply line from tank	Top-Flo	3120656-7TL
7	2 inch supply line to Panel A, Valve 2	Top-Flo	3120656-7TL
8	2 inch supply line to Panel A, Valve 1	Top-Flo	3120656-7TL
9	Pump #1	Top-Flo	2 Inch TF-C114
10	Pressure gauge	Winter's	PFP824R1
11	5-Micron Filter	Harmsco HUR	1x170FL-XP Cart: HC/170
12	Sampling port	Optimum	Sanitary Sampling Valve OFSV45N
13	Pressure gauge	Winter's	PFP824R1
14	2in 3-Way Tee	McMaster-Carr	316-4452K439
15	2 inch pipe to Panel B, Valve 10	Top-Flo	3120656-7TL
16	2 inch pipe to P-B, V19 to P-B, V16 to P-B, V14 to Air Valve	Top-Flo	3120656-7TL
17	Air Valve	Top-Flo	TL60ARV Air Relief Valve 2
18	Hess One Stainless Steel Buffer Tank (for CIP)	Hess One	T-300 Gallon
19	Sampling port	Optimum	Sanitary Sampling Valve OFSV45N
20	2 inch Butterfly valve	Top-Line	38-S-20-E
21	Pump #2	Top-Flo	2 Inch TF-C114
22	Heat Exchanger	CPE	CPE 30H-XXD
23	Flow Meter	Pro Mag	50H50 DN50 2"
24	Sampling port	Optimum	Sanitary Sampling Valve OFSV45N
25	UV Disinfection	Atlantium	RZ-104-11
26	Sampling port	Optimum	Sanitary Sampling Valve OFSV45N
27a, b, c	2 inch Stainless Steel 3-Way Tees	McMaster-Carr	316-4452K439
28a, b	2 inch butterfly valves	Top-Line	38-S-20-E
29a, b	Pressure guages	Winter's	PFP824R1
30a, b	0.2 Micron Filter	Sartorius	HU33U77X50T0E
31a, b	2 inch Butterfly Valves	Top-Line	38-S-20-E
32	2 inch 3-way valve (1/4 inch on one side; 2" top & bottom		
33	.25 inch screw-in tee		
34	Pressure gauge	Winter's	PFP824R1
35	Sampling port	Optimum	Sanitary Sampling Valve OFSV45N
36	2 inch pipe to P-C, V20 to P-C, V19	Top-Flo	3120656-7TL
37	2 inch pipe to the Diverter	Top-Flo	3120656-7TL
38	Diverter Valve	TRIAG	33-F1-0200
39	2 inch bypas line back to Panel A, Valve 5	Top-Flo	3120656-7TL
40	2 inch return line to P-A, V7 to Check Valve	Top-Flo	3120656-7TL
41	2 inch check valve	Top-Flo	38-K45-20-V-A
42	3 inch 3-Way Tee	McMaster-Carr	316-4464K142
43	3 inch Butterfly Valve	Top-Line	38-S-30-E
44	Santa Rosa Ozone Tank		
45	Butterfly Valve	Top-Flo	38-S-20-E
46	Santa Rosa Ozone Tank	Santa Rosa	500G (ser #: 3900 1 2004)
47	Sampling port	Optimum	Sanitary Sampling Valve OFSV45N
48	Ozone generator	Absolute Ozone	Atlas 30
49	Ozone air separator	New Life	Intensity
50	Pump #3	Top-Flo	2 Inch TF-C114
51	1 inch Ozone injection loop	Linker	36-36-12
Appendix 32			

[Microsoft Excel Worksheet Object]

Waiakea Hawaiian Volcanic Water	DIAGRAM – Process Flow – Bottling Diagram		
	Completed by: Jay Malloe	Date: May 14, 2019	Rev # 2.0
	Approved by: Jerry Clark	Supersedes: August 1, 2018	Doc # DIAG-04
	Waiakea Hawaiian Volcanic Water	Hilo, HI	

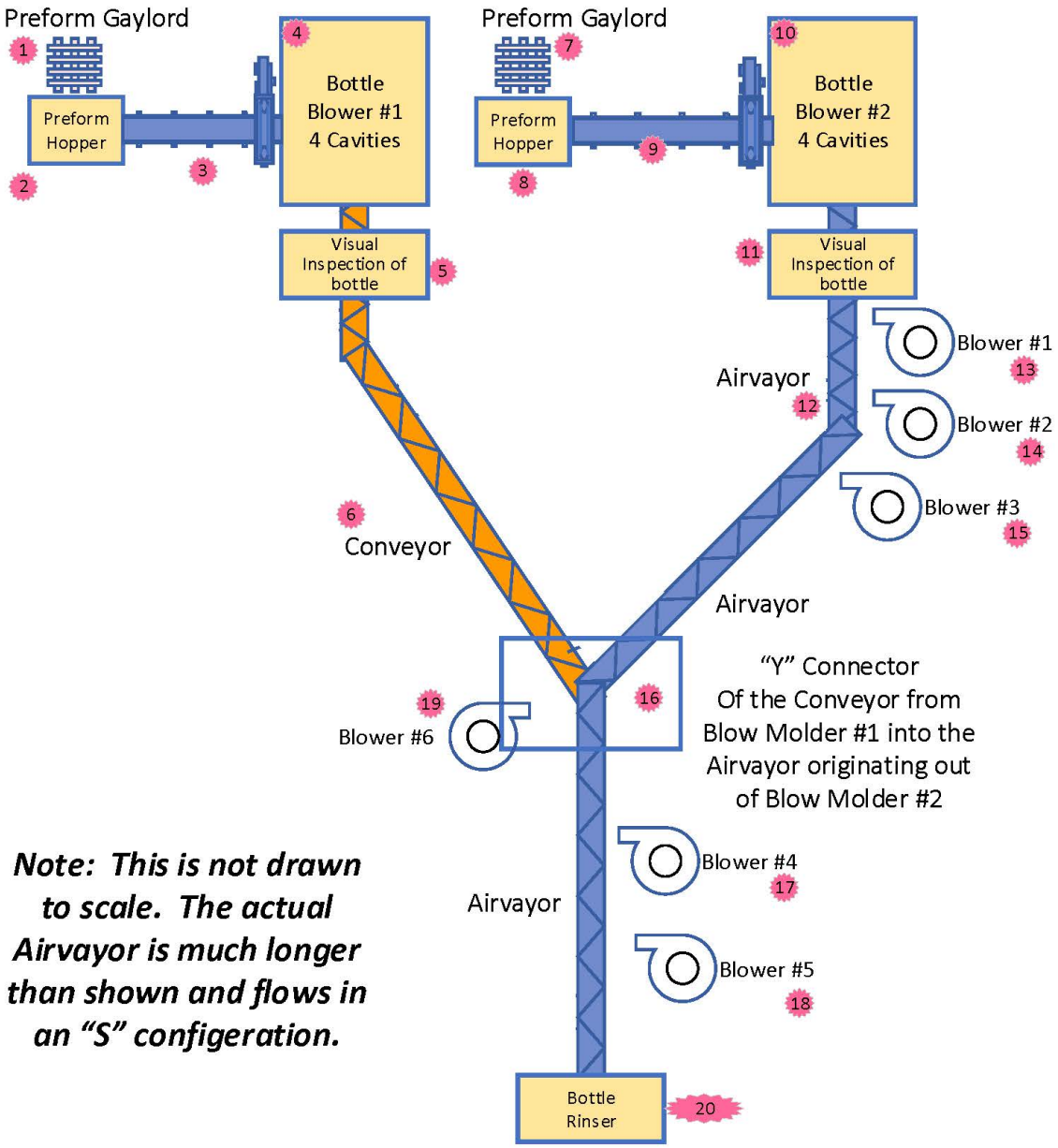


#	Item	Make	Model
1A	Enclosed Filler Room with Positive Air Pressure - Diagram	Technical Air Products	file# 180066
1B	Enclosed Filler Room with Positive Air Pressure - Details	Technical Air Products	file# 180066
2	Diverter Valve	Triac	Series33-SA
3	2 inch return line to Panel A, Valve 5	Top Line	3120656-7TL
4	Air conveyor	ArrowHead	
5	Bottle Rinser	Linker	36-36-12
6	Bottle Filler	Linker	36-36-12
7	Bottle Capper	Linker	36-36-12
8	Cap Hopper		
9	Air Blade	Republic Manufacturing	RB1200HC
10	Laser Date Code	ID Technology	iCon 2-30
11A	Accumulator Table #1 - Diagram	Nercon	custom
11B	Accumulator Table #1 - Details	Nercon	custom
12A	Krones Bottle labeler - Diagram	Krones	Autocal
12B	Krones Bottle labeler - Details	Krones	Autocal
13A	Accumulator Table #2 - Diagram	Nercon	custom
13B	Accumulator Table #2 - Details	Nercon	custom
14	Visual Inspection	NA	NA
15A	Box erector - Diagram	Wexxar	WF-20
15B	Box erector - Manual	Wexxar	WF-20
16A	Case packer - Diagram	Hamrick	Challenger
16B	Case packer - Detail	Hamrick	Challenger
17	Box Printer	Marsh	Unicorn
18A	Case Sealer - Diagram	Hamrick	CS30HM
18B	Case Sealer - Details	Hamrick	CS30HM
19	Manual Stacking of Boxes on Pallets	NA	NA
20	Pallet Wrapper	Highlight Industries	#702596 0.5 Spiral Unit
21	24-Hour Quality Control Hold	NA	NA
22	Finished Product Inventory	NA	NA

Appendix 39

[Microsoft Excel Worksheet Object]

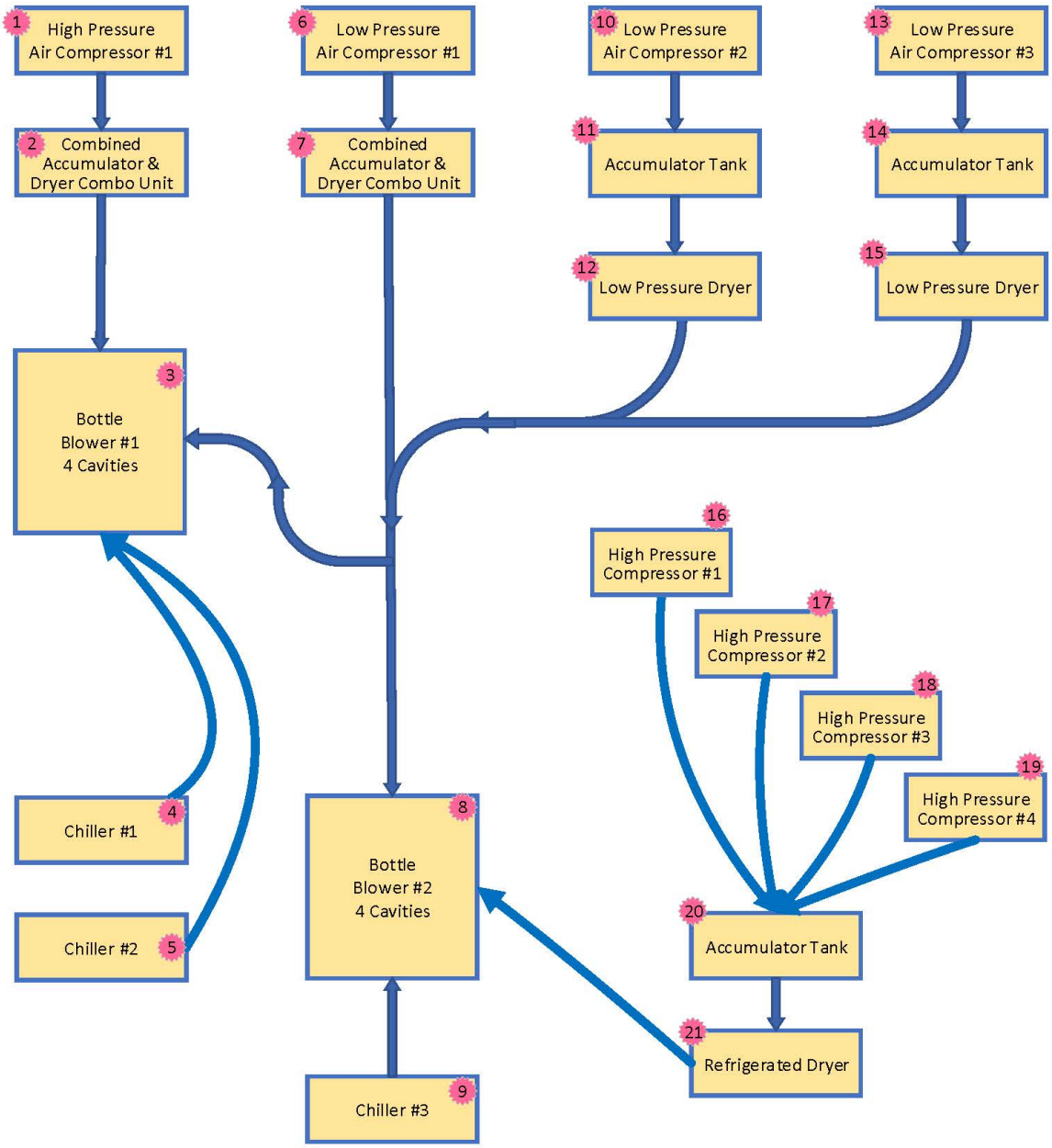
Waiakea Hawaiian Volcanic Water	DIAGRAM – Process Flow – Bottle Transport Diagram		
	Completed by: Jay Malloe	Date: May 14, 2019	Rev # 2.0
	Approved by: Jerry Clark	Supersedes: August 1, 2018	Doc # DIAG-05
	Waiakea Hawaiian Volcanic Water	Hilo, HI	



#	Item	Make	Model
1	Preform Gaylord (loading platform) - #1		
2	Preform Hopper - #1		
3	Preform Elevator - #1		
4	Bottle Blowmolder #1	Demark	DMK-DBS1500104
5	Visual Inspection of Bottles - #1 Blow Molder	custom	
6	Bottle Conveyor - #1 Blow Molder	custom	
7	Preform Gaylord (loading platform) - #2		
8	Preform Hopper - #2		
9	Preform Elevator - #2		
10	Bottle Blowmolder #2 (Newer Unit)	PET Technologies	APF-6004
11	Visual Inspection of Bottles - #2 Blow Molder	custom	
12	Airveyor	custom	
13	Blower #1		
14	Blower #2		
15	Blower #3		
16	Converging Y Airveyor	Arrowhead	
17	Blower #4		
18	Blower #5		
19	Blower #6 (At the Y)		
20	Feed to Bottle rinser / filler / capper	Linker	36-36-12
Appendix 48			

[Microsoft Excel Worksheet Object]

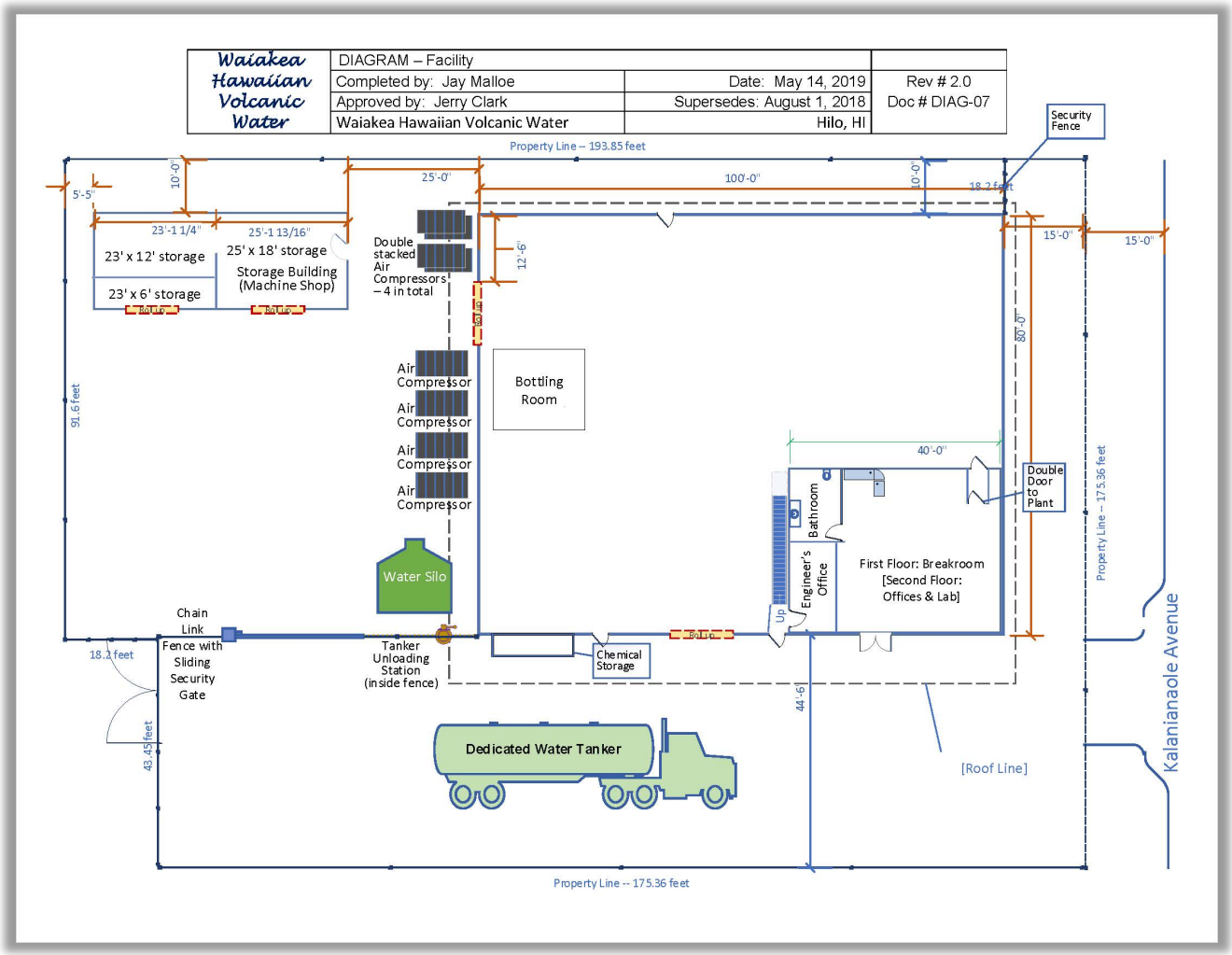
Waiakea Hawaiian Volcanic Water	DIAGRAM – Process Flow Diagram – Blow Molding		
	Completed by: Jay Malloe	Date: May 14, 2019	Rev # 2.0
	Approved by: Jerry Clark	Supersedes: August 1, 2018	Doc # DIAG-06
	Waiakea Hawaiian Volcanic Water	Hilo, HI	



#	Item	Make	Model
1	High pressure air compressor - old blowmolder	Shangair	3-34CSH-1230
2	Combined accumulator/dryer unit	NT	NTZH-5/30
3	Blowmolder number 1		
4	Chiller (1 of 2) - blowmolder number 1	Plastic Machinery	XC-05ACI
5	Chiller (2 of 2) - blowmolder number 1	Plastic Machinery	XC-03ACI
6	Low pressure air compressor (1 of 3) - house air	Kaeser	ASD-30
7	Combined accumulator/dryer unit	NT	NTZH-5/30
8	Blowmolder number 2	PET Technologies	APF-6004
9	Chiller - blowmolder number 2	M.T.A. S.p.A.	TAE evo TECH 081
10	Low pressure air compressor (2 of 3) - house air	Kaeser	ASD-30
11	Accumulation tank	Kaeser	TC44
12	Low pressure refrigerated dryer unit	NB	D24G120
13	Low pressure air compressor (3 of 3) - house air	Kaeser	ASD-30
14	Accumulation tank	China Inc.	TS32433-2022
15	Low pressure refrigerated dryer unit	Kaeser	KAD-60
16	High pressure air compressor (1 of 4) - new blowmolder	Hengda	49 SH-3.3/40
17	High pressure air compressor (2 of 4) - new blowmolder	Hengda	49 SH-3.3/40
18	High pressure air compressor (3 of 4) - new blowmolder	Hengda	49 SH-3.3/40
19	High pressure air compressor (4 of 4) - new blowmolder	Hengda	49 SH-3.3/40
20	Accumulation tank	Hengda	CW-2.2/12
21	Refrigerated dryer unit	Armstrong	NH-13HP4.0
Appendix 49			

[Microsoft Excel Worksheet Object]

Preliminary Step 4b - Plant Schematic



Preliminary Step 5 - On Site verification

Both the Flow Diagram and Plant Schematic have been reviewed by one of our Preventative Controls Qualified Individual (PCQI) listed on "Qualified Individuals" page.

Any time there is a change in the process or plant layout, these forms will be updated, reviewed, signed and dated. Updates and changes may be handwritten.

Plant policy is to prepare new diagrams and/or schematics at least 30 days in advance of any construction or material change. The changes are highlighted so that the Food Safety team can evaluate the proposed or anticipated changes to determine if any change in the hazard analysis or preventative controls needs to be made. They are not made a part of the official plan until the change has been completed.

All actual changes are incorporated into our official plan document within 30 days of being effective. Working drafts may be available earlier by request to our Food Safety team manager.

Preliminary Step 6 – Process Narrative

Ingredients and raw materials are purchased from reputable suppliers that comply with internationally recognized food safety and quality systems. For each ingredient the same brand is used consistently to minimize variation. Ingredients are stored according to manufacturers' recommendations when specified. Records of batch numbers are kept for traceability.

Receiving ingredients:

Source Water is drawn from our own source located about 10 miles from our facility. It is transported by our own tanker truck and driver.

Treatment:

Our treatment begins at the source. We bring the water to the surface from our deep well. It goes through a bag filter to remove any natural sediment and is then routed through our validated 4-log reduction UV before being loaded into our own dedicated tanker the short trip to our bottling facility.

Upon arrival at our bottling plant, we transfer the water into a 15,000 HDPE storage tank. The water remains here until called for by our bottling process. The air in the storage tank is protected by entering and exiting through a PFTE 0.2-micron filter to protect against any undesirable microbial contaminants.

We periodically subject the water in the water storage tank to Clean-in-place procedure that routes the water in the tank through another validated 4-log reduction UV system before being returned to the tank. We time the CIP cycle to insure we expose all the water held in the tank to the disinfection.

Our bottling process then calls for water from the water storage tank, once again passes it through our validated 4-log reduction UV system and deliveries it after micro-filtration to our filler where it is put into bottles that we have blown-molded on location and then capped, date coded and put into secondary packaging.

After being held for 24 hours to allow us to receive the results of testing each batch for coliforms, we release the finished product for distribution.

Ingredient storage:

We have no added ingredients.

Receiving Food Contact Packaging (FCS):

New bottles are produced on the premises in our bottling plant from preforms. We operate in a blow-fill-cap process. Since occasionally we run up a stockpile of blown bottles, we subject each blown bottle to an ozonated water rinse prior to filling.

Caps are kept stored in their original boxes until used. Cardboard cases for secondary packaging are formed on demand.

Cleaning:

All caps are new and all bottles blown immediately prior to filling to minimize any potential hazards. As a precaution, all bottles are rinsed with ozonated water though we expect no contaminates to be present.

Processing Aids:

We utilize various filters as precautionary measures. The filter media is NSF certified and preventive maintenance performed on a scheduled basis designed to optimize the useful life of media while minimizing any hazards passing through into finished product.

Pathogen destruction:

We believe that we effectively preclude hazards from being present in our product water. Our 4-log validated UV serves as our Process Preventive Control. The limited use of ozone in the rinse of bottles and/or caps is not deemed to be critical and is only used a GMP control.

Environmental testing of caps and containers are checked quarterly (4 each) for HPC and Coliforms.

Swabs are taken randomly around the filler heads and capper heads to verify the absence of coliforms.

Every batch of finished product is tested for total coliform and Escherichia coli.

Storage:

Finished product is stored in our warehouse at ambient temperatures until distributed.

Shipping:

Product is shipped in dry containers at ambient temperature to customers.

HAZARD ANALYSIS - METHODOLOGY

We used our teams experience, scientific reports, FDA Reportable Foods Registry, CDC foodborne outbreaks, FDA recall notifications, FDA 2013 Bad Bug Book, IBWA web site and training materials, IBWA Plant Technical Manual, and our own historical information from complaints and quality assurance staff . We also asked ourselves the 40 questions the FDA put forth in their August 2016 PCHF guidance document. This research and discussion lead us to evaluate the most likely contaminates and defects within our plants. Almost all of the reference materials we used were examined online or exist in digital format. **We did not deem it necessary maintain hardcopies**.

Our analysis of potential hazards included ingredients, processing procedures, facility and equipment design, packaging, storage, intended use and users as well as employee health, hygiene and training.

Biological Hazards

Our source of water for our product is from our own deep well.

Based on our knowledge of our industry and the reference materials we consulted, we think E. coli and other coliforms are the most significant potential pathogenic bacteria risks that could be present. There are other opportunistic pathogenic and non-pathogenic that could be present but based on our analysis of water coming from our source over several years, we believe the risk are effectively managed by the process and procedures we have put into place.

The operations water used in the plant comes from the Hilo Public Water System. We have verified through research that our PWS complies with EPA regulations for potable drinking water. We reviewed the most recently published copy of our systems "Consumer Confidence Report" which the EPA requires that our PWS publish. We saw no notices of anything that exceeds the EPA's standards. We also did a Google search to see if there were any articles discussing public health risks from the system that supplies us. We will revisit our search periodically in case there are any new that should be considered.

On the EPA web site are published standards set forth for PWS which we reviewed and found to be in compliance:

- 2-log removal/inactivation of Cryptosporidium
- 3-log reduction of removal/inactivation of Giardia lamblia
- 4-log removal/inactivation of viruses
- 4-log removal/inactivation equivalence of bacteria. Note: the specific log-reduction for bacteria is not as straightforward as other limits. We based our interpretation of the effects of disinfection (i.e. chlorine) found on the EPA website and concluded this would be equivalent to a 4+-log reduction. Our reasoning was:
  - No detectable E coli, fecal coliform or total coliform. We interpret this as meaning zero. We think this can be expressed as a limit of one-in-ten thousand which can also be expressed as 4-log reduction.
  - The standards EPA requires for biological water purification (we assume they strive to be as good as these devices) which their 1987 protocol for biological water purification testing puts at a 6-log reduction.

Since we only utilize the PWS for operations purposes, we have determined it does not present a known or reasonably foreseeable for the uses that we make of it.

Our product water source is protected through a multi-barrier water treatment process that is designed to prevent any food safety hazard from being in our final product.

Chemical Hazards

For our PWS, we reviewed their CCR and did not find any violations of EPA limits.

For our finished product water source, we rely on our source water protection plan that includes the research done prior to putting in our well and reaffirmed by annual chemical testing to Title 21 standards.

Chemicals used in the plant for operations and maintenance such as cleaners, sanitizers, lubricants, are approved for use in food establishments, so the most likely hazard would be with improper handling or use by our employees. We review all the chemicals we use in the plant related to our production of bottled water. In Exhibit 3 we listed the regulatory basis for approval. We review the SDS sheets for the chemicals. We teach all of our employees how to use each chemical as intended and what to watch out for that could cause potential hazards.

Pesticides are not handled by our employees; we instead rely on an outside licensed Pest Control Operator.

Our source water is consistent in its chemistry, microbiologic and physical properties. We conduct frequent testing to verify the source water remains free of contaminants.

We also considered chemical leeching from our infrastructure and have confirmed to our satisfaction that all the wetted surfaces are of materials approved for food contact.

Physical Hazards

Physical hazards are deemed to be those things that could adulterate our finished product. The presence of these materials could cause illness or injury upon consumption. We divide these hazards into three categories based on the source of the material.

First is what might come in from our sources. We confirmed through review of testing data that the turbidity of our source is well below regulatory limits. We do, as a precautionary step, filter all incoming water through micron filters which would catch any occasional sediment.

Second would be any foreign matter associated with equipment or building materials including: wood, metal particles/shards, glass, insulation, paint chips, rust, Plexiglas, nuts/bolts. We keep these out of our food ingredients and equipment through preventive maintenance and sanitation augmented by ongoing observations by our Staff.

Third is foreign material associated with personnel hygienic practices including: hair, band-aids, hairnets, jewelry, artificial nails, nail polish chips, gum, rags and shop supplies, grease and pens/pencils are managed through our Employee Policies that outline what is acceptable attire and personal care products, use of personal protective devices such as hair and beard nets and proper hygiene around hand washing.

We also referenced our Consumer Complaint logs and found no significant occurrences or trends that could be systemic. We do frequent visual inspections of our operation and perform maintenance before any potential hazards occur. We also routinely inspect containers before filling and routinely spot check finish product for any physical hazards.

Hazards tied to our staff .
We rely on our training and management to ensure that our employees follow our policies related to food safety and employee hygiene. Our single biggest focus is on adequate hand washing.

We use our routine testing as verification that we are effectively controlling hazards.
We test every batch of finished product for the **biological** contaminates Coliforms and E.coli. We also test periodically test for HPC which a proxy for is also Pseudomonas aeruginosa (PA). Our limit for Coliforms is zero. If our HPC count is above average, we instigate a review, and repeat of any procedure that may appear sub-standard.

We do broad spectrum **chemical** tests annually and selective substances where necessary more frequently to insure we don't have food safety hazards.

Control Measures
The water treatment we deploy helps us insure not only a better tasting product more efficiently but acts as a multi-barrier prevention against potential contaminants. Throughout our hazard analysis we raise the possibility of certain hazards and then explain that we feel few if any raise to the level of concern because of our ongoing processes and procedures. We determined, based on our hazard analysis, that we have one Process Preventive Control. While we do not necessarily maintain or specifically track the accomplishment of each and every task or inspection activity we reference, we think that our daily testing of Finished Product is a proxy that reflects effective and adequate implementation with expected results of safe product.

Risk Assessment

As we identified and researched each potential hazard, we used a risk matrix to determine the most appropreate types of controls.

Severity (also known as consequence) is ranked in one of five categories. The assignment of a value is based on the collective knowledge and on the evidence we have.

Likeliness speaks to the frequency. We use the experience of our plant, research within and outside the industry and other data collectively known to the team.the plant or the industry.

We started in one corner and sequencing through the possibilities. We drew a line at "10" which we deem to capiture most if not all hazards that could be categorized as high risk. For those, we will have defined Preventive Controls. Other numbers still represent potential hazards, but most often can be addressed through one or more "non-critical" controls; using including one or more GMPs and/or prerequises.

