SCS Global Services *does hereby certify that an independent assessment has been conducted on behalf of:*

Edison Grain, Inc.

531 Getty Court , Suite C, Benicia, CA, United States

This company developed, maintains and administers a

HACCP-Based Good Manufacturing Practices (GMPs) Food Safety Program

at 531 Getty Court, Suite C, Benicia, CA 94510, United States

CERTIFIED by SCS GLOBAL SERVICES™ GOOD MANUFACTURING PRACTICES FOOD SAFETY PROGRAM

For the following product(s) handled during inspection: Dry re-pack of agricultural goods: seeds, grains, pasta, flour, beans, cereal.

Audit Type: Dry Goods Storage Warehouse with Repack Facility Practices
Rating: SUPERIOR
Inspection Date: 10/19/2018 Expiry Date: 11/19/2019
Registration #: 003936

An inspection includes a program review and performance evaluation. Assessment of the program is based on Conformance with the 21 CFR Parts 117 Good Manufacturing Practices (GMPs) and Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (Section IV, V, VII, VIII), published by the U.S. Department of Health and Human Services, Food and Drug Administration, and Center for Food Safety and Applied Nutrition (CFSAN), October 1998. Assessment of performance is based on compliance with the operation's stated program requirements.

SCSglobal SERVICES

Stanley Mathuram, PE
Vice President
2000 Powell Street, Ste. 600, Emeryville, CA 94608 USA, (510) 452-8000

2000 Powell Street
Suite 600, Emeryville, CA 94608
Phone: 510-452-8000
Fax: 510-452-6886

Manufacturing Facility Audit Checklist

Auditor Name	Jessica Duong
Auditor's contact phone number	310-951-4195
Auditor's email address	jessica@dtduong.com
SCS Contact Person	Ryan DeCoster
SCS Contact Phone #	510-452-8028
SCS Contact Email	rdecoster@scsglobalservices.com
Audited Facility Name	Edison Grain Inc.
Audited Facility Address (include full address)	531 Getty Ct. Suite C Benicia, CA 94510
Contact Person	Amy Barnes, Owner
Phone Number	707-590-7010
Email Address	amy@edisongrainery.com
Has the Facility Inspected by Government Authority? (e.g., Local County, State, FDA)	Solano County, Environmental Health Division
Does this facility audit their supplier either through a first/second/third party audit?	Yes
What other types of audit have been conducted at this facility (e.g., Organic, Kosher, Non-GMO, Gluten Free, customer)	cRc (Kosher), OTCO (Organic)
Type of Primary Packaging (e.g., poly, cardboard boxes, etc.)	(Retail)-BPA-free rice & corn resin stand-up pouch with zipper closure (Food Service)-PET & LLDPE pouch with zipper closure (Industrial)-Kraft paper
Type of Secondary Packaging (e.g., poly, cardboard boxes, etc.)	Corrugated cartons
Channels of Trade (Retail, Wholesale, International, etc.)	Industrial/commercial, food service, direct to consumers
Hours of Operation	7 a.m - 6 p.m.; Mondays-Fridays
Months of Operation (e.g., January - December)	January-December
Number of Employees	3 owners, 6 full-time employees
Year Built	1985
Year(s) Updated	2017
Size of Facility	25,280 sqft.
Property Size (~ acres)	Unknown
Neighboring Land Use	Light industrial businesses
Building Material, Exterior Walls	Concrete
Building Material, Interior Walls	Dry wall
Building Material, Floors	Cement
Building Material, Exterior Roof	Conventional built-up roof
Building Material, Interior Ceiling	Wood/steel, drop ceiling
Areas of the Facility Excluded from the Audit	2 personal rooms, contract warehouse area, dock doors 1, 2
Date of Audit Exit Meeting	10/19/2018
Length of Audit	1 day
Facility Personnel	Amy Barnes (Owner), Rhiannon Woo (Consultant), Kathy Wondolleck (Art Director), Luis Padilla (PCQI)
Date of Last Audit	10/3/2017
Product(s) Handled	Organic GF dry goods (pantry staples: seeds, grains, pasta, flour, etc.)

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Fax: 510-452-6886

Facility Construction and Design	Dry storage areas with separated repack rooms.
Brief Description of the Process	Raw materials are received, sampled and tested, cleaned by optical laser color sorter/magnet/metal detection, repacked, shipped.
Food Safety Total Score (≥ 80% Satisfactory per SCS Rating system)	**99.80%**
Rating	**Superior**

SCSglobal SERVICES

GMP Manufacturing Food Safety Assessment Detailed Report & Final Summary Score						
Category/Subcategory	**Food Safety Section**			**Other Section**		
	Points Scored	**Points Possible**	**Percent (%)**	**Points Scored**	**Points Possible**	**Percent (%)**
SECTION A: GOOD MANUFACTURING PRACTICES AND PROCEDURES						
Management Commitment and Review	10	10	100.00%	11	11	100.00%
Employee Practices	50	50	100.00%	46	46	100.00%
Training and Education	20	20	100.00%	20	22	90.91%
Employee Welfare Facilities	40	40	100.00%	81	81	100.00%
Utilities: Water, Ice, Air, Steam, and Other Gases	10	10	100.00%	26	26	100.00%
Exterior Grounds	20	20	100.00%	18	18	100.00%
Building Size, Construction and Design	60	60	100.00%	39	39	100.00%
Pest Control Program and Procedures	60	60	100.00%	63	63	100.00%
Handling Practices: Products, Packaging, Containers	60	60	100.00%	49	49	100.00%
Product Microbiological or Chemical Testing	10	10	100.00%	14	14	100.00%
Hold and Release Program	10	10	100.00%	7	7	100.00%
Packaging Materials	30	30	100.00%	25	25	100.00%
Foreign Material Control/Indirect Product Additives	20	20	100.00%	28	28	100.00%
Calibration	0	0	0.00%	29	29	100.00%
Recall/Traceability Program	10	10	100.00%	18	18	100.00%
Facility Inspection/Product Safety Program Review	0	0	0.00%	18	18	100.00%
Visitor and Contractor Access Control	0	0	0.00%	15	15	100.00%
Cleaning Equipment and Chemicals	20	20	100.00%	17	18	94.44%
Cleaning, Sanitation and Housekeeping	50	50	100.00%	94	94	100.00%
Equipment Construction, Design and Maintenance	30	30	100.00%	25	25	100.00%
Receiving, Storage and Distribution	30	30	100.00%	7	7	100.00%
SECTION B: HACCP PLAN AND PROCESS PRACTICES						
Management Commitment and Review	N/A	N/A	N/A	7	7	100.00%
HACCP/Hazard Prevention Program	220	220	100.00%	29	29	100.00%
Allergens	40	40	100.00%	21	21	100.00%
SECTION C: DOCUMENT CONTROL						
Document Control	N/A	N/A	N/A	24	24	100.00%
TOTAL SCORE	**800**	**800**	100.00%	**731**	**734**	99.59%

Food Safety (GMP) Final Summary			
	Points Scored	**Points Possible**	**% Percentage**
Food Safety Section	800	800	100.00%
Other Section	731	734	99.59%
TOTAL SCORE	**1531**	**1534**	99.80%