Likely Occurrence Frequency / Severity Consequence	**Daily** Common Occurrence **A**	**Weekly** Known to Occur **B**	**Monthly** Could Occur **C**	**Yearly** Not Expected **D**	**5 Years** Practically Impossible **E**
1. **Fatality** Morbidity is expected	1	2	4	7	11
2. **Serious Illness** Morbidity is possible	3	5	8	12	16
3. **Product Recall**	6	9	13	17	20
4. **Customer Complaint** Quality defects	10	14	18	21	23
5. **Insignificant**	15	19	22	24	25

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures

Hazard Analysis for Ingredients

(1)		(2)	(3)	(4)			(5)
Ingredient/ Processing Step		Identify reasonably foreseeable food safety hazards introduced, controlled or treated at this step.	Nature of the hazard and how it exists in finished product.	Risk Assessment: Consequence /Severity (C) Frequency/Likelihood (F) Score(S)			What control measure(s), Preventive or otherwise, are applied to significantly minimize, control or prevent the food safety hazard or otherwise negatively impact quality and acceptability? Clearly indicate where any applicable PCHF Preventive Control(s) is applied.
Hazard Analysis for Ingredients							
A	**SOURCE WATER** Ingredient Subject to sediment filtration and disinfection	**Biological** ❖ Pathogenic bacteria (TC/E. coli)	– Problem with well – Breakdown in treatment after received at plant. – Breakdown/failure in piping and/or infrastructure.	1	D	**7 (PPC)**	***PRP's*** - Proper well construction affirmed by current permit from state of Hawaii. - Periodic sanitizing of the well - Routine inspection of well platform & surroundings - Routine testing of source for TC/E. - Annual Title 21 test of the source water. ***Process Preventative Control (PPC#1) – PLANT*** - Disinfection of our well water via Atlantium validated 4-log reduction at plant prior to bottling. ***Process Control(s) (PC)*** - Well water in its original form after its emergence from the ground is passed through 5µ nominal bag filter. - Well water is its original form after passing through the micron bag filter is then passed through validated Atlantium 4-log reduction UV disinfection. ***Sanitation Controls - SSOP*** - Routine sanitation of well and related pipping as well as the bag filter and UV system. - Routine sanitation of the well platform ***Sanitary Transportation - SSOP*** - Dedicated Tanker truck is used to move deep well water from our source to our bottling facility. - The tanker is subjected to routine sanitation that is compliant with the Juice Product Association Model Tanker Cleaning and Sanitizing Procedures reference by FDA in the CFR's. ***Sanitary Storage - SSOP*** - Well water from our source is transported in dedicated tanker to our bottling facility where it is transferred to our 15,000-gallon water storage tank. - We routinely perform CIP of the water storage tank to insure the well water remains clean and sanitary. - Water tank itself has 0.2-micron air filter that is routinely monitored and maintained. ***Testing/Verification*** - Annual Title 21 analysis of the well water from source. - Weekly Total Coliform and HPC test of well water drawn from the well source. - Testing of every tanker load of water for TC after loading into the tanker. - Periodic testing of well water while it is in the Water Storage tank for TC and HPC. - Testing of every batch of finished product for TC. - Annual testing of finished water insures radiological hazards are not present
		❖ Protozoa (Giardia lamblia, Cryptosporidium) ❖ Viruses including Enteroviruses	– Potential seepage into well. – (Potential exist but no findings of Protozoa have been found in the raw water to date.)	3	D	17	
		❖ Other bacteria (e.g. Pseudomonas Aeruginosa)	– Biofilm (Pseudomonas Aeruginosa) in storage tank or water lines	4	D	21	
		Chemical ❖ Bromate ❖ Others	Ground intrusion – Any excess level of inorganic or organic chemical that has limits set by local, national or applicable international standards, including agricultural chemicals such as herbicides and fertilizers or other industrial chemicals – Excess nitrate levels that find their way to the well water catchment and ultimately finished product – Excess application of ozone to water sources that could result in conversion of bromide to bromate.	3	C	13	
		Radiological (Part of Chemical hazards)	– Any excess level of radiologicals – Any level of radium 226 or radium 228 in excess of standards	3	D	17	
		Physical ❖ Sand particles and other foreign matter	– Damaged pumps, contamination of storage tanks, breakdown in filter media. – Metal flakes or fragments from equipment failure – Insects or other filth	4	D	21	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
B	**One-Way BOTTLES MADE OF PET RESIN** Food Contact Substances (FCS)	**Biological** ❖ Pathogenic bacteria (TC/E) ❖ Fungus (Y&M) ❖ Protozoa (Glamb & Crypto) ❖ Viruses (incl Entero)	– Airborne bacteria, fungus or viruses could settle on surface or inside of the bottle prior to our filling them. – Bottles could have been contaminated while in temporary storage before filling.	4	D	21	***PRP's*** - Blow molding area set up and managed to minimize any contaminations from coming in contact with preforms and resulting blown bottles. - Bottles are covered from time of emerging from blow molder until they are rinsed and then filled. ***Supplier Assurance*** - We retain documentation pertaining to the original purchase of new preforms ***Processing*** - New bottles are protected from airborne contaminates through covered conveyors until they are rinsed, filled and capped. ***SSOPs*** - Employee hygiene – handwashing before operating blow molding equipment or handling packaging.
		Chemical ❖ BPA	– Irregular blowing of bottles – Formulation of resin	4	D	21	
		Physical ❖ Foreign Material, dust, dirt, insects, sabotage	– Airborne materials could precipitate on bottle surface attracted by static electricity	4	D	21	
C	**28MM CAPS FOR PET Closures** Food Contact Substances (FCS)	**Biological** ❖ Pathogenic bacteria (TC/E) ❖ Fungus (Y&M) ❖ Protozoa (Glamb & Crypto) ❖ Viruses (incl Entero)	– Airborne bacteria, fungus or viruses could settle on surface or inside of the cap prior to being applied	4	D	21	***Supplier Assurance program SOP*** • We procure our caps only from approved suppliers. • We require supplier to warranty that plastics and labels are made from FDA compliant materials including use of approved inks. We also ask suppliers to affirm there are not heavy metals in the ink and that materials are compliant with CONEG Toxin standards. ***Processing*** • Caps are kept in original sealed factory cartons until they are used. • Cap hopper is emptied and cleaned at end of production daily. • Storage area for Cap cases is routinely inspected to insure no negative environmental factors are present. ***SOPs*** • Startup controls and checklists. ***SSOPs*** • Cap Hopper and Chutes SSOP
		Chemical ❖ Heavy metals ❖ Excess plastizers	– Could potentially have excessive leaching of plastic or colorants in finished caps	4	D	21	
		Physical ❖ Foreign Material (dust, broken bits of plastic)	– Potential for incidental contaminates that might be airborne or otherwise present in the cap supplier facility settling into box of caps.	4	D	21	
D	**ADHESIVE LABELS FOR ONE-WAY CONTAINERS** (POLY WITH ADHESIVE BACKING ON ROLLS – front and back) Food Contact Substances (FCS)	**Biological** ❖ Pathogenic bacteria (TC/E) ❖ Fungus (Y&M) ❖ Viruses (incl Entero)	– Labels kept on hand could potentially harbor biologicals on the surface of labels. – Biologicals transferred during the process of applying labels in the plant.	4	D	21	***Supplier Assurance program SOP*** • We maintain an inventory of new labels that are applied in-plant to finished product prior to putting the bottles in secondary packaging such as boxes. • Our label supplier(s) are approved in advance by our company. • Label artwork on new bottles is visually confirmed upon receipt to make sure they have requisite legal verbiage. ***Processing*** • In affixing labels, we follow good GMP practices as it relates to our employees and our equipment ***SOPs*** • General operating controls and checklists.
		Chemical ❖ Heavy metals ❖ Allergen listings	– Heavy metals in ink on label – Inaccurate text relating to allergens on the label	4	D	21	
		Physical ❖ Foreign Material (dust, broken bits of plastic)	– Potential for incidental contaminates that might be airborne or otherwise present settling onto replacement labels	4	D	21	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
E	**CARDBOARD BOXES FOR ONE-WAY PACKAGES** Food Contact Substances (FCS)	**Biological** ❖ Pathogenic bacteria (TC/E) ❖ Fungus (Y&M) ❖ Viruses (incl Entero)	– Note: new bottles come to the plant pre-labeled. – Labels kept on hand could potentially harbor biologicals on the surface of labels kept for used to cover up old, obsolete or competitive labels. – Biologicals transferred during the manual process of applying labels in the plant.	4	D	21	***Supplier Assurance program SOP*** • We maintain an inventory of cardboard boxes that are constructed in-plant and used for finished product. • Our box supplier(s) are approved in advance by our company. • Box artwork on new bottles is visually confirmed upon receipt to make sure they have requisite legal verbiage. ***Processing*** • In packing the boxes, we follow good GMP practices as it relates to our employees and our equipment ***SOPs*** • General operating controls and checklists.
		Chemical ❖ Heavy metals ❖ Allergen listings	– Heavy metals in ink on label – Inaccurate text relating to allergens on the label	4	D	21	
		Physical ❖ Foreign Material (dust, broken bits of plastic)	– Potential for incidental contaminates that might be airborne or otherwise present settling onto replacement labels	4	D	21	
F	**Stretch wrap Film for Pallets And Bottle Racks** Food Contact Substances (FCS)	**Biological** ❖ Pathogenic bacteria (TC/E) ❖ Fungus (Y&M) ❖ Viruses (incl Entero)	– Airborne bacteria or viruses could settle on surface of wrap prior to being applied	4	D	21	***Supplier Assurance program SOP*** • We maintain an inventory of stretch film which is used as needed to secure product on a pallet or in a rack. • Our film supplier(s) are approved in advance by our company. ***Processing*** • In using shrink film, we follow good GMP practices as it relates to our employees and our equipment ***SOPs*** • General operating controls and checklists. • Raw Materials Receiving Procedures SOP to inspect incoming material for damage or other unacceptable conditions. • Inspection while loading each new role by production staff.
		Chemical ❖ Off Odor	– Might have been stored next to non-food product that transferred odor.	4	D	21	
		Physical ❖ Foreign material	– Unintended filth that originated from supplier	4	D	21	
G & H	**Wood Pallets** **Regular (Domestic & Mainland)** **Heat Treated (International shipments)** Food Contact Substances (FCS)	**Biological** ❖ Pathogenic bacteria ❖ Fungus (Y&M) ❖ Viruses	– Pests, mature and/or in larval stage that could transfer to food packaging and/or finished product.	4	D	21	***Supplier Assurance program SOP*** • We purchase all pallets from an approved supplier. We specify the pallets should not have any wood preservatives or other visible contaminants. • For Domestic shipments (including mainland) we specify Grade A pallets. They can be new or used. They are subject to physical inspection prior to use. • For International shipments we utilize certified heat-treated pallets. ***Processing*** • Prior to using a pallet, we visually inspect it for any objectional odors or traces of contaminants. ***SOPs*** • All incoming pallets must be inspected for damage, residue or pest infestation.
		Chemical ❖ Off Odor ❖ Toxic residue	– Prior use might have been for non-food product that left behind residual on surface.	4	D	21	
		Physical ❖ Pest ❖ Foreign material such as wood slivers and nails	– Might hide in pallets that have been previously used from supplier or while on site at HOD while stored outside	4	C	18	

PROCESS AIDS

I	**Ozone** Processing Aid	**Biological** ❖ Pathogenic bacteria ❖ Fungus (Y&M) ❖ Viruses (incl Entero)	– None Expected	4	D	21	***Training*** • Training of employees so they understand proper use of ozone. ***SOP*** • Filtering of incoming air to the ozone generator so as to minimize contaminants and dry the air to improve efficiency of ozone production. ***SSOP*** • Periodic sanitation of the ozone equipment.
		Chemical ❖ Off Odor ❖ Aerosolized compressor oil or chemicals	– Improperly maintained or calibrated ozone generator could mix the ozone with chemical vapors creating dangerous toxins such as aldehydes or formic acid.	4	D	21	
		Physical ❖ Dust particles	– Not expected	4	D	21	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
J	**Filter Media** Media Cartridge for filters (Processing Aids)	**Biological** ❖ Pathogenic bacteria ❖ Y, M & Viruses	– Improperly manufactured media could harbor bacteria from where they were constructed.	4	D	21	***Supplier Assurance Program*** • Filters purchased from approved supplier • The purchased media meets the specification. • 3rd party certification preferred such as NSF Std 60 ***SOPs*** • Raw Material Handling SOP • Operator training to insure awareness of hazards. • Procedures to check media for damage prior to use. ***SSOPs*** • After replacement media is installed, the unit is properly sanitized.
		Chemical ❖ Off Odor ❖ Toxic residue	– Improperly manufactured media could harbor trace chemicals. – Media could be substandard and not perform in removing unwanted chemicals.	4	D	21	
		Physical ❖ Sediment ❖ Foreign material e.g. wood slivers, nails	– Manufacturing imperfections could allow breakthrough in the media that allows water to pass through without being subject to filtration.	4	C	18	

CHEMICAL CLEANERS & SANTIZERS

K	**Sodium hypochlorite "Clorox" 5.25%** **Sanitizer** Chemical Cleaners & Sanitizers	**Biological** ❖ Pathogenic bacteria (TC) ❖ Fungus (Y&M) ❖ Viruses (incl Entero)	– Biological contamination due to poor employee practices – Receiving of product that is visually contaminated or package integrity has been compromised – Poor manufacturing practice that allowed for biological contamination of chemical.	4	D	21	***Supplier Assurance*** • We approved the chemical and the supplier prior to purchasing. • The product was evaluated to insure the active ingredients are approved for use in a food plant. • We reviewed the SDS sheet for the product and found nothing objectionable. ***Training*** • We train our staff in how to use this chemical including the proper dose or concentration. **Testing/Verification** • If we think it is necessary or practical, we will use a test strip to confirm the concentration. ***SOPs*** • Chemical handling SOP • Raw Materials Receiving SOP ***SSOPs*** • When we use this chemical for disinfecting and sanitizing, we delineate the proper use and concentration.
		Chemical ❖ Impurities in the ingredients ❖ Off Odor ❖ Leaking chemicals	– Chemical contamination due to poor employee practices – Leaks from handling (dripage, fork lift, etc.) – Cross contamination from transferring chemical into unsuitable secondary container. – Adverse chemical reaction if put in contact with quats based chemical	4	D	21	
		Physical ❖ Foreign Materials ❖ Other filth	– Physical contamination due to poor employee handling (receiving) practices – Receiving of product that is visually contaminated or package integrity has been compromised	4	D	21	

L	**Clorox Wipes** **Cleaner & Sanitizer** Chemical Cleaners & Sanitizers	**Biological** ❖ Pathogenic bacteria (TC) ❖ Fungus (Y&M) ❖ Viruses (incl Entero)	– Biological contamination due to poor employee practices – Poor manufacturing practice that allowed for biological contamination of chemical.	4	D	21	***Supplier Assurance*** • We approved the chemical and the supplier prior to purchasing. • The product was evaluated to insure the active ingredients are approved for use in a food plant. • We reviewed the SDS sheet for the product and found nothing objectionable. ***Training*** • We train our staff in how to use this chemical including the proper dose or concentration. **Testing/Verification** • If we think it is necessary or practical, we will use a test strip to confirm the concentration. ***SOPs*** • Chemical handling SOP • Raw Materials Receiving SOP ***SSOPs*** • When we use this chemical for disinfecting and sanitizing, we delineate the proper use and concentration.
		Chemical ❖ Impurities in the ingredients ❖	– Chemical contamination due to poor employee practices – Adverse chemical reaction if put in contact with quats based chemical	4	D	21	
		Physical ❖ Foreign Materials ❖ Other filth	– Physical contamination due to poor employee handling (receiving) practices – Receiving of product that is visually contaminated or package integrity has been compromised	4	D	21	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
M	**Isopropyl Alcohol** **Sanitizer** Chemical Cleaners & Sanitizers	**Biological** ❖ Pathogenic bacteria ❖ Fungus (Y&M) ❖ Viruses	– Biological contamination due to poor employee practices – Adulterated product.	4	E	23	***Supplier Assurance*** • Chemicals are purchased from approved supplier. • NSF certification (Std 60) preferred • Certificate of analysis or Statement of Continuing Warrantee affirming compliance with 117.35(b)(1) re free from undesirable microorganisms. When not available we test the chemical ourselves for TC and HPC. ***SOPs*** • Chemical handling SOP • Raw Materials Receiving SOP ***SSOPs*** • Delineating the proper strength and application of the chemicals specific to cleaning or sanitizing task.
		Chemical ❖ Impurities in the ingredients ❖ Off Odor ❖ Leaking ❖ Excess residue	– Factory deficiency resulting in improper formulation. – Leaks from handling (dripage, fork lift, etc.) – Cross contamination from transferring into unsuitable secondary container.	4	D	21	
		Physical ❖ Foreign Materials ❖ Other filth	– Physical contamination due to poor employee handling (receiving) practices – Receiving of product that is visually contaminated or package integrity has been compromised	4	D	21	
N	**Peroxide**	**Biological**	– This chemical is intended as a sanitizer in connection with cleaning process for the inside of the water storage tanks. It is not used for routine sanitizing. – Thus, we see no biological risk.	5	E	25	***Training*** • Proper use for application with equipment requiring lubrication. ***Supplier Assurance*** • Review/approve as a qualified supplier. ***SOPs*** • Chemical handling SOP ***SSOPs*** • Water Storage Tank Cleaning
		Chemical ❖ Leaking chemicals ❖ Not rinsing when specified	– Not intended to enter food – Higher than intended concentrations could cause burning if not adequately rinsed from surfaces or end up diluted in product water causing mild off-taste	3	D	17	
		Physical ❖ Foreign Materials ❖ Other filth	– Not intended to enter food	5	E	25	
O	**ZEP FS Amine Z** Chemical Cleaners & Sanitizers	**Biological**	– These chemicals are intended as sanitizers in connection with cleaning process for direct and indirect food contact surfaces. – Thus, we see no biological risk.	5	E	25	***Training*** • Proper use for application with equipment requiring lubrication. ***Supplier Assurance*** • Review/approve as a qualified supplier. ***SOPs*** • Chemical handling SOP ***SSOPs*** • Equipment Cleaning and Sanitizing procedures
		Chemical ❖ Leaking chemicals ❖ Not rinsing when specified	– Higher than intended concentrations could cause burning if not adequately rinsed from surfaces or end up diluted in product water causing mild off-taste – Adverse chemical reaction if put in contact with chlorine based chemical	3	D	17	
		Physical ❖ Foreign Materials ❖ Other filth	– If chemicals are left on surface for extended period of time in high concentration discoloring and possible corrosion could occur on equipment surfaces.	4	D	21	
P **&** **Q** **&** **R** **&** **S** **&** **T**	**EcoLab Cleaning Products** **Drysan Duo** **Ecowipe Duo** **Ecolab Quorum Clear V** **Soil-Off II** **Vortexx**	**Biological**	– These chemicals are intended as sanitizers in connection with cleaning process for direct and indirect food contact surfaces. – Thus, we see no biological risk.	5	E	25	***Training*** • Proper use for application with equipment requiring lubrication. ***Supplier Assurance*** • Review/approve as a qualified supplier. ***SOPs*** • Chemical handling SOP ***SSOPs*** • Equipment Cleaning and Sanitizing procedures
		Chemical ❖ Leaking chemicals ❖ Not rinsing when specified	– Higher than intended concentrations could cause burning if not adequately rinsed from surfaces or end up diluted in product water causing mild off-taste – Adverse chemical reaction if put in contact with chlorine based chemical	3	D	17	
		Physical ❖ Foreign Materials ❖ Other filth	– If chemicals are left on surface for extended period of time in high concentration discoloring and possible corrosion could occur on equipment surfaces.	4	D	21	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
U	**Softsoap** Antibacterial **Liquid Soap**	**Biological**	– These soap is intended as a surfactant in hand washing. – Thus, we see no biological risk.	5	E	25	***Training*** • Handwashing training ***Supplier Assurance*** • Review/approve as a qualified supplier. ***SOPs*** • Chemical handling SOP ***SSOPs*** • Handwashing procedures
		Chemical ❖ Leaking chemicals ❖ Not rinsing when specified	– We see no chemical risk	5	E	25	
		Physical ❖ Foreign Materials ❖ Other filth	– We see no physical risk	5	E	25	
W	**Vinegar** **Cleaner (mixed with RO water)** Chemical Cleaners & Sanitizers	**Biological** ❖ Pathogenic bacteria ❖ Fungus (Y&M) ❖ Viruses	– Biological contamination due to poor employee practices – Adulterated product.	4	E	23	***Supplier Assurance*** • Chemicals are purchased from approved supplier. • NSF certification (Std 60) preferred • Certificate of analysis or Statement of Continuing Warrantee affirming compliance with 117.35(b)(1) re free from undesirable microorganisms. When not available we test the chemical ourselves for TC and HPC. ***SOPs*** • Chemical handling SOP • Raw Materials Receiving SOP ***SSOPs*** • Delineating the proper strength and application of the chemicals specific to cleaning or sanitizing task.
		Chemical ❖ Impurities in the ingredients ❖ Off Odor ❖ Leaking ❖ Excess residue	– Factory deficiency resulting in improper formulation. – Leaks from handling (dripage, fork lift, etc.) – Cross contamination from transferring into unsuitable secondary container.	4	D	21	
		Physical ❖ Foreign Materials ❖ Other filth	– Physical contamination due to poor employee handling (receiving) practices – Receiving of product that is visually contaminated or package integrity has been compromised	4	D	21	
X	**H1 Sanitary Spray Lubricant**	**Biological**	– Not intended to enter food	5	E	25	***Training*** • Proper use for application with equipment requiring lubrication. ***Supplier Assurance*** • Review/approve as a qualified supplier. • Require the product is designated "H1" in the NSF Nonfood Compound directory.
		Chemical	– Not intended to enter food – Substitution of lubricant that is not designed for food processing environment could cause chemical contamination.	3	D	17	
		Physical	– Not intended to enter food	5	E	25	

Note: This material, activated carbon, is only used to dechlorinate flush water from well sanitizing. It does not come into contact with any product water and is totally disconnected from the system when not in use.

OTHER AIDS

Y	**Granulated Activated Carbon** Note: this does not come into contact with any source or finished product; it only dechlorinates flush water from CIP of well	**Biological** ❖ Pathogenic bacteria (TC) ❖ Fungus (Y&M) ❖ Protozoa (Glamb & Crypto) ❖ Viruses (incl Entero)	– Improperly serviced filter could allow the growth of Biologicals on the surface or in the layers of media. – The formation of DBPs if using municipal chlorinated water and /or back-flushing with chlorinated water through a bed with the build-up of organic material	3	D	20	***Training*** • Training of employees so they understand proper handling of material. ***Supplier Assurance*** • Specifications for qualified provider and included specifications that no harmful or unauthorized ingredients are used. • Verification that carbon does not have coconut tree nut antigens. ***SOPs*** • Chemical handling SOP • Raw Materials Receiving SOP ***SSOPs*** • Backflushing of Carbon filtration
		Chemical ❖ Unk substances	– Not expected to occur	3	D	17	
		Physical ❖ Foreign Material	– Break in pipeline	4	D	23	

End of Ingredients - (Food Contact Substances/Processing Aids/Chemicals having Direct & Indirect food contact)

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures

Hazard analysis for process

(1)	(2)	(3)	(4)	(5)
Environmental Hazard location and type	Identify reasonably foreseeable food safety hazards introduced, controlled or treated at this step.	Nature of the hazard and how it exists in finished product.	Risk Assessment: Consequence /Severity (C) Frequency/Likelihood (F) Score(S)	What control measure(s), Preventive or otherwise, are applied to significantly minimize, control or prevent the food safety hazard or otherwise negatively impact quality and acceptability? Clearly indicate where any applicable PCHF Preventive Control(s) is applied.

#1	**Submerged Well Pump** Draws water to the surface based on demand.	**Biological** ❖ Airborne bacteria, yeast & mold	– If biologicals got into the well, they could colonize on the surfaces of the well pump contributing to biofilm which could taint the water.	3	D	17	***PRPs*** • Proper installation of the well pump. ***Process Controls*** • NA ***Training*** • Training of staff on proper sanitizing of the well and the pump contained within. ***SSOPs*** • Routine cleaning and sanitizing of the well and the pump. ***Testing/Verification*** • Test of source water used as surrogate for bacteria.
		Chemical ❖ Metal leaching	– If the pump were made out of the wrong material it could leach elements like lead into the well water.	3	D	17	
		Physical ❖ Foreign Material, dust, dirt, insects	– Excess turbidity in the well could clog the pump or otherwise interfere with pumping the water.	3	E	20	
#2	**SOURCE WATER Extraction from 6" Well Head** Drawn from Well	**Biological** ❖ Pathogenic bacteria (TC) ❖ Fungus (Y&M) ❖ Protozoa (Glamb & Crypto) ❖ Viruses (incl Entero) ❖ Other bacteria (e.g. HPC & Pseudomonas Aeruginosa)	– Contamination of the well – Intrusion of biological hazards	**1**	**D**	**7**	***While there is inherent risk in any water source, we do not deem this to be PPC. We do apply a PPC prior to bottling in the form of validated 4-log reduction via our Atlantium UV.*** ***We further subject the source water to another 4-log reduction UV prior to loading into a tanker to our plant. (See step #22)*** ***PRPs*** • Integrity of well and immediate surroundings • Well platform ***SSOPs*** • Well sanitizing • Pipe sanitation ***Equipment*** • Check valve after emergence to prevent any backflow ***Monitoring*** • Routine inspection of well housing & surroundings • Annual inspection of check valve ***Testing/Verification*** • Annual title 21 testing of source • Other routine tests are used to evaluate the presence of any undesirable contaminates. If any were found, research would be conducted until the source was identified and corrected. • Weekly TC/E testing of source (outside lab) • Weekly HPC testing of source (outside lab) • Testing of every tanker load brought from the source to the bottling plant for TC/E (inhouse lab)
		Chemical ❖ Nitrate or other chemical ❖ Bromate	– Excessive contaminant levels occurring in the source water. – Excess of bromate from source water coming into contact with oxidizer resulting in conversion. – Surface runoff that enters the source.	3	D	17	
		Physical ❖ Foreign Material	– Sediment emerging from the aquifer – Intrusion of surface water that brings sediment or other extraneous materials	4	E	23	
#3	**Air Filter (Well Casing)** Filters any air drawn into the well casing when the pump is turned off	**Biological** ❖ Airborne bacteria, yeast & mold	– Unfiltered air could result in introducing biologicals which could contaminate the well water or contribute to forming biofilm.	3	D	17	***PRPs*** • Installation of air filter on the well head where air is introduced or expelled to compensate for water level in the well when pump is turned on/off. ***Process Controls*** • Filtering air to standard equivalent to MIRV 13 or higher. ***Training*** • Training of staff on the maintenance of the filters. ***SSOPs*** • Routine cleaning and sanitizing after replacing air filter media.
		Chemical ❖ Air pollutants	– Air drawn in could contribute chemical contaminates which could transfer to product water.	3	D	17	
		Physical ❖ Foreign Material, dust, dirt, insects	– Airborne dust or insects could contaminate source water.	3	E	20	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#4	**Vacuum Release** Prevents destructive vacuum conditions from existing allowing for effective draining	**Biological** ❖ Airborne bacteria, yeast & mold	– Protects integrity of the pipe when the pump is shut off and water pressure falls back. – Otherwise a rupture could occur allowing contaminants to enter the pipe.	3	D	17	***PRPs*** • Proper Installation. ***Training*** • Training of staff on the maintenance of the device. ***SSOPs*** • Routine cleaning and sanitizing via our CIP of the well.
		Chemical ❖ Air pollutants	– Protects against Air drawn in could contribute chemical contaminates which could transfer to product water.	3	D	17	
		Physical ❖ Foreign Material, dust, dirt, insects	– Airborne dust or insects could contaminate source water.	3	E	20	
#5	**Air Filter (off Vacuum release)** Filters any air drawn into the pipe when vacuum release functions	**Biological** ❖ Airborne bacteria, yeast & mold	– Unfiltered air could result in introducing biologicals which could contaminate the well water or contribute to forming biofilm.	3	D	17	***PRPs*** • Installation of air filter on the Vacuum Release where air is introduced or expelled to compensate for water level in the pipe when pump is turned on/off. ***Process Controls*** • Filtering air to standard equivalent to MIRV 13 or higher. ***Training*** • Training of staff on the maintenance of the filters. ***SSOPs*** • Routine cleaning and sanitizing after replacing air filter media and/or CIP the pipping. ***Testing/Verification*** • Test of source water used as surrogate for bacteria.
		Chemical ❖ Air pollutants	– Air drawn in could contribute chemical contaminates which could transfer to product water.	3	E	20	
		Physical ❖ Foreign Material, dust, dirt, insects	– Airborne dust or insects could contaminate source water.	4	E	23	
#6	**Stainless Steel Water Pipe** (Running from the well head) 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. • Insure any exposed/welded surface is properly passivated. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from pipe material	– Undesirable chemicals could leach from plumbing material into the water. – Improper passivation could result in Chromium leaching.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment or scale could impede flows. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	
#7	**Backflow Preventer Check Valve**	**Biological** ❖ Other bacteria (e.g. HPC & Pseudomonas Aeruginosa)	– Contaminants that build up in the pipe that could interfere with proper operation of the valve, thus allowing back siphonage of contaminants.	2	E	16	***PRPs*** • Proper installation device. • Training of staff in how device work. ***SSOPs*** • Sanitizing pipe & fitting after any exposure to contaminants ***Monitoring*** • Annual inspection by licensed plumber confirming proper operation and compliance with plumbing standards.
		Chemical ❖ Leaching from device	– Inadequate maintenance of device. – Materials no longer in compliance with GMPs	2	E	16	
		Physical ❖ Foreign Material, dust, dirt, insects	– Failure of the backflow valve thus resulting in contaminants or water of another characteristic flow backward.	2	E	16	
#8	**Pressure Relief Valve**	**Biological** ❖ Other bacteria (e.g. HPC & Pseudomonas Aeruginosa)	– Contaminants that build up in the pipe that could interfere with proper operation of the valve, thus allowing back siphonage of contaminants.	2	E	16	***PRPs*** • Proper installation device. • Training of staff in how device work. ***SSOPs*** • Sanitizing pipe & fitting after any exposure to contaminants ***Monitoring*** • Annual inspection by licensed plumber confirming proper operation and compliance with plumbing standards.
		Chemical ❖ Leaching from device	– Inadequate maintenance of device. – Materials no longer in compliance with GMPs	2	E	16	
		Physical ❖ Foreign Material, dust, dirt, insects	– Failure of the pressure relief valve could result in excess pressure causing physical failure in the water treatment train.	2	E	16	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#9	**Flow Meter**	**Biological** ❖ Bacteria build up inside pipping and valve	– Biologicals build up around the flow meter as biofilm could cause false readings. – Invalid reading could negatively impact the operation of the Atlantium UV.	3	D	17	***PRPs*** • Proper installation of meter; compliance with plumbing standards. • Training of staff ***SSOPs*** • Sanitizing fitting after any exposure to potential contaminants ***Monitoring*** • Inspection for drips or excess condensation indicative of failure or other hazard. ***Testing/Verification*** • Confirm accuracy through recommended calibration per manufacturer
		Chemical ❖ Leaching from pipe & valve fittings	– Inadequate maintenance of meter. – Materials no longer in compliance with GMPs	3	D	17	
		Physical ❖ Biofilm sluff ❖ Metal fatigue	– Growth of biofilm to the stage where it becomes physical substance capable of fouling meter.	4	E	23	
#10	**Stainless Steel Water Pipe "Tee"** (Provides option to route CIP flush to drain) 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from pipe material	– Undesirable chemicals could leach from plumbing material into the water.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment or scale could impede flows. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	
#11	**Stainless Steel Butterfly Valve** 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from valve material	– Undesirable chemicals could leach from plumbing material into the water. – O-ring could degrade or leak.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment, scale or grit could impact the seat, body or disk of the valve impeding flow or full closure. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	
#12	**Stainless Steel Water Hose Bib** (Provides route to flush pipes by connecting temporary hose to drain) 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Exterior and interior could provide surfaces that facilitate colonizing biofilm or other biologicals that could cross-contaminate wetted surfaces.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of routine cleaning and sanitizing to prevent biological colonizing. • Prior to use – cleaning and then sanitizing with 600 ppm concentration chlorine solution. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test strips to verify concentration.
		Chemical ❖ Leaching from material	– Undesirable chemicals could leach from fixture material into the water. – Excess sanitizing residue could taint water being transferred.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment or scale could impede seal. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#13	**Stainless Steel Butterfly Valve** 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from valve material	– Undesirable chemicals could leach from plumbing material into the water. – O-ring could degrade or leak.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment, scale or grit could impact the seat, body or disk of the valve impeding flow or full closure. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	
#14	**Pressure Gauge** (before the Bag filter)	**Biological** ❖ Any biological buildup.	– Biologicals build up around the gauge fitting anchoring themselves as biofilm that interfere with gauge functionality.	3	D	17	***PRPs*** • Utilize liquid filled gauge more resistant to vibration. • Insure water pressures within gauge tolerances. • Filter water to minimize sediment clogging of gauge. • Proper installation; compliance with plumbing code. ***SSOPs*** • Sanitizing after any direct exposure to contaminants. ***Monitoring*** • Inspection for drips or excess condensation. ***Testing/Verification*** • Confirm accuracy through recommended initial calibration of the gauge per manufacturer.
		Chemical ❖ Leaching from pipe & valve fittings	– Inadequate maintenance of gauge. – Materials no longer in compliance with GMPs.	3	D	17	
		Physical ❖ Biofilm sluff ❖ Excessive vibration	– Growth of biofilm to where it clogs gauge and impedes function. – Excessive vibration leading to gauge failure. – Overpressure and pressure spikes that bend gauge pointer.	4	E	23	
#15	**1µ Nominal Bag Filter** Sediment Filtration of Well Water	**Biological** ❖ Pathogenic bacteria (TC) ❖ Fungus (Y&M) ❖ Protozoa (Glamb & Crypto) ❖ Other bacteria (HPC & P. Aeruginosa)	– Contaminants originating from the well source. – Biofilm growing on the inside of the filter housing and/or media.	3	D	17	***PRPs*** • Proper installation of the Filter unit. • Training of staff ***Process*** • Check of pre/post pressure to insure the filter is working within normal range ***SSOPs*** • Sanitizing filter housing after installing new media ***Monitoring*** • Inspection/recording of pressure until replacement of filter media based on pre-determined pressure differential or elapsed time. • Periodic inspection for leaks in filter housing
		Chemical ❖ Unk substances	– Contaminants originating from well source.	4	D	21	
		Physical ❖ Foreign Material	– Contaminants emerging from well source.	4	E	23	
#16	**Pressure Gauge (Post)** (after the Bag filter) [Filter maintenance required when psi differential moves outside range]	**Biological** ❖ Any biological buildup.	– Biologicals build up around the gauge fitting anchoring themselves as biofilm that interfere with gauge functionality.	3	D	17	***PRPs*** • Utilize liquid filled gauge more resistant to vibration. • Insure water pressures within gauge tolerances. • Filter water to minimize sediment clogging of gauge. • Proper installation; compliance with plumbing code. ***SSOPs*** • Sanitizing after any direct exposure to contaminants. ***Monitoring*** • Inspection for drips or excess condensation. ***Testing/Verification*** • Confirm accuracy through recommended initial calibration of the gauge per manufacturer.
		Chemical ❖ Leaching from pipe & valve fittings	– Inadequate maintenance of gauge. – Materials no longer in compliance with GMPs.	3	D	17	
		Physical ❖ Biofilm sluff ❖ Excessive vibration	– Growth of biofilm to where it clogs gauge and impedes function. – Excessive vibration leading to gauge failure. – Overpressure and pressure spikes that bend gauge pointer.	4	E	23	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#17	**Stainless Steel Butterfly Valve** 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from valve material	– Undesirable chemicals could leach from plumbing material into the water. – O-ring could degrade or leak.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment, scale or grit could impact the seat, body or disk of the valve impeding flow or full closure. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	
#18	**Stainless Steel Water Hose Bib** (Provides route to flush pipes by connecting temporary hose to drain) 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Exterior and interior could provide surfaces that facilitate colonizing biofilm or other biologicals that could cross-contaminate wetted surfaces.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of routine cleaning and sanitizing to prevent biological colonizing. • Prior to use – cleaning and then sanitizing with 600 ppm concentration chlorine solution. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test strips to verify concentration.
		Chemical ❖ Leaching from material	– Undesirable chemicals could leach from fixture material into the water. – Excess sanitizing residue could taint water being transferred.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment or scale could impede seal. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	
#19	**Stainless Steel Water Pipe "Tee"** (Provides option to route CIP flush to drain) 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize and either result in biofilm or get carried through in the source water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. ***SSOPs*** • Routine cleaning and sanitizing after exposure to any type of contaminate. ***Testing/Verification*** • Test of source water used as surrogate for bacteria.
		Chemical ❖ Air pollutants	– Source water could contain undesirable chemicals from the source. – Undesirable chemicals could leach from plumbing material into the water.	3	E	20	
		Physical ❖ Foreign Material, dust, dirt, insects	– Source water could contain undesirable sediment from the source. – Undesirable sediment could build up in plumbing and/or imped the flow of source water.	4	E	23	
#20	**Stainless Steel Water Pipe** (Flairs out from 3" to 6" diameter for 10D length prior to UV) 316 stainless	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. • Insure any exposed surface is properly passivated. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of CIP using highly ozonated water for sanitizing and prevention of biological buildup. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Air pollutants	– Undesirable chemicals could leach from plumbing material into the water. – Improperly passivated pipes could result in leaching of Chromium if the oxide is not fully restored.	3	E	20	
		Physical ❖ Foreign Material, dust, dirt, insects	– Undesirable sediment could build up in plumbing and/or imped the flow of source water.	4	E	23	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#21	**Sampling Port**	**Biological** ❖ Any biological buildup.	– Biologicals build up around the port tainting the sample.	3	D	17	***PRPs*** • Locating the port to insure it can draw representative sample from water. • Material specification that allows adequate cleaning and sanitizing prior to drawing sample without cross-contamination. • Controllable flow so that sample collection vessel is not overwhelmed. • Proper installation; compliance with plumbing code. ***SSOPs*** • Sanitizing after any direct exposure to contaminants. ***Testing/Verification*** • Periodic visual inspection for leaks.
		Chemical ❖ Material leaching ❖ Sanitizer residue	– Materials no longer GMP compliant. – Residue from cleaning/sanitizing taints the sample.	3	D	17	
		Physical ❖ Biofilm sluff ❖ Excessive vibration	– Sluff from biofilm taints the sample. – Water is static or drawn from dead leg which is NOT reflective of water.	4	E	23	
#22	**Atlantium RZ163 Ultraviolet Disinfection of Well Water** Validated 4-Log Reduction (Disinfection of Well water)	**Biological** ❖ Pathogenic bacteria ❖ HPC/P.Aeruginosa ❖ Fungus (Y&M) ❖ Viruses	– Biofilm growing on the inside of the UV housing (quartz sleeve and outer wall) that could impair the effective operation. – Contamination of the seals separating the bulbs from water chamber allowing biological growth.	2	D	12	**PRPs** • Proper sizing and installation of the UV unit • Training of staff **Process Control** • The UV is not a Process Preventive Control because the source water is subject to further treatment prior to bottling. **SSOPs** • Servicing of UV via preventative maintenance (cleaning quartz, etc.) **Monitoring** • Automatic controls will shut down or divert water flow if the unit falls outside of 4-log reduction. • Monitoring of key parameters is done continuously the hours of usage and the intensity of the bulb. • Daily Inspection to verify unit is operating with no leaks. • Reviewing the validated 4-log reduction data and print weekly hard copy record. **Testing/Verification** • Insure the UV software is functioning properly.
		Chemical ❖ Mineral buildup	– Scale build-up on the glass sleeve that impairs the effectiveness of the UV. – Mercury contamination from broken bulb.	4	E	23	
		Physical ❖ Foreign Material	– Glass breakage stemming from broken UV light or quartz sleeve – High turbidity impedes UV effectiveness	3	D	17	
#23	**Stainless Steel Water Pipe** (Section of 6" Stainless Steel pipe minimum of 4D [24 inches]) 316 stainless	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. • Insure any exposed/welded surface is properly passivated. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from pipe material	– Undesirable chemicals could leach from plumbing material into the water. – Improper passivation could result in Chromium leaching.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment or scale could impede flows. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	
#24	**Sampling Port**	**Biological** ❖ Any biological buildup.	– Biologicals build up around the port tainting the sample.	3	D	17	***PRPs*** • Locating the port to insure it can draw representative sample from water. • Material specification that allows adequate cleaning and sanitizing prior to drawing sample without cross-contamination. • Controllable flow so that sample collection vessel is not overwhelmed. • Proper installation; compliance with plumbing code. ***SSOPs*** • Sanitizing after any direct exposure to contaminants. ***Testing/Verification*** • Periodic visual inspection for leaks.
		Chemical ❖ Material leaching ❖ Sanitizer residue	– Materials no longer GMP compliant. – Residue from cleaning/sanitizing taints the sample.	3	D	17	
		Physical ❖ Biofilm sluff ❖ Excessive vibration	– Sluff from biofilm taints the sample. – Water is static or drawn from dead leg which is NOT reflective of water.	4	E	23	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#25	**Stainless Steel Three-way Butterfly Valve With Diverter** 3"Dia/316 SS (Controlled by Atlantium; opens whenever parameters exceed limits.	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from valve material	– Undesirable chemicals could leach from plumbing material into the water. – O-ring could degrade or leak.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment, scale or grit could impact the seat, body or disk of the valve impeding flow or full closure. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	
#26	**Sanitary Hose Coupler** 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Exterior and interior could provide surfaces that facilitate colonizing biofilm or other biologicals that could cross-contaminate wetted surfaces.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of routine cleaning and sanitizing to prevent biological colonizing. • Prior to use – cleaning and then sanitizing with 600 ppm concentration chlorine solution. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test strips to verify concentration.
		Chemical ❖ Leaching from material	– Undesirable chemicals could leach from fixture material into the water. – Excess sanitizing residue could taint water being transferred.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment or scale could impede seal. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	
#27	**Sanitary Hose**	**Biological** ❖ Pathogenic bacteria (TC) ❖ Other bacteria (e.g. HPC)	– Dirty or unsanitary hose could contribute contaminates to the water being loaded from tanker.	3	D	17	***SSOPs*** • Cleaning and Sanitizing Sanitary Hose used for loading. ***SOPs*** • Loading of tanker SOP ***Monitoring*** • Management observations insuring procedures are followed. ***Testing/Verification*** • Sanitizer used on hose and fitting is right concentration.
		Chemical ❖ NA	– Excess residue from sanitizing chemicals could taint water being loaded.	3	D	17	
		Physical ❖ NA	– Dirt or debris lodged in hoses could transfer to source water being loaded.	3	D	17	
#28	**Hose Pipe** (fixed – allows hose to pass through the fence)	**Biological** ❖ Pathogenic bacteria (TC) ❖ Other bacteria (e.g. HPC)	– Dirty or unsanitary hose stanchion could contribute contaminates to staff engaged in handling hose and loading.	3	D	17	***SSOPs*** • Clean and Sanitize stanchion periodically.
		Chemical ❖ NA					
		Physical ❖ NA					
#29	**Hose Stanchion** (moveable to keep hose off ground)	**Biological** ❖ Pathogenic bacteria (TC) ❖ Other bacteria (e.g. HPC)	– Dirty or unsanitary hose stanchion could contribute contaminates to staff engaged in handling hose and loading.	3	D	17	***PRPs*** • Steel stand provides support for the hose during the loading process, keeping it off the ground. ***SSOPs*** • Clean and Sanitize stanchion periodically.
		Chemical ❖ NA	– If hose is allowed to lay on the ground it could come into contact with chemicals that possibly get into the hose and cause cross-contamination.	3	D	17	
		Physical ❖ NA					