AUDIT SCORING SYSTEM

SCORE			RATING	DESCRIPTION	DOCUMENTATION COMPLIANCE
10 pts	7 pts	4 pts	AUTO	*Automatic Unsatisfactory (Refer to next page)*	
N/A	N/A	N/A	N/A	Not Applicable	Not Applicable
				The particular question doesn't apply to the facility in question or are not controlled at the facility.	The particular question doesn't apply to the facility in question or are not controlled at the facility.
0	0	0	US	Unsatisfactory	Unsatisfactory
				Critical food safety hazards, which compromise the safety of the product, are observed.	A) No written Food Safety Program in place. B) Records Review: No records
1	1	1	NI	Needs Improvement	Needs Improvement
				Serious food safety hazards, which may eventually compromise the safety of the product, are observed. Significant improvements in operational practices and procedures are needed to avoid food safety	A) Written Food Safety Program in place and/or needs serious improvement. B) Records Review: Very few records may be available and/or current.
3	2	2	NI	Needs Improvement	Needs Improvement
				Major food safety hazards, which may not immediately compromise the safety of the product, are observed. Partial improvements in operational practices and procedures are needed to avoid food safety	A) Written Food Safety Program in place and/or needs major improvement. B) Records Review: Some records may be unavailable and/or current.
5	4	3	NI	Needs Improvement	Needs Improvement
				Minor food safety hazards, which may not immediately compromise the safety of the product, are observed. Minimum improvements in operational practices and procedures are needed to avoid food	A) Written Food Safety Program in place and/or needs minor improvement. B) Records Review: Very few records may be unavailable and/or not current.
10	7	4	S	Satisfactory	Satisfactory
				No food safety hazards are observed. Meets the intent of the checklist in design and execution.	A) A complete written Food Safety Program in place. B) Records Review: All records are available and kept current.

Food Safety Assessment Rating System

This rating system describes the status of processing, packing, storage operations in regards to food safety issues associated with the particular operations they perform. It should be noted that it is not possible to completely eliminate the risk of contamination associated with production (GMPs) / food environment. This fact remains true regardless of the practices employed or the rating level achieved as a result of an audit. The Good Manufacturing Practices (21 CFR, Part 117) are used as references to assess the levels of risk associated with these operations.

Percentage	Assessmen	Description
95.00 or more	Superior (Pass)	The food is produced in an exemplary environment.
90.00-94.99	Excellent (Pass)	The food is being produced in an environment that significantly reduces the likelihood of contamination.
80.00-89.99	Good (Pass)	Procedures and guidelines to protect the food product against contamination need some improvement. However, there is a low likelihood that current practices will lead to contamination of the food product.
Less than 79.99	Fair (Fail).	The food is being produced in an environment where critical deficiencies and/or serious potential or actual contamination were observed. Immediate improvements in procedures and operating practices should occur.

Conditions for an Automatic Failure

A. General

1. An immediate product safety risk is present due to a violation of the Good Manufacturing Practices (Code of Federal Regulations Title 21, Part 110).
2. Product is manufactured under conditions that promote or cause the product to become contaminated, and thus rendered harmful to one's health.
3. Sanitation procedures are not in place.
4. Products are stored at improper conditions (e.g., temperature, humidity, etc.)
5. Presence or evidence of contaminated product with foreign material or filth (e.g., flaking paint, rust, glass, wood, metal, jewelry, lubricants, etc.), during production, packing or storage.

B. Rodents, Insects, Birds, Animals, and other Pests

1. Absence of pest control program in the manufacturing areas including packaging material and product storage areas.
2. Presence or evidence of rodents, insects, or other pests in the product during packing, or storage (e.g., excreta, bird feathers, etc.)
3. Presence or evidence of decomposed rodent(s) in pest control traps or in other areas in the facility
4. Extensive infestation in manufacturing areas, including infestation of the area overhead where product or packaging material is present (e.g., presence of birds' nests).
5. Any roach activity in product handling or storage areas.
6. Presence of pets inside the facility (e.g., dogs, cats, etc.). Pets are not allowed in the office or on the property

C. Cleaning Chemicals, Pesticides and other Poisonous Materials

1. Product is adulterated.
2. An imminent product safety risk is present due to violation of the Environmental Protection Agency (EPA) and/or State pesticide regulations.
3. Illegal use of pesticides (e.g., pesticides not meeting EPA or other regulatory standards).
4. Recommended guidelines for the preparation and handling of pesticides are not followed (i.e., not following label instructions).
5. Non-food grade cleaning agents (detergents and sanitizers) are used.
6. Presence or evidence of contaminated product with chemicals, pesticides or other poisonous materials.
7. Products stored with toxic substances.

D. Employee Practices

1. Observation of employee practices that jeopardize or may jeopardize the safety of the product (e.g. open sores and boils on employees who have direct contact with product or product handling areas, employees not following hand washing requirements, etc.)
2. Gross negligence or actions, which render product unsafe.

E. Sanitary Facilities

Toilet facilities and hand washing stations not provided.

F. Water

Water supply in the facility is known to be contaminated.

G. HACCP/Hazard Prevention Program (Legally Manadated-Juice, meat and poultry, seafood, dairy (PMO))

1. No HACCP program exists where legally mandated such as documented HACCP program, detailing 7 principles, is not established, is not up-to-date, and is not available for review.
2. Identified Critical Control Points not implemented and monitored and is not available for review.
3. Falsification of CCP (Critical Control Point(s)) records.

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
	SECTION A: GOOD MANUFACTURING PRACTICES AND PROCEDURES								
	1.0	**MANAGEMENT RESPONSIBILITY**							
Sub Category	**1.1**	**Management Commitment and Review**							
Mgmt. Commitment	1.1.1	1. Has senior management prepared and implemented a food safety policy statement that includes as a minimum (i) commitment to supply safe food, (ii) comply with its customer and regulatory requirements (iii) continually improve its food safety program, and (iv) commitment to establish and review food safety objectives? 2. Is policy documented in languages understood by all employees? 3. Is policy posted in prominent areas and communicated to all levels of organization?	7		7				
Mgmt. Commitment	1.1.2	Is an organizational chart in place that identifies positions responsible for Product Safety System Compliance including descriptions of responsibilities?	4		4				
Mgmt. Commitment	1.1.3	Are Current Good Manufacturing Practices (cGMPs) (21 CFR Part 117) and HACCP program implemented? *This is an overall assessment (answer last)*	10		10				
		*Product Safety Section Total Points	10		10	0	0	0	10
		Other Section Total Points	11		11	0	0	0	11
	2.0	**FUNDAMENTALS**							
Sub Category	**2.1**	**Employee Practices** (Assessed by Observation and Documentation)							
Employee Practices		**General Expectation: Compliance with Employee Practices (21 CFR 117.10)**							
Employee Practices	2.1.1*	1. Are employees with: a. open and/or infected wounds or cuts on their hands or face, or with symptoms of infectious illness (e.g., diarrhea, vomiting), prohibited from having direct contact with exposed product or production and/or storage areas, and packaging materials? b. signs of communicable disease evaluated? (e.g., observations) 2. Are open and/or infected wounds or cuts covered with a colored bandage containing a metal strip or an alternative suitable waterproof and colored dressing? 3. Are corrective actions taken and documented if a worker is found to be infected? *(Records of Corrective Action and Preventive Action Plans are required)*	10		10				
Employee Practices	2.1.2	Are employees engaged in handling food maintaining: a. clean clothing or uniforms including outer garments? (e.g., aprons, smocks, lab coats) b. adequate personal cleanliness? Note: Protective clothing cannot be taken home or stored in personal lockers.	7		7				
Employee Practices	2.1.3*	1. Are employees removing aprons, gloves, and other protective clothing (when in use) before leaving the product handling areas? 2. Are protective clothing stored in designated areas prior to leaving product handling areas? 3. Are clean protective clothing provided on a daily basis? Note: Disposable gloves and aprons must be changed after each break, upon re-entry into the production areas and when damaged. Non-disposable aprons and gloves must be cleaned and sanitized as required and when not in use stored in designated storage area. Soiled clothing must be changed.	10		10				
Employee Practices	2.1.4	Are employees wearing protective clothing (e.g., hairnets, beard nets, arm sleeves, sneeze guards, etc.) in an effective manner in product handling areas? Note: Precautions must be taken to protect form any foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin).	7		7				