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#30	**Sanitary Hose Coupler** 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Exterior and interior could provide surfaces that facilitate colonizing biofilm or other biologicals that could cross-contaminate wetted surfaces.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of routine cleaning and sanitizing to prevent biological colonizing. • Prior to use – cleaning and then sanitizing with 600 ppm concentration chlorine solution. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test strips to verify concentration.
		Chemical ❖ Leaching from material	– Undesirable chemicals could leach from fixture material into the water. – Excess sanitizing residue could taint water being transferred.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment or scale could impede seal. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	
#31	**Pump loads water into tanker** (Truck mounted pump draws in ~ 6,500 gallons of well water)	**Biological** ❖ Pathogenic bacteria (TC) ❖ Other bacteria (e.g. HPC)	– Dirty or unsanitary hoses and/or pump could contribute contaminates to the water being unloaded from tanker. – Pump remains primed with spring water that is allowed to have air contact and potentially grow bacteria waiting for the next load.	3	D	17	***SSOPs*** • Cleaning and Sanitizing the pipe used for loading. ***SOPs*** • Loading of tanker SOP ***Monitoring*** • Management observations insuring procedures are followed. ***Testing/Verification*** • Sanitizer used on pipe is right concentration.
		Chemical ❖ NA	– Excess residue from sanitizing chemicals in the transfer pipe could taint water being unloaded.	3	D	17	
		Physical ❖ NA	– Dirt or debris lodged in hoses could transfer to source water being unloaded.	3	D	17	
#32	**Tanker Truck Security** Security tags or combo lock placed on truck	**Biological** ❖ Pathogens	– Intentional Adulteration of the contents.	3	D	17	***SOPs*** • Part of Food Defense/Security. • Prevents unauthorized entry into Water Tanker. ***Verification*** Note: Water received at the plant with broken or missing security tags not accepted; contents destroyed. If the combo lock is used, the driver/loader and the plant have the combination.
		Chemical ❖ Unk substances	– Intentional Adulteration of the contents.	3	D	17	
		Physical ❖ Foreign Material	– Intentional Adulteration of the contents.	3	D	17	
#33	**Tractor for the Tanker**	**Biological** ❖ Pathogens	– The Tractor Driver could accidently contaminate surfaces of the pipping or hoses with bacteria causing cross contamination.	3	D	17	***SSOPs*** • Handwashing by the tractor driver. ***SOPs*** • Loading of tanker SOP ***Monitoring*** • Management observations insuring procedures are followed.
		Chemical ❖ Unk substances	– The Tractor Driver could accidently contaminate surfaces of the pipping or hoses with grease or hydrocarbons causing cross contamination.	3	D	17	
		Physical ❖ Foreign Material	– The Tractor Driver could accidently contaminate surfaces of the pipping or hoses with dirt causing cross contamination.	3	D	17	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#34	**Faucet & Hose to rinse off the back of the Tanker**	**Biological** ❖ Pathogens	– The back of the tanker could pick up road dirt as it goes back and forth to the Bottling facility possibly introducing cross contamination to workers and the loading process.	3	D	17	***SSOPs*** • Handwashing by the tractor driver. ***SOPs*** • Loading of tanker SOP • Procedure calls for the wash down of the back of the tanker if there is visual evidence of potential contamination. • There is a dedicated PWS [city of Hilo] water faucet and sanitary hose that is utilized when deemed necessary. *PRP/GMP* - We have inspected and reviewed all the plumbing used to deliver the water to the well site. - Pipes from our property line to the spigot are constructed of EPA approved materials and routinely checked for leaks. - All pipes are kept filled and under pressure. *Testing* - PWS Annual water quality testing is reviewed (CCR). • Our facility conducts our own testing of the PWS for Total Coliform & E.coli of the incoming PWS. ***Monitoring*** • Management observations insuring procedures are followed.
		Chemical ❖ Unk substances	– The back of the tanker could pick up chemical residue as it goes back and forth to the Bottling facility possibly introducing cross contamination to workers and the loading process.	3	D	17	
		Physical ❖ Foreign Material	– The back of the tanker could pick up dirt and foreign material as it goes back and forth to the Bottling facility possibly introducing cross contamination to workers and the loading process.	3	D	17	
#35	**Security Fence** (6' of chain link with 2' barbed wire)	**Biological** ❖ NA		3	D	17	***SOPs*** • Part of Food Defense/Security. • Prevents unauthorized entry into Source Water Area.
		Chemical ❖ NA					
		Physical ❖ NA					
#36	**Security Gate** (3' gate of chain link with 2' barbed wire)	**Biological** ❖ NA		3	D	17	***SOPs*** • Part of Food Defense/Security. • Prevents unauthorized entry into Source Water Area.
		Chemical ❖ NA					
		Physical ❖ NA					
#37	**Stainless Steel Water Pipe** 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. • Insure any exposed/welded surface is properly passivated. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from pipe material	– Undesirable chemicals could leach from plumbing material into the water. – Improper passivation could result in Chromium leaching.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment or scale could impede flows. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	
#38	**Air Gap** **Twice diameter of the 3" pipe for total of 6" minimum** 316 stainless	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Prevent any back syphon of water back into the system.	4	E	23	***PRPs*** • Insure the gap is the requisite 2 x the diameter of the pipe from which the water is flowing into the drain. ***SSOPs*** • Routine cleaning and sanitizing the area around the air gap (as part of the cleaning of the concrete pad). ***Monitoring – Periodically*** • Visual inspection
		Chemical ❖ Air pollutants	– Prevent any back syphon of water back into the system.	4	E	23	
		Physical ❖ Foreign Material, dust, dirt, insects	– Prevent any back syphon of water back into the system.	4	E	23	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#39	**Sanitary Drain** (Flush from CIP Cleaning & Sanitizing the Well)	**Biological** ❖ Pathogens ❖ Non-Pathogens	– Buildup of biologicals at the drain. – Potential to aerosolize back into the well equipment area.	3	C	13	***PRP's*** • Proper installation of the drain to plumbing code. ***SSOP*** • Periodic cleaning and sanitizing of drains ***Monitoring*** • Visual inspection of the water flow; any unusual odors or biologicals
		Chemical ❖ Unk substances	– pH outside of allowable range for discharge; require remediation to comply with discharge regulations	4	D	21	
		Physical ❖ Foreign Material, dust, dirt, insects	– Buildup of material could impede the water from properly draining.	4	D	21	
#40	**Pipe** (Under slab and under-ground) (Flush from CIP Cleaning & Sanitizing the Well)	**Biological** ❖ Pathogens ❖ Non-Pathogens	– Buildup of biologicals at the drain. – Potential to aerosolize back into the well equipment area.	3	C	13	***PRP's*** • Proper installation of the drain to plumbing code. ***SSOP*** • Periodic cleaning and sanitizing of drains and pipe with chlorinate water ***Monitoring*** • Visual inspection of the water flow; any unusual odors or biologicals
		Chemical ❖ Unk substances	– pH outside of allowable range for discharge; require remediation to comply with discharge regulations	4	D	21	
		Physical ❖ Foreign Material, dust, dirt, insects	– Buildup of material could impede the water from properly draining.	4	D	21	
#41	**Dry Well** Dechlorinated water put down dry well below the well field)	**Biological** ❖ Pathogens ❖ Non-Pathogens	– Buildup of biologicals at the drain. – Potential to aerosolize back into the well equipment area.	4	D	21	***PRP's*** • Proper installation of the dry well. ***SSOP*** • Periodic cleaning of bush around the drain to insure water flow is not impeded. ***Monitoring*** • Visual inspection of the water flow; any unusual odors or biologicals
		Chemical ❖ Unk substances	– pH outside of allowable range for discharge; require remediation to comply with discharge regulations	4	D	21	
		Physical ❖ Foreign Material, dust, dirt, insects	– Buildup of material could impede the water from properly draining.	4	D	21	
#42	**Flexible Hose Pipe to Carbon** (Only connected when flushing well CIP water)	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize resulting in biofilm.	3	D	17	***PRPs*** • Proper installation of hose; compliance with plumbing standards. ***SSOPs*** • Periodic sanitizing hose after any exposure to potential contaminants • Discharge of well CIP water containing chlorine and/or Hydrogen Peroxide will help prevent biological buildup. ***Monitoring – Periodically*** • Inspection for any evidence of biological growth or other hazards or unusual odors.
		Chemical ❖ Leaching from pipe & valve fittings	– Source water could contain undesirable chemicals into discharge water.	3	E	20	
		Physical ❖ Biofilm sluff ❖ Metal fatigue	– Undesirable sediment could build up in plumbing and/or imped the flow of the discharge water.	4	E	23	
#43	**Sanitary Hose Coupler** 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Exterior and interior could provide surfaces that facilitate colonizing biofilm or other biologicals that could cross-contaminate wetted surfaces.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of routine cleaning and sanitizing to prevent biological colonizing. • Prior to use – cleaning and then sanitizing with 600 ppm concentration chlorine solution. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test strips to verify concentration.
		Chemical ❖ Leaching from material	– Undesirable chemicals could leach from fixture material into the water. – Excess sanitizing residue could taint water being transferred.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment or scale could impede seal. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#44	**Stainless Steel Water Pipe "Tee"** (Provides option to route CIP flush to drain) 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Dirty or unsanitary pipe could contribute contaminates that allow biofilm or mildew to build up on surfaces.	3	D	17	**Note:** This part of the process does not touch source water. The system is physically disconnected unless draining discharge. ***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. ***SSOPs*** • Routine cleaning and sanitizing to prevent biological buildup. ***Testing/Verification*** • Sanitizer used is the right concentration.
		Chemical ❖ Air pollutants	– None expected.	3	E	20	
		Physical ❖ Foreign Material, dust, dirt, insects	– Dirt or debris could interfere with water flow.	4	E	23	
#45	**Stainless Steel Water Pipe 3" to 2" Reducer** 316 stainless	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. • Insure any exposed/welded surface is properly passivated. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from pipe material	– Undesirable chemicals could leach from plumbing material into the water. – Improper passivation could result in Chromium leaching.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment or scale could impede flows. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	
#46	**Stainless Steel Butterfly Valve** 2"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from valve material	– Undesirable chemicals could leach from plumbing material into the water. – O-ring could degrade or leak.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment, scale or grit could impact the seat, body or disk of the valve impeding flow or full closure. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	
#47	**Stainless Steel Pipe** 2"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. • Insure any exposed/welded surface is properly passivated. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from pipe material	– Undesirable chemicals could leach from plumbing material into the water. – Improper passivation could result in Chromium leaching.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment or scale could impede flows. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#48	**Air Gap** **Twice diameter of the 2" pipe for total of 4" minimum** 316 stainless	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Prevent any back syphon of water back into the system.	4	E	23	**Note:** This part of the process does not touch source water. The system is physically disconnected unless draining discharge. ***PRPs*** • Insure the gap is the requisite 2 x the diameter of the pipe from which the water is flowing into the drain. ***SSOPs*** • Routine cleaning and sanitizing the area around the air gap (as part of the cleaning of the concrete pad). ***Monitoring – Periodically*** • Visual inspection
		Chemical ❖ Air pollutants	– Prevent any back syphon of water back into the system.	4	E	23	
		Physical ❖ Foreign Material, dust, dirt, insects	– Prevent any back syphon of water back into the system.	4	E	23	
#49	**Sanitary Drain** (Flush from CIP Cleaning & Sanitizing the Well)	**Biological** ❖ Pathogens ❖ Non-Pathogens	– Buildup of biologicals at the drain. – Potential to aerosolize back into the well equipment area.	3	C	13	**Note:** This part of the process does not touch source water. The system is physically disconnected unless draining discharge. ***PRP's*** • Proper installation of the drain to plumbing code. ***SSOP*** • Periodic cleaning and sanitizing of drains ***Monitoring*** • Visual inspection of the water flow; any unusual odors or biologicals
		Chemical ❖ Unk substances	– pH outside of allowable range for discharge; require remediation to comply with discharge regulations	4	D	21	
		Physical ❖ Foreign Material, dust, dirt, insects	– Buildup of material could impede the water from properly draining.	4	D	21	
#50	**Stainless Steel Water Pipe 3" to 2" Reducer** 316 stainless	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. • Insure any exposed/welded surface is properly passivated. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from pipe material	– Undesirable chemicals could leach from plumbing material into the water. – Improper passivation could result in Chromium leaching.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment or scale could impede flows. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	
#51	**Sanitary Hose Coupler** 2"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Exterior and interior could provide surfaces that facilitate colonizing biofilm or other biologicals that could cross-contaminate wetted surfaces.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of routine cleaning and sanitizing to prevent biological colonizing. • Prior to use – cleaning and then sanitizing with 600 ppm concentration chlorine solution. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test strips to verify concentration.
		Chemical ❖ Leaching from material	– Undesirable chemicals could leach from fixture material into the water. – Excess sanitizing residue could taint water being transferred.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment or scale could impede seal. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	
#52	**2" Quick Dis-connect Sanitary Hose**	**Biological** ❖ Pathogenic bacteria (TC) ❖ Other bacteria (e.g. HPC)	– Dirty or unsanitary hose coupler could contribute contaminates that allow biofilm or mildew to build up on surfaces.	3	D	17	**Note:** This part of the process does not touch source water. The system is physically disconnected unless draining discharge. ***SSOPs*** • Cleaning and Sanitizing Sanitary Hose coupler (600 ppm of chlorine solution) ***Testing/Verification*** • Sanitizer used is the right concentration.
		Chemical ❖ NA	– None expected	4	E	21	
		Physical ❖ NA	– Dirt or debris could interfere with tight hose connection	4	E	21	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#53	**Carbon Filter** Single tank (Dichlorination of CIP cleaning and disinfection water on its way to dry well) NOTE: NO SOURCE WATER USED FOR PRODUCT PASSES THROUGH THIS TANK.	**Biological** ❖ Bacteria buildup	– Improperly serviced filter could allow the growth of Biologicals on the surface or in the layers of media which could interfere with the chlorine reduction.	3	D	17	**Note:** This part of the process does not touch source water. The system is physically disconnected unless draining discharge. ***PRPs*** • Proper installation of the carbon tower and control systems. • Training of staff ***SSOPs*** • Cleaning and Sanitizing after replacement of media. ***SOPs*** • Operation of the carbon tower; including calibration of manual backflush. ***Monitoring*** • Checking for adequate chlorine removal
		Chemical ❖ None expected.	– Routine servicing of filter, including backflushing and media cleaning/replacement to insure absorption is adequate to remove impurities and/or contaminates.	3	D	17	
		Physical ❖ Foreign Material, dust, dirt, insects	– Could clog media and prevent its proper function to dechlorinate.	4	E	23	
#54	**Stainless Steel Water Pipe and Air Gap** (Flowing to Drain) Reduces 3" to 1.5" diameter which then has 3" air gap	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize resulting in biofilm.	3	D	17	**Note:** This part of the process does not touch source water. The system is physically disconnected unless draining discharge. ***PRPs*** • Proper installation of pipping. • Insure the gap is the requisite 2 x the diameter of the pipe from which the water is flowing into the drain. ***SSOPs*** • Periodically clean/sanitize pipes to prevent buildup of biologicals that could impede flow or promote growth of biologicals which could cross-contaminate other equipment. • Discharge of well CIP water containing chlorine and/or Hydrogen Peroxide will help prevent biological buildup. ***Monitoring – Periodically*** • Visual inspection
		Chemical ❖ Leaching from pipe & valve fittings	– Source water could contain undesirable chemicals into discharge water.	3	E	20	
		Physical ❖ Biofilm sluff ❖ Metal fatigue	– Undesirable sediment could build up in plumbing and/or imped the flow of the discharge water.	4	E	23	

END OF SOURCE EXTRACTION PROCESS.

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
START OF THE TANKER UNLOAD PROCESS AT BOTTLING PLANT.							
#1a	**Tanker Truck Inspection** (Receiving staff verify the security seals are in place upon delivery of truck to bottling plant.)	**Biological** ❖ Pathogenic bacteria (TC) ❖ Other bacteria (e.g. HPC)	– If seals are broken it is possible that dirt or other contamination could have been introduced into the load of water.	2	D	12	***Monitoring*** • Presence of broken security seal or open vent on the truck prior to acceptance voids the load; water will be dumped and tanker subject to being cleaned and sanitized. ***Testing/Verification*** • Physical inspection and verification of proper seals and closed vents. • Documented on the unloading tanker form.
		Chemical ❖ NA	– Intentional Adulteration could have introduced undesirable chemical.	2	D	12	
		Physical ❖ NA	– Intentional Adulteration could have introduced undesirable chemical.	2	D	12	
#1b	**Back End of tanker washed off with water if visible road dirt; otherwise the hose coupler is rinsed off**	**Biological** ❖ Airborne yeast & mold ❖ Airborne bacteria	– Road dirt could be accidentally transferred to the water as it unloaded. – Tanker could become contaminated once lid and vent opened from road contaminants.	3	D	17	***GMP Control*** • Back end and other critical sanitary surfaces are washed off with water to prevent accidental contamination during offloading. ***Training*** • Staff is trained on tanker wash off. ***SSOPs*** • Hose used to wash off back end is not contaminated before use. ***SOPs*** • Offloading of tanker SOP ***Monitoring*** • Supervisor routinely visually verifies procedures are being followed. ***Testing/Verification*** • Visual observation made by person unloading tanker for any evidence of contamination that could impact source water.
		Chemical ❖ Air pollutants	– Road salts and other chemicals splashed up on the tanker could get into the source water.	3	D	17	
		Physical ❖ Foreign Material, dust, dirt, insects	– Airborne dust or insects could contaminate source water.	3	D	17	
#1c	**Water Testing drawn from tanker**	**Biological** ❖ Pathogenic bacteria (TC) ❖ Other bacteria (e.g. HPC)	– Contaminates originating from the well or introduced during transit.	3	D	17	***Controls*** • Biological testing for Coliform and HPC done by drawing sample from tanker. • Chemical and physical testing for TDS and pH done by drawing sample from tanker. ***SOPs*** • Offloading of tanker SOP ***Monitoring*** • Observe results for TC in 24 & HPC in 48 hours ***Testing/Verification*** • Reject load if chemical and physical testing are out of spec.
		Chemical ❖ NA	–				
		Physical ❖ NA					
#2	**Sanitary Hose Coupler** (Coupler is on the tanker; capped when not in use) 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Exterior and interior could provide surfaces that facilitate colonizing biofilm or other biologicals that could cross-contaminate wetted surfaces.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of routine cleaning and sanitizing to prevent biological colonizing. • Prior to use – cleaning and then sanitizing with 600 ppm concentration chlorine solution. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test strips to verify concentration.
		Chemical ❖ Leaching from material	– Undesirable chemicals could leach from fixture material into the water. – Excess sanitizing residue could taint water being transferred.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment or scale could impede seal. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#3	**3" PVC Sanitary Hose**	**Biological** ❖ Pathogenic bacteria (TC) ❖ Other bacteria (e.g. HPC)	– Dirty or unsanitary hoses could contribute contaminates to the water being unloaded from tanker.	3	D	17	***SSOPs*** • Cleaning and Sanitizing Sanitary Hoses used for unloading. ***SOPs*** • Offloading of tanker SOP ***Monitoring*** • Management observations insuring procedures are followed. ***Testing/Verification*** • Sanitizer used on hoses is right concentration.
		Chemical ❖ NA	– Excess residue from sanitizing chemicals could taint water being unloaded.	3	D	17	
		Physical ❖ NA	– Dirt or debris lodged in hoses could transfer to source water being unloaded.	3	D	17	
SUPPORT ITEMS FOR TANKER UNLOADING THAT DO NOT TOUCH THE WATER ITSELF.							
#4a	**Security Fence** (6' of chain link with 2' barbed wire)	**Biological** ❖ NA		3	D	17	***SOPs*** • Part of Food Defense/Security. • Prevents unauthorized entry into Tanker Area.
		Chemical ❖ NA					
		Physical ❖ NA					
#4	**Security Gate** (3' gate of chain link with 2' barbed wire)	**Biological** ❖ NA		3	D	17	***SOPs*** • Part of Food Defense/Security. • Prevents unauthorized entry into tanker Area.
		Chemical ❖ NA					
		Physical ❖ NA					
#5	**Emergency Eye Wash**	**Biological** ❖ NA					***SOPs*** • Part of OSHA program
		Chemical ❖ NA					
		Physical ❖ NA					
PROCESS CONTINUES WITH UNLOADING OF WATER FROM DEDICATED TANKER TRUCK.							
#6	**Sanitary Hose Coupler** (Coupler is capped when not in use) 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Exterior and interior could provide surfaces that facilitate colonizing biofilm or other biologicals that could cross-contaminate wetted surfaces.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of routine cleaning and sanitizing to prevent biological colonizing. • Prior to use – cleaning and then sanitizing with 600 ppm concentration chlorine solution. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test strips to verify concentration.
		Chemical ❖ Leaching from material	– Undesirable chemicals could leach from fixture material into the water. – Excess sanitizing residue could taint water being transferred.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment or scale could impede seal. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#7	**Stainless Steel Butterfly Valve** (Valve is in closed position when not loading) 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from valve material	– Undesirable chemicals could leach from plumbing material into the water. – O-ring could degrade or leak.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment, scale or grit could impact the seat, body or disk of the valve impeding flow or full closure. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	
#8	**Stainless Steel Water Pipe** (Section of 3" pipe goes through the wall to inside the water treatment area of Production Plant) 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. • Insure any exposed/welded surface is properly passivated. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from pipe material	– Undesirable chemicals could leach from plumbing material into the water. – Improper passivation could result in Chromium leaching.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment or scale could impede flows. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	
#9	**Pump #5** (Pulls water from the tanker towards the Water Storage Tank)	**Biological** ❖ Other bacteria (e.g. HPC) build up inside valve)	– Contaminants that build up in the hard surfaces of the pump and fittings; impinging the flow. – Biofilm that promotes the growth of pathogenic bacteria.	3	D	17	***PRPs*** • Proper installation of valve. • Training of staff ***SSOPs*** • Sanitizing valve after any exposure to potential contaminants ***Monitoring*** • Daily Inspection for drips or excess condensation indicative of failure or other hazard. ***Testing/Verification*** • Confirmation of proper materials current with plumbing standards.
		Chemical ❖ Leaching from pipe & valve fittings	– Metal used in the pump water contact surfaces no longer in compliance with brass/lead/copper plumbing standards. – Metal leaching out of pump into water flow.	3	D	17	
		Physical ❖ Biofilm sluff ❖ Metal fatigue	– Growth of biofilm to the stage where it becomes physical substance capable of fouling pump.	4	E	23	
#10	**Stainless Steel Water Pipe** (Section of 3" pipe goes back out through the wall to outside) 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. • Insure any exposed/welded surface is properly passivated. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from pipe material	– Undesirable chemicals could leach from plumbing material into the water. – Improper passivation could result in Chromium leaching.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment or scale could impede flows. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#11	**Flexible Pipe Section** (3" x 24" section of flexible pipe bridging fixed pipe sections) (allows for thermal flex so stainless pipe does not break)	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize resulting in biofilm.	3	D	17	***PRPs*** • Proper installation of pipe & fittings; compliance with plumbing standards. • Labeling of the pipe on outside to be able to track flows. ***SSOPs*** • Periodic sanitizing pipe & fitting after any exposure to potential contaminants. ***Monitoring – Periodically*** • Inspection for drips or any evidence of biological growth or other hazard.
		Chemical ❖ Leaching from pipe & valve fittings	– Source water could contain undesirable chemicals that pass through with source water – Improperly passivated pipes contribute chemical contamination	3	E	20	
		Physical ❖ Biofilm sluff ❖ Metal fatigue	– Undesirable sediment could build up in plumbing and/or imped the flow of the discharge water.	4	E	23	
#12	**Water Storage Tank** Holds Well water from deliveries (15,000 gal)	**Biological** ❖ Pathogens - Coliforms and/or E. Coli ❖ Pseudomonas aeruginosa	– Biofilm or other biological in the storage tanks that entered with water or through tank air vent – Contamination due to poor personal hygiene during maintenance activities	3	D	17	***PRPs*** • Proper installation piping/plumbing • Compliance with material specification for tank ***SSOPs*** • Review of preventative maintenance schedule for cleaning/sanitizing tank; especially the inside top surface that is most often exposed to air. No physical entry required if the CIP system functions properly. ***Monitoring*** • Periodic inspection for leaks
		Chemical ❖ Unk substances	– Not expected to occur	3	D	17	
		Physical ❖ Foreign Material	– Contamination from poorly maintained air filter	4	E	23	
#13	**Spray Ball for CIP Process**	**Biological** ❖ Pathogens - Coliforms and/or E. Coli ❖ Pseudomonas aeruginosa	– Biofilm or other biologicals foul the ball preventing it from operating properly. – Contamination due to poor personal hygiene during maintenance activities	3	D	17	***PRPs*** • Proper installation piping/plumbing • Compliance with material specification ***SSOPs*** • Review of preventative maintenance schedule for cleaning/sanitizing tank; especially the inside top surface that is most often exposed to air. No physical entry required if the CIP system functions properly. ***Monitoring*** • Scheduled inspection of the ball to insure there are no clogging of sprays.
		Chemical ❖ Unk substances	– Not expected to occur	3	D	17	
		Physical ❖ Foreign Material	– Sediment or foreign materials could clog the spray ball preventing its proper operation.	4	E	23	
#14	**Electronic Water Level Sensor**	**Biological** ❖ Pathogens - Coliforms and/or E. Coli ❖ Pseudomonas aeruginosa	– Biofilm or other biological in the storage tanks that interferes with the sensor – Contamination due to poor personal hygiene during maintenance activities	3	D	17	***PRPs*** • Proper installation piping/plumbing • Compliance with material specification for tank ***SOPs*** • Calibration per the user's manual ***Monitoring*** • Periodic inspection for leaks where the device mounts to the tank.
		Chemical ❖ Unk substances	– Not expected to occur	3	D	17	
		Physical ❖ Foreign Material	– Contamination from poorly maintained air filter	4	E	23	
#15	**Air Filtration** Air entering and exiting storage tank	**Biological** ❖ Airborne yeast & mold	– Unfiltered air could result in introducing biologicals which could contaminate the water or form biofilm. – High risk due to lack of any residual disinfection in the tank.	2	D	***12***	***PRPs*** • Installation of air filters on tanks where air is introduced or expelled to compensate for fill level. ***Process Controls*** • Filtering air to standard equivalent to MIRV 13 or higher. ***Training*** • Training of staff on the maintenance of the filters ***SSOPs*** • Routine cleaning and sanitizing after replacing air filter media. ***Testing/Verification*** • Periodic test for airborne bacteria, yeast & molds and virus in air that is inside tank.
		Chemical ❖ Air pollutants	– Air drawn in could contribute chemical contaminates which could transfer to product water.	3	D	17	
		Physical ❖ Foreign Material, dust, dirt, insects	– Airborne dust or insects could contaminate product water.	3	D	17	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#16	**Stainless Steel Butterfly Valve & Drain** (Valve is from bottom where it turns 90 degrees) 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from valve material	– Undesirable chemicals could leach from plumbing material into the water. – O-ring could degrade or leak.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment, scale or grit could impact the seat, body or disk of the valve impeding flow or full closure. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	
#17	**Stainless Steel Butterfly Valve** 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from valve material	– Undesirable chemicals could leach from plumbing material into the water. – O-ring could degrade or leak.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment, scale or grit could impact the seat, body or disk of the valve impeding flow or full closure. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	
#18	**Flexible Pipe Section** (2" x 24" section of flexible pipe bridging fixed pipe sections)	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize resulting in biofilm.	3	D	17	***PRPs*** • Proper installation of pipe & fittings; compliance with plumbing standards. • Labeling of the pipe on outside to be able to track flows. ***SSOPs*** • Periodic sanitizing pipe & fitting after any exposure to potential contaminants. ***Monitoring – Periodically*** • Inspection for drips or any evidence of biological growth or other hazard.
		Chemical ❖ Leaching from pipe & valve fittings	– Source water could contain undesirable chemicals that pass through with source water – Improperly passivated pipes contribute chemical contamination	3	E	20	
		Physical ❖ Biofilm sluff ❖ Metal fatigue	– Undesirable sediment could build up in plumbing and/or imped the flow of the discharge water.	4	E	23	
#19	**Stainless Steel Water Pipe** (Section of 2" pipe goes through the wall from water tank to inside to UV and ultimately bottling process) 2"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. • Insure any exposed/welded surface is properly passivated. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from pipe material	– Undesirable chemicals could leach from plumbing material into the water. – Improper passivation could result in Chromium leaching.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment or scale could impede flows. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#20	**Pump #1** (Pulls water from the water tank to the UV)	**Biological** ❖ Other bacteria (e.g. HPC) build up inside valve)	– Contaminants that build up in the hard surfaces of the pump and fittings; impinging the flow. – Biofilm that promotes the growth of pathogenic bacteria.	3	D	17	***PRPs*** • Proper installation of valve. • Training of staff ***SSOPs*** • Sanitizing valve after any exposure to potential contaminants ***Monitoring*** • Daily Inspection for drips or excess condensation indicative of failure or other hazard. ***Testing/Verification*** • Confirmation of proper materials current with plumbing standards.
		Chemical ❖ Leaching from pipe & valve fittings	– Metal used in the pump water contact surfaces no longer in compliance with brass/lead/copper plumbing standards. – Metal leaching out of pump into water flow.	3	D	17	
		Physical ❖ Biofilm sluff ❖ Metal fatigue	– Growth of biofilm to the stage where it becomes physical substance capable of fouling pump.	4	E	23	
#21	**Stainless Steel Water Pipe** (Travels from the Pump to Panel D, Valve 33) 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. • Insure any exposed/welded surface is properly passivated. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from pipe material	– Undesirable chemicals could leach from plumbing material into the water. – Improper passivation could result in Chromium leaching.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment or scale could impede flows. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	