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Employee Practices	2.1.5	Are employees prohibited from: a. wearing any jewelry other than a plain wedding band? b. wearing false eyelashes or finger nails and finger nail polish? c. carrying loose items, such as pens or thermometers, in above-the-waist pockets? Note: If hand jewelry is allowed due to religious reasons and cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.	7		7				
Employee Practices	2.1.6*	Are employees washing and/or sanitizing hands prior to beginning or returning to work, or whenever the hands and/or gloves may have become soiled or contaminated?	10		10				
Employee Practices	2.1.7	Are employees maintaining hairnets, beard nets, gloves, aprons, arm sleeves in an intact, clean, and sanitary condition? NOTE: The gloves must be of an impermeable material and latex free.	7		7				
Employee Practices	2.1.8*	Are employees prohibited from eating product, drinking beverages, spitting, chewing gum, smoking, and using tobacco and/or toothpicks in product handling areas? NOTE: product consumption should also be prohibited in locker rooms.	10		10				
Employee Practices	2.1.9*	1. Are all products, materials, and packaging that come in contact with blood or bodily fluids destroyed, and any equipment, tools, and/or product contact surfaces that come in contact with blood or bodily fluids cleaned and sanitized before use? 2. Is there a documented procedure on handling such incidents? *Records of Corrective Action and Preventive Action Plans are required.*	10		10				
Employee Practices	2.1.10	Does the operation have a written policy, which addresses applicable worker health and hygiene issues and does it include the requirements in this section?	7		7				
Employee Practices	2.1.11	Are readily understandable written signs and/or pictures in appropriate language(s) strategically located around the product handling areas? (e.g., reminding employees to wash and sanitize their hands, when necessary, cGMPs policy)	4		4				
Employee Practices	2.1.12	Are employees storing their clothing or personal belongings in appropriate designated areas away from the product handling areas? NOTE: Food storage is prohibited in lockers.	7		7				
Employee Practices	2.1.13	1. Where smoking is allowed under national law, are designated smoking areas provided? 2. Are these areas isolated to the exterior of the building? 3. Are smokers' waste disposal units provided? 4. Are electronic cigarettes prohibited to be used or brought into product handling and storage areas?		x					Smoking is not permitted.
		*Product Safety Section Total Points	50		50	0	0	0	50
		Other Section Total Points	46		46	0	0	0	46
Sub Category	**2.2**	**Training and Education** (Assessed by Observation, Interview, and Documentation)							
Training & Educ.		**General Expectation: Compliance with 21 CFR 110.10 (c)**							
Training & Educ.	2.2.1	Is there a documented employee training program, which includes methods and responsibilities (initial and ongoing and/or refresher food safety training (e.g., HACCP, cGMPs, personnel practices, sanitation procedures and other prerequisite programs)).	7		7				
Training & Educ.	2.2.2*	1. Is there an initial and ongoing and/or refresher employee training program that addresses product safety related issues (e.g., HACCP, product safety, cGMPs, and other prerequisite programs) to all employees, including new employees? 2. Is the general content of the training sessions included? (e.g., topics covered)	10		10				

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Training & Educ.	2.2.3	Does the training program include documented evaluation criteria for knowledge learned?	4			3			Site is performing comprehension verification through visual observation by trainer or manager/supervisor. However, the practice is not included in the written program.
Training & Educ.	2.2.4	Are workers participation in respective training programs (initial and ongoing and/or refresher, addressed in 2.2.3) documented? (employee's signature, who provided the training, date of training, training duration)	4			3			Workers participation in training programs are documented. However, a copy of one specific training record that was performed by a third party was not accessible for review.
Training & Educ.	2.2.5	Do employees appear to have received and understood training and are they practicing proper product handling procedures? *Note: Workers in their areas of responsibilities must be interviewed to verify knowledge on food safety, including CCP Operators.*	7		7				
Training & Educ.	2.2.6*	1. Is there a designated Food Safety Manager with relevant educational background and/or experience, who oversees the food safety program? 2. Has the Food Safety Manager taken a 16 hr. HACCP course? *Note: the Food Safety Manager must be interviewed to verify knowledge on food safety.*	10		10				
		*Product Safety Section Total Points	20		20	0	0	0	20
		Other Section Total Points	22		14	6	0	0	20
Sub Category	**2.3**	**Employee Welfare Facilities** (Assessed by Observation and Documentation)							
Sanitary Facilities		**General Expectation: Compliance with 21 CFR 117.37 (d). Each facility shall provide its employees with adequate, readily accessible toilet facilities.**							
Toilet Facilities	**(a)**	**Toilet Facilities 21 CFR 117.37 (d)**							
Toilet Facilities	2.3.1*	1. Is a minimum of one toilet facility provided for every 20 people? 2. Are separate toilet facilities provided if there are 5 or more employees of each gender? 3. Are toilet facilities located within a 5-minute walk or 1/4 mile for all workers?	10		10				
Toilet Facilities	2.3.2*	1. Are toilet facilities located and/or designed so as to reduce the possibility of contamination to water sources or product in the event of a malfunction? (e.g., adequate drainage). 2. Are doors to toilet facilities situated so they do not open into areas where product is exposed to air-borne contamination, except where alternate means have been taken to protect against such contamination? (e.g., double doors or positive air-flow systems)	10		10				
Toilet Facilities	2.3.3	Do toilet facilities have: a. self-closing doors? b. ventilation systems to eliminate odors? c. floors, walls, ceilings and toilets built in such a way that they can be cleaned and sanitized properly? d. floors, walls and ceilings in good repair? e. functional toilets and urinals? f. trash receptacles?	7		7				
Toilet Facilities	2.3.4	Are toilet facilities maintained in clean condition?	7		7				

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Toilet Facilities	2.3.5	Are toilet supplies monitored and/or stocked throughout the day?	7		7				
Toilet Facilities	2.3.6	1. Are the cleaning procedures described in a document that details how and when to clean (at least daily)? 2. Is cleaning documented and are records legible?	7		7				
Hand washing	**(b)**	**Hand washing facilities**							
Hand washing		**General Expectation: Compliance with 21 CFR 117.37 (e). Each facility shall provide its employees with adequate, readily accessible hand washing sinks.**							
Hand washing	2.3.7*	Are hand washing stations provided inside or next to the toilet facilities to facilitate their use?	10		10				
Hand washing	2.3.8	Are additional hand washing stations and, where appropriate, hand sanitizer stations (e.g., hand dips, wall units) provided in the facility where good sanitary practices require employees to wash and/or sanitize their hands? (e.g., at entries to manufacturing areas)	7		7				
Hand washing	2.3.9*	Are hand washing stations located and/or designed: a. to prevent contamination of the product (e.g., water is not splashed near product or product contact surfaces) and to protect against recontamination of clean, sanitized hands? (e.g., installation of devices and/or fixtures such as water control valves) b. to facilitate hands-free operations?	10		10				
Hand washing	2.3.10	1. Are single-use paper towels or air drying devices used at hand washing stations? 2. Are hand washing stations functional (e.g., not leaking) and equipped with warm running water, bacteriostatic soap, and/or an appropriate hand sanitizer? 3. Are written signs and/or pictures in appropriate language(s) located next to the hand washing stations reminding employees to wash and sanitize their hands, when necessary?	7		7				
Hand washing	2.3.11	1. Are hand washing stations and/or hand sanitizing stations (e.g., hand-dips, wall units) monitored and/or stocked throughout the day? 2. Is the chemical concentration in hand-dips maintained at appropriate concentration at all times, documented, and available for review?	7		7				
Hand washing	2.3.12	1. Are hand washing and/or hand sanitizing stations maintained in clean condition? 2. Are hand washing and/or hand sanitizing stations cleaned on a scheduled basis and as needed?	7		7				
Hand washing	2.3.13	Are drainage pipes connected directly or located on top of the drains? Note: Adequate air space must be provided between the drain and the drain pipe to prevent back-suction.	4		4				
Lunch room	(c)	**Lunch Facilities**							
		General Expectation: Compliance with 21 CFR 117.37 (e). Each facility shall provide its employees with lunch facilities							
Lunch room	2.3.13	Are separate lunch room facilities provided and are they located away from food handling and storage areas?	7		7				

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Lunch room	2.3.14	1. Is lunch room ventilated and have adequate lighting? 2. Are adequate tables and seating provided to accommodate maximum number of staff at one sitting? 3. Is it equipped with a sink serviced with hot and cold potable water for washing utensils, refrigeration and heating equipment to store or heat food and to prepare food if required? 4. Is it kept clean and free from waste and pests? 5. Is adequate space provided behind vending machines and other storage cabinets for cleaning and inspection?	7		7				
Lunch room	2.3.15	1. Are the cleaning procedures described in a document that details how and when to clean (at least daily)? 2. Is cleaning documented and are records legible?	7		7				
		*Product Safety Section Total Points	40		40	0	0	0	40
		Other Section Total Points	81		81	0	0	0	81
Sub Category **Water, Ice, Air, and Other Gases**	**2.4**	**Utilities: Water, Ice, Air, Steam, and Other Gases** (Assessed by Observation and Documentation) **General Expectation: Compliance with 21 CFR 117.37 (a)** **Monitoring of Water microbiology and Quality**							
Utilities	2.4.1	Is there a documented utilities monitoring program, which includes methods and responsibilities (water, ice, air, steam, and /or other gases)?	7		7				
Steam	**(a)**	**Steam**							
	2.4.2	If water is used as steam and if steam comes in contact with food and product contact surfaces, it must comply with local, national or internationally recognized potable water microbiological and quality standards as required.		x					Steam is not used.
Steam	2.4.3	1. Are chemicals used in boiler approved and are there letters of guarantee? 2. Are there records on boiler blow downs and titrations?		x					
Water Supply	**(b)**	**Water Supply**							
Water	2.4.4	1. Is City water with adequate quality provided in sufficient quantities ? 2. Is recent Consumer Confidence Report on file?	4		4				
Ice Supply	**(c)**	**Ice Supply**							
Ice	2.4.5	Applicable if ice is made in-house and in contact with food. Is ice made from water that is safe and of adequate sanitary quality and used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.		x					Ice is not used.
Ice	2.4.6	Ice rooms and receptacles must be constructed of suitable materials and designed to minimize contamination of the ice during storage and distribution.		x					

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Ice	2.4.7	Applicable if ice is bought from the ice manufacturer. Are letters of guarantee and microbiological results received and reviewed on each delivery?		x					
Compressed Air	**(d)**	**Compressed Air**							
Compressed Air	2.4.8	Is compressed air mechanically introduced into food or used to used to clean product contact surfaces or equipment handled in such a way as not to contaminate the products with unlawful indirect product additives and regularly monitored for purity so that it does not present any risk to food safety?	4		4				
Compressed Air	2.4.9	Is compressed air used directly in contact with the product filtered and are change of filters included in the maintenance program? Are records kept on filter changes?	4		4				
Gases	**(e)**	**Gases**							
Gases	2.4.10	Is letter of guarantee on file on gases, such as Nitrogen used for MAP packaging?		x					Gas is not used.
Water Test	**(f)**	**In-house Water Testing**							
Water	2.4.11*	1. Is water supply checked for microbial quality from several different locations in the facility on a periodic basis? 2. Are analytical tests for water kept on file? 3. If results are out of specification, are corrective actions documented and legible?	10		10				
Water	2.4.12	Is laboratory accredited to ISO 17025 or an equivalent national standard?	7		7				
		*Product Safety Section Total Points	10		10	0	0	0	10
		Other Section Total Points	26		26	0	0	0	26
Sub Category Grounds	**2.5**	**Exterior Grounds** (Assessed by Observation and Documentation) **General Expectation: Compliance with 21 CFR 117.20 (a)**							
Grounds	2.5.1*	1. Is there a documented ground maintenance program, which includes methods and responsibilities 2. Are roads, yards, and parking lots maintained in a condition so that they do not constitute a source of contamination in areas where product is exposed? (e.g., keeping weeds or grass cut, no pot holes and adequate surface drainage to prevent foot-borne filth and breeding places for pests)	10		10				
Grounds	2.5.2.	Is 16-18 inches of clearance maintained around the outside perimeter of the building?	7		7				
Grounds	2.5.3	Is equipment and/or materials, which is stored on the grounds, stored in a manner so as to prevent harborage of pests? (e.g., idle equipment and/or material is at least 20 feet away from any buildings and 6 inches off the ground (pallets are acceptable), pipes must have sealed ends)	7		7				
Grounds	2.5.4	Do all trash receptacles have closed lids and not overflowing?	4		4				
Grounds	2.5.5*	Is litter collected and waste stored and/or disposed of in a manner adequate to minimize the odor, prevent contamination of product and/or become an attractant to vermin?	10		10				