END OF THE SOURCE WATER FROM TANKER RECEIVING PROCESS

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
START OF WATER TREATMENT PROCESS							
#1	**Water Storage Tank** Holds Well water from deliveries (15,000 gal)	**Biological** ❖ Pathogens - Coliforms and/or E. Coli ❖ Pseudomonas aeruginosa	– Biofilm or other biological in the storage tanks that entered with water or through tank air vent – Contamination due to poor personal hygiene during maintenance activities	3	D	17	***PRPs*** • Proper installation piping/plumbing • Compliance with material specification for tank ***SSOPs*** • Review of preventative maintenance schedule for cleaning/sanitizing tank; especially the inside top surface that is most often exposed to air. No physical entry required if the CIP system functions properly. ***Monitoring*** • Periodic inspection for leaks
		Chemical ❖ Unk substances	– Not expected to occur	3	D	17	
		Physical ❖ Foreign Material	– Contamination from poorly maintained air filter	4	E	23	
#2	**Air Filtration** Air entering and exiting storage tank	**Biological** ❖ Airborne yeast & mold	– Unfiltered air could result in introducing biologicals which could contaminate the water or form biofilm. – High risk due to lack of any residual disinfection in the tank.	2	D	***12***	***PRPs*** • Installation of air filters on tanks where air is introduced or expelled to compensate for fill level. ***Process Controls*** • Filtering air to standard equivalent to MIRV 13 or higher. ***Training*** • Training of staff on the maintenance of the filters ***SSOPs*** • Routine cleaning and sanitizing after replacing air filter media. ***Testing/Verification*** • Periodic test for airborne bacteria, yeast & molds and virus in air that is inside tank.
		Chemical ❖ Air pollutants	– Air drawn in could contribute chemical contaminates which could transfer to product water.	3	D	17	
		Physical ❖ Foreign Material, dust, dirt, insects	– Airborne dust or insects could contaminate product water.	3	D	17	
#3	**Electronic Water Level Sensor**	**Biological** ❖ Pathogens - Coliforms and/or E. Coli ❖ Pseudomonas aeruginosa	– Biofilm or other biological in the storage tanks that interferes with the sensor – Contamination due to poor personal hygiene during maintenance activities	3	D	17	***PRPs*** • Proper installation piping/plumbing • Compliance with material specification for tank ***SOPs*** • Calibration per the user's manual ***Monitoring*** • Periodic inspection for leaks where the device mounts to the tank.
		Chemical ❖ Unk substances	– Not expected to occur	3	D	17	
		Physical ❖ Foreign Material	– Contamination from poorly maintained air filter	4	E	23	
#4	**Spray Ball for CIP Process**	**Biological** ❖ Pathogens - Coliforms and/or E. Coli ❖ Pseudomonas aeruginosa	– Biofilm or other biologicals foul the ball preventing it from operating properly. – Contamination due to poor personal hygiene during maintenance activities	3	D	17	***PRPs*** • Proper installation piping/plumbing • Compliance with material specification ***SSOPs*** • Review of preventative maintenance schedule for cleaning/sanitizing tank; especially the inside top surface that is most often exposed to air. No physical entry required if the CIP system functions properly. ***Monitoring*** • Scheduled inspection of the ball to insure there are no clogging of sprays.
		Chemical ❖ Unk substances	– Not expected to occur	3	D	17	
		Physical ❖ Foreign Material	– Sediment or foreign materials could clog the spray ball preventing its proper operation.	4	E	23	
#5	**Stainless Steel Butterfly Valve & Drain** (Valve is from bottom where it turns 90 degrees) 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize and either result in biofilm or get carried through to the water storage tank.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. • Insure any exposed surface is properly passivated. ***SSOPs*** • Routine cleaning and sanitizing after exposure to any type of contaminate. ***Testing/Verification*** • Test of source water used as surrogate for bacteria.
		Chemical ❖ Air pollutants	– Source water could contain undesirable chemicals from the source. – Undesirable chemicals could leach from plumbing material into the water.	3	E	20	
		Physical ❖ Foreign Material, dust, dirt, insects	– Source water could contain undesirable sediment from the source. – Undesirable sediment could build up in plumbing and/or imped the flow of source water.	4	E	23	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures

STEP #6 – PRODUCT WATER TRAVELS FROM WATER STORAGE TANK TO PANEL A, VALVE 2. (VIA STEP #7)

STEP #8 – PRODUCT WATER TRAVELS FROM PANEL A, VALVE 2 TO PANEL A, VALVE 1 AND THEN OUT TO PUMP #1

#9	**Pump #1** (Pulls water from the water tank to the micron filter)	**Biological** ❖ Other bacteria (e.g. HPC) build up inside valve)	– Contaminants that build up in the hard surfaces of the pump and fittings; impinging the flow. – Biofilm that promotes the growth of pathogenic bacteria.	3	D	17	***PRPs*** • Proper installation of valve. • Training of staff ***SSOPs*** • Sanitizing valve after any exposure to potential contaminants ***Monitoring*** • Daily Inspection for drips or excess condensation indicative of failure or other hazard. ***Testing/Verification*** • Confirmation of proper materials current with plumbing standards.
		Chemical ❖ Leaching from pipe & valve fittings	– Metal used in the pump water contact surfaces no longer in compliance with brass/lead/copper plumbing standards. – Metal leaching out of pump into water flow.	3	D	17	
		Physical ❖ Biofilm sluff ❖ Metal fatigue	– Growth of biofilm to the stage where it becomes physical substance capable of fouling pump.	4	E	23	

#10	**Pressure Gauge** (before the Bag	**Biological** ❖ Any biological buildup.	– Biologicals build up around the gauge fitting anchoring themselves as biofilm that interfere with gauge functionality.	3	D	17	***PRPs*** • Utilize liquid filled gauge more resistant to vibration. • Insure water pressures within gauge tolerances. • Filter water to minimize sediment clogging of gauge. • Proper installation; compliance with plumbing code. ***SSOPs*** • Sanitizing after any direct exposure to contaminants. ***Monitoring*** • Inspection for drips or excess condensation. ***Testing/Verification*** • Confirm accuracy through recommended initial calibration of the gauge per manufacturer.
		Chemical ❖ Leaching from pipe & valve fittings	– Inadequate maintenance of gauge. – Materials no longer in compliance with GMPs.	3	D	17	
		Physical ❖ Biofilm sluff ❖ Excessive vibration	– Growth of biofilm to where it clogs gauge and impedes function. – Excessive vibration leading to gauge failure. – Overpressure and pressure spikes that bend gauge pointer.	4	E	23	

#11	**5µ Nominal Filter**	**Biological** ❖ Biological remnants left by the disinfection action of the UV 4-log reduction. ❖ Help to prevent any re-growth of biologicals	– Contaminants left in the water after 4-log reduction. – Biofilm growing on the inside of the filter housing and/or media.	3	D	17	***PRPs*** • Proper installation of the Filter unit. • Training of staff ***Process*** • Check of pre/post pressure to insure the filter is working within normal range ***SSOPs*** • Sanitizing filter housing after installing new media ***Monitoring*** • Inspection/recording of pressure until replacement of filter media based on pre-determined pressure differential or elapsed time. • Periodic inspection for leaks in filter housing
		Chemical ❖ Unk substances	– Not expected	4	D	21	
		Physical ❖ Foreign Material	– Physical breakdown of the filter media	4	D	21	

#12	**Sampling Port**	**Biological** ❖ Any biological buildup.	– Biologicals build up around the port tainting the sample.	3	D	17	***PRPs*** • Locating the port to insure it can draw representative sample from water. • Material specification that allows adequate cleaning and sanitizing prior to drawing sample without cross-contamination. • Controllable flow so that sample collection vessel is not overwhelmed. • Proper installation; compliance with plumbing code. ***SSOPs*** • Sanitizing after any direct exposure to contaminants. ***Testing/Verification*** • Periodic visual inspection for leaks.
		Chemical ❖ Material leaching ❖ Sanitizer residue	– Materials no longer GMP compliant. – Residue from cleaning/sanitizing taints the sample.	3	D	17	
		Physical ❖ Biofilm sluff ❖ Excessive vibration	– Sluff from biofilm taints the sample. – Water is static or drawn from dead leg which is NOT reflective of water.	4	E	23	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#13	**Pressure Gauge** (post 5-micron filter)	**Biological** ❖ Any biological buildup.	– Biologicals build up around the gauge fitting anchoring themselves as biofilm that interfere with gauge functionality.	3	D	17	***PRPs*** • Utilize liquid filled gauge more resistant to vibration. • Insure water pressures within gauge tolerances. • Filter water to minimize sediment clogging of gauge. • Proper installation; compliance with plumbing code. ***SSOPs*** • Sanitizing after any direct exposure to contaminants. ***Monitoring*** • Inspection for drips or excess condensation. ***Testing/Verification*** • Confirm accuracy through recommended initial calibration of the gauge per manufacturer.
		Chemical ❖ Leaching from pipe & valve fittings	– Inadequate maintenance of gauge. – Materials no longer in compliance with GMPs.	3	D	17	
		Physical ❖ Biofilm sluff ❖ Excessive vibration	– Growth of biofilm to where it clogs gauge and impedes function. – Excessive vibration leading to gauge failure. – Overpressure and pressure spikes that bend gauge pointer.	4	E	23	
#14	**Stainless Steel 3-Way Tee Valve** (One path goes to Ozone system for CIP and ultimately bottle rinse; other path goes to filler) 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize and either result in biofilm or get carried through in the source water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. • Insure any exposed surface is properly passivated. ***SSOPs*** • Routine cleaning and sanitizing after exposure to any type of contaminate. ***Testing/Verification*** • Test of source water used as surrogate for bacteria.
		Chemical ❖ Air pollutants	– Source water could contain undesirable chemicals from the source. – Undesirable chemicals could leach from plumbing material into the water.	3	E	20	
		Physical ❖ Foreign Material, dust, dirt, insects	– Source water could contain undesirable sediment from the source. – Undesirable sediment could build up in plumbing and/or imped the flow of source water.	4	E	23	

STEP 15 – PRIMARY PATH GOES TO PANEL B, VALVE 10

STEP 16 – ALL WITHIN PANEL B: VALVE 10 TO VALVE 9 TO VALVE 16 TO VALVE 14 THEN EXITS TO THE AIR VALVE

#17	**Air Valve** 316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize and either result in biofilm or get carried through to the water storage tank.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. • Insure any exposed surface is properly passivated. ***SSOPs*** • Routine cleaning and sanitizing after exposure to any type of contaminate. ***Testing/Verification*** • Test of source water used as surrogate for bacteria.
		Chemical ❖ Air pollutants	– Source water could contain undesirable chemicals from the source. – Undesirable chemicals could leach from plumbing material into the water.	3	E	20	
		Physical ❖ Foreign Material, dust, dirt, insects	– Source water could contain undesirable sediment from the source. – Undesirable sediment could build up in plumbing and/or imped the flow of source water.	4	E	23	
#18	**HESS Stainless Steel Buffer Tank** (This tank is used to buffer water – nothing is added or subtracted)	**Biological** ❖ Pathogens ❖ Non-Pathogens	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm.	3	D	20	***PRPs*** • Proper installation; compliance with plumbing code. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching	– Any improper welds that are in water contact may not have adequate oxide coating resulting in Chromium leaching	3	D	17	
		Physical ❖ Foreign Material	– Accumulation of sediment falling out from the water.	4	D	21	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#19	**Sampling Port** (Draws water from the HESS One tank)	**Biological** ❖ Any biological buildup.	– Biologicals build up around the port tainting the sample.	3	D	17	***PRPs*** • Locating the port to insure it can draw representative sample from water. • Material specification that allows adequate cleaning and sanitizing prior to drawing sample without cross-contamination. • Controllable flow so that sample collection vessel is not overwhelmed. • Proper installation; compliance with plumbing code. ***SSOPs*** • Sanitizing after any direct exposure to contaminants. ***Testing/Verification*** • Periodic visual inspection for leaks.
		Chemical ❖ Material leaching ❖ Sanitizer residue	– Materials no longer GMP compliant. – Residue from cleaning/sanitizing taints the sample.	3	D	17	
		Physical ❖ Biofilm sluff ❖ Excessive vibration	– Sluff from biofilm taints the sample. – Water is static or drawn from dead leg which is NOT reflective of water.	4	E	23	
#20	**Stainless Steel Butterfly Valve** 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from valve material	– Undesirable chemicals could leach from plumbing material into the water. – O-ring could degrade or leak.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment, scale or grit could impact the seat, body or disk of the valve impeding flow or full closure. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	
#21	**Pump #2** (Pulls water from the HESS tank)	**Biological** ❖ Other bacteria (e.g. HPC) build up inside valve)	– Contaminants that build up in the hard surfaces of the pump and fittings; impinging the flow. – Biofilm that promotes the growth of pathogenic bacteria.	3	D	17	***PRPs*** • Proper installation of valve. • Training of staff ***SSOPs*** • Sanitizing valve after any exposure to potential contaminants ***Monitoring*** • Daily Inspection for drips or excess condensation indicative of failure or other hazard. ***Testing/Verification*** • Confirmation of proper materials current with plumbing standards.
		Chemical ❖ Leaching from pipe & valve fittings	– Metal used in the pump water contact surfaces no longer in compliance with brass/lead/copper plumbing standards. – Metal leaching out of pump into water flow.	3	D	17	
		Physical ❖ Biofilm sluff ❖ Metal fatigue	– Growth of biofilm to the stage where it becomes physical substance capable of fouling pump.	4	E	23	
#22	**Heat Exchanger**	**Biological** ❖ Other bacteria (e.g. HPC) build up inside valve)	– Contaminants that build up in the hard surfaces of the device providing growth media for bacteria that could establish colonies, contributing biologicals to the water.	3	D	17	***PRPs*** • Proper installation of equipment. • Training of staff ***SSOPs*** • Sanitizing wetted surfaces after any direct exposure to contaminants ***Monitoring*** • Daily Inspection for drips or excess condensation indicative of failure or other hazard. ***Testing/Verification*** • Confirmation of proper materials current with plumbing standards.
		Chemical ❖ Leaching from pipe & valve fittings	– Metal used subject to corrosion under certain water chemistry including pH. – Metal leaching out of interior surfaces.	3	D	17	
		Physical ❖ Crystallization ❖ Decomposition ❖ Oxidation ❖ Biofilm sluff ❖ Corrosion/Metal fatigue	– Fouling that impedes flow and decreases thermal efficiency. – Excessive temperature can promote the crystallization, decomposition and oxidation processes. – Rusting as the result of corrosive condensation forming on inside and outside. – Cracking of metal caused by thermal shock or excessive water hammering.	4	D	21	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#23	**Flow Meter**	**Biological** ❖ Bacteria build up inside pipping and valve	– Biologicals build up around the flow meter as biofilm could cause false readings. – Invalid reading could negatively impact the operation of the Atlantium UV.	3	D	17	***PRPs*** • Proper installation of meter; compliance with plumbing standards. • Training of staff ***SSOPs*** • Sanitizing fitting after any exposure to potential contaminants ***Monitoring*** • Inspection for drips or excess condensation indicative of failure or other hazard. ***Testing/Verification*** • Confirm accuracy through recommended calibration per manufacturer
		Chemical ❖ Leaching from pipe & valve fittings	– Inadequate maintenance of meter. – Materials no longer in compliance with GMPs	3	D	17	
		Physical ❖ Biofilm sluff ❖ Metal fatigue	– Growth of biofilm to the stage where it becomes physical substance capable of fouling meter.	4	E	23	
#24	**Sampling Port** (Prior to the UV)	**Biological** ❖ Any biological buildup.	– Biologicals build up around the port tainting the sample.	3	D	17	***PRPs*** • Locating the port to insure it can draw representative sample from water. • Material specification that allows adequate cleaning and sanitizing prior to drawing sample without cross-contamination. • Controllable flow so that sample collection vessel is not overwhelmed. • Proper installation; compliance with plumbing code. ***SSOPs*** • Sanitizing after any direct exposure to contaminants. ***Testing/Verification*** • Periodic visual inspection for leaks.
		Chemical ❖ Material leaching ❖ Sanitizer residue	– Materials no longer GMP compliant. – Residue from cleaning/sanitizing taints the sample.	3	D	17	
		Physical ❖ Biofilm sluff ❖ Excessive vibration	– Sluff from biofilm taints the sample. – Water is static or drawn from dead leg which is NOT reflective of water.	4	E	23	
#25a	**Stainless Steel Water Pipe** (Section of 4" Stainless Steel pipe minimum of 10D [40 inches] ahead of UV) 4"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. • Insure any exposed/welded surface is properly passivated. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from pipe material	– Undesirable chemicals could leach from plumbing material into the water. – Improper passivation could result in Chromium leaching.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment or scale could impede flows. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	
#25b	**PPC#1** **Atlantium RZ104 Ultraviolet Disinfection of Product Water** Validated 4-Log Reduction (Disinfection of Product water)	**Biological** ❖ Pathogenic bacteria ❖ HPC/P.Aeruginosa ❖ Fungus (Y&M) ❖ Viruses	– Biofilm growing on the inside of the UV housing (quartz sleeve and outer wall) that could impair the effective operation. – Contamination of the seals separating the bulbs from water chamber allowing biological growth.	**1**	**D**	**7**	**Process Preventive Control #1** • The UV is the Process Preventive Control because the source water is not subject to further treatment prior to bottling. • Documentation of the training of individuals managing this control. **PRPs** • Proper sizing and installation of the UV unit • Training of staff **SSOPs** • Servicing of UV via preventative maintenance (cleaning quartz, etc.) **Monitoring** • Automatic controls will shut down water flow if the unit falls outside of 4-log reduction. • Monitoring of key parameters is done continuously the hours of usage and the intensity of the bulb. • Daily Inspection to verify unit is operating with no leaks • Reviewing the validated 4-log reduction data and print weekly hard copy record. **Testing/Verification** • Insure the UV software is functioning properly.
		Chemical ❖ Mineral buildup	– Scale build-up on the glass sleeve that impairs the effectiveness of the UV. – Mercury contamination from broken bulb.	4	E	23	
		Physical ❖ Foreign Material	– Glass breakage stemming from broken UV light or quartz sleeve – High turbidity impedes UV effectiveness	3	D	17	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#25c	**Stainless Steel Water Pipe** (Section of 4" Stainless Steel pipe minimum of 4D [16 inches]) 4"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. • Insure any exposed/welded surface is properly passivated. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from pipe material	– Undesirable chemicals could leach from plumbing material into the water. – Improper passivation could result in Chromium leaching.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment or scale could impede flows. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	
#26	**Sampling Port**	**Biological** ❖ Any biological buildup.	– Biologicals build up around the port tainting the sample.	3	D	17	***PRPs*** • Locating the port to insure it can draw representative sample from water. • Material specification that allows adequate cleaning and sanitizing prior to drawing sample without cross-contamination. • Controllable flow so that sample collection vessel is not overwhelmed. • Proper installation; compliance with plumbing code. ***SSOPs*** • Sanitizing after any direct exposure to contaminants. ***Testing/Verification*** • Periodic visual inspection for leaks.
		Chemical ❖ Material leaching ❖ Sanitizer residue	– Materials no longer GMP compliant. – Residue from cleaning/sanitizing taints the sample.	3	D	17	
		Physical ❖ Biofilm sluff ❖ Excessive vibration	– Sluff from biofilm taints the sample. – Water is static or drawn from dead leg which is NOT reflective of water.	4	E	23	
#**	**If Atlantium System goes outside Specifications unit stops flow** (Controlled by Atlantium; opens whenever parameters exceed limits.	**Biological** ❖ Bacteria ❖ Yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize and either result in biofilm or get carried through in the source water.	3	D	17	***Process Control*** • The UV system opens the diverter valve electrically whenever the system goes out of 4-log reduction so as to prevent source water from proceeding if outside of specifications. Water is diverted to water storage tank. ***SSOPs*** • Routine cleaning and sanitizing after exposure to any type of contaminate. ***Testing/Verification*** • Test of source water used as surrogate for bacteria. • UV system operation
		Chemical ❖ NA	– Not expected.				
		Physical ❖ NA	– Not expected.				
#27 a.b.c	**Stainless Steel 3-Way Tee Valve** 2" diameter **a:** Splits flow into two flows; right/left. **b:** Splits flow into two flows; back to Valve 21 or to the 0.2 µ filter #1 **c:** Splits flow into two flows; back to Valve 21 or to the 0.2 µ filter #2	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize and either result in biofilm or get carried through in the source water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. • Insure any exposed surface is properly passivated. ***SSOPs*** • Routine cleaning and sanitizing after exposure to any type of contaminate. ***Testing/Verification*** • Test of source water used as surrogate for bacteria.
		Chemical ❖ Air pollutants	– Source water could contain undesirable chemicals from the source. – Undesirable chemicals could leach from plumbing material into the water.	3	E	20	
		Physical ❖ Foreign Material, dust, dirt, insects	– Source water could contain undesirable sediment from the source. – Undesirable sediment could build up in plumbing and/or imped the flow of source water.	4	E	23	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#28 a,b	**Stainless Steel Butterfly Valves** Similar valves in front of the 0.2µ filters on both sides. 2"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from valve material	– Undesirable chemicals could leach from plumbing material into the water. – O-ring could degrade or leak.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment, scale or grit could impact the seat, body or disk of the valve impeding flow or full closure. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	
#29 a,b	**Pressure Gauges** (on the top of each 0.2-micron filter)	**Biological** ❖ Any biological buildup.	– Biologicals build up around the gauge fitting anchoring themselves as biofilm that interfere with gauge functionality.	3	D	17	***PRPs*** • Utilize liquid filled gauge more resistant to vibration. • Insure water pressures within gauge tolerances. • Filter water to minimize sediment clogging of gauge. • Proper installation; compliance with plumbing code. ***SSOPs*** • Sanitizing after any direct exposure to contaminants. ***Monitoring*** • Inspection for drips or excess condensation. ***Testing/Verification*** • Confirm accuracy through recommended initial calibration of the gauge per manufacturer.
		Chemical ❖ Leaching from pipe & valve fittings	– Inadequate maintenance of gauge. – Materials no longer in compliance with GMPs.	3	D	17	
		Physical ❖ Biofilm sluff ❖ Excessive vibration	– Growth of biofilm to where it clogs gauge and impedes function. – Excessive vibration leading to gauge failure. – Overpressure and pressure spikes that bend gauge pointer.	4	E	23	
#30 a,b	**0.2µ Absolute Filters** (Unit on right and left; flow can be directed through one, split or neither)	**Biological** ❖ Biological remnants left by the disinfection action of the UV 4-log reduction. ❖ Help to prevent any re-growth of biologicals	– Contaminants or particulates (dead biologicals) left in the water after 4-log reduction. – Biofilm growing on the inside of the filter housing and/or media.	3	D	17	***PRPs*** • Proper installation of the Filter unit. • Training of staff ***Process*** • Check of pre/post pressure to insure the filter is working within normal range ***SSOPs*** • Sanitizing filter housing after installing new media ***Monitoring*** • Inspection/recording of pressure until replacement of filter media based on pre-determined pressure differential or elapsed time. • Periodic inspection for leaks in filter housing
		Chemical ❖ Unk substances	– Not expected	4	D	21	
		Physical ❖ Foreign Material	– Physical breakdown of the filter media	4	D	21	
#31 a,b	**Stainless Steel Butterfly Valves** Similar valves after each 0.2µ filter on both sides. 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from valve material	– Undesirable chemicals could leach from plumbing material into the water. – O-ring could degrade or leak.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment, scale or grit could impact the seat, body or disk of the valve impeding flow or full closure. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#32	**Stainless Steel 3-Way Tee Valve** Flows from both sides join together to head towards filler. 2"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize and either result in biofilm or get carried through in the source water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. • Insure any exposed surface is properly passivated. ***SSOPs*** • Routine cleaning and sanitizing after exposure to any type of contaminate. ***Testing/Verification*** • Test of source water used as surrogate for bacteria.
		Chemical ❖ Air pollutants	– Source water could contain undesirable chemicals from the source. – Undesirable chemicals could leach from plumbing material into the water.	3	E	20	
		Physical ❖ Foreign Material, dust, dirt, insects	– Source water could contain undesirable sediment from the source. – Undesirable sediment could build up in plumbing and/or imped the flow of source water.	4	E	23	
#33	**Stainless Steel 3-Way Tee Valve** 2" diameter + ¼" tee Flows through towards filler but also branches off through ¼ inch line.	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize and either result in biofilm or get carried through in the source water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. • Insure any exposed surface is properly passivated. ***SSOPs*** • Routine cleaning and sanitizing after exposure to any type of contaminate. ***Testing/Verification*** • Test of source water used as surrogate for bacteria.
		Chemical ❖ Air pollutants	– Source water could contain undesirable chemicals from the source. – Undesirable chemicals could leach from plumbing material into the water.	3	E	20	
		Physical ❖ Foreign Material, dust, dirt, insects	– Source water could contain undesirable sediment from the source. – Undesirable sediment could build up in plumbing and/or imped the flow of source water.	4	E	23	
#34	**Pressure Gauge** (post both of the 0.2 micron filters)	**Biological** ❖ Any biological buildup.	– Biologicals build up around the gauge fitting anchoring themselves as biofilm that interfere with gauge functionality.	3	D	17	***PRPs*** • Utilize liquid filled gauge more resistant to vibration. • Insure water pressures within gauge tolerances. • Filter water to minimize sediment clogging of gauge. • Proper installation; compliance with plumbing code. ***SSOPs*** • Sanitizing after any direct exposure to contaminants. ***Monitoring*** • Inspection for drips or excess condensation. ***Testing/Verification*** • Confirm accuracy through recommended initial calibration of the gauge per manufacturer.
		Chemical ❖ Leaching from pipe & valve fittings	– Inadequate maintenance of gauge. – Materials no longer in compliance with GMPs.	3	D	17	
		Physical ❖ Biofilm sluff ❖ Excessive vibration	– Growth of biofilm to where it clogs gauge and impedes function. – Excessive vibration leading to gauge failure. – Overpressure and pressure spikes that bend gauge pointer.	4	E	23	
#35	**Sampling Port**	**Biological** ❖ Any biological buildup.	– Biologicals build up around the port tainting the sample.	3	D	17	***PRPs*** • Locating the port to insure it can draw representative sample from water. • Material specification that allows adequate cleaning and sanitizing prior to drawing sample without cross-contamination. • Controllable flow so that sample collection vessel is not overwhelmed. • Proper installation; compliance with plumbing code. ***SSOPs*** • Sanitizing after any direct exposure to contaminants. ***Testing/Verification*** • Periodic visual inspection for leaks.
		Chemical ❖ Material leaching ❖ Sanitizer residue	– Materials no longer GMP compliant. – Residue from cleaning/sanitizing taints the sample.	3	D	17	
		Physical ❖ Biofilm sluff ❖ Excessive vibration	– Sluff from biofilm taints the sample. – Water is static or drawn from dead leg which is NOT reflective of water.	4	E	23	

STEP #36 – WATER FLOWS TOWARDS PANEL C, VALVE 20; THEN TO PANEL C, VALVE 19

STEP #37 – WATER FLOWS TOWARDS DIVERTER VALVE.

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#37	**Stainless Steel Water Pipe** (Flows towards the Diverter Valve) 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. • Insure any exposed/welded surface is properly passivated. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from pipe material	– Undesirable chemicals could leach from plumbing material into the water. – Improper passivation could result in Chromium leaching.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment or scale could impede flows. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	
#38	**Stainless Steel Three-way Butterfly Valve With Diverter** (Controlled by Atlantium; opens whenever parameters exceed limits. 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. ***Process Control*** • The UV System opens or closes the valve electronically based on the PLC continuous reading of parameters necessary to assure the validated 4-log reduction of the water. Non-compliant water is diverted from product water flow. • Operational performance is data logged for verification. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from valve material	– Undesirable chemicals could leach from plumbing material into the water. – O-ring could degrade or leak.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment, scale or grit could impact the seat, body or disk of the valve impeding flow or full closure. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	
#39	**Failed water is diverted back to Outside Water Storage Tank**	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize resulting in biofilm.	3	D	17	***PRPs*** • Proper installation of pipe & fittings; compliance with plumbing standards. • Labeling of the pipe on outside to be able to track flows. ***SSOPs*** • Periodic sanitizing pipe & fitting after any exposure to potential contaminants. ***Monitoring – Periodically*** • Inspection for drips or any evidence of biological growth or other hazard.
		Chemical ❖ Leaching from pipe & valve fittings	– Source water could contain undesirable chemicals. – Improperly passivated pipes contribute chemical contamination.	3	E	20	
		Physical ❖ Biofilm sluff ❖ Metal fatigue	– Undesirable sediment could build up in plumbing and/or imped the flow of the discharge water.	4	E	23	

NOTE: GO TO BOTTLING PROCESS TO FOLLOW THE WATER SUCESSFULLY PASSING THROUGH THE DIVERTER VALVE

STEP 39 – WATER FLOWS TO PANEL A, VALVE 5; THEN TO PANEL A, VALVE 7

STEP 40 – WATER FLOWS TOWARDS THE CHECK VALVE

#41	**Backflow Preventer Check Valve**	**Biological** ❖ Other bacteria (e.g. HPC & Pseudomonas Aeruginosa)	– Contaminants that build up in the pipe that could interfere with proper operation of the valve, thus allowing back siphonage of contaminants.	2	E	16	***PRPs*** • Proper installation device. • Training of staff in how device work. ***SSOPs*** • Sanitizing pipe & fitting after any exposure to contaminants ***Monitoring*** • Annual inspection by licensed plumber confirming proper operation and compliance with plumbing standards.
		Chemical ❖ Leaching from device	– Inadequate maintenance of device. – Materials no longer in compliance with GMPs	2	E	16	
		Physical ❖ Foreign Material, dust, dirt, insects	– Failure of the backflow valve thus resulting in contaminants or water of another characteristic flow backward.	2	E	16	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures

STEP 42 – WATER FLOWS THROUGH 3-WAY TEE VALVE.