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
		*Product Safety Section Total Points	20		20	0	0	0	20
		Other Section Total Points	18		18	0	0	0	18
Sub Category	**2.6**	**Building Size, Construction and Design** (Assessed by Observation and Documentation)							
Size, Construction & Design		**General Expectation: Compliance with 21 CFR 117.20 (b), 21 CFR 117.37 (b)**							
Size, Construction & Design	**(a)**	**Building Size, Construction and Design (21 CFR 117.20 (b))**							
Size, Construction & Design	2.6.1	Is the facility located where adjacent and adjoining buildings, and land use do not interfere with safe and hygienic operations?	7		7				
Size, Construction & Design	2.6.2*	1. Is the facility constructed and/or designed so to allow complete separation of incoming, in-process, and finished products, to reduce potential for cross-contamination? (e.g., a. product handling areas separate from storage and distribution areas, dedicated cold rooms for raw and processed products; b. one direction of personnel traffic, product, and air flow; c. product areas to have traffic patterns that separate raw and finished product using either linear product flow (raw to finished product) or by physical partition; d. short direct routes for both product and personnel flow). 2. Is the facility fully enclosed to avoid cross-contamination coming from environment?	10		10				
Size, Construction & Design	2.6.3	Are working spaces provided between equipment and walls, and are they adequately unobstructed and of adequate width to allow employees to perform their duties and to protect against contaminating product or product contact surfaces with clothing or personal contact?	7		7				
Size, Construction & Design	2.6.4	Is adequate lighting available in all areas where the product is manufactured, examined, packaged, or stored, and in all employee welfare areas?	4		4				
Size, Construction & Design	2.6.5*	a. Does the cull system for removing waste materials from product handling area work efficiently? (e.g., litter and waste stored and/or disposed of in a manner adequate to prevent contamination of product and/or become an attractant to vermin). b. Are trash bins emptied on frequent basis and not overflowing?	10		10				
Structures/ Fixtures	**(b)**	**Building Structures/Fixtures**							
Structures/ Fixtures	2.6.6*	Is the roof properly maintained? (e.g., no signs of leaks on the walls and other structures and fixtures)	10		10				
Structures/ Fixtures	2.6.7	1. Is the facility and its structures, such as ceilings, walls, floors, windows, and floor drains designed and constructed of materials to be adequately cleaned and maintained in good repair, to protect product from cross-contamination? (e.g., using appropriate construction materials) 2. Are these areas kept in good repair? (e.g., no deep holes or cracks, exposed foam materials, and broken windows and lights)	7		7				
Structures/ Fixtures	2.6.8*	Are overhead fixtures, such as air vents, conduits, and pipes located over product contact surfaces, packaging materials, and exposed products maintained in clean and suitable condition? (e.g., no cracks, rust, breakage, missing parts, or drips)	10		10				
Plumbing	**(c)**	**Plumbing (21 CFR 117.37 (b))**							

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Plumbing	2.6.9	1. Is hot and cold water provided? 2. Is water used for cleaning of equipment, utensils, and for employee sanitary facilities maintained at a suitable pressure?	7		7				
Plumbing	2.6.10*	Are sewer pipes and water pipes placed to avoid possible contamination of product or equipment in the event of a leak or dripping from condensation, and are preventative measures in place?	10		10				
Plumbing	2.6.11*	1. Are water lines for product and/or employee use protected against back-flow or cross-connections from the wastewater and sewage plumbing system? (e.g., there is a main water back-flow device as well as devices at points where there is potential for back-flow into potable water lines). 2. Is back-flow prevention device inspection conducted annually and inspection record maintained?	10		10				
Plumbing	2.6.12*	If potable and non-potable water is provided at the facility, is the water source and plumbing system identified potable vs. non potable, and are they separate?		x					Non-potable water is not used.
Env. Control	**(d)**	**Environmental Control**							
Env. Control	2.6.13	1. Is proper ventilation or control equipment in place to minimize odors? 2. If fans or other blowing equipment are used, are they operated in a manner that minimizes the potential for contaminating product, equipment, or packaging materials?	7		7				
Env. Control	2.6.14	1. Are disinfectant foot foamers, foot baths, or foot sprayers provided at entries to product handling areas if appropriate? 2. Are sanitizer concentrations monitored regularly and records available for review?		x					Not applicable.
Env. Control	2.6.15	1. Are hand dips and/or utensil storage containers with sanitizers provided at entries to product handling areas and other exposed product areas, if appropriate? 2. Are sanitizer concentrations monitored regularly and records available for review?		x					
		*Product Safety Section Total Points	60		60	0	0	0	60
		Other Section Total Points	39		39	0	0	0	39
Sub Category **Pest Control**	**2.7**	**Pest Control Program and Procedures** (Assessed by Observation and Documentation) **General Expectation: Compliance with 21 CFR 117.20 (b)(7), 21 CFR 117.35c**							
Pest Control	2.7.1	Is there a documented pest control program, which includes methods and responsibilities?	7		7				
Pest Control	2.7.2	1. Are pesticide applications performed by trained and licensed/certified personnel? 2. Are the service agreement, license and certificate of insurance (if service is provided by an outside company) current and available for review? 3. Does the facility have an assigned person responsible for overseeing the pest control program and is this responsibility documented?	4		4				
Pest Control	2.7.3*	1. Do pesticides, chemicals, or other pest control measures meet applicable regulations (e.g., USDA, EPA, OSHA)? 2. Are safety date sheets for all chemicals and compounds used available for review?	10		10				
Pest Control	2.7.4	1. Are locations of all traps (e.g., glue boards, bait stations, light traps, pheromone traps or any other device in use) indicated on a facility map, which is cross-referenced to a list or a key on the map showing the descriptions and/or types of traps at each station? 2. Is the facility map signed and dated (verified as accurate) within last year?	4		4				

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Pest Control	2.7.5	Are pest control stations properly coded (e.g. ID #, bar code) to correspond with the master identification map?	4		4				
Pest Control	2.7.6*	1. Is there an adequate number of interior pest control devices, spaced at intervals (typically 25-30 feet) along the interior perimeter of the facility, including on both interior sides of overhead doors? 2. Is there an adequate number of secured (to the ground, building or some type of block), tamper resistant (lid must be secured and require some type of "key" or other device to open) exterior pest control devices, spaced at intervals (typically 30-50 feet) around the building perimeter? 3. Are pest control stations set-up or constructed to avoid product, packaging, or equipment contamination?	10		10				
Pest Control	2.7.7	Are live catch devices and glue boards checked at least bi-monthly, insect traps checked at least monthly, and bait stations checked for fresh bait at least monthly?	7		7				
Pest Control	2.7.8	1. Are pest control devices functioning properly? 2. Are pest control exclusion devices (e.g., light traps, mechanical traps) cleaned and maintained on a scheduled basis?	4		4				
Pest Control	2.7.9*	Is there no evidence of decomposed rodents in the interior or exterior pest control devices?	10		10				
Pest Control	2.7.10	Does the inside of the facility appear to be free from insects, rodents, birds, and domestic animals?	7		7				
Pest Control	2.7.11*	Is there no evidence of insect, rodent, or bird activity on or in product, packaging, and product-contact surfaces (e.g., excreta, feathers)?	10		10				
Pest Control	2.7.12	1. Are insect-exclusion devices used appropriately at exterior entrances (e.g., air curtains, light traps)? 2. Are insect exclusion devices cleaned and maintained on a scheduled basis?	4		4				
Pest Control	2.7.13	Are all light traps positioned so that they will not attract insects from outside, into the building?	4		4				
Pest Control	2.7.14	Are destructive type traps located at least 30 feet from exposed product or packaging and 5 feet away from covered product or packaging?		x					Self-destructive traps are not used.
Pest Control	2.7.15	Are birds controlled by netting, screens, traps, or other exclusion methods? (Application of avicides are prohibited in the facility.)	7		7				
Pest Control	2.7.16*	Is toxic bait used only in exterior bait stations?	10		10				
Pest Control	2.7.17	Are inspection records from the past twelve months available for review? (e.g., findings, corrective actions, trap observations, pesticide application, equipment used)	7		7				
Pest Control	2.7.18*	1. Have cracks or crevices been sealed to prevent entrance or harborage of pests? 2. Are outside drains protruding from exterior building walls screened? 3. Are exterior doors and windows sealed to prevent gaps greater than 1 inch? 4. Are exterior windows, vents, fans, and other similar features screened, and rodent-proofed to protect against insect and rodent entry and infestation? 5. Do dock door levelers have intact seals?	10		10				

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Pest Control	2.7.19	Are exterior doors and entrances closed when not in use?	4		4				
Pest Control	2.7.20*	1. If pest control chemicals are stored on site for pest control, are they properly labeled and kept in secure, locked areas, away from any product handling and packaging material storage areas? 2. Does the person responsible hold a PCA license? 3. Are there training records of person handling toxic baits?		x					Pest control is performed by a third party and chemicals are not stored on site.
		*Product Safety Section Total Points	60		60	0	0	0	60
		Other Section Total Points	63		63	0	0	0	63
Sub Category	**2.8**	**General Operational Practices and Procedures** (Assessed by Observation and Documentation)							
General Operational Practices		**General Expectation: Compliance with 21 CFR 117.80 (7): Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or product shall be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination. 21 CFR 117.80 (8): Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in product. Compliance with 21 CFR 117.80: Raw materials shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into product and shall be stored under conditions that will protect against contamination and minimize deterioration. Compliance with 21 CFR 117.80: Effective measures shall be taken to protect finished product from contamination by raw materials, other ingredients, or refuse.**							
product Handling Practices	**(ii)**	**Handling Practices: Incoming, In-Process and Finished products, Packaging Materials, Containers**							
Product Handling Practices	2.8.1*	Is risk assessment conducted on all raw materials and ingredients?	10		10				
Product Handling Practices	2.8.2	Are raw materials/ingredients stored in designated areas to prevent cross-contamination?	7		7				
Product Handling Practices	2.8.3*	1. Are incoming raw materials and ingredients purchased under supplier's guarantee or certification? 2. Are letters of guarantee or certificates of analysis kept on file and available for review?	10		10				
Product Handling Practices	2.8.4	Are first-in/first-out (FIFO) and first expiration/first out (FEFO) rotation practices used and documented for all raw materials/ingredients?	7		7				
Product Handling Practices	2.8.5	Are raw materials/ingredients inspected for evidence of contamination prior to use?	7		7				
Product Handling Practices	2.8.6	Are containers, totes, and other equipment used to hold incoming products, in-process, rework or finished products appropriate for use, properly labeled and/or color coded and covered appropriately?	7		7				
Product Handling Practices	2.8.7	1. Does the facility prohibit the reuse of: a. in-house containers for holding products, unless they are adequately sanitized or (if applicable) have protective liners? b. ingredient containers for holding products or ingredients, unless they are adequately sanitized or have protective liners?	7		7				
Product Handling Practices	2.8.8*	Are raw materials treated during manufacturing operations so that they no longer contain levels of microorganisms that would cause the product to be adulterated?		x					Not applicable.

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Product Handling Practices	2.8.9*	Are manufacturing mechanical steps performed to protect product against contamination; this may be accomplished by adequate physical protection of product from contaminates that may drip, drain or be drawn into product?	10		10				
Product Handling Practices	2.8.10*	Are physical factors such as temperature, humidity and manufacturing operations carefully monitored to ensure that mechanical breakdown, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of product?	10		10				
Product Handling Practices	2.8.11*	1. Are raw materials which are rejected or on hold, properly identified (clearly tagged, etc.), adequately segregated, stored under appropriate conditions and disposed of appropriately if not used? 2. Are findings from receiving inspections and corrective actions (if any) documented and are these documents available for review?	10		10				
Product Handling Practices	2.8.12*	Is work in progress (WIP) and/or rework conducted? If yes, does the facility have policies and procedures that address the: a. use of materials intended for WIP and/or rework? b. storage conditions of rework materials? c. identifications and coding of materials intended for rework?		x					Not applicable.
Product Handling Practices	2.8.13	Does the facility have procedures that address percent of rework that can be added back to the regular formula?		x					
Product Handling Practices	2.8.14	Does the facility maintain batch formulation records that identify the addition of rework product?		x					
Product Handling Practices	2.8.15	Does the facility enforce periodic breaks in rework cycle, if required?		x					
Product Handling Practices	2.8.16	Are products inspected for evidence of contamination prior to packaging?	7		7				
Product Handling Practices	2.8.17*	Are adulterated products disposed of in a manner that protects against the contamination of other products?	10		10				
Product Handling Practices	2.8.18	Are first-in/first-out (FIFO) and first expiration/first out (FEFO) rotation practices used and documented for all finished products?	7		7				
		*Product Safety Section Total Points	60		60	0	0	0	60
		Other Section Total Points	49		49	0	0	0	49
Microbiological Testing	**(ii.c)**	**Product Microbiological or Chemical Testing**							
Microbiological Testing	2.8.19	Is there a documented procedure on microbiological or chemical testing on incoming raw materials, final products, and/or work-in-progress?	7		7				
Microbiological Testing	2.8.20	Does the testing program include: a. acceptance limits/standards used to determine product acceptability? b. actions to be taken when out-of-standard results are found for ingredients or products? (e.g., resampling and/or retesting protocols)	7		7				
Microbiological Testing	2.8.21*	Does the testing program document corrective actions when out-of-standard results are found for incoming raw materials or products?	10		10				
		*Product Safety Section Total Points	10		10	0	0	0	10

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
		Other Section Total Points	14		14	0	0	0	14
Hold & Release Program	**(ii.d)**	**Hold and Release Program**							
Hold & Release Program		**General Expectation: Products shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for packing and shall be stored under conditions that will protect against contamination and minimize deterioration.**							
Hold & Release Program	2.8.21	Is there a documented Hold and Release Program, which includes methods and responsibilities? (a. who is responsible for putting items on hold and releasing them? b. how products are marked and controlled? c. how "hold" product is monitored, how often it is reconciled and by whom).	7		7				
Hold & Release Program	2.8.22*	1. Are non-conforming products (incoming and outgoing), which are rejected or on hold, properly identified (e.g., clearly tagged), adequately segregated, and controlled against inadvertent shipment, and protected from contamination? 2. Are adulterated products disposed of in a manner that protects against the contamination of other products?	10		10				
		*Product Safety Section Total Points	10		10	0	0	0	10
		Other Section Total Points	7		7	0	0	0	7
Pkaging Materials	**(ii.e)**	**Packaging Materials**							
Pkaging Materials		**General Expectation: Compliance with 21 CFR 110.80**							
Packaging Materials	2.8.23*	1. Are packaging material storage areas maintained under conditions that prevent or minimize the likelihood of contamination? 2. Are restricted chemicals that are used in processing or as an ingredient, stored in secure, locked areas away from product and packaging supplies?	10		10				
Packaging Materials	2.8.24	a. Is a sanitation program in place for the packaging materials storage area, and is the area cleaned on a regular basis and inspected from a sanitation standpoint? b. Are the areas monitored for pest activities on a continuous basis?	7		7				
Packaging Materials	2.8.25	Is FIFO (First In First Out) practiced (i.e., stock rotated on packaging materials)?	4		4				
Packaging Materials	2.8.26*	Are packaging materials inspected for evidence of contamination prior to use? (e.g., a. packaging materials, which are damaged, dirty, wet, or which have evidence of pest activity, foreign materials, and/or chemicals, must be prohibited from reuse, b. inspected and released into inventory)	10		10				
Packaging Materials	2.8.27	During production, are packaging materials handled in a manner that eliminates contamination from the ground or from inappropriate employee handling?	7		7				
Packaging Materials	2.8.28*	Are damaged cases or packages segregated immediately and products repacked or properly disposed of?	10		10				
Packaging Materials	2.8.29	Are packaging materials used only for their intended purpose and not used to store other items?	7		7				