NORMAL FLOW IS TO CONTINUE TO THE WATER STORAGE TANK

ALTERNATIVELY, WATER COULD COME THROUGH THIS TEE FROM THE TANKER UNLOADING STATION INTO THE WATER TANKER.

#43	**Stainless Steel Butterfly Valve** (Water flows through on its way to the water storage tank) 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from valve material	– Undesirable chemicals could leach from plumbing material into the water. – O-ring could degrade or leak.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment, scale or grit could impact the seat, body or disk of the valve impeding flow or full closure. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	

STEP 44 – WATER FLOWS INTO THE WATER STORAGE TANK.

THIS FLOW PICKS UP FROM STEP 14 AT THE 3-WAY TEE WHERE INSTEAD OF FLOWING THROUGH WATER TREATMENT, IT FLOWS INTO THE OZONE TANK TO BE OZONATED.

#45	**Stainless Steel Butterfly Valve** (Water flows through on its way to the ozone tank) 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from valve material	– Undesirable chemicals could leach from plumbing material into the water. – O-ring could degrade or leak.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment, scale or grit could impact the seat, body or disk of the valve impeding flow or full closure. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	

#46	**Ozone Tank a.k.a. Santa Rosa Tank 500 Gallons Stainless Steel** (Water is infused with ozone from Atlas 30 system)	**Biological** ❖ Pathogens ❖ Non-Pathogens	– Ozonator device malfunctions where it fails to saturate the water with an adequate level of Ozone.	3	D	20	***Monitoring*** • Recording the ozone ppm as required; depending on the procedure the ozonated water is being used for. • Daily inspection of ozone system for leakage or evidence of malfunction. ***Testing*** • Lab testing of finished product is used as surrogate for verifying equipment is clean. ***SSOPs*** • Cleaning of tank as required. • Ozone contact provides continuous disinfection for the designated usage.
		Chemical ❖ Unknown substances	– Potential for nitric oxide to mix with ozone gas and then convert to nitric acid when it meets h2o water molecules.	3	D	17	
		Physical ❖ Foreign Material	– Not expected to occur	4	D	21	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#47	**Sampling Port**	**Biological** ❖ Any biological buildup.	– Biologicals build up around the port tainting the sample.	3	D	17	***PRPs*** • Locating the port to insure it can draw representative sample from water. • Material specification that allows adequate cleaning and sanitizing prior to drawing sample without cross-contamination. • Controllable flow so that sample collection vessel is not overwhelmed. • Proper installation; compliance with plumbing code. ***SSOPs*** • Sanitizing after any direct exposure to contaminants. ***Testing/Verification*** • Periodic visual inspection for leaks.
		Chemical ❖ Material leaching ❖ Sanitizer residue	– Materials no longer GMP compliant. – Residue from cleaning/sanitizing taints the sample.	3	D	17	
		Physical ❖ Biofilm sluff ❖ Excessive vibration	– Sluff from biofilm taints the sample. – Water is static or drawn from dead leg which is NOT reflective of water.	4	E	23	
#48	**Ozone Generator** Atlas 30 from Absolute Ozone	**Biological** ❖ Ineffective log reduction kill rate	– Hazard to workers subjected to excess ozone exposure. – Inadequate generation of ozone fails to effect disinfection.	3	D	***17***	***PRPs*** • Proper installation. ***Process Controls*** • Insure air compressor & dryer warm up 5 minutes before desired use. ***Training*** • Training of staff ***SSOPs*** • Routine cleaning and sanitizing. ***Monitoring*** • Excess exposure levels of ozone in production area. • Water saturation based on task being done with ozonated water. ***Testing/Verification*** • Review of preventative maintenance schedule • Analytical measurement of ozone concentration in water using HACH ACCUVAC or similar device.
		Chemical ❖ None expected	– Water vapor in a corona discharge ozone generator can react with nitrogen in the air to create corrosive nitric acid which can destroy the ozone generator.	3	D	17	
		Physical ❖ None expected	– Power brownout causing generator to malfunction resulting in not enough ozone being generated.	3	D	17	
#49	**Ozone Air Separator** New Life Intensity Equipment (For drying air for ozone production)	**Biological** ❖ None expected	– Inadequate generation of dried air will negatively impact generation of ozone gas.	3	D	***17***	***PRPs*** • Proper installation. • Avoid freezing temperatures that could cause frozen condensation from blocking off vent. ***Process Controls*** • Insure air compressor & dryer warm up 5 minutes before desired use. ***Training*** • Training of staff ***SSOPs*** • Routine cleaning and sanitizing. ***Monitoring*** • Daily inspection for evidence of nitric acid creation • Monitor the incoming psi and post drier psi • Clean fan and filter as needed to prevent buildup of heat. ***Testing/Verification*** • Review of preventative maintenance schedule
		Chemical ❖ Nitric acid	– Water vapor left in the air fed into the corona discharge ozone generator can react with nitrogen in the air to create corrosive nitric acid which can destroy the ozone generator and taint ozone gas.	3	D	17	
		Physical ❖ None expected	– Power brownout causing Air Separator to malfunction resulting in not enough dried air being fed to ozone generator.	3	D	17	
#50	**Pump #3** (Pulls water from the ozone Santa Rosa tank to intended use)	**Biological** ❖ Other bacteria (e.g. HPC) build up inside valve)	– Contaminants that build up in the hard surfaces of the pump and fittings; impinging the flow. – Biofilm that promotes the growth of pathogenic bacteria.	3	D	17	***PRPs*** • Proper installation of valve. • Training of staff ***SSOPs*** • Sanitizing valve after any exposure to potential contaminants ***Monitoring*** • Daily Inspection for drips or excess condensation indicative of failure or other hazard. ***Testing/Verification*** • Confirmation of proper materials current with plumbing standards.
		Chemical ❖ Leaching from pipe & valve fittings	– Metal used in the pump water contact surfaces no longer in compliance with brass/lead/copper plumbing standards. – Metal leaching out of pump into water flow.	3	D	17	
		Physical ❖ Biofilm sluff ❖ Metal fatigue	– Growth of biofilm to the stage where it becomes physical substance capable of fouling pump.	4	E	23	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#51	**Recirculating Loop for Santa Rosa Ozone Tank** (Returns back to the tank being re-ozonated as needed) 316 stainless	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize resulting in biofilm.	3	D	17	***PRPs*** • Proper installation of pipe & fittings; compliance with plumbing standards. • Labeling of the pipe on outside to be able to track flows. ***SSOPs*** • Periodic sanitizing pipe & fitting after any exposure to potential contaminants. ***Monitoring – Periodically*** • Inspection for drips or any evidence of biological growth or other hazard.
		Chemical ❖ Leaching from pipe & valve fittings	– Source water could contain undesirable chemicals. – Improperly passivated pipes contribute chemical contamination.	3	E	20	
		Physical ❖ Biofilm sluff ❖ Metal fatigue	– Undesirable sediment could build up in plumbing and/or imped the flow of the discharge water.	4	E	23	

END OF WATER TREATMENT

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures

START OF BOTTLING PROCESS

#1	**Enclosed Filler Room** Contains the rinser, filler & capper	**Biological** ❖ Pathogens - Coliforms and/or E. Coli ❖ Pseudomonas aeruginosa	– If humidity and airflow are not adequate, biologics could grow and establish colonies. – Biofilm or other biologicals could aerosolize inside the room and deposit themselves on or in containers. – Contamination due to poor personal hygiene by line staff	2	D	***12***	***PRPs*** • Proper installation • Compliance with material specification ***SSOPs*** • Preventative sanitation schedule for cleaning/sanitizing filler room. ***Training*** • Training of staff on the maintenance of the room including maintenance of air filtration. ***Monitoring*** • Periodic inspection for standing water after cleaning/sanitizing activities.
		Chemical ❖ Air pollutants	– Fumes from fork lifts or outside environment deposit themselves on wetted surfaces	3	D	17	
		Physical ❖ Foreign Material	– Dirt brought into the room on the shoes and clothing of line staff.	4	E	23	

#1a	**Air Filtration** Air entering enclosed filler room	**Biological** ❖ Airborne yeast & mold	– Unfiltered air could result in introducing biologicals which could contaminate the water or deposit themselves inside form biofilm.	2	D	***12***	***PRPs*** • Installation of air filter on tanks where air is introduced or expelled to compensate for fill level. ***Process Controls*** • Filtering air to standard equivalent to MIRV 13 where possible. ***Training*** • Training of staff on the maintenance of the filters ***SSOPs*** • Periodic cleaning and/or replacement as needed.
		Chemical ❖ Air pollutants	– Air drawn in could contribute chemical contaminates which could transfer to product water.	3	D	17	
		Physical ❖ Foreign Material, dust, dirt, insects	– Airborne dust or insects could contaminate product water.	3	D	17	

#2a	**Stainless Steel Water Pipe** (brings disinfected water from the treatment system)	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize resulting in biofilm.	3	D	17	***PRPs*** • Proper installation of pipe & fittings; compliance with plumbing standards. • Labeling of the pipe on outside to be able to track flows. ***SSOPs*** • Periodic sanitizing pipe & fitting after any exposure to potential contaminants. ***Monitoring – Periodically*** • Inspection for drips or any evidence of biological growth or other hazard.
		Chemical ❖ Leaching from pipe & valve fittings	– Source water could contain undesirable chemicals. – Improperly passivated pipes contribute chemical contamination.	3	E	20	
		Physical ❖ Biofilm sluff ❖ Metal fatigue	– Undesirable sediment could build up in plumbing and/or imped the flow of the discharge water.	4	E	23	

#2b	**Stainless Steel Three-way Butterfly Valve With Diverter** (Controlled by Atlantium; opens whenever parameters exceed limits. 3"Dia/316 SS	**Biological** ❖ Bacteria, yeast & mold ❖ Virus	– Source water could contain undesirable biologics which could colonize on surfaces creating biofilm or break off into the water.	3	D	17	***PRPs*** • Supplier specification that material be compliant with and properly installed to plumbing code. ***Process Control*** • The UV System opens or closes the valve electronically based on the PLC continuous reading of parameters necessary to assure the validated 4-log reduction of the water. Non-compliant water is diverted from product water flow. • Operational performance is data logged for verification. ***SSOPs*** • Cleaning and sanitizing after exposure to any type of contaminate. • Part of Clean-In-Place sanitizing using highly ozonated water to prevent biological colonizing. ***Testing/Verification*** • Periodic visual inspection for leaks. • Test of source water used as surrogate for bacteria.
		Chemical ❖ Leaching from valve material	– Undesirable chemicals could leach from plumbing material into the water. – O-ring could degrade or leak.	3	E	20	
		Physical ❖ Foreign Materials ❖ Metal Fatigue	– Sediment, scale or grit could impact the seat, body or disk of the valve impeding flow or full closure. – Stress fractures or micro-leaks if subjected to tensile stress.	4	E	23	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures

STEP 3 – IF DIVERTED BY THE 3-WAY DIVERTER VALVE, FAILED WATER WILL RETURN TO THE WATER SOURCE TANK BY BEING ROUTED FROM THE DIVERTER TO PANEL B, VALVE 5.

#4	**NEW BOTTLES BROUGHT FROM BLOW MOLDING** New bottles come via airvayor to the filler	**Biological** ❖ Pathogenic bacteria (TC) ❖ Fungus (Y&M) ❖ Viruses (incl Entero)	– Contamination contained inside the new bottles that come from any short-term plant storage where dust and debris may have gotten on top of and into the bottles. – Contamination coming from airborne source as bottles travel on airvayor to filler.	3	C	13	***Supplier Assurance*** • Advanced approval of merchant bottle suppliers. ***SOPs*** • Receiving Raw Materials SOP ***SSOPs*** • Routine cleaning of warehouse to prevent contamination to bottles in storage ***Monitoring*** • Visual observation of each bag of new bottles to make sure the original bag had integrity and no foreign substances, odors or coloration is notable. (Done as part of the Blow Molding Process)
		Chemical ❖ Unk substances	– Chemical contamination coming from airborne source as bottles travel on airvayor to filler.	3	C	13	
		Physical ❖ Foreign Material	– Physical objects coming from airborne source as bottles travel on airvayor to filler.	3	C	13	
#5	**Rinser** (bottles are rinsed with ozonated water)	Biological ❖ Bacteria (TC) ❖ Fungus (Y&M) ❖ Viruses	– Insufficient water and/or ozone to remove any contaminant that was deposited on the inside surface of the bottle from when it was blow molded till reaching the rinser. – Clogged nozzles prevents flow of rinse water.	3	D	17	***PRPs*** • Proper installation. • Labeling of water flow pipes to track flows. ***Training*** • Employee training on operation ***GMP Controls*** • Proper water flow/pressure maintained.
		Chemical ❖ Unk substances	– Not expected	5	E	25	***SOPs*** • Rinser SOP
		Physical ❖ Foreign Material, dust, dirt, insects	– Dust from bottle friction while being conveyed to rinser	4	D	23	***SSOPs*** • Daily and weekly cleaning ***Monitoring*** • Checking ozone concentration in the rinse water
#6	**Bottle Filler** 36 Heads	**Biological** ❖ Pathogenic bacteria (TC) ❖ Fungus (Y&M) ❖ Viruses	– Inadequate sanitation of the filler results in biological contamination of the water as it moves from the filler to the container. – Environmental contamination from air borne pathogenic bacteria and/or mold spores at the point of exposure between the filler and container. – Contamination from improper employee handling practices	3	C	13	***PRPs*** • Proper installation. • Labeling of water flow pipes to track flows. ***Training*** • Employee training on operation ***Sanitation Preventive Control*** • Extraordinary cleaning of the filler heads • Verified by visual observation • Swabbed for HPC periodically ***SOP*** • Filler operation SOP
		Chemical ❖ Unk substances	– Non-food grade lubricants coming in contact with containers.	3	D	17	
		Physical ❖ Foreign Material, dust, dirt, insects	– Introduction of foreign material from equipment, employees and environment	4	C	18	
#7	**Capper**	**Biological** ❖ Pathogenic bacteria (TC) ❖ Fungus (Y&M) ❖ Viruses	– Inadequate sanitation of the capper results in biological contamination of the water after it moves to the container. – Environmental contamination from air borne pathogenic bacteria and/or mold spores could be contributed through the cap. – Contamination from improper employee handling practices	3	C	13	***PRPs*** • Proper installation. • Labeling of water flow pipes to track flows. ***Training*** • Employee training on operation ***Sanitation Preventive Control*** • Cleaning of the capper heads • Verified by visual observation • Swabbed for HPC periodically ***SOP*** • Capper SOP ***SSOP*** • Capper sanitation
		Chemical ❖ Unk substances	– Non-food grade lubricants coming in contact with caps.	3	D	17	
		Physical ❖ Foreign Material, dust, dirt, insects	– Introduction of foreign material from equipment, employees and environment	4	C	18	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#8	**Cap Hopper** Feeds caps from outside the bottling room to inside via hopper and elevator	**Biological** ❖ Pathogenic bacteria (TC) ❖ Fungus (Y&M) ❖ Viruses	– Inadequate sanitation of the cap hopper results in biological contamination of the caps. – Environmental contamination from air borne pathogenic bacteria and/or mold spores could be deposited on the caps while in the hopper. – Contamination from improper employee handling practices	3	C	13	***PRPs*** • Proper installation. ***Training*** • Employee training on operation ***SSOP*** • Empty the cap hopper at end of production • Cleaning and sanitizing of the cap hopper daily • Verified by visual observation • Swabbed for HPC periodically • Periodic cleaning of the elevator carrying the caps from the hopper to the capper • Periodic cleaning of air filter for air pushed up through the elevator. ***SOP*** • Cap Hopper SOP
		Chemical ❖ Unk substances	– Non-food grade lubricants coming in contact with caps.	3	D	17	
		Physical ❖ Foreign Material, dust, dirt, insects	– Introduction of foreign material from equipment, employees and environment – Micro plastic dust.	4	C	18	
#9	**Air Knife**	**Biological** ❖ Pathogenic bacteria (TC) ❖ Fungus (Y&M) ❖ Viruses	– Dirty air blown down on sealed bottles could leave biological residue in secondary packaging.	5	D	24	***PRPs*** • Proper installation. • Labeling of air flow pipes to track flows. ***Training*** • Employee training on operation **SSOP** • Air Knife SSOP **SOP** • Air Knife operation ***Monitoring*** • Visual observation at start of run to insure adequate amount of moisture is being blown off bottles.
		Chemical ❖ Unk substances	– Wet bottles could interfere with the application of the laser date coding.	5	D	24	
		Physical ❖ Foreign Material, dust, dirt, insects	– Excessive humidity (water droplets) could condense in the secondary packaging causing failure.	5	D	24	
#10	**Date Coder** Laser coding of each bottle	**Biological** ❖ Pathogenic bacteria (TC) ❖ Fungus (Y&M) ❖ Viruses	– Not expected	5	D	24	***PRPs*** • Proper installation. ***Training*** • Employee training on operation **SSOP** • Laser Date Coder SSOP **SOP** • Date Coder operation ***Monitoring*** • Check of date coder to insure first bottle match parameters • Employee training on operations to set code.
		Chemical ❖ Unk substances	– Not expected	5	D	24	
		Physical ❖ Foreign Material, dust, dirt, insects	– Not expected	5	D	24	
#11	**Accumulator Table No 1**	**Biological** ❖ Bacteria ❖ Virus ❖ Fungus (Y&M)	– Biologicals build up on the table that get transferred to the bottle.	4	E	23	***PRPs*** • Proper installation of table and conveyor links. • Training of staff ***SSOPs*** • Cleaning and Sanitizing of table and rail surfaces to prevent transference of contaminants. ***Monitoring - monthly*** • Inspection for any sharp edges or other issue that could cause product damage.
		Chemical ❖ Lubricant	– Non-food grade lubricants coming in contact with caps.	4	E	23	
		Physical ❖ Foreign Material	– Sharp edge on surface that has bottle contact could cause physical damage.	3	D	17	
#12	**Krones Bottle Labeler** Bottled have label applied after filling	**Biological** ❖ Bacteria ❖ Virus ❖ Fungus (Y&M)	– Improperly serviced equipment or poor employee hygiene could contaminate the labels prior to application on the surface of the finished product.	3	D	17	**Supplier Assurance** • Labels purchased from an approved supplier. **SSOP** • Labeler cleaning **SOP** • Labeler operation **Process control** • Check of labels to insure they are properly applied; watching for off-center or other quality defects.
		Chemical ❖ Glue/adhesive	– Wrong type of adhesive; not food grade	4	E	23	
		Physical ❖ Foreign Material	– Not expected to occur	4	E	23	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#13	**Accumulator Table No 2**	**Biological** ❖ Bacteria ❖ Virus ❖ Fungus (Y&M)	– Biologicals build up on the table that get transferred to the bottle.	4	E	23	***PRPs*** • Proper installation of table and conveyor links. • Training of staff ***SSOPs*** • Cleaning and Sanitizing of table and rail surfaces to prevent transference of contaminants. ***Monitoring - monthly*** • Inspection for any sharp edges or other issue that could cause product damage.
		Chemical ❖ Lubricant	– Non-food grade lubricants coming in contact with caps.	4	E	23	
		Physical ❖ Foreign Material	– Sharp edge on surface that has bottle contact could cause physical damage.	3	D	17	
#14	**Final Product Inspection Station** Bottle passed through inspection station.	**Biological** ❖ Bacteria ❖ Virus ❖ Fungus (Y&M)	– Looking for any visual evidence of biological substances on the inside or outside of bottles. – Anything other than clear water.	4	E	23	SOP • finished product bottle inspection. • Training of staff of what to look for. Note: Checking of finished product is done during several steps of the filling and labeling as opposed to be a distinct activity.
		Chemical ❖ Unk substances	– Observe any chemical substances inside the bottle or on outside	4	E	23	
		Physical ❖ Foreign Material	– Observe any physical objects inside the bottle. – Short fills. – Defect on the bottle – Poor alignment of the label on bottle.	4	C	18	
#15	**Case/Box Erector** Forms cardboard into full-depth box	Biological ❖ Pathogenic bacteria (TC) ❖ Fungus (Y&M) ❖ Viruses	– Contamination due to improper employee handling practices that result in transfer to product.	4	D	23	**Supplier Assurance** • Cardboard boxes purchased from an approved supplier. **SOP** • Operation of the box erector machine **Process control** • Check to make sure the outside of the box is properly identified as to inside contents.
		Chemical ❖ Unk substances	– Not expected to occur	4	D	23	
		Physical ❖ Foreign Material	– Trash/debris that falls into the box	4	D	23	
#16	**CASE Packer** Into cardboard full-depth boxes and sealed with tape	Biological ❖ Pathogenic bacteria (TC) ❖ Fungus (Y&M) ❖ Viruses	– Contamination due to improper employee handling practices	4	D	23	**SOP** • Operation of the case packer **Process control** • Check to make sure the outside of the box is properly identified as to inside contents.
		Chemical ❖ Unk substances	– Not expected to occur	5	E	25	
		Physical ❖ Foreign Material	– Box does not properly close the box – Excess glue on box	4	D	23	
#17	**PALLET Stacking (Manual)** (Selection and placement of pallet)	Biological ❖ Pathogenic bacteria (TC) ❖ Fungus (Y&M) ❖ Viruses	– Contamination due to improper employee handling practices – Contaminated pallet incorrectly selected.	3	D	17	**Supplier Assurance** • Pallets are obtained from approved source • Stretch wrap purchased from an approved supplier. **SOP** • Operation of the pallet wrapper **Process control** • Physical inspection of each pallet as it is utilized for finished product; defective pallets removed.
		Chemical ❖ Unk substances	– Not expected to occur	5	E	25	
		Physical ❖ Foreign Material	– Broken pallets	4	B	14	

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
#18	**PALLET Wrapping (Automatic)**	Biological ❖ Pathogenic bacteria (TC) ❖ Fungus (Y&M) ❖ Viruses	– Contamination due to improper employee handling practices – Contaminated pallet incorrectly selected.	3	D	17	**Supplier Assurance** • Pallets are obtained from approved source • Stretch wrap purchased from an approved supplier. **SOP** • Operation of the pallet wrapper **Process control** • Physical inspection of wrap for integrity.
		Chemical ❖ Unk substances	– Not expected to occur	5	E	25	
		Physical ❖ Foreign Material	– Excess plastic wrap does not stay attached to the pallet.	4	D	23	
#19	**24 hour QC Hold for Total Coliform Product Testing of each batch** (Test run in-house except for one day a week where it is sent to outside lab)	**Biological** ❖ Pathogens	– Presence of Coliforms in finished product that would result in quarantine of product to prevent sale pending further review.	3	C	13	**SOP** • Product release is predicated on lot testing for Total Coliforms. • Any testing for HPC is informational only. • If TC test shows positive, procedures are in place to put suspect batch into quarantine until final disposition can be determined through Corrective Actions analysis and management review. • Release of product to another warehouse or distributor prior to TC results is only authorized for situations where the product is not released into the trade or to a consumer until the 24-hour period to elapse and notification being made if necessary. **Monitoring** • There is a presumptive release automatically after 24 hours for all finished product unless positive results are received. • Lab results are periodically reviewed by management. • Extraordinary HPC results are reviewed by management with corrective action taken as deemed necessary.
		Chemical ❖ Unk substances	– Not Applicable.	NA	NA	NA	
		Physical ❖ Foreign Material	– Not Applicable.	NA	NA	NA	
#20	**FINISHED PRODUCT INVENTORY**	**Biological** ❖ Pathogens ❖ Non-Pathogens	– Contamination due to poorly maintained transportation and transfer equipment – Containers for finished product have contamination inside that could negatively impact finished product.	4	C	18	**SOP** • Warehouse Housekeeping SOP • SOP for transport Inspection **Sanitary Transportation** • Container selection and loading SOP
		Chemical ❖ Unk substances	– Vapors, ambient contamination from materials handling equipment in warehouses with inadequate ventilation	3	D	17	
		Physical ❖ Foreign Material	– Containers for finished product have contamination inside that could negatively impact finished product.	4	E	23	

END OF BOTTLING PROCESS

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures

BOTTLE TRANSPORT DIAGRAM - 05

We deem the food safety hazards and risk to be minimal in our process of taking preforms and blowing them into Containers that we fill with our Product Water.

The PET preforms are semi-crystalline thermoplastic, which softens at approx. 76°C/169°F (what is called "Glass Transition"). Above this temperature, the material becomes elastic, and can be formed, a property utilized effectively in the Stretch Blow Molding process. During the stretch blow phase, the resin is taken up to as high as 240°C/464°F which insures any biological substance are vaporized during blow molding.

PET is a **biologically inert material** that doesn't react with foods or beverages and is resistant to attack by micro-organisms. It's been thoroughly reviewed and approved as safe for contact with foods and drinks by the FDA, Health Canada, the European Food Safety Authority and other health-safety agencies. It has also been used by consumers around the world for more than 30 years without any known adverse effects. Extensive testing of PET and PET packaging has repeatedly shown it to be safe. PET itself is biologically inert if ingested.

In terms of chemical risk, we know that **PET does not contain BPA**. Bisphenol-A (BPA) is a compound used in polycarbonate, a different type of plastic that is sometimes used in baby bottles, the lining of metal cans, and reusable sports bottles. PET does not contain BPA and never has.

No. **PET does not contain dioxins**, nor can it produce dioxins, and no dioxins are created in the manufacturing of PET. Dioxins are a group of compounds sometimes formed by high-temperature combustion (over 750 degrees F.) and certain types of industrial processes involving chlorine. Dioxins can't be created without the presence of chlorine, and PET does not contain chlorine. Consequently, dioxins can't be produced when a PET container is heated or microwaved, exposed to sunlight, or washed and reused (all urban myths).

PET contains no phthalates. Phthalates (**i.e.**, phthalate ester plasticizers) are not used in PET, and PET is not a phthalate. Plasticizer phthalates are sometimes used to soften other types of plastic, but they are not used in PET. Some consumers may have incorrectly assumed that PET is a phthalate because PET's chemical name is polyethylene terephthalate. Despite the suffix, PET is not a phthalate. Phthalates are low molecular weight monoesters made from ortho-phthalic acid. By comparison, PET is a high molecular weight polyester made from tere-phthalic acid. Chemically they are very different.

Very **small amounts of antimony compounds are used** in the production of both PET and glass. Antimony oxide is typically used as the catalyst in making PET, which is chemically bound into the polymer at very low levels. Over time and with extended exposure to heat, trace amounts of antimony may migrate into water or other beverages bottled in PET. Laboratory tests on the migration of antimony compounds from PET have consistently found these levels **far below all safety thresholds** - typically less than 1/40th of the World Health Organization's daily safe-consumption level for drinking water. As part of our Supplier Assurance program we confirm our supplier of preforms warrantees Antimony levels are below any regulatory level.

The worst risk is that PET bottles coming out of the blow molder may have a slight static charge which can act as an attractant of airborne dust particles and possible yeast and molds. If this occurred, such particles would most likely be on the outside of the container. We thus subject our blown bottles to an ozonated water rinse to remove any potential hazards.

Process:

STEP #1 – Containers of preforms are brought from raw material storage area in sealed plastic bags contained within a disposable cardboard gaylord container.

STEP #2 – Preforms and loaded in bulk into the "Preform Hopper".

STEP #3 – Preforms travel from the hopper to the blow molder via covered conveyor.

STEP #4 – Preforms move inside the blow molder via conveyor to the blow molder where they are subjected to heat, stretched, blow and set as blown bottles.

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures

STEP #5 – **Visual Inspection** is conducted by the blow mold operator. As bottles exit the molds, they stop momentarily before moving away from the blow molder via conveyor. It's during this time that each blown bottle is physically inspected for any foreign debris or quality flaws. The rejected bottles are thrown away as scrap.

STEP #6 – Blown bottles move via a covered conveyor to a juncture with bottles coming out from a second blow molder.

The essential steps are repeated with our second blow molder …

STEP #7 – Containers of preforms are brought from raw material storage area in sealed plastic bags contained within a disposable cardboard gaylord container.

STEP #8 – Preforms and loaded in bulk into the "Preform Hopper".

STEP #9 – Preforms travel from the hopper to the blow molder via covered conveyor.

STEP #10 – Preforms move inside the blow molder via conveyor to the blow molder where they are subjected to heat, stretched, blow and set as blown bottles.

STEP #11 – **Visual Inspection** is conducted by the blow mold operator. As bottles exit the molds, they stop momentarily before moving away from the blow molder via Airvayor. It's during this time that each blown bottle is physically inspected for any foreign debris or quality flaws. The rejected bottles are thrown away as scrap.

STEP #12 – Blown bottles move via an Airvayor to a juncture with bottles coming out from first blow molder.

STEP #13 – Bottles are moved along the Airvayor by forced air originating from Blower #1. Air sucked into the blower is first filtered to remove impurities.

STEP #14 – Bottles are moved along the Airvayor by forced air originating from Blower #2. Air sucked into the blower is first filtered to remove impurities.

STEP #15 – Bottles are moved along the Airvayor by forced air originating from Blower #3. Air sucked into the blower is first filtered to remove impurities.

STEP #16 – At the "Y" Connector, Bottles from the conveyor and merged together with the bottles traveling on the Airvayor. This zone has covers over the bottles as they transit.

STEP #17 – Bottles are moved along the Airvayor by forced air originating from Blower #4. Air sucked into the blower is first filtered to remove impurities.

STEP #18 – Bottles are moved along the Airvayor by forced air originating from Blower #5. Air sucked into the blower is first filtered to remove impurities.

STEP #19 – Bottles are moved through the "Y" connection by forced air originating from Blower #6. Air sucked into the blower is first filtered to remove impurities. CROSS-REFERENCE STEP #16.

STEP #20 – The final step is to route the blown bottles to the bottle rinser before then moving to the filler.

Bottles are moved along the Airvayor by forced air originating from Blower #5. Air sucked into the blower is first filtered to remove impurities.

END OF BOTTLE TRANSPORT DIAGRAM - 05

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures

BLOW MOLDING COMPRESSED AIR AND WATER DIAGRAM - 06

We deem the food safety hazards and risk to be minimal in the use of air by our compressors water in our chiller tied to the blow molder.

The Air Compressors are located outside our bottling facility. They draw on ambient air drawn through filters to remove airborne particles.

The water utilized is from the public water system but does not come into direct contact with any packaging materials, instead, it only impacts the thermal structure of the molds used to form bottles to facilitate release of the formed bottle after the blowing process is completed.

Air compression is essentially a twofold process in which the pressure of air rises while the volume drops. This is done with reciprocating piston technology. At one end of the cylinder are the inlet and discharge valves. Shaped like metal flaps, the two valves appear at opposite sides of the cylinder's top end. The inlet sucks air in for the piston to compress. The compressed air is then released through the discharge valve. What the piston effectively does with its back and forth movements is create a vacuum. As the piston retracts, the space in front gets filled with air, which is sucked through the inlets from the outside. When the piston extends, that same air is compressed and therefore given the strength to push through the discharge valve — simultaneously holding the inlet shut — and into the tank. As more air is sent into the tank, the pressure gains intensity.

Some of our units are of a Rotary Screw design which allow for high air pressures to be created.

We utilize Oil-free pumps: The bearings are treated with lasting lubrication. This minimizes any potential for airborne oil particles.

Process:

STEP #1 – High Pressure Air Compressor #1 creates dry compressed air.
STEP #2 – The high-pressure air flows into Combined Accumulator and Dryer unit to remove any residual moisture.
STEP #3 – The dry high-pressure air is then used by the Blow Molder to create bottles. Afterward the air is vented to the atmosphere.
STEP #4 & #5 – After the bottles are subjected to heat and compression of the blow molder, cool water originating from Chiller #1 and Chiller #2 is used to cool the mold and facilitate the blown bottle to release from the mold cavity.
STEP #5 – Similar to Step #4, after the bottles are subjected to heat and compression of the blow molder, cool water originating from Chiller #2 is used to cool the mold and facilitate the blown bottle to release from the mold cavity.
STEP #6 – Low Pressure Air Compressor #1 creates dry compressed air.
STEP #7 – The low-pressure air flows into Combined Accumulator and Dryer unit (item 7) to remove any residual moisture.
STEP #8 – The dry pressurized air is then used by the Blow Molder #2 to create bottles. Afterward the air is vented to the atmosphere.
STEP #9– After the bottles are subjected to heat and compression of the blow molder #2, cool water originating from Chiller #3 is used to cool the mold and facilitate the blown bottle to release from the mold cavity.
STEP #10 thru STEP #12 plus STEP #13 thru STEP #15 contribute additional dried compressed air to assist with the blow molding in blower #2.
STEP #16 thru STEP #21 contribute additional dried compressed air to assist with the blow molding in blower #2.