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
		*Product Safety Section Total Points	30		30	0	0	0	30
		Other Section Total Points	25		25	0	0	0	25
Foreign Material Control	**(iii)**	**Foreign Material Control/Indirect Product Additives**							
Foreign Material Control	2.8.30	Is there a documented procedure on foreign material detectors used on the production lines, which includes methods and responsibilities?	7		7				
Foreign Material Control	2.8.31*	If yes, are they inspected on a routine basis to ensure proper performance and are inspections recorded?	10		10				
Foreign Material Control	2.8.32	1. Is there a documented procedure on glass and/or brittle plastic management, which includes methods and responsibilities? (e.g., no unprotected glass or brittle plastic will be allowed in the facility) 2. Does it include procedures for: a. line stoppage?, b. segregation of suspect materials? c. clean-up? d. re-inspection? e. inspection of clothing and foot wear?	7		7				
Foreign Material Control	2.8.33*	Is exposed glass, brittle plastic, ceramics and/or porcelain prohibited, and are product handling and storage areas highly audited and maintained ? (e.g., a. are light bulbs shatter-proof and/or light bulbs covered with protective covers, including insectocutors, dock lights; b. windows coated or made of tempered glass or of plastic; c. no exposed glass thermometers; d. no storage or use of product and drinks in glass containers in product handling areas, e. protected skylights).	10		10				
Foreign Material Control	2.8.34	1. Are all glass objects or similar material in food handling/contact zones listed in a glass register including details of their location? 2. Is glass or similar material register audited on a scheduled basis?	7		7				
Foreign Material Control	2.8.35	1. Are product grade lubricants approved for use in appropriate areas and are they properly stored? 2. Are material safety data sheets maintained on file? 3. Are excess grease or lubricants removed from the equipment located over or close to product contact surfaces?		x					Not applicable.
Foreign Material Control	2.8.36	1. Is there a documented procedure on temporary repairs with monitoring timeline on temporary repairs? 2. Are temporary structures constructed during building work or refurbishment etc., designed and located to avoid pest harborage and ensure the safety and quality of products? 3. Are there records on monitoring of temporary repairs?	7		7				
		*Product Safety Section Total Points	20		20	0	0	0	20
		Other Section Total Points	28		28	0	0	0	28
Calibration	**(iv)**	**Calibration**							
Calibration	2.8.36	1. Is there a documented calibration procedure, which includes methods and responsibilities on calibration and re-calibration of equipment used for monitoring activities in prerequisite programs, food safety plans, and other process controls? 2. Are procedures documented and implemented to address the disposition of potentially affected products should equipment be found to be out of calibration state? 3. Are calibrated equipment protected from damage and unauthorized adjustment?	7		7				

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Calibration	2.8.37	Is calibration performed according to regulatory requirements and/or to the equipment manufacturers recommended schedule?	4		4				
Calibration	2.8.38	Is equipment calibrated against national or international reference standards or to accuracy appropriate to its use. Note: In cases where standards are not available, the site must provide evidence to support the calibration reference method applied.	7		7				
Calibration	2.8.39	Is there a register of equipment and calibration frequency?	4		4				
Calibration	2.8.40	Are temperature measuring devices (thermometers, probes) and other monitoring equipment (product weighing scales), including foreign material detectors (magnets, metal detectors, x-ray, optical sorters), calibrated on a specified schedule and documented?	7		7				
		*Product Safety Section Total Points	0		0	0	0	0	0
		Other Section Total Points	29		29	0	0	0	29
Recall/ Traceability	**(v)**	**Recall/Traceability Program**							
Recall/ Traceability		**General Expectation: A written recall procedure, which identifies the steps required to retrieve product.**							
Recall/ Traceability	2.8.41	Is there a formal, written product Recall and Withdrawal Program that includes: a. a recall coordinator, b. a 24 hour recall team contact list, c. a description of categories (e.g., class 1, class II, class III), d. regulatory contacts and procedures to notify regulatory agency?	7		7				
Recall/ Traceability	2.8.42*	Is there a product coding system that can identify products and can the system track finished products back to their source? (e.g., date of receipt, lot and/or date codes for incoming products; identification, lot codes on outer case and/or inner packages for finished products, etc.)	10		10				
Recall/ Traceability	2.8.43	Are mock recalls for lot code backwards and lot code forward performed at least annually and are results (e.g., % product recovery, elapsed time) documented and maintained on file?	7		7				
Recall/ Traceability	2.8.44	In the event of an actual recall, is the associated documentation available for review?		x					Actual recall has not occurred.
Recall/ Traceability	2.8.45	1. Is a product-safety-related customer complaint program in place? 2. Are records of product-safety-related customer complaints and company responses kept on file and available for review? (e.g., tracking /trending of customer complaints, including notification of QA of issues reported, assignment of responsibilities, and follow ups)	4		4				
		*Product Safety Section Total Points	10		10	0	0	0	10
		Other Section Total Points	18		18	0	0	0	18
Facility Inspection/ Facility Inspection	**(vi)**	**Facility Inspection/Product Safety Program Review**							
		General Expectation: Periodic facility inspections will assist in assessing effectiveness of product safety practices and periodic reviews of written procedures will assure that product safety practices will continue to control hazards.							