END OF BLOW MOLDING COMPRESSED AIR AND WATER DIAGRAM - 06

Environmental Hazards

Bioaerosols carrying environmental pathogen microorganisms may occur in our processing and filler area by:

- Foot and wheeled (e.g., forklifts, handcarts) traffic through standing water where microorganisms grow;
- Application of pressure washers to contaminated surfaces;
- Compressed air lines that do not have appropriate air filters;
- Air containing dust to which microorganisms have attached themselves; or
- People who carry infection and exhale breath laden with microorganism.

The bioaerosols suspend in the air for various lengths of time. As bacteria enters open space, they become diluted and injured as they mix with the air in the environment. We know they will move from high-to-low pressure on air currents in the plant. These bacteria are capable of surviving and persisting such that food may be contaminated and may result in foodborne illness. Examples include Coliforms and other types.

Direct Contamination

We've assessed that the direct contamination of our water product from the air is not significant. It is improbable that detectable airborne contamination will occur because of the limited exposure our finished product is given to the atmosphere (very short span of space after the bottle is filled and before it is capped.) We recognize that if bottles remain longer than normal (during line stoppage), the risk rises that airborne contaminates could settle on the exposed surface of the water but we still characterize this as unlikely.

Indirect Contamination

While risk of airborne contamination is low, there still may be trace numbers of undesirable microorganisms present in the air in areas conducive to growth and recovery of injured cells. Such areas may include standing water, sandwiched structures on equipment or in areas that entrap wet residues. We believe that pathogens are most likely to be introduced as a byproduct of a sanitation procedure such as spraying a contaminated floor with a high-pressure hose, foot traffic through contaminated standing water or release from an inappropriately designed or serviced air handling unit. We believe the routine spillage from our washer and filler of ozonated water which ultimately flows down our drains helps to reduce or eliminate the growth of organisms around the area that our product could be exposed.

Pest Control

Our pest control program seeks to create a barrier through which intrusion of insects and other pest that could bring environmental hazards into our plant is minimized. We have a contract with a licensed pest control company to provide traps and to conduct on-site inspections. We review any findings of pests and take preventative action where necessary.

Air Handling units

We seek to minimize time when roll-up doors are open. Any place it is practical, and equipment allows, we deploy air filtration. Our preference, subject to the limitations of equipment and space, is a standard known as MIRV 13. This is designed to block or absorb particles such as yeast & molds that are 1 micron or larger. We are also aware that filter maintenance is important to proper operation.

We have also installed a filter on our water storage tank to filter air being drawn into the tank.

We believe particles smaller than 10 microns are likely to remain suspended in the air of a facility for an extended time and may thus remove themselves from our facility through the normal exchange of air. Particles larger than 10 microns are likely to settle on surfaces and are thus removed by our routine cleaning and sanitization programs, especially those applied to the production area.

We are aware that yeast, mold and HPC are the most common airborne bacteria. We assign a low food safety risk to these organisms but seek to limit as they have the potential to cause quality defects.

Our GMP program is designed to manage airborne bacteria to low levels. Our use of ozonated water in cleaning and ultimately flowing down our drains is proactive in reducing potential environmental contaminants.

Our program of quarterly testing all of our caps and containers helps us to verify that our sanitation program is effective in controlling potential hazards.

(1)	(2)	(3)	(4)			(5)
Environmental Hazard location and type	Identify reasonably foreseeable food safety hazards introduced, controlled or treated at this step.	Nature of the hazard and how it exists in finished product.	Risk Assessment: Consequence /Severity (C) Frequency/Likelihood (F) Score(S)			What control measure(s), Preventive or otherwise, are applied to significantly minimize, control or prevent the food safety hazard or otherwise negatively impact quality and acceptability? Clearly indicate where any applicable PCHF Preventive Control(s) is applied.
Hazard Analysis for Environment						
#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
Primary Pathogen Zone **Bottling Room Areas**	Airborne Contaminates	**Biological** ❖ Pathogenic bacteria (E. coli, Listeria, Salmonella) ❖ Protozoa (not airborne) ❖ Viruses including Enteroviruses and noroviruses	– Airborne pathogens in the bottling area sourced from ○ Air handling equipment ○ Vents from outside to inside ○ Air currents from other areas of the plant ○ Employees ○ Contractors ○ Visitors ○ Protozoa highly unlikely to be airborne. ○ Viruses could be spread through respiration of staff & visitors.	4	D	21	**Plant Design** - Establish the Bottling area as the highest hygiene area cascading to the production areas and then elsewhere. - Minimize outside air that has not come in through mechanical air filtering. ***SOPs*** - Servicing of any Evaporator Coils to prevent build-up of grease & potential contaminants. - Target temperature is ambient temperature. ***Testing*** - Quarterly caps & container testing provides data on successful control of environmental pathogens. ***Training*** 1. Employee training on HR policies that state anyone with infectious disease should be on sick leave.
		Chemical ❖	– We are not aware of any agricultural chemicals such as herbicides, insecticides and fertilizers that are aerosolized within proximity of our bottling. – We are not aware of any Industrial chemicals such as solvents, lubricating oils & petroleum that are aerosolized within proximity of our bottling.	4	D	21	***Monitoring*** - Routine inspections of the Plant property - Observation of adjacent property owners
		Radiological ❖	– We do not have any excess level of Radon in the building.	5	E	25	***Testing*** - The building was tested prior to occupancy as part of the occupancy permit. No radon was measured.
		Physical ❖ Sand particles and other foreign airborne matter. ❖ Asbestos fibers from worn tiles	– Broken doors, HVAC or AHUs that could allow the inflow of air laden with aerosols particles. – Insects or other filth. – **NOTE**: In this plant the hazard has been considered but viewed not relevant as there are no asbestos containing tiles used anywhere in the Plant.	4	D	21	***SSOPs*** - Maintenance of filters. ***Checklist*** - Assurance that policies about keeping doors shut are enforced. ***General Housekeeping*** - Dedicated cleaning equipment including shop vac equipped with filters of MIRV 13 or higher including HEPA filters offered on portable devices to minimize dust and airborne particles. - Preventive maintenance on doors and equipment to insure proper closure.

Hazard Analysis for Environment							
#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
Bottle Handling Areas For New one-way bottles	Airborne Contaminates	**Biological** ❖ Pathogenic bacteria (E. coli, Listeria, Salmonella) ❖ Protozoa (not airborne) ❖ Viruses including Enteroviruses and noroviruses	– Airborne pathogens floating into the plant area; sourced from o Air handling equipment o Vents from outside to inside o Air currents from other areas of the plant o Employees o Contractors o Visitors – Protozoa highly unlikely to be airborne. – Viruses could be spread through respiration of staff & visitors.	3	C	13	**Plant Design** - Establish areas outside of the bottling/filler room as basic GMP zone designed to be cleanable. - Minimize outside air that has not come in through some type of mechanical air filtering (MIRV 13 wherever possible or practical). - Effective closures to minimize intrusion of outside environmental issues such as dust or other unwanted airborne particulates. - Maintenance of floors, walls & ceilings so as to minimize areas that could harbor contaminants or make routine cleaning difficult. ***SOPs*** - Procedures that minimize the durations when doors and or loading bays are open without protective screening. ***Testing*** - Sampling for environmental pathogens based on risk assessment. ***Training*** - Employee training on HR policies that state anyone with infectious disease should be on sick leave.
		Chemical ❖	– We are not aware of any agricultural chemicals such as herbicides, insecticides and fertilizers that are aerosolized within proximity of the plant. – chemicals such as solvents, lubricating oils & petroleum that are aerosolized within proximity of exposed water.	4	D	21	***Monitoring*** - Routine inspections of the Plant property - Observation of adjacent property owners
		Radiological ❖	– We do not have any excess level of Radon in the building.	5	E	25	***Testing*** - According to past employees the build was tested for Radon more than 20 years ago. We do not have any records but local realtors have told us the area is low risk.
		Physical ❖ Sand particles and other foreign airborne matter.	– Broken doors, HVAC or AHUs that could allow the inflow of air laden with aerosols particles. – Insects or other filth.	4	D	21	***SSOPs*** - Maintenance of filters used for air handling. ***Checklist*** - Assurance that policies about keeping doors shut are enforced. ***General Housekeeping*** - Dedicated cleaning equipment for each functional area of the plant. - Use of shop vac equipped with filters instead of brooms/sweeping so as to minimize dust and airborne particles where practical. - Preventive maintenance on doors and equipment to insure tight seals are possible.

Hazards not Controlled by Facility

There are some risks which are outside the direct control of our company. This includes the watershed surrounding the Spring Water source as Spring as extraordinary events which could potentially impact our municipal source. Our Food Safety team has conducted a risk assessment shown below.

(1)	(2)	(3)	(4)	(5)
Hazard not controlled by Plant	Identify reasonably foreseeable food safety hazards introduced, controlled or treated at this step.	Nature of the hazard and how it exists in finished product.	Risk Assessment: Consequence /Severity (C) Frequency/Likelihood (F) Score(S)	What control measure(s), Preventive or otherwise, are applied to significantly minimize, control or prevent the food safety hazard or otherwise negatively impact quality and acceptability? Clearly indicate where any applicable PCHF Preventive Control(s) is applied.
Hazards not controlled by Plant				

#	Name	Hazard	Origin/Nature	C	F	S	Other Potential Threats not controlled
Source Water	Ingredient	**Biological** ❖ Pathogenic bacteria, Protozoa and/or Viruses ❖ Intentional Sabotage	– Septic tank from other property in the nearby area develop seepages that infiltrates areas that could result in contamination of source. – Earthquake creates new fractures in the early adjacent to our source; introducing contaminated water from surface runoff or other non-stable source. – Breakdown or absence of controls at the spring site; broken or deteriorating distribution piping or equipment.	3	D	**17**	**Tsunamis** ➢ The last three tsunamis that caused significant damage in Hilo occurred in 1946, 1960 and 1975. In 1980 waves were reported as high as 17 feet. This could potentially cause flooding near the plant as a result of storm surge, but there are no records indicating the plant has ever had flooding. ➢ The bottling plant is located in the official tsunami evacuation zone. ➢ The source is located inland at elevation of 242 feet above sea level, thus it is out of the tsunami evacuation zone. **Tornados** ➢ Hawaii County is a Very Low Risk area for tornados. There is an average of 0 tornado per year. There have been 5 since 1950. According to records, the largest tornado in the area was an F1 in 1980 that caused 0 injuries and 0 deaths. **Volcanos** ➢ There are four active volcanoes on the Island of Hawai'i. Kilauea is an active volcano that has been continuously erupting since January 1983. It is located 30 miles (straight line) from the bottling plant. ➢ Mauna Loa is an active volcano that last erupted in 1984 and is believed to be building for a new eruption within the next few years. The Loihi volcano last erupted in 1996, and Hualalai last erupted in 1801, however is expected to erupt again within the next 100 years. **Earthquakes**) ➢ Near Hilo Earthquakes typically result from magmatic migration underground. As there are four volcanoes currently classified as "active", future earthquakes associated with underground lava movements are expected. There have been 22 large earthquakes with a magnitude of 6.0 or greater recorded since 1868 (Atlas of Hawai'i, Third Edition, 1998). Large earthquakes of this magnitude can cause structural damage to non-reinforced buildings and can cause coastal subsidence. The entire Island of Hawaii is designated as Seismic Zone 4, based upon the United Building Code's (UBC) seismic zone criteria that ranges from 0 to 4 (highest risk). ➢ There have been a total of 16,221 earthquakes (almost all below 3.0) since 1931. The USGS database shows that there is a low chance of a major earthquake within 50km over the next 50 years due to frequent minor quakes. **EPA Superfund** ➢ Hawaii County has 0 Active NPL, 4 Non-Active NPL and 22 Archived Superfund sites. None to be near well site ➢ There are 6 brownfields. ➢ There are 14 polluters. ➢ There have been 433 tanks/spills; none appear to be near the well site. **Nuclear Plants** ➢ No Risk. There are no nuclear power plants in the state of Hawaii. **Fracking** ➢ This area has NO FRACKING. **Watershed/rivers** ➢ Not Applicable.
		Chemical ❖ Intentional Sabotage ❖ Natural causes	– Contamination of water source through accident; spill of toxic chemicals that sink from surface to aquifer. – Agricultural activity in the area can increase the natural nitrate level in the ground water.	2	D	12	
		Radiological ❖ Unintentional Sabotage	– Release of radioactive cloud from nuclear power plant that settles on land (including the source)	2	E	16	
		Physical ❖ Particles and other foreign matter ❖ Forest Fires	– Excessive rain/hurricane causes overload of septic tank capacity in areas near source. – Forest Fires destroy water shed causing runoff with fire retardant chemicals that seep down into the aquifer.	3	D	17	

Hazards Intentionally Introduced for Economic Gain

The FDA only requires consideration of hazards in ingredients with a pattern of economically motivated adulteration in the past. We recognize that most EMA are intentional acts designed to evade detection. Therefore, our primary control is through our Supply Chain program.

Term	Example	Type	Risk	Secondary Effects
Substitution	Intentional dilution or substitution of chemicals in cleaning and/or sanitizing chemicals.	Indirect; supplier uses poorer quality of raw materials to make up cleaning and/or sanitizing solutions.	Class I or Class II	Inadequate cleaning leading to excess bacteria some of which could be pathogenic. Adulterated product, damage to company and industry, recall expense and public fear
Substitution	Intentional contamination or substitution of lead into inks used to print on our labels.	Direct or Indirect depending on safety of product. Supplier uses non-food grade ink to make our run after using approved material for our samples.	Class II	Potential damage via extended contact with product label containing lead-based dye; damage to company and industry, recall expense and public fear
Fraud	Intentionally sells our branded materials such as labels to unauthorized purchaser	Direct. Unauthorized purchaser manufacturers product using our unauthorized name.	Class III	Potential damage to our reputation by producing product that is sold on the basis of another company's brand reputation in the market. May or may not have actual food safety risk depending on the producing facilities standards.

(1)	(2)	(3)	(4)	(5)
Ingredient/ Processing Step	*Identify reasonably foreseeable food safety hazards introduced, controlled or enhanced at this step.*	*Nature of the hazard and how it exists in finished product.*	*Risk Assessment: Consequence/Severity (C) Frequency/Likelihood (L) Score(S)*	*What control measure(s) are applied to significantly minimize or prevent the food safety hazard?* *Controls include Process Preventative Controls (PPC), Process Controls (PC), Sanitation (SSOP), Supply chain, testing and all other Preventative controls.*

Hazards intentionally introduced for Economic Gain

#	Name	Hazard	Origin/Nature	C	F	S	Control Measures
	Ingredient	Biological ❖ Substitution	– Unauthorized replace of a lower grade cleaning solution that had not been tested for bacteriological safety. – Higher than expected (based on history) of biofilms developing on surfaces of food contact materials.	4 Low	D	21	GMP Supplier Qualification
		Chemical ❖ Substitution	– Unauthorized replace of food-safe dye with formula containing non-approved dye that contains excess lead. – Consumers absorb excess lead by means of contact with label.	2 Low	E	16	GMP Supplier Qualification
		Other ❖ Fraud	– Our label maker produces unauthorized overrun and sells them to off-brand producer who then sells our brand for cheaper price.	3 Low	E	20	GMP Supplier Qualification
		Physical ❖ None identified	– None foreseen				

PROCESS PREVENTIVE CONTROLS (PPCS) A.K.A. CCPS

Based upon the Hazard Analysis and risk assessment completed by our team, we have determined there is need for the following "Process Preventative Control(s)" a.k.a. Critical Control Point(s):

Process Preventative Control (PPC) aka Critical Control Point (CCP)									
Process Control (PPC#)	**Hazard**	**Critical Limits**	**MONITORING**				**Corrective Action**	**Verification**	**Records**
			What	**How**	**Frequency**	**Who**			
UV *Water passing through validated 4-log reduction UV system prior to bottling*	**Biological** *Fecal Coliform or E. Coli* *In water*	The Atlantium Unit must be in the "green" operational range which assures adequate UV energy is radiating the water passing through to effect 4-log reduction.	The system must be in the "green" zone on the control screen.	Visual observation of the Screen visible in the water treatment area.	Monitoring is continuous.	Designated individual who has been trained to know what to observe.	*If the unit falls outside of performance specifications the diverter value will prevent product water from moving forward to filler.* • Quality Manager is notified. • Production is shut down until the UV system problem is identified and corrected. • The Quality Manager consults with the PCQI to assess whether potential hazard has been introduced into the product. If yes, all potentially contaminated water is discarded, system flushed and sanitized before restart.	Water is tested for presence of Coliforms and *E.coli* daily and must contain no detectable *E.coli* or Total Coliform bacteria Batch is put into automatic 24-hour quality hold until negative results are confirmed by Quality Manager	Daily Operations Checklist showing Monitoring Observation. Microbiological lab results. *UV Disinfection Maintenance Log* Corrective Action Report for any observation failures Signoff by Plant Mgr.

Other Process related controls(non-critical)

Controls other than those designated Process Preventative Control are important to our food safety plan. These include procedures, practices and processes to ensure the control of parameters during operations.

Controls have parameters associated with the control of hazards; often have maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled as part of our overall operation. They either prevent a hazard from emerging or control our operations to prevent the hazard from impacting our overall level of safety.

These Control Points do not require formal Validation, though as a matter of practice we seek to insure each of these controls accomplishes its intended purpose.

We utilize the same format that is used for PCHF Preventive Controls for our other controls to insure we have adequate monitoring, corrective actions, verification and records as appropriate.

Other Control Points (non-critical)									
GMP Controls (GMP)	**Hazard**	**Critical Limits**	**MONITORING**				**Corrective Action**	**Verification**	**Records**
			What	**How**	**Frequency**	**Who**			
Source Inspection and maintenance *Observation of source* **(GMP#1)**	**Biological** *Visible biofilm* **Chemical** *Notable Odor* **Physical** *Visible cap plug or other object*	No visible biologic; notable odor; or physical object	1) The presence of visible biologics, notable odors or physical objects	1) Visual check of employee performing inspection.	• Every time a load is taken from the well.	Staff person assigned to do tanker loading.	• Stop loading of tanker. • Correct deficiency. • Determine root cause – retrain or correct as appropriate. • Clean and sanitize the well casing and/or affected parts of the system.	• QA Supervisor visits the well site at least 3 times weekly.	• Recording of observation if anything is out of standard. • Corrective Action Report for any observation failures
Tanker Truck *Washing and Sanitizing* **(GMP#2)** **Reference SOP and Validation of SOP**	**Biological** *Bacteria* Protozoa *Viruses* **Chemical** *Excess Cleaning solutions* *Excess sanitizers* **Physical** *Sediment* *Dirt*	Absence of any pathogenic bacteria Absence of any detectable cleaning solutions Absence of observable sediment Absence of any objectional odor	1) Successful cleaning and sanitizing of the Tanker	1) Visual check of inside tanker 2) Swab for TC of water drawn from inside or inside wetted surface.	1) Formal Level 2 "wash" done a minimum of every 4 weeks. 2) Formal Level 1 "wash" done at end of each day loads are transported or the tanker sits idle for more than 72 hours.	Production Manager Or QC Manager or Designee (someone other than person assigned to perform the "wash"	• Stop use of tanker • Repeat the "wash" • Retest • Repeat until TC is negative. • If fails twice for TC, add HPC testing with count of 10 or less to criteria for release to haul water again.	• **PCQI reviews and initials** records within 7 business days of observation • **Production Manager** reviews records to evaluate trends.	• Recording of observation of the inspector and results of the testing. • Corrective Action Report for any observation or test failures

Other Control Points (non-critical)									
GMP Controls (GMP)	**Hazard**	**Critical Limits**	**MONITORING**				**Corrective Action**	**Verification**	**Records**
			What	**How**	**Frequency**	**Who**			
Blow Molding *Observation* **(GMP#3)**	**Biological** *Visible biofilm* **Chemical** *Notable Odor* **Physical** *Visible object or excess scuffing*	All empty containers pass through a bottle inspection process. No visible biologic; notable odor; or physical object	1) The presence of the bottle inspection process. 2) The presence of visible biologics 3) The presence of notable odors 4) The presence of physical objects	1) Visual check of employee performing inspection. 2) Visual examination of a representative sample of bottles after blowing.	1) Beginning of run. 2) Three times per shift.	Operations Manager or Designee (someone other than person assigned to inspection process)	• Stop Blowing • Remove deficient bottles • Correct operating procedure to ensure that the deficiency is corrected and won't repeat • Evaluate last 15 minutes of blow molding; discard or release • Determine root cause – retrain or correct as appropriate.	• PCQI reviews and initials records within 7 business days of observation • Operations Manager reviews records to evaluate trends.	• Recording of observation of the inspector and of finished product bottles. • Corrective Action Report for any observation failures

ALLERGEN PREVENTATIVE CONTROLS

For hypersensitive individuals, certain foods and their derivatives can cause allergic reactions. Food allergy is an abnormal immune response to proteins found in the allergen food. Allergic reactions cannot occur in the absence of proteins. These proteins (antigens) can stimulate the production of antibodies in the body, thereby, triggering allergic reactions. Immediate response to an allergic reaction can range in severity from a skin rash or itching of the mouth, to migraine headaches, a drop in blood pressure, anaphylaxis (a very severe allergic reaction to food involving failure of multiple organ systems), and death. There is no current cure for food allergies and the only way for an allergic individual to protect themselves is strict avoidance of the allergen.

We do not utilize raw materials or ingredients that contain any allergens. Therefore, our Production Line Allergen Assessment shows zero risk.

We do utilize activated charcoal in our Carbon filtration tank that removes chlorine at our well site after we do chemical CIP of the well. However, all the water running through the carbon is sent to drain; none is used for product or operational water.

Since we do allow employees to bring allergen-containing food into the Employee Break Room and offices, we have developed an Allergen Plan and Policy specific to our facility.

Ingredient Allergen Identification

Raw material name	Supplier	US Allergens defined by FDA (*)								Allergens in Precautionary Labeling
		Egg	Milk	Soy	Wheat	Tree Nut	Peanut	Fish	Shellfish	
All	None	None	None	None	None	None	None	None	None	None

(*) Canada also recognizes Mustard, Sesame & Sulphites as allergens

Allergen Label Declaration

#	Allergen Hazard(s)	Parameter	MONITORING				Corrective Action	Verification	Records
			What	How	Frequency	Who			
1	Undeclared allergens	We have determined that we have no allergens and therefore no allergen labeling.							

Allergen Control

#	Allergen Control	Parameter	MONITORING				Corrective Action	Verification	Records
			What	How	Frequency	Who			
1	None	Not Applicable							

Allergen Control Policy

TO: All employees of Waiakea Hawaiian Volcanic Water

FROM: Jerry Clark, Plant Manager

SUBJECT: **Allergen Policy**

Waiakea does not use any allergens in the manufacturing of our products.

The absence of potential allergens in our production process has been verified as part of the hazard analysis conducted by our Food Safety team, reviewed by plant management and our PCQI.

We will view allergens annually and any time there is a significant change in operations that could possibly impact the presence of allergens.

To prevent any potential allergen contamination, we have adopted prerequisite programs and preventative controls which constitute our Allergen Control Policy:

- Employees, contractors or visitors are prohibited from bring any food or beverage products inside the production area other than plain water which is provided in authorized locations inside the plant.
- Employees, contractors or visitors are required to wash their hands following our hand washing hygiene guide prior to entering or re-entering the production area.
- Employees, contractors or visitors are required to wear hair nets (and beard snoods if applicable) while inside the production area.
- Employees, contractors or visitors are required to wear clean clothing that to the best of their knowledge are absent any allergen particles or proteins. If incidental contact might have been made while consuming allergen-containing products in the break room, care and attention will be taken to remove any observable residue.
- Suppliers must verify that their materials have no allergen ingredients.

The only locations in our facility where allergen containing food is permitted is in the break room area and administrative offices.

We do not have any designated peanut-free or allergen free break areas within the facility.

If any employee, contractor or visitor has allergy concerns, please bring these to the attention of or request a meeting with management to discuss. Additional accommodations will be discussed at this time.

We appreciate your support of this policy. If you have any questions, please contact us.

[This document is posted on the Employee Notice board in the facility]

SANITATION PREVENTATIVE CONTROLS

Sanitation practices are required by Good Manufacturing Practices of Part 117. Our facilities meet all applicable requirements. Sanitation preventive controls are a subset of the sanitation procedures.

In our Hazard Analysis we identified that we had no areas deserving of extraordinary efforts requiring Sanitation Preventive Controls as a proactive measure. But we did identify two areas that warranted designation as GMP Controls to focus our team on sanitation.

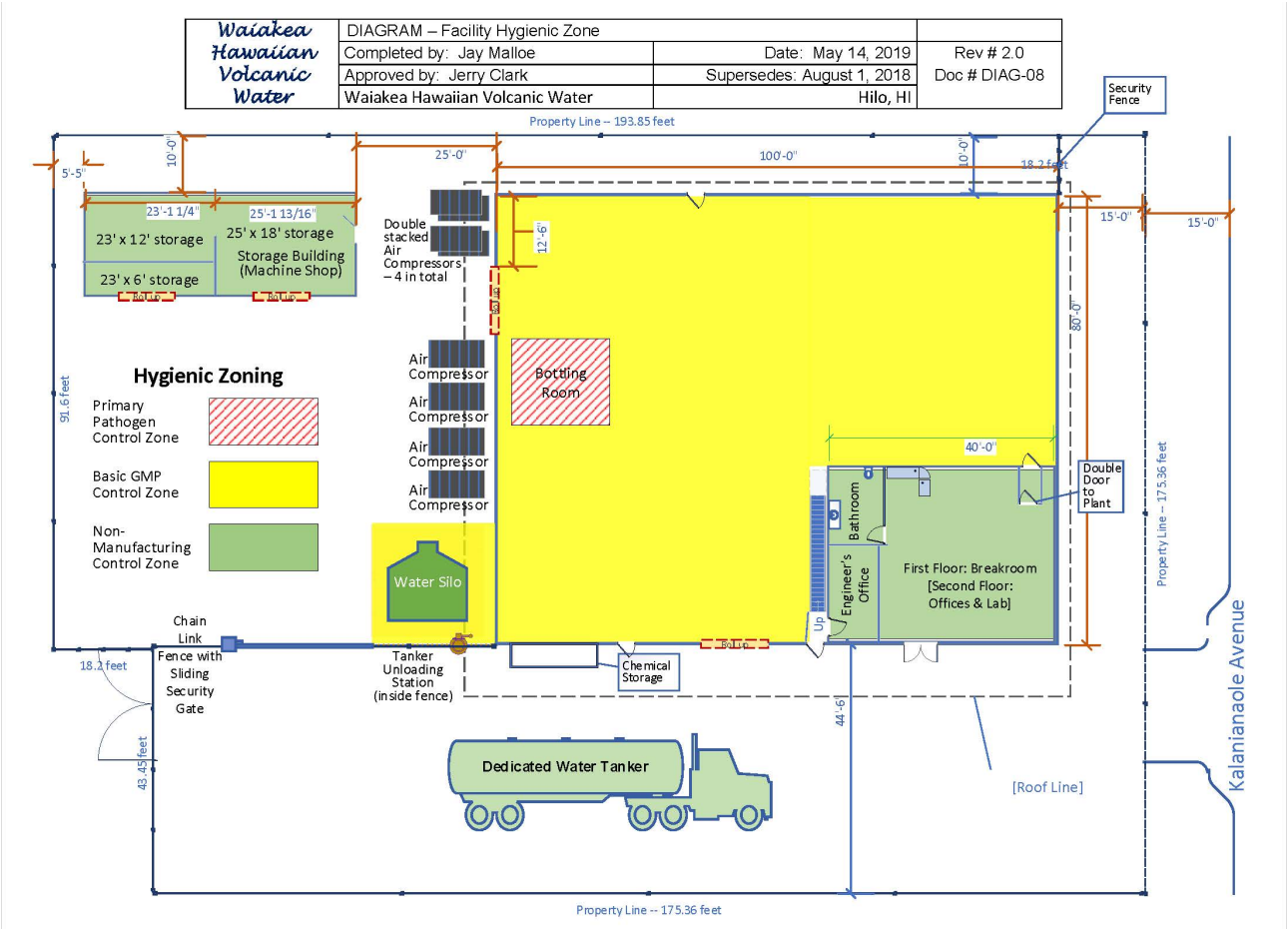
GMP Control									
GMP Control (GMP#)	**Hazard**	**Critical Limits**	**MONITORING**				**Corrective Action**	**Verification**	**Records**
			What	**How**	**Frequency**	**Who**			
Cleaning and sanitizing filler "heads" GMP #1	Bacterial residue or mineral buildup that could harbor bacteria *Fecal Coliform or E. Coli*	Must be visually clean with no residue Procedure is verified by swabbing quarterly.	Cleaning & sanitizing filler heads	1. Spray fill heads with 200 ppm chlorine spray. 2. Allow to air dry or rinse with ozonated water. 3. Note: during the morning spray down the disinfectant is rinsed off with ozonated product water.	End of shift on any production day. Startup of each shift.	Operations Manager or Production Lead or other designated individual	If there is visible residue, the process must be repeated until results within critical limits.	1. Visual inspection of equipment by supervisor. 2. Operations Manager reviews cleaning/ sanitizing log weekly. 3. Quarterly swab of heads with limit of 10.	Visual Observation recorded on Daily Checklist. ---- Corrective Action Report for any observation failures ------ • Signoff by Quality Manager

Hygienic Zoning

We have adopted the concept of hygienic zoning to help manage environmental and other risk. This is where we identify, separate and differentiate one part from another inside the production facility. Because of design and process differences, the actual zoning is unique to each facility. There is no regulatory standard for zoning. For our plant we have identified through research and risk assessment the following zones:

- **Primary Pathogen control zone** … Filler room
  - Receives filtered air under positive pressure
  - Prevent transient microorganisms (no raw material storage)
  - Higher lighting levels to facilitate inspection
  - Quarterly environmental sampling of caps & containers
- **Basic GMP zone** … Lab, Restrooms, hand washing stations, water treatment, raw material storage areas, breakroom
  - No positive air pressure
  - High lighting levels to facilitate inspection of raw materials and work in progress
  - Risk based frequency of environmental sampling
- **Non-manufacturing zone** … offices, warehouse, storage
  - Draws air from basic GMP zone and negatively vent to outside where possible
  - Resident microorganisms controlled by normal cleaning and sanitizing

Our GMP controls include ongoing maintenance program to prevent any drain trap from becoming clogged. We also routinely inspect roof drains to prevent creation of standing water on roofs that may leak into the plant.



Clean-In-Place

Clean-in-place (CIP) is a method of cleaning the interior surfaces of pipes, vessels, process equipment, filters and associated fittings, without disassembly.

Due to the climatic influences of our facility location, we utilize frequent internal cleaning that would be extremely time-consuming and resource-intense if it were not being able to clean while the system remains intact.

The benefit to us is CIP is faster, less labor-intensive and more repeatable, and poses less of a chemical exposure risk.

Our CIP has evolved to include predetermined configurations and time intervals that optimize cleaning effectiveness and efficiency.

Based on our soil load and process geometry, our CIP system was designed to deliver turbulent, high flow-rate solution (ozonated water) to effect good cleaning (applies to pipe circuits and some filled equipment).

We also utilize deliver through medium-energy spray balls to fully wet the surface (applies to our water tanker and water storage tank and buffer tank.

We have the capability to introduce chemical cleaning/sanitizing agents whenever we feel the ozonated water may not be sufficient.

Since our CIP flows, durations and timing is dynamic, the diagrams and sequences for establishing and then running loops are contained in a Sanitary Standard Operating Procedure rather than displayed in our Food Safety Plan.

SUPPLY CHAIN

Supply Chain Preventative Controls

After conducting our supply chain analysis, we have determined we have no ingredients or materials that require specific Supply Chain Preventative Controls.

We believe that along with our standard operating procedures and our Supplier Assurance program, we can meet the requirements to have safe and approved materials for use in our operation.

Supplier Assurance Program

Waiakea complies with § 117.420 which requires that suppliers must be approved in accordance with the requirements of § 117.410 (d). Authority to approve a supplier is vested with the corporate office; sometimes with the assistance of our office manager. We utilize only prior approved suppliers for all reasonably foreseeable materials and providers. All suppliers are asked to complete our Supplier Information Sheet. When necessary, on a temporary basis, we purchase goods and services that normally requires prior approval. In each of these situations we will close the loop by gathering Supplier profile. Where appropriate we will take extra steps to insure food safety is not compromised.

Goods and services that we receive fall into several categories; each with its own set of procedures:

I. Goods and Services that require Supply Chain Preventive Controls
   1. None

II. Goods and Services that require prior Supplier Approval but not subject to Preventive Controls
   1. Food Contact Substances (FCS)
      Bottles, Caps, Labels, Video Jet date coding ink
      Pallets (new and used sources including minimal specifications)
   2. Processing Aids
      Carbon for filter
      Filter media (filters, membranes)
   3. Chemical cleaners & sanitizers
      Chemicals that have 3rd party certification are accepted without further review
   4. Other
      Lubricants

III. **A**. Goods and Services we contract for but do not require prior approval other than agreeing to our terms and conditions which address awareness of our allergen control program and their employee practices while on-site where applicable.
   Janitorial services
   Plumber services
   Waste Removal
   Pest Control

   B. Goods and Services we contract for but do not require any type of prior approval other than ensuring they are suitable for use in a food establishment.
   Test Strips for chemical strength
   Testing instruments (HACH)
   Testing materials (IDEXX & others)
   Hosing & plumbing fixtures
   Epoxy paint

Supplier Information Form

All suppliers are asked to complete this form and review annually.

WAIAKEA	Waiakea Startup Procedure		Page 1 of 1
	Completed by: Jay Malloe	Revised: May 13, 2019	Rev # 2.0
	Approved by: Jerry Clark	Supersedes: February 11, 2019	Doc #SOP 5
	Waiakea Hawaiian Volcanic Water	Hilo, HI	

Contact Information – Commercial Address					
Manufacturer/Supplier:			**Distributor:**		
Commercial Address:			**City:**		
State:	**Province:**	**Zip:**	**Country:**		
Contact First Name:		**Last Name:**		**Title:**	
Email:		**Phone No:**		**Cell No:**	
Material Information – Manufacturing Address					
Product Name:			**Product #**		
Trade Name if different:			**Country Origin:**		
Manufacturing Address:			**City:**		
State:	**Province:**	**Zip:**	**Country:**		
Contact First Name:		**Last Name:**		**Title:**	
Email:		**Phone No:**		**Cell No:**	

Compliance Information		
Are all ingredients compliant with FDA Food Regulations?	Yes	No
Are any of the ingredients a known carcinogen, mutagen or reproductive toxicant as defined by FDA, EPA, CDC or USDA?	Yes	No
Anything in raw material that could be source of spoilage organisms?	Yes	No
Does the product contain any chemical listed under California Proposition 65?	Yes	No
Does this product contain any known Allergens as defined by FDA?	Yes	No
Do you have a current Recall Plan applicable to the material you would be providing us?		
Does this product require any special storage conditions for temperature and/or humidity? If so, please explain.	Yes	No
Certification and/or testing		
Are you GFSI certified? If so, please provide type and certificate #.	Yes	No
Do you have any type of product certification such as NSF? If so, please provide standard and how product is listed.	Yes	No
Do you have any type of trade association audit or certification? If so, please provide details.	Yes	No
Do you have any independent 3rd party audits that have been done for your facility related to the material you would be providing us?	Yes	No
Additional documents		
Internal Specification sheet	Attached	N/A
Ingredient Statement	Attached	N/A
Safety Data Sheet	Attached	N/A
Testing results specific to the material you would be providing us	Attached	N/A
Certificate of Analysis (COA)	Attached	N/A
Letter of Guarantee	Attached	N/A
Explanation of Lot Code	Attached	N/A
Country of Origin Statement	Attached	N/A
Comments		
Any additional information we should consider about material and/or services you would be providing us?	Yes	No

Received (date)	**Reviewed/Approved by (Office use only)**
Comments	

Sanitary Transportation Controls

Designed to promote proactive management of food safety, this plant has developed policies and procedures to ensure we are in compliance **FSMA Final Rule on Sanitary Transportation of Human and Animal Food,** published April 6, 2016 in the Federal Registry. We believe we are in full compliance.

We do not believe our product contains ingredients that supports the rapid growth of unsafe microorganisms in the absence of temperature extremes during transportation. We do however focus on time/temperature control to prevent spoilage that could diminish the quality and/or salability of our product.

The elements within the final rule that we believe to be applicable to our company include:

§ 1.906 What requirements apply to vehicles and transportation equipment?

(a) Vehicles and transportation equipment used in transportation operations must be so designed and of such material and workmanship as to be suitable and adequately cleanable for their intended use to prevent the food they transport from becoming unsafe.

Section § 1.906 (a) is managed through our Purchasing specifications for leased or purchased vehicles. We include sustainable operating range, FDA approved surfaces coming in contact with product and doors that can be closed and secured.

(b) Vehicles and transportation equipment must be maintained in such a sanitary condition for their intended use as to prevent the food they transport from becoming unsafe during transportation operations.

Section § 1.906 (b) is managed through our SOPs for vehicle maintenance, cleaning & inspection. This includes a regular program of truck washing of exterior and cleaning of interior. Exterior frequency varies by time of year and road conditions with the frequency determined based on local weather conditions.

Reference next page for our Water Tanker Sanitary Transportation regulations including compliance with the "Model Tanker Wash Guidelines for the Fruit Juice Industry" which has received FDA approval.

§ 1.910 What training requirements apply to carriers engaged in transportation operations?

(a) … must provide adequate training to personnel engaged in transportation operations that provides an awareness of potential food safety problems that may occur during food transportation, basic sanitary transportation practices to address those potential problem … training must be provided upon hiring and as needed thereafter.

Section § 1.910 (a) is managed through our Prerequisite Training Requirement program applicable to all drivers under our control. We require similar training for any contract drivers. Training is completed before an individual is allowed to operate vehicle. Re-training is annual during the 1st quarter and again when we take on seasonal drivers in the late-spring, early-summer.

We require all drivers to complete the FDA online training course at https://collaboration.fda.gov/sanitary_transportation_carrier_training/ . The certificate obtained after completing this course is then kept in personal records as verification of training. We request this of tank hauling drivers too.

(b) … maintain records documenting the training …

Section § 1.910 (b) is managed through our Prerequisite Training Requirement program documentation which is kept on file for a minimum of 2 years. We require similar documentation for any contract drivers. Based upon a request from our vehicle insurance carrier, we retain training records for the duration of employment or at least 5 years for both full, part and temporaries. Recall Preventative Controls

Tank Wash Procedures

Where our bottling plant is located, there is NO commercial truck washing company in operation. We have researched the entire island of Hawaii and could not locate a facility that could be contracted or rented to accomplish the routine sanitation of our tanker truck.

While there are diary companies on the island, none would agree to provide any type of cleaning or sanitizing service.

Thus, we established our own Tanker Wash Procedures following the process outlined in the Juice Products Association Model Tanker Wash Guideline for the Fruit Juice industry as it applied to tankers only used for potable water.

We own our own tanker.

No other use other than to haul water from our source to our facility is made with the tanker.

We have a Standard Operating Procedure that outlines the process and procedure that we follow to clean and sanitize the truck.

We have two types of cleanings:

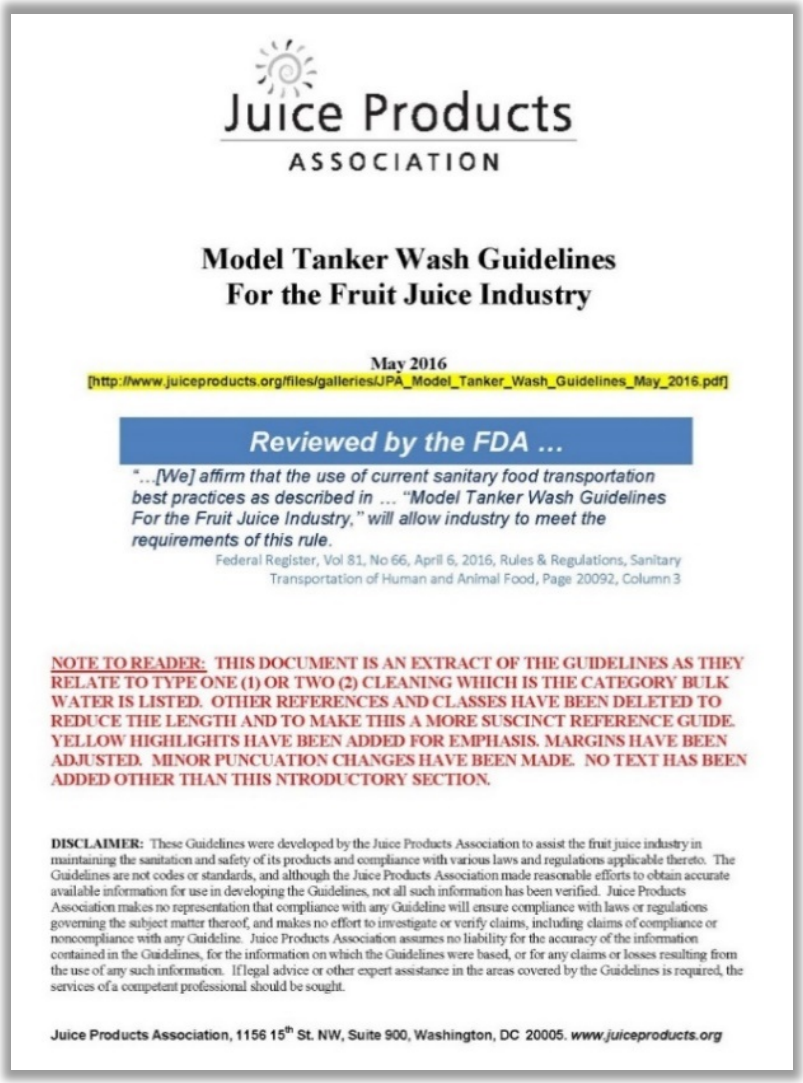
Level 1 cleaning after the last load of each day. It is also done anytime the tanker sits idle for more than 72 continuous hours.

Level 2 cleaning every 4 weeks or as needed. It is more analogous to a commercial wash.

We have validated the method by doing the procedure and then running micro testing for both Total coliforms and HPC through our own in-house lab. We also sent one set of samples to a State of Hawaii accredited lab to further validate our own testing.

We have set a minimum frequency of Level 2 washing at least every four weeks.

After a Level 2 cleaning, we wait the requisite 24 hours after doing the test for the results of the Total Coliform test and only after getting a "negative" do we then utilize the tanker for product water.



Juice Products
ASSOCIATION

Model Tanker Wash Guidelines
For the Fruit Juice Industry

May 2016
[http://www.juiceproducts.org/files/galleries/JPA_Model_Tanker_Wash_Guidelines_May_2016.pdf]

Reviewed by the FDA …

"…[We] affirm that the use of current sanitary food transportation best practices as described in … "Model Tanker Wash Guidelines For the Fruit Juice Industry," will allow industry to meet the requirements of this rule.

Federal Register, Vol 81, No 66, April 6, 2016, Rules & Regulations, Sanitary Transportation of Human and Animal Food, Page 20092, Column 3

NOTE TO READER: THIS DOCUMENT IS AN EXTRACT OF THE GUIDELINES AS THEY RELATE TO TYPE ONE (1) OR TWO (2) CLEANING WHICH IS THE CATEGORY BULK WATER IS LISTED. OTHER REFERENCES AND CLASSES HAVE BEEN DELETED TO REDUCE THE LENGTH AND TO MAKE THIS A MORE SUSCINCT REFERENCE GUIDE. YELLOW HIGHLIGHTS HAVE BEEN ADDED FOR EMPHASIS. MARGINS HAVE BEEN ADJUSTED. MINOR PUNCUATION CHANGES HAVE BEEN MADE. NO TEXT HAS BEEN ADDED OTHER THAN THIS NTRODUCTORY SECTION.

DISCLAIMER: These Guidelines were developed by the Juice Products Association to assist the fruit juice industry in maintaining the sanitation and safety of its products and compliance with various laws and regulations applicable thereto. The Guidelines are not codes or standards, and although the Juice Products Association made reasonable efforts to obtain accurate available information for use in developing the Guidelines, not all such information has been verified. Juice Products Association makes no representation that compliance with any Guideline will ensure compliance with laws or regulations governing the subject matter thereof, and makes no effort to investigate or verify claims, including claims of compliance or noncompliance with any Guideline. Juice Products Association assumes no liability for the accuracy of the information contained in the Guidelines, for the information on which the Guidelines were based, or for any claims or losses resulting from the use of any such information. If legal advice or other expert assistance in the areas covered by the Guidelines is required, the services of a competent professional should be sought.

Juice Products Association, 1156 15th St. NW, Suite 900, Washington, DC 20005. *www.juiceproducts.org*

Supply Chain Preventative Controls

After conducting our supply chain analysis, we have determined we have no ingredients or materials that require specific Supply Chain Preventative Controls.

We believe that along with our standard operating procedures and our Supplier Assurance program, we can meet the requirements to have safe and approved materials for use in our operation.

Requiring Supply Chain Preventive Controls:		
	Item	Received from
Materials:	NA	
Hazards requiring a supply-chain-applied control	None identified	
Preventive controls applied by the supplier		
Monitoring activities		
Verification procedures		
Records		
	Last	Next Due Date
Review Date		
Receiving Procedure for Ingredients/Materials Requiring a Supply-chain-applied Control		

RECALL PREVENTATIVE CONTROLS

In our Hazard Analysis we have identified one or more hazards that warrant Preventive Controls. We have therefore developed a written Recall Plan specific to our facility.

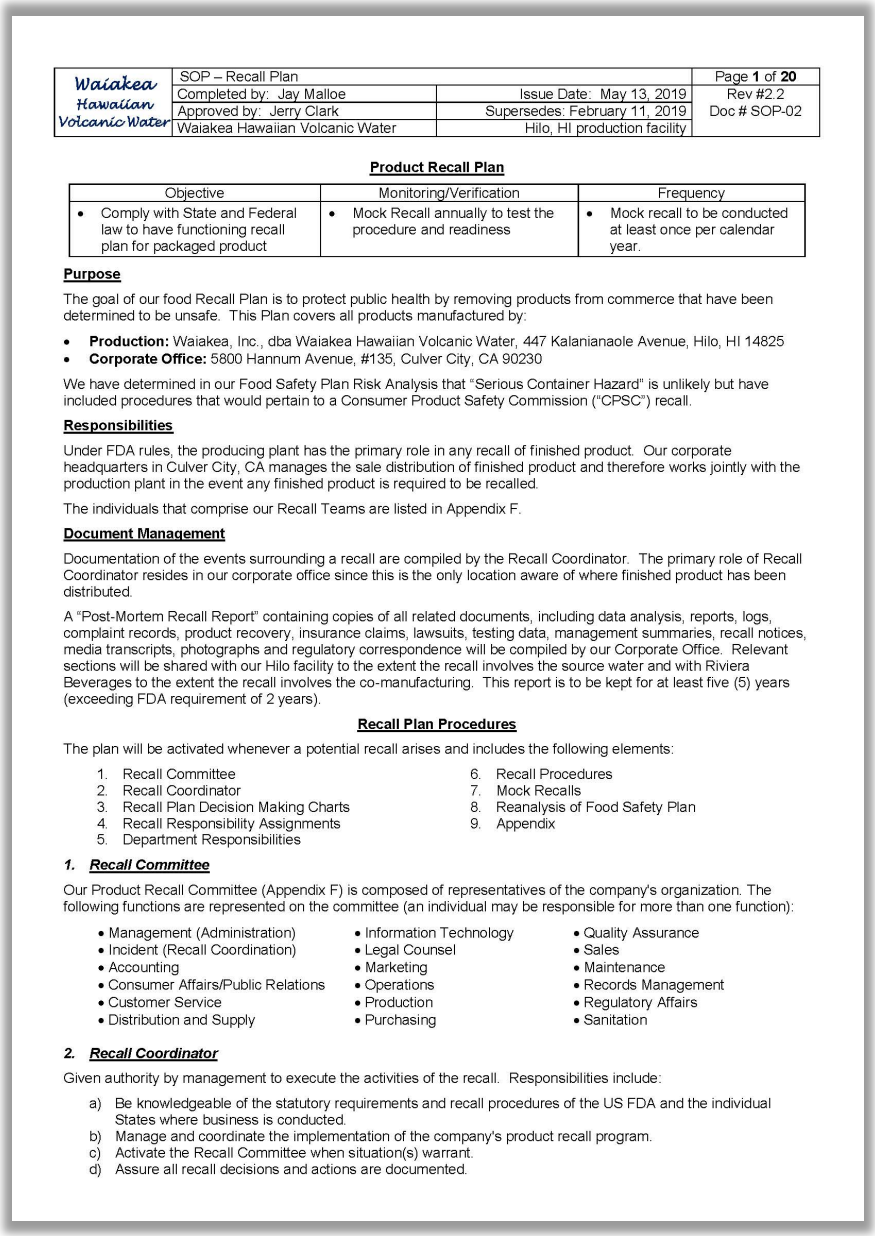
Our plan describes steps to take and assigns responsibility to: a) Notify direct customers and consignees; b) Notify the public, when appropriate; c) Conduct effectiveness checks; and d) Execute disposition of food.

We have put this Plan in place prior to any adverse event to ensure that actions taken to recall a food are conducted efficiently and as soon as possible.

The Plan is kept as a separate document but is available upon request.

We acknowledge that while the FDA has statutory authority to order a recall, states also have this authority. Thus, our plan contains the contacts that we will be simultaneously communicating with in the event of an incident that may warrant a recall.

Note: Some of our products are copacked by another supplier. Should there be a food safety issue that requires recall, we will coordinate directly with the Recall Coordinator of the facility that produced the product. We have included procedures for how we handle this in our own Recall Plan realizing the FDA will expect our copacker to take the lead since they are the ones who produced the product.



Waiakea Hawaiian Volcanic Water	SOP – Recall Plan		Page **1** of **20**
	Completed by: Jay Malloe	Issue Date: May 13, 2019	Rev #2.2
	Approved by: Jerry Clark	Supersedes: February 11, 2019	Doc # SOP-02
	Waiakea Hawaiian Volcanic Water	Hilo, HI production facility	

Product Recall Plan

Objective	Monitoring/Verification	Frequency
• Comply with State and Federal law to have functioning recall plan for packaged product	• Mock Recall annually to test the procedure and readiness	• Mock recall to be conducted at least once per calendar year.

Purpose

The goal of our food Recall Plan is to protect public health by removing products from commerce that have been determined to be unsafe. This Plan covers all products manufactured by:

- **Production:** Waiakea, Inc., dba Waiakea Hawaiian Volcanic Water, 447 Kalanianaole Avenue, Hilo, HI 14825
- **Corporate Office:** 5800 Hannum Avenue, #135, Culver City, CA 90230

We have determined in our Food Safety Plan Risk Analysis that "Serious Container Hazard" is unlikely but have included procedures that would pertain to a Consumer Product Safety Commission ("CPSC") recall.

Responsibilities

Under FDA rules, the producing plant has the primary role in any recall of finished product. Our corporate headquarters in Culver City, CA manages the sale distribution of finished product and therefore works jointly with the production plant in the event any finished product is required to be recalled.

The individuals that comprise our Recall Teams are listed in Appendix F.

Document Management

Documentation of the events surrounding a recall are compiled by the Recall Coordinator. The primary role of Recall Coordinator resides in our corporate office since this is the only location aware of where finished product has been distributed.

A "Post-Mortem Recall Report" containing copies of all related documents, including data analysis, reports, logs, complaint records, product recovery, insurance claims, lawsuits, testing data, management summaries, recall notices, media transcripts, photographs and regulatory correspondence will be compiled by our Corporate Office. Relevant sections will be shared with our Hilo facility to the extent the recall involves the source water and with Riviera Beverages to the extent the recall involves the co-manufacturing. This report is to be kept for at least five (5) years (exceeding FDA requirement of 2 years).

Recall Plan Procedures

The plan will be activated whenever a potential recall arises and includes the following elements:

1. Recall Committee
2. Recall Coordinator
3. Recall Plan Decision Making Charts
4. Recall Responsibility Assignments
5. Department Responsibilities
6. Recall Procedures
7. Mock Recalls
8. Reanalysis of Food Safety Plan
9. Appendix

1. Recall Committee

Our Product Recall Committee (Appendix F) is composed of representatives of the company's organization. The following functions are represented on the committee (an individual may be responsible for more than one function):

- Management (Administration)
- Incident (Recall Coordination)
- Accounting
- Consumer Affairs/Public Relations
- Customer Service
- Distribution and Supply
- Information Technology
- Legal Counsel
- Marketing
- Operations
- Production
- Purchasing
- Quality Assurance
- Sales
- Maintenance
- Records Management
- Regulatory Affairs
- Sanitation

2. Recall Coordinator

Given authority by management to execute the activities of the recall. Responsibilities include:

a) Be knowledgeable of the statutory requirements and recall procedures of the US FDA and the individual States where business is conducted.
b) Manage and coordinate the implementation of the company's product recall program.
c) Activate the Recall Committee when situation(s) warrant.
d) Assure all recall decisions and actions are documented.

Our Recall Plan includes:

- predefined roles and responsibilities;
- procedures to determine if a recall is needed;
- contact lists for external notification of regulators,
- customers, and the public;
- lot identification descriptions;
- effectiveness checks procedure to be used during a recall;
- forms to record information; and
- draft notices to complete in the event of a recall.

Traceability

We know that lots in a recall must be accurately identified. Our lot coding and labeling is designed to assist consumers to be aware of the product and its content. The code provides information to help in stock rotation and help with rapidly and efficiently remove from the marketplace any product deemed unsafe.

We have a system for assigning codes to finished products that identify when a product was produced, where and by extension its source. Codes provided on packaging are legible and durable for the lifespan of the product. We record the amount of product manufactured for each lot and have records that tie to processing, inventory and distribution for each lot.

Our **code on our individual bottles** is done by laser. The code is printed on the bottom shoulder of the bottle in letters approximately 1/8th inch high. We use a two lines. It offers information on the date and time of production as well as offering a best by date suggestion.

Bottle Code Line One	LLCYYJJJ HHMMSS	WB119133 130433	Lot produced at Waiakea bottling plant in Hilo, Hawaii, in Julian Century of 2000, in the year of 2019, on May 13th , at 1:04 PM and 33 seconds
Bottle Code Line Two	ENJOY BY: MM/DD/YYYY	ENJOY BY: 05/13/2021	"ENJOY BY:" + [Date of Production + two calendar years] … May 13, 2021

LL	Location	WB=HILO
C	Julian Century	1900 = 0, 2000 = 1, 2100 = 2.
YY	Last two digits of year	2019 = 19
JJJ	Julian day	days since January 1 of current year

HH	Hours	(00-24)
MM	Minute	One = 01, 59 = 59
SS	Seconds	One = 01, 59 = 59

Our **case code** consist of one line with up to 14 characters 2" high by inkjet along the top – long side of case.

Box Code: (printed on side of box)	LCYYJJJsS HHMM	011913361 0804	Case produced in Hilo, Julian Century of 2000, in the year of 2019, containing 1L bottles, produced by 1st shift, at 8:04 AM

L	Location Identifier	0=Hilo
C	Julian Century	1900 = 0, 2000 = 1, 2100 = 2.
YY	Last two digits of year	
JJJ	Julian day	days since January 1 of current year

s	Size	1/6th of a L: 330ml = 2, 500ml = 3,700 = 4, 1L=6 1.5L =9
S	Shift Code	1=first, 2=second, 3=third
HH	Hours	(00-24)
MM	Minute	One = 01, 59 = 59

Our **code on our Pallet Sheet** consist of up to 8 lines including bar code via laser printer.

Company	Waiakea	Constant	L – Location – 0 = Hilo
Size	1L x 12 bottles	330ml/500ml/700ml/1L/1.5L	C – Julian Century – 1 for 2000
SRC (Source)	KAI	Constant	YY – Last two digits of year
Production Date	2019-05-13	Calendar date of production	JJJ – Julian day since January 1st
# Cases ! Skid #	70 14	# cases on pallet -- 14th skid of lot	s – Size of bottle (in 6th) 1/6th of a L: 330ml = 2, 500ml = 3,700 = 4, 1L=6 1.5L =9
Lot Number	011913361	LCYYJJJsS	
Bar Code	01191336114	Code represents the Lot Number + Skid Number	S – Shift … 1=first, 2=second, 3=third
Same Bar Code with extra spaces	0 1 1 9 1 3 3 6 1 1 4	Software driven code;	PP – Pallet/Skid number (embedded in bar code)

Translation: *This is Waiakea brand of bottled water utilizing the KAI source produced in Hilo, Hawaii on August 29, 2019 by the 1st shift. It contains 70 cases of 1 liter with each case having 12 bottles. It is the 14th skid.*

Mock Recalls

We periodically test the system to ensure that it will work if a recall is necessary. We call this a "mock recall." These mock recalls typically include verifying that the information in the recall plan is current and testing the recall team to determine if they can do what needs to be done if there was a recall. Tracing products and ingredients one step forward in the supply chain is also a part of our mock recalls, however, actual customers and suppliers are not contacted to avoid confusion.

Mock Recalls are performed in Q1 of each year. Refer to our Recall Plan and Mock Recall SOP for procedures and responsibilities as revised.

Customer Complaints

We believe tracking and acting upon Customer Complaints is part of our Recall Strategy and Quality process management. Watching the types of complaints and their frequency helps us to spot trends or incidents before they expand to cause harm to our consumers. We conduct an annual trend analysis for all complaints and non-conformance issues and request the same type of information from our co-packers.

We have internal procedures to follow from initial contact through the resolution of the issue.

If the complaint originates through our 800-phone number or other corporate contact, the issue will be sent via email to the Plant Manager or QC Manager depending on applicability. The facility will investigate and resolve, reporting back to corporate the final disposition.

If the complaint originates locally, the issue will be handled within the branch. Anything of a potentially serious nature including food safety or security related, is reported back to Corporate to senior management.

INTENTIONAL ADULTERATION CONTROLS

The ***FSMA Final Rule on Mitigation Strategies to Protect Food Against Intentional Adulteration of Human and Animal Food*** was published May 27, 2016 in the Federal Registry with effective date of July 26, 2016. The FDA has announced that businesses with more than $10,000,000 annual revenue and 500 employees need to comply by July of 2019 while companies with less than $10,000,000 in annual revenue and fewer than 500 hundred employees have until July 2020.

However, our business currently does less than $10,000,000. Thus, we are not required to comply with the requirements of the IA regulation.

We do have a Food Security Plan designed to protect against vulnerabilities.

Facility Food Defense Plan

In 2002, the U.S. Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act. As part of this the FDA issued several guidance documents intending to help deter intentional contamination. Our Food Defense plan (aka Food Security Plan) is contained in a separate document and is verified as part of our annual third-party audit by NSF.

Visitor's Procedures

Access to the Bottled Water facility is controlled.

- All visitors must enter through the office or other designated entry and sign visitors log and acknowledge visitor's policies. Individuals who make routine visits such as the same FedEx or UPS driver may receive a waiver from signing log on every visit. All first-time visitors must register.
- No visitor may walk around the premises without chaperoned unless authorized by the manager in charge and wearing some type of identifying garment that makes their non-employee status clear and observable.
- No visitor (including contractor, repair person or auditor/inspector) may enter a production area without the appropriate personal protective equipment (e.g. hairnet, clean hands, etc.).
- All employees are trained as part of their basic food safety curriculum to report to senior manager on duty any suspicious activity observed of any individual including employee or visitors.
- All visitors and employees must adhere to the Accident Reporting and First Aid Procedures.

MANAGING CONTROLS

Monitoring

Part §117.145 addressed the requirement to incorporate within the Preventative Control rules written procedures on "planned sequence of observations or measurements to assess whether control measures are operating as intended" also known as "monitoring".

Monitoring procedures must be written, including the frequency with which they are to be performed to provide assurance that they are consistently performed.

Monitoring observations must be recorded and depending on their nature and importance may be subject to verification.

Exception records that record monitoring only when the controls are exceeded can be acceptable but must be appropriate to the nature of the control.

The monitoring system must test the specified parameter for the designated control, so that the operation can proceed when the critical limits are being met.

We answer four questions when we establish our monitoring:

1. What will be monitored?

   What we monitor is directly related to control of the hazard. For example, for process controls we monitor parameters to ensure the minimum/maximum values are met. For other preventive controls, we sometimes monitor that the activity has been conducted consistent with a defined procedure.

2. How will monitoring be done?

   Continuous monitoring is always preferable. When it is not necessary or practical, we monitor often enough that the normal variability in the values we are measuring can be determined and a deviation from normal will be detected. Even with continuous monitoring, we periodically check and sometimes confirm by another type of measurement.

3. How often will monitoring be done (frequency)?

   We check as often as necessary but vary it based on what we are measuring, how it is done and our resources to complete it. It is always at least daily and anytime water is being produced.

   Parameters such as room temperature for various sections of the plant are monitored at the beginning, scheduled mid-point and end of shift along with any other time that an operating parameter is perceived to be outside the expected range.

   When we find a measurement showing that a deviation from the control value has occurred, we should assume that the control value had not been met since the last check in which the value was acceptable. As a result, the greater the time span between measurements, the more products we are putting at risk.

4. Who will do the monitoring.

   We specify in the written procedures the position of the employee who will do the monitoring and describe how they are to perform the monitoring procedure. We then make sure the individual is properly trained.

5. What type of measurements.

   To the extent possible all measurements should be defined as data points rather than subjective observations. Example would be for temperature where an upper/lower limit would be established and observations acceptable within that range. Allowances for aberrations are outlined in training such as a door remaining open during a loading in of materials which causes a temporary but expected deviation from the target range.

Corrective Actions

Part §117.150 addressed the requirement to incorporate within the Preventative Control rules written procedures on what is to be done when monitoring of a control fall outside of the control limits. This is known as "Corrective Actions".

We view Corrective Actions in two contexts.

First, in relation to a Preventive Control, setting forth a predetermined course of action to follow in the event the control limits are exceeded. The focus is to have already thought through the possible consequences and options so that staff is acting to immediately contain the hazard and seize control of any potentially contaminated product. ***Act first, analyze second***.

When critical limit(s) is exceeded, or a non-conforming environment created, a corrective action must be taken to avoid producing unsafe product. This may involve an immediate adjustment in the process to bring the product within the Critical Limits, or it may involve a complete stoppage of production until the problem is corrected. In some cases, a recall may be required in conjunction with the corrective action(s).

We have predetermined responses that staff are trained on before they could potentially occur.

Second is a deviation from what is expected or should be the situation. It relates to a broader range of events linked to anytime something happens or is observed that should not occur. This could be a sudden failure, unanticipated hazard or lapse in GMP/PRP programs thought to be in place. The emphasis is on determining not only what happened, but the cause and the solution to preventing it from occurring again. Accountability is assigned based on the circumstances and available resources. It may be almost instantaneous in its solution or could require systemic changes. ***Analyze first, act second***.

The non-conformances can be in a GMP control or the breakdown of a piece of equipment. Using a consistent approach helps to enculturate our team on the importance of 'closing the loop' each time something deviates from our expectations.

Our methodology embedded in our form called a "Corrective Action Report" follows these steps:

1. Explanation of unusual occurrence, deviation, non-conformance or breech of control
2. Root Cause Analysis … why did it occur?
3. Corrective Action Plan … how we fix it
4. Preventive Action Plan … how we make sure it does not happen again
5. Who is responsible person … accountability
6. Completion Date … can have short and long term dates
7. Supporting documents … photos, work orders, test data, etc.

During our next Food Safety team meeting, we will do a post-mortem on each Corrective Action, regardless of the type, to determine if we need to make changes to our Food Safety Plan and System. We will also confirm that the completion dates for making corrections are on track.

The FORM we use for this is SOP-20 Corrective Actions.

Validation

- Critical review of the hazard analysis for depth and accuracy?
  Yes. The Team has confirmed this was accomplished.

- Were the correct PPC/CCPs chosen?
  Yes. The Team has confirmed this was accomplished.

- Are critical limits meaningful and actionable?
  Yes. The Team has confirmed this was accomplished.

- Are monitoring activities sufficient?
  Yes. The Team has confirmed this was accomplished.

- Are the correct parameters monitored at the correct frequency?
  Yes. The Team has confirmed this was accomplished.

The Team will review and redo as necessary any of the Validations based on this table:

Activity	Frequency	Responsibility	Reviewer
Were all hazards considered?	Yearly or when Critical Limits changed, significant changes to process, equipment changed, after system failure, etc.	Food Safety Team	Plant Manager, Quality Manager & Preventative Controls Qualified Individual
Were correct PPCs (CCP's) chosen?	Yearly or when Critical Limits changed, significant changes to process, equipment changed, after system failure, etc.	Food Safety Team	Plant Manager, Quality Manager & Preventative Controls Qualified Individual
Are Critical Limits meaningful/ actionable?	Yearly or when Critical Limits changed, significant changes to process, equipment changed, after system failure, etc.	Food Safety Team	Plant Manager, Quality Manager & Preventative Controls Qualified Individual
Are the correct parameters monitored at the correct frequency?	Yearly or when Critical Limits changed, significant changes to process, equipment changed, after system failure, etc.	Food Safety Team	Plant Manager, Quality Manager & Preventative Controls Qualified Individual

During the first quarter our Food Safety team determines if any conditions have occurred that would trigger a reassessment. If nothing of significance is noted, the PCQI will do a general review of the Plan and insure the plan has been reviewed by the designated management authority and the PCQI.

Note: Our Quality team and plant staff completed self-validation of our Tanker Cleaning procedures. This was done because there are no commercial truck wash businesses operating on the island of Hawaii.

UV Validation

Credible science-based information has established that when bacteria, viruses and protozoa are exposed to ozone, they are rendered incapable of reproducing and infecting. UV has demonstrated efficacy against pathogenic organisms, including those responsible for cholera, polio, typhoid, hepatitis, Giardia, Cryptosporidium and other bacterial, viral and parasitic diseases.

The contents listed in our summary document is available on request and is kept at our office in the facility.

Waiakea deploys two Atlantium UV units both of which are certified for 4-log reduction of virus.

The RZ-104 unit that is installed at the bottling plant is our Process Preventive Control.

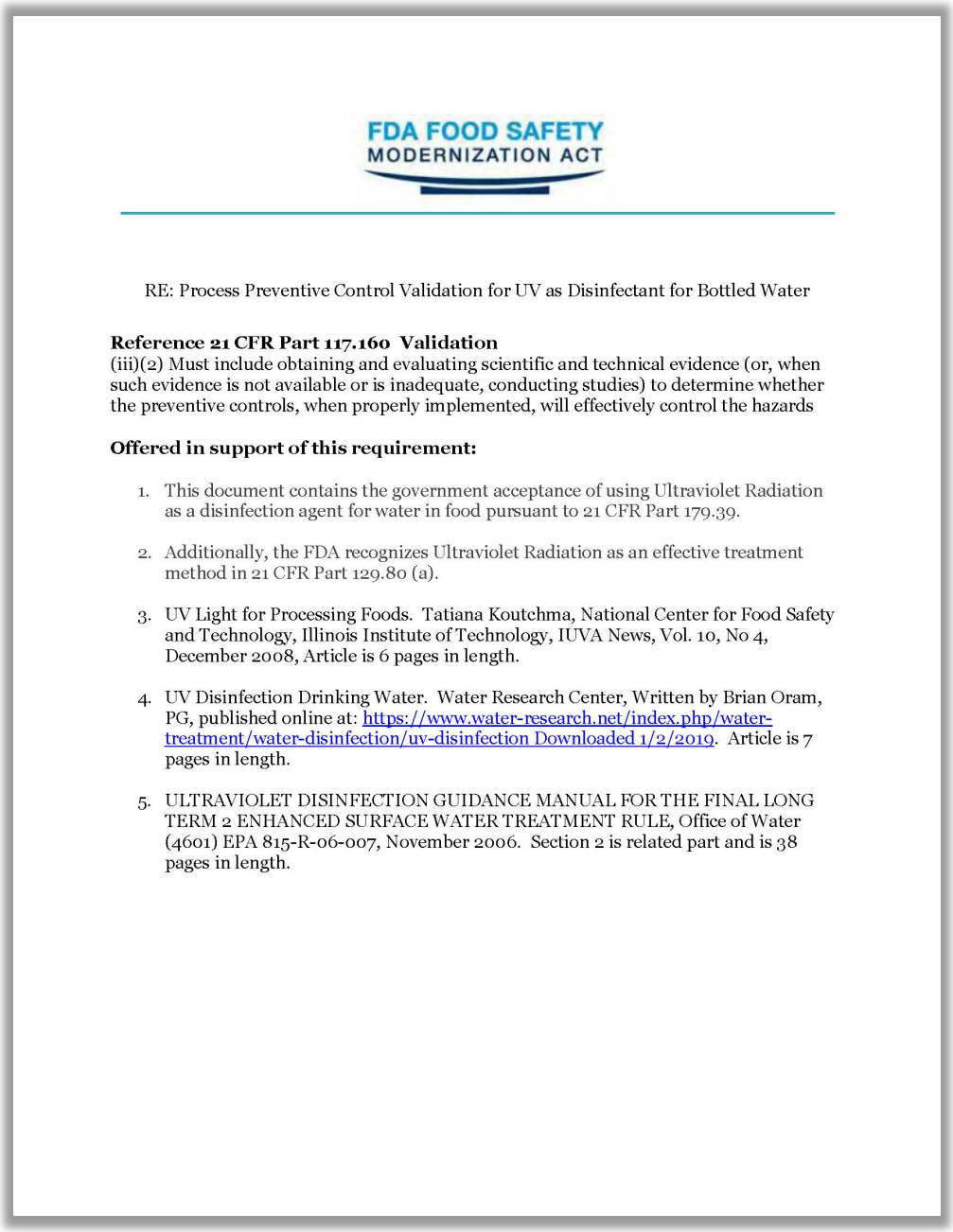
The 2nd unit, RZ-163, is installed at the Kai Well Site. It treats all water before it is loaded on our dedicated water tanker.

Documents confirming the accreditation are available on request.

1st: The inflow of water first goes through Flow Control insuring no more than 40 Gallons per minute is sent to the UV units.

2nd: Each of the Atlantium's are equipped with an electronic metering systems and software.

3rd: Each unit is tied electronically to a Diverter valve that in the event of a system failure causes the water to either stop flowing or be diverted from the product flow.



FDA FOOD SAFETY MODERNIZATION ACT

RE: Process Preventive Control Validation for UV as Disinfectant for Bottled Water

Reference 21 CFR Part 117.160 Validation
(iii)(2) Must include obtaining and evaluating scientific and technical evidence (or, when such evidence is not available or is inadequate, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards

Offered in support of this requirement:

1. This document contains the government acceptance of using Ultraviolet Radiation as a disinfection agent for water in food pursuant to 21 CFR Part 179.39.
2. Additionally, the FDA recognizes Ultraviolet Radiation as an effective treatment method in 21 CFR Part 129.80 (a).
3. UV Light for Processing Foods. Tatiana Koutchma, National Center for Food Safety and Technology, Illinois Institute of Technology, IUVA News, Vol. 10, No 4, December 2008, Article is 6 pages in length.
4. UV Disinfection Drinking Water. Water Research Center, Written by Brian Oram, PG, published online at: https://www.water-research.net/index.php/water-treatment/water-disinfection/uv-disinfection Downloaded 1/2/2019. Article is 7 pages in length.
5. ULTRAVIOLET DISINFECTION GUIDANCE MANUAL FOR THE FINAL LONG TERM 2 ENHANCED SURFACE WATER TREATMENT RULE, Office of Water (4601) EPA 815-R-06-007, November 2006. Section 2 is related part and is 38 pages in length.

Conclusion: The UV germicidal wavelengths generated by each of the two Atlantium units delivers in excess of a validated 4-log reduction for target organisms.

A copy of the Validation and installation reports may be seen on request.

HDR | HydroQual

Atlantium Technologies Ltd.
Bet Shemesh, Israel

VALIDATION REPORT FOR THE
ATLANTIUM RZ104-11 and RZ104-12
HYDRO-OPTIC WATER DISINFECTION SYSTEMS

USEPA ULTRAV

Hennings

VALIDATION TEST CERTIFICATION

Atlantium Technologies Ltd. RZ104 Series Hydro Optic Disinfection Systems

This is to certify that validation testing has been satisfactorily completed for the Atlantium RZ104-11 and RZ104-12 Hydro Optic Disinfection Systems in compliance with the USEPA Ultraviolet Disinfection Guidance Manual (UVDGM, November 2006). The test plan for this validation (November 2008) was written by HydroQual Environmental Engineers and Scientists, P.C., which is now Henningson, Durham & Richardson Architecture and Engineering, P.C. (HDR|HydroQual), and approved for implementation by Atlantium Technologies. In addition, a validation for virus disinfection credit based on challenge testing with live adenovirus was performed as part of the validation program. The test plan for this validation was written by HDR|HydroQual, Dr. Karl Linden of the University of Colorado at Boulder, Dr. Chuck Gerba and Dr. Akrum Tamimi of the University of Arizona and approved for implementation by Atlantium Technologies.

HDR|HydroQual conducted all testing, sampling and analysis, data analysis and documentation, and prepared this final validation report, which compiles the results of the validation tests and presents the validated performance summary for the subject system. The calculation of the validation factor for credited RED and log inactivation is in conformance with the UVDGM. The RZ104 was validated with one- (RZ104-11) and two-lamp (RZ104-12) configurations for modularity over a range of flow rates, feed water UV transmittances, and power levels to encompass a wide range of MS2, QB and T1UV coliphage reduction equivalent doses (RED) between 8.7 and 161.0 mJ/cm^2.

Testing defined the operating envelope for disinfection credits under the Long Term Enhanced Surface Water Treatment Rule (LT2): For the RZ104-11 Hydro Optic Disinfection system, this is between 10 and 605 gpm (2.35 to 137.48 m^3/hr), 77.9 and 97.3 %/cm UVT and 40 to 100% input power; For the RZ104-12 system it is between 16 and 601 gpm (3.60 to 136.64 m^3/hr), 79.2 and 97.3 %/cm UVT and 40 to 100% input power.

In addition, validation biodosimetry using a live strain of Adenovirus 2 was conducted on the RZ104 reactor. These results demonstrate that the UV reactor is able to accomplish 4-log virus inactivation as required by the UVDGM dose requirements Table 1-4. The Adenovirus validation is restricted to UVTs 85.3% and above, power levels between 40 and 100%, and flows between 44 and 248 gpm.

Henningson, Durham & Richardson Architecture and Engineering, P.C.
HDR|HydroQual
Mahwah, NJ 07430

O. Karl Scheible — Date: November 7, 2013
O. Karl Scheible, UV Center Managing Director

Chengyue Shen — Date: November 7, 2013
Chengyue Shen, P.E., Ph.D., UV Center Technical Director

CONFIDENTIAL: Atlantium RZ104-11 and RZ104-12 V2.1 November 2013

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VALIDATION TEST CERTIFICATION

Atlantium Technologies Ltd. RZ163 Series Hydro Optic Disinfection Systems

This is to certify that validation testing has been satisfactorily completed for the Atlantium RZ163 Series Hydro Optic Disinfection Systems, equipped with Atlantium newly developed 3-kW medium-pressure UV lamps, in compliance with the USEPA Ultraviolet Disinfection Guidance Manual (UVDGM, November 2006).

As an independent validation consultant with extensive experience in validating UV systems, I developed the Test Plan including full validation for *Cryptosporidium*, *Giardia* and virus EPA credits based on microbial challenges with MS2, T1UV and live Adenovirus, and directed the scientific and engineering teams that conducted the field testing at the HDR UV Technology Validation Center in Johnstown, NY. Bacteriophage sample analysis was conducted by GAP EnviroMicrobial Laboratory. The Principal Investigator and site manager for the full live adenovirus challenge testing and validation was Dr. Karl Linden. Adenovirus stock preparation and sample assay were all conducted by Dr. Charles Gerba and his virus laboratory at Arizona State University. The calculation of the validation factors for credited RED and log inactivation is in conformance with the UVDGM. I am currently finalizing the documentation and the full validation report.

The RZ163 Series was validated with one and two lamps and various piping configurations for modularity over a broad range of conditions to encompass a wide range of MS2, T1UV and Adenovirus reduction equivalent doses in accordance with UV dose requirements that meet EPA Standards.

The validated operational envelope covers the full RZ163 Series (RZ163-11, RZ163-12, RZ163-13, RZ163-14, and etc.) from 55.6% to >99% UVT (at 254 nm), 50 to 1697 gpm (11.4 to 385.3 m^3/hr) flow, and 30% to 100% nominal lamp input power. Based on the validation results, the Atlantium RZ163 (with 3-kW lamps) Disinfection Systems can deliver sufficient dose to achieve 4-log adenovirus inactivation, which provides a credited dose of 186 mJ/cm^2 per the UVDGM requirement.

Date: April 8, 2019

Chengyue Shen, Ph.D., P.E

About Chengyue Shen Consulting

Chengyue Shen has more than 12 years of experience with over 80 UV validations in compliance with UVDGM, NWRI, as well as state-specific validation protocols.

CHENGYUE SHEN
Consulting

161 Frank Ln
Paramus, NJ 07652

Phone: 413-354-4999
E-mail: **shenchengyue@hotmail.com**

Verification

1. We have conducted an internal audit to confirm the Food Safety Plan is being followed as written.
2. We have confirmed the operators are trained and have competence with respect to monitoring our PPC/CCP and addressing out-of-compliance occurrences.
3. Critical records are reviewed by the Plant Manager weekly. Those requiring review by a PCQI are done within 7 business days.
4. GMP and Prerequisite Programs have been spot-checked. Deficiencies are being managed through Corrective Actions.

Activity	Frequency	Responsibility	Reviewer
Initial Review of Food Safety Plan	Prior to and during initial implementation of plan	Food Safety & Compliance Consultant	GM, Quality Manager & Preventative Controls Qualified Individual
Verification Activities Scheduling	Has been done as the Plan has been implemented; will also be done in January of each year or any significant change in process.	Plant Manager & Preventative Controls Qualified Individual	GM, Quality Manager & Preventative Controls Qualified Individual
Subsequent Review of Food Safety Plan	When Critical Limits changed, significant changes to process, equipment changed, after system failure, etc.	Food Safety & Compliance Consultant	GM, Quality Manager & Preventative Controls Qualified Individual
Verification of PPC/CCP Monitoring as Described in the Plan	According to Food Safety Plan	According to Food Safety Plan	GM, Quality Manager & Preventative Controls Qualified Individual
Review of Monitoring Corrective Action Records to Show Compliance with the Plan	Quarterly	Food Safety Team	GM, Quality Manager & Preventative Controls Qualified Individual
Comprehensive Food Safety System Verification - External Audit	Yearly	3rd Party Auditor	GM, Quality Manager & Preventative Controls Qualified Individual

We use Internal audits to help identify the strengths and weaknesses of our food safety system and discover areas for improvement before an external audit occurs. All non-conformances are reviewed by the facility and addressed via Corrective Action Report.

We use analytical testing as a means of verification where appropriate.

Our outside labs are:

Daily/Weekly Micro Testing

Aecos
45-939 Kamehameha Highway
Suite 104
Kaneohe, Oahu, HI 96744
Phone: (808) 243-7770
Fax:(808) 234-7775

Other – Annual

Eurofins
750 Royal Oaks Drive
Suite 100
Monrovia, CA 91016-3629
Phone: (626) 386-1250
Fax: (626) 386-1101

GMP & PREREQUISITE CONTROLS

We have developed programs to insure compliance with all applicable GMPs. Our programs help us operate in a proactive manor that is both operational and preventative. We believe many hazards are prevented from occurring or are reduced to a manageable level before they ever come close to becoming critical or in need of specific Process Preventative Control management through effective design and execution of Work Instructions which include our Policy statements, Diagrams, Forms, Checklists, Logs, SSOP's & SOPs.

Subpart A – General Provisions

1)	§ 117.0	Food Safety Plan
2)	§ 117.4	Qualifications of individuals [Training] **Training -** General principles, Application to our facility and product, **Al**lergens and personal hygiene, **Preventive Controls – M**onitoring, CA's, verification and records, **Technical** - training appropriate to the task or equipment, **PCQI** – qualified individual

Subpart B – Good Manufacturing Practices

3)	§ 117.10	Personnel
4)	§ 117.20 § 129.20	Plant and grounds, Plant construction and design … [Building, Lighting, Air, Waste, Facilities]
5)	§ 117.35 § 129.37	Sanitary operations … [Pest Control and Chemical Control] Sanitary operations
6)	§ 117.37 § 129.35 § 165.110(a)	Sanitary facilities and controls Sanitary facilities Water Sources and Treatment
7)	§ 117.40 § 129.40	Equipment and utensils Equipment and procedures
8)	§ 117.80 § 129.80	Processes and controls Processes and controls
9)	§ 117.93	Warehousing and distribution … [Sanitary Transportation]

Subpart C—Hazard Analysis and Risk-Based Preventive Controls

10)	§ 117.139	Recall Plan
11)	§ 117.165(1)	Calibration
12)	§ 117.165(2) § 165.110	Testing … [Laboratory Management] Testing

Subpart F - Records

13)	§ 117.305 § 117.315	General requirements applying to records Requirements for record retention

Subpart G – Supply Chain Program

14)	§ 117.405-475	General requirements applying to records
15)	§ 117.315	Requirements for record retention

Other – Intentional Adulteration

16)	§ 11 & § 121	Food Defense Plan, Vulnerability Assessment, Mitigation Strategies

Other – Sanitary Transportation

17)	§ 1.906	Sanitary Transportation – vehicle requirements (including tankers)

Compliance with the above sections of the regulations is the responsibility of the individual employee(s) assigned. The Quality Manager, along with our Preventative Controls Qualified Individual, has the day-to-day responsibility for ensuring all programs are or have been followed and that the assigned person(s) is adequately trained, coached and supervised.

WORK INSTRUCTIONS

Work Instructions are an umbrella for the documents we have created to describe how to accomplish a specific job as well as the forms and other documents used to create records, checklists, surveys, or other documentation.

Document Title	Document Number
Policies	
Management Letter of Commitment to Food Safety	*Contained within Food Safety Plan – Preliminary Steps*
Scope of Food Safety Document	*Contained within Food Safety Plan – Preliminary Steps*
Allergen Policy	*Contained within Food Safety Plan – Allergens Section*
Visitor's Policy - General	*Summary Contained within Food Safety Plan – Visitor's Section*
Visitor's Policy	*Stand-alone SOP 8 – Policy and Procedures related to Visitors*
Record Retention Policy	*Contained within Food Safety Plan – Record Retention Section*
Gloves Policy	*Stand-alone Policy #15 – Gloves*
Personnel Items and Storage Policy	*Stand-alone Policy #16 – Personnel Items and Storage*
Personnel Hygiene Practices Policy	*Stand-alone Policy #17 – Personnel Hygiene Practices*
Scrap Material Procedures Policy	*Stand-alone Policy #18 – Scrap Material Procedures*
Diagrams	
§ 117 – Food Safety Plan	
Process Flow Diagrams	*Contained within Food Safety Plan*
Plant Schematic Diagram	*Contained within Food Safety Plan*
Plant Schematic for Hygienic Zoning	*Contained within Food Safety Plan*
CIP Diagrams	*Contained within Food Safety Plan*
Product Disinfection Diagrams	*Contained within Food Safety Plan*
Forms	
§ 117 – Food Safety Plan	
Employee Training Record	*SOP 4 – FORM for Employee Training*
Corrective Action Form	*SOP 2 – FORM for Corrective Action*
Periodic Food Safety Meeting Form	*SOP 10 – FORM for Periodic Food Safety Meetings*
§ 117.10 Personnel	
FORM for Employee Training	*SOP 4 – FORM for Employee Training*
§ 117.20 Plant and grounds	
Visitor's Log	*SOP 8 – FORM for Visitors LOG – Kept in Office*
§ 117.37 – Sanitary Facilities and Controls	
Pest Control Inspection for Facility	*SOP 38a – FORM for Pest Control Inspection of HILO Production*
Pest Control Inspection for Well Site	*SOP 38b – FORM for Pest Control Inspection of KAI WELL SITE*
§ 117.40 Equipment and utensils	
Preventative Maintenance Repair Work Order	*SOP 40 – FORM for Preventive Maintenance Repair Work Order*
§ 117.110 – Defect action levels	
Customer Complaint Form	*SOP 3 – FORM for Customer Complaints*
§ 117.135-139 – Recall Preventive Controls	
Mock Recall Exercise	*SOP 139 – FORM for Mock Recall Traceability Exercise*
§ 117.165 – Testing & Calibration	
…Daily Incubator Accuracy Checks	*SOP 9 – FORM Daily Incubator Accuracy Checks LOG*
§ 117.405-475 – Supply Chain	
Supplier Information Form	*SOP 5 – FORM for Supplier Information*
Checklists	
§ 117.37 – Sanitary Facilities and Controls	
Water Tanker Washing	*CHECKLIST 12 – Wash Ticket for Bulk Water Tanker*
Cleaning & Sanitizing Production Facility	*CHECKLIST 20 – Daily Sanitation Production Facility*
Cleaning & Sanitizing Water Treatment	*CHECKLIST 37 – Water Treatment Sanitation Checklist*
§ 117.80 – Processes and Controls	
Daily Start Up/Changeover/Shut Down Checklist #1	CHECKLIST 1 – Startup-Changeover-Shutdown
Daily Batch Production Checklist #2	CHECKLIST 2 – Daily Batch Production
Daily Quality Checks Checklist #3	CHECKLIST 3 – Daily Quality Checks
Water Treatment Quality Checklist #4	CHECKLIST 4 – Water Treatment Quality Checks
Daily Process Preventive Control Checklist #5	CHECKLIST 5 – Daily Process Preventive Control
Atlantium UV System Parameters Checklist #7	CHECKLIST 7 – Atlantium UV System Parameters
Unloading-Receiving Tanker Checklist #10	CHECKLIST 10 – Unloading Receiving Tanker
Logs	
§ 117.80 – Processes and Controls	
…LOG for INCOMING Bottled Water Raw Materials	SOP 80 – LOG for Incoming BW Raw Materials
§ 117.135-139 – Recall Preventive Controls	
Incident Tracking Log	*SOP 139 – LOG Incident Tracking Log*
§ 117.165 – Testing & Calibration	
Batch Product Testing Log	SOP 165 – Product Testing LOG
Instrument Calibration & Accuracy Checks Log	SOP 11 – LOG for Instrument Calibration

Sanitary Standard Operating Procedures (SSOPs)

These are designed to ensure proper cleaning and sanitation of equipment and food contact surfaces.

Document Title	Document Number
§ 117.10 - Personnel	
None specific to this part	*Not Applicable*
§ 117.20 – Plant and Grounds	
Facility Cleaning Procedure	*SSOP 20 – Procedures for Cleaning-Sanitizing Building and Grounds*
Restroom Cleaning and Sanitizing Procedure	*Included in SSOP - 20*
§ 117.35 – Sanitary Operations	
Master Sanitation Program	*SSOP 35 – Procedures for Master Sanitation Program*
Master Sanitation Program LIST of Tasks	*SSOP 35 – LIST of TASKS for Master Sanitation Program*
Hygiene zoning	*See Food Safety Plan – Sanitation Preventive Controls*
§ 117.37 – Sanitary Facilities and Controls	
KAI Well Source Sanitation Procedures	*SSOP 36 – Procedures for Clean-In-Place (CIP) for Kai Well*
KAI Well Source Sanitation Parameter Calculations	*SSOP 36A - Calculation of water volume in Well for sanitizing analysis*
§ 117.40 – Equipment and Utensils	
Well Site	
- Bag Filter	
- UV Atlantium – RZ163 (at source)	Cross Reference SOP 41E – Preventive Maintenance, Cleaning and Sanitizing Atlantium RZ 163
Bottling Facility Treatment	
Water Treatment inside Facility Procedures - Storage tank for Kai Well Water - 5 Micron Filter - 0.2 Micron Filter - HESS Buffer Tank - Santa Rosa Ozone Contact Tank - Atlantium RZ 104 - Water Pipping - Pumps - Air Handling for water storage tank	*SSOP 37 – Procedures for Cleaning-Sanitizing-CIP Treatment Inside Facility*
Bottling	
- 3-in-1 Monoblock including Cap Hopper - Filler Room - Air Blade - Laser Coder - Accumulation Tables - Box Erector - Case Packer - Case Coder - Pallet Wrapper	*SSOP 39 – Procedures for Cleaning-Sanitizing Bottling-Packaging*
Disinfection Product Water	
Treatment – UV Atlantium – RZ104	Cross Reference SOP 41F – Preventive Maintenance, Cleaning and Sanitizing Atlantium RZ 104
Atlas Ozone System	
§ 117.80 – Processes and Controls	
Tanker loading	*SSOP 11 – Procedures for Kai Source Tanker Filling*
§ 117.93 – Warehousing and Distribution	
Warehouse cleaning procedure	*Cross Reference SSOP 20 – Procedures for Cleaning-Sanitizing Building and Grounds*
§ 117.165(2)–Testing (& Laboratory Management)	
…Laboratory Cleaning & Sanitation	*Cross Reference SSOP 20 – Procedures for Cleaning-Sanitizing Building and Grounds*
§ 1.906(b)–Sanitary Transportation	
Tanker Wash Procedures	SSOP 906 – Washer Tanker Wash

Standard Operating Procedures (SOPs)

Compliance with these procedures is the responsibility of the assigned individual; some may require manager signoff.

Document Title	Document Number
§ 117.4 – Qualifications of individuals [Training]	
Procedures for Employee Training	*SOP4 – Procedures for Employee Training*
Preventive Controls Training, Technical Training	*Done individually as necessary by supervisor*
§ 117.10 - Personnel	
Employee Handbook – Sick Policy Section	*Reference HR Employee Handbook*
Accident Reporting and First Aid Procedures	*Reference HR Employee Handbook*
§ 117.20 – Plant and Grounds	
Lighting-illumination Procedures	*Copy available on request*
Procedures for Visitor's	*SOP 8 – Procedures for Visitors*
§ 117.35 – Sanitary Operations	
SDS Sheets	*Notebook kept on the Production Floor with SDS sheets*
§ 117.37 – Sanitary Facilities and Controls	
Water Testing Program	*Copy available on request*
Chemical Control	SOP 37 – Procedures for Chemical Control
Chemical SDS List	SOP 371 – LIST of Chemicals requiring SDS Sheets
Procedures for Pest Control	*SOP 38 – Procedures for Pest Control*
Pest Control Company – PCO Manual	*Kept in Manager's office*
§ 117.40 – Equipment and Utensils	
Equipment User manuals on file at facility	*Kept in file in Manager's office*
Preventive Maintenance Program	*SOP 40 – Procedures for Preventive Maintenance Program*
Preventive Maintenance Program List of Equipment	*SOP 40 – LIST of Tasks for Preventive Maintenance Program*
Procedures for Preventive Maintenance 3-in-1 Monoblock Filler	*SOP 41A – PM for 3-in-1 Filler Monoblock*
Procedures for Preventive Maintenance Atlas Ozone	*SOP 41B – Atlas Ozone PM Procedures*
Procedures for Preventive Maintenance 5 micron	*SOP 41C – 5-Micron PM Procedures*
Procedures for Preventive Maintenance 0.2 micron	*SOP 41D – 0.2 Micron PM Procedures*
Procedures for Preventive Maintenance Atlantium RZ 163 (at source)	SOP 41E – Preventive Maintenance, Cleaning and Sanitizing Atlantium RZ 163
Procedures for Preventive Maintenance Atlantium RZ 104 (at plant)	SOP 41F – Preventive Maintenance, Cleaning and Sanitizing Atlantium RZ 104
Procedures for Preventive Maintenance Bag Filter (at source)	*SOP 41G – Bag Filter at the Kai Source PM Procedures*
§ 117.80 – Processes and Controls	
Procedures for BW Raw Materials Handling	*SOP 80 – Procedures for BW Raw Materials Handling*
Supplier Assurance and Information Program	*SOP 5 – Procedures for Supplier Assurance*
§ 117.93 – Warehousing and Distribution	
Warehouse Management program	*Copy available on request*
§ 117.110 – Defect action levels	
Customer Complaint Procedures	*SOP 3 – Procedures for Customer Complaints*
…Blow Molding Inspection (prior to rinsing)	*SOP 6 – Procedure for Bottle Inspection*
§ 117.135(c)(5) – Recall Preventive Controls	
Recall Plan	*SOP-139 Waiakea Recall Plan*
Mock Recall	*Reference Food Safety Plan – Mock Recalls*
Product Date Coding and Traceability	*Reference Food Safety Plan – Traceability*
§ 117.165 – Verification of implementation and effectiveness	
Internal Audits	*Reference NSF GMP/Food Safety audit checklist template*
§ 117.165(a)(1) - Calibration	
Calibration Procedures (cross reference calibration log)	*Copy available on request*
Procedures for Instrument Calibration	*SOP 11 – Procedure for Instrument Calibration*
List of Instruments for Calibration and Accuracy Checks	*SOP 11 – LIST for Instrument Calibration and Accuracy Checks*
…Procedures for Daily Incubator Accuracy Checks	SOP 9 – Procedures for Incubator Accuracy Checks
§ 117.165(2) – Testing (& Laboratory Management)	
Procedures for 24 HR Product Hold	*SOP 7 – Procedures for 24 HR Product Hold*
Procedures for Product Testing	*SOP 165 – Procedures for Testing*
Procedures for Retained Samples	*SOP 166 – Procedures for Retained Samples*
§ 117.305 – General Requirements applying to records	
Document Standards	*SOP 1 – Procedures for Document Standards*
§ 117.405-475 – Supply Chain	
Procedures for Supplier Information	*SOP 5 – Procedures for Supplier Information*
List of Authorized Suppliers	*SOP 5 – LIST of Authorized Suppliers*
§ 11 and § 121 – Intentional Adulteration	
Food Security Plan	*SOP 121-11 – Food Security Plan*

APPENDIX - SUPPLEMENTAL DOCUMENTS

Note: Waiakea does NOT use public water for any product. It is only used for operations water. There is no physical connection anywhere in our plumbing between our Kai Well source water and the public water source.

Supplemental Information on Water Sources for Bottling Facility

PWSID: HI0000101
DWS HILO
345 Kekuanaoa Street, Suite 20, Hilo, HI 96720
(808) 961-8050
Source of water: Ground
The facility is connected to the public water system of Hilo for purposes of Operations water (for toilets, handwashing sinks, etc.)

https://www.hawaiidws.org/
The sources of water that are normally used for the Hilo Water System are Pana'ewa Well Nos. 1, 2 and 3, Pi'ihonua Well Nos. A, B, and C, and Saddle Road Well "A" (all of which are groundwater sources). In addition to the wells listed above, on November 30, 2016, the UH Hilo Well was activated for use in the Hilo Water System. These source(s) may change depending on the supply and demand.

Minimal reporting data

Supplemental Information on Water Sources for Kai Well Site

PWSID: HI0000101
DWS HILO
345 Kekuanaoa Street, Suite 20, Hilo, HI 96720
(808) 961-8050
Source of water: Ground
The facility is connected to the public water system of Hilo for purposes of Operations water (for toilets, handwashing sinks, etc.)

https://www.hawaiidws.org/
The sources of water that are normally used for the Hilo Water System are Pana'ewa Well Nos. 1, 2 and 3, Pi'ihonua Well Nos. A, B, and C, and Saddle Road Well "A" (all of which are groundwater sources). In addition to the wells listed above, on November 30, 2016, the UH Hilo Well was activated for use in the Hilo Water System. These source(s) may change depending on the supply and demand.

Minimal reporting data

Abbreviations Commonly used in Food Safety

Abbreviation	Full Description	Abbreviation	Full Description
µ	Micron	NSRL	No Significant Risk Level
APC	Allergen Preventive Control	O3	Ozone
BrO3	Bromate	PArg	Pseudomonas Aeruginosa
CCP	**C**ritical **C**ontrol **P**oint (Now known as **P**reventative **P**rocess **C**ontrol)	PC	Process Control (Not necessarily a Preventive Control)
CDC	Centers for Disease Control and Prevention	PC	Preventative Control
COA, CA	Certificate of Analysis	PC	Polycarbonate resin (Recycling symbol 7)
CONEG	Coalition of Northeast Governors (CT, ME, MA, NH, NJ, NY, RI, VT)	PFOA PFOB	Perfluorooctanoic acid (fire retardant) Perfluorooctylbromide (PFOB)
CP	Control Process	PCHF	Preventive Controls for Human Foods
CPSC	Consumer Product Safety Commission	rPET	Recycled PET resin
Crypto	Cryptosporidium	PET & Components	PE = 'polymerized Ethylene'; T = terephthalate; (terephthalic acid + ethylene glycol)
DBP	Disinfection byproduct	PCQI	Preventive Controls Qualified Individual
DI	Deionized Water	PIQCS	Packaged Ice Quality Control Standards
Enero	Enteroviruses	PP	Polypropylene (Recycling symbol 5)
EPA	Environmental Protection Agency	PPC	**P**reventative **P**rocess **C**ontrol a.k.a. Critical Control Point
FCS	Food Contact Substances	Prop 65	California Proposition 65 aka Safe Drinking Water and Toxic Enforcement Act of 1986
FDA	U.S. Food & Drug Administration	PRP	Prerequisite Program
FSMA	Food Safety Modernization Act of 2011	PSI	Pressure pounds per square inch
FSP	Food Safety Plan.	PWS	Public Water Supply
GFSI	Global Food Safety Initiative Certifications (SQF, BRC, Etc.)	PWSID	Public Water Supply Identification Number (issued by EPA).
GLamb	Giardia lamblia	RO	Reverse Osmosis
GMP	Good Manufacturing Practice	SCPC	Supply Chain Preventive Control
GMP Control	Good Manufacturing Practice Controls that are not critical	SDS	Safety Data Sheets
HAA's/HAA-5	Haloacetic Acids	SSOP	Sanitary Standard Operating Procedure
HDPE	High-Density Polyethylene (Recycling symbol 2)	SOP	Standard Operating Procedure
HR	Human Resources	SPC	Sanitation Preventive Control
HACCP	Hazard Analysis and Critical Control Points	STC	Sanitary Transportation Controls
HARPC	Hazard Analysis and Risk-Based Preventive Controls	TC	Total Coliform
Heavy Metals	Cadmium, mercury, lead arsenic, chromium	TC/E	Total Coliform / E. Coli
HPC	heterotrophic plate count of bacteria	TDS	Total Dissolved Solids
Incl	Include	THM's/TTHM's	Total Trihalomethanes
IBWA	International Bottled Water Association	TPC	Total Plate count (same as HPC)
LDPE	Low-Density Polyethylene (Recycling symbol 4)	UCMR	Unregulated Contaminant Monitoring Rule (EPA)
LG LCW	Letter of Guarantee Letter of Continuing Warranty	UHMW	Ultra-High Molecular Weight Polyethylene (recycling symbol 2)
LLDPE	Linear Low-Density Polyethylene (Recycling symbol 4)	Unk	Unknown
MADL	Maximum Allowable Dose Levels	UV	Ultra Violet
MIRV	Minimum Efficiency Reporting Value (rating for Air filtration)	UVT%	Ultra Violet Transmittance Percentage (Expression of the clarity of water)
MMP	Master Maintenance Program	WI	Work Instructions (Policies, Logs, Checklists, SOP's, SSOP's)
		Y&M	Yeast & Mold fungus

End of Food Safety Plan and System Document