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Self-Inspection	2.8.46	Are good manufacturing practices or facility inspections conducted periodically, and are findings, corrective actions, and follow ups documented?	7		7				
Regulatory Inspection	2.8.47	Are regulatory inspection procedures documented and are inspection records available for review?	4		4				
Product Safety Program Internal Review	2.8.48	1. Are reviews of the written product safety management plan and associated procedures conducted when changes are made and at least on an annual basis and are periodic reviews documented? 2. Are reviews conducted with HACCP team and documented?	7		7				
		*Product Safety Section Total Points	0		0	0	0	0	0
		Other Section Total Points	18		18	0	0	0	18
Access Control	**(vii)**	**Visitor and Contractor Access Control**							
Access Control	2.8.49	Are truck drivers restricted from production and warehouse areas?	4		4				
Access Control	2.8.50	Is facility access limited to authorized personnel?	4		4				
Access Control	2.8.51	1. Is there a policy requiring inspectors, visitors, and contractors to comply with good manufacturing practices? 2. Are they required to read or are they briefed on cGMPs policy upon entry to the facility?	7		7				
		*Product Safety Section Total Points	0		0	0	0	0	0
		Other Section Total Points	15		15	0	0	0	15
Sub Category	**2.9**	**Cleaning Equipment and Chemicals**							
Cleaning Equip & Chemicals		**General Expectation: Compliance with 21 CFR 117.35 (d)(e). Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of the use.**							
Equip & Chemicals	2.9.1*	1. Are cleaning compounds and sanitizing agents appropriate (anti-microbial, product grade approved) for product and non-product contact surfaces? 2. Are safety data sheets and copies of specimen labels maintained for cleaning and sanitizing chemicals?	10		10				
Equip & Chemicals	2.9.2	Are cleaning compounds and sanitizing agents used by the sanitation crew or for production clearly identified with chemical name, when in original container and when not in original container? (e.g., chemical barrels, spray bottles, spray containers, buckets)	7		7				
Equip & Chemicals	2.9.3	1. Are cleaning compounds and sanitizing agents stored in secure, locked areas away from any product handling or storage areas? 2. Do chemical storage areas have clean floors (no excessive or old spills)?	7		7				
Equip & Chemicals	2.9.4	1. Are first-in/first-out (FIFO) rotation practices used for all cleaning and sanitizing chemicals? 2. Is up-to-date usage inventory maintained on sanitation chemicals?	4			3			Site is maintaining usage inventory of chemicals. However, evidence of FIFO rotation is not available for review.

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Equip & Chemicals	2.9.5*	1. Are containers, brushes, and applicators, which are used for cleaning and/or sanitizing, color coded or labeled to properly identify them for their intended use? (e.g., cleaning items used in restrooms should not be used elsewhere) 2. If a color coding system is used, is appropriate signage posted regarding use of the containers and equipment?	10		10				
		*Product Safety Section Total Points	20		20	0	0	0	20
		Other Section Total Points	18		14	3	0	0	17
Sub Category **Sanitation**	**2.10**	**Cleaning, Sanitation, and Housekeeping Procedures** **General Expectation: Compliance with 21 CFR 117.35**							
Sanitation	2.10.1	1. Is there documented sanitation program, which includes methods and responsibilities? (describes how sanitation in and around the facility is managed, who is responsible for managing it, and policies related to sanitation (Internal or external contract)). 2. Are the cleaning procedures (for product contact and non-product contact equipment surfaces, including other product handling areas) described in a document that details frequency of cleaning, type(s) of cleaning chemicals used (with concentrations), cleaning items used, and how and when to clean?	7		7				
Sanitation	2.10.2*	1. Are non-product contact surfaces and areas throughout the facility, including dry and cold storage areas, cleaned on a scheduled basis and as needed? (e.g., daily and/or weekly housekeeping, master sanitation schedule) 2. Is cleaning documented (initialed by sanitation person and/or supervisor), reviewed (dated and initialed by reviewer), and are records legible?	10		10				
Sanitation	2.10.3*	1. Are product contact equipment and surfaces throughout the facility cleaned on a scheduled basis, or as needed? (e.g., master sanitation schedule, daily/weekly housekeeping) 2. Is cleaning documented (initialed by sanitation person and/or supervisor), reviewed (dated and initialed by reviewer), and are records legible and available for review?	10		10				
Sanitation	2.10.4	Are pre-operative inspections conducted and documented, and are records legible and available for review?	7		7				
Sanitation	2.10.5	1. Is procedure documented on environmental and equipment sampling, which includes methods and responsibilities? (periodic basis to monitor the effectiveness of cleaning and sanitizing procedures e) 2. Is environmental air quality monitored on a scheduled basis to ensure that it is of suitable quality? (e.g., testing air for Yeast and Mold, Aerobic Plate Count)	7		7				
Sanitation	2.10.5.a	Are testing records available for review and does the environmental testing program document corrective actions in response to isolated positive results (to eliminate harborage sites)?	7		7				
Sanitation	2.10.5.b	Have trends or recurring environmental positives been identified through periodic in-house record reviews and are corrective actions taken to eliminate recurring positive results?	4		4				
Sanitation	2.10.6	1. Are chemical preparations tested by trained personnel for concentration, via test kits or sanitizer strength strips, prior to use or on a periodic basis? 2. Is chemical concentration documented, and are records legible and available for review?	7		7				
Sanitation	2.10.7	Is safety equipment provided to sanitation crew?	4		4				

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Sanitation	2.10.8	Are water hoses stored off the floor? (e.g., on wall-mounted hangers)	4		4				
Sanitation	2.10.9	Are adequate staffing and time allocated to ensure complete cleaning of all areas?	4		4				
Sanitation	2.10.10*	Are product and packaging materials protected during cleaning procedures?	10		10				
Sanitation	2.10.11*	Are cleaned and sanitized portable equipment and utensils protected from contamination during storage?	10		10				
Sanitation	2.10.12	Is there a documented procedure on hygiene clearance, which includes methods and responsibilities? (to ensure that equipment is cleaned, sanitized and inspected after having been worked on and/or repaired. This includes equipment that has stopped functioning during production and has been repaired on the line, or equipment that has been moved out of the production area and repaired in another area.)	7		7				
Sanitation	2.10.13*	1. Are equipment product contact surfaces, which have undergone repairs, maintenance or re-assembly, cleaned and sanitized prior to use? 2. Is this task on hygiene clearance recorded?	10		10				
Sanitation	2.10.14	Are maintenance tools, gloves, rags, and other miscellaneous materials stored in secured areas away from product handling equipment to prevent contamination?		x					Not applicable. Facility uses contracted third party.
Sanitation	2.10.15	Are floors kept free of standing water and/or ice? (e.g., floors sloped towards drains)	7		7				
Sanitation	2.10.16	Are product handling and storage areas maintained in clean condition?	7		7				
Sanitation	2.10.17	Is there a documented pallet inspection program?	4		4				
Sanitation	2.10.18	Is storage of wooden pallets in product handling or storage areas prohibited? (e.g., pallets are brought to these areas only as needed)	4		4				
Sanitation	2.10.19	Are employee break and/or locker rooms, and all other employee welfare areas maintained in sanitary conditions?	7		7				
Sanitation	2.10.20	1. Is sufficient aisle space (typically 12-18 inches) maintained along walls to permit cleaning and inspection for pest activity? 2. Are materials stored at an adequate height (typically the height of a pallet) above the floor?	7		7				
		*Product Safety Section Total Points	50		50	0	0	0	50
		Other Section Total Points	94		94	0	0	0	94
Sub Category	**2.11**	**Equipment Construction, Design, and Maintenance**							
Equipment Construction, Design, and Maintenance		**General Expectation: Compliance with 21CFR 117.40: All facility equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained; 21 CFR 117.80 (7): Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or product shall be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination.**							

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Equipment/ Containers/ Utensils	**(a)**	**Equipment/Containers/Utensils**							
Equipment	2.11.1*	Is equipment designed to: a. prevent adulteration of product with lubricants, oil, or other similar contaminants? (e.g., catch pans used under the motors and/or bearings on production lines located over product contact surfaces, where there is potential for leakage of oil or other lubricants, b. prevent water collection? (suggest cautious use of hollow structures, such as catwalk framework, table legs, conveyor rollers, and racks, because they may collect water and debris, and harbor pathogens)	10		10				
Equipment	2.11.2*	Are production lines, which are underneath ladders and walkways protected to prevent potential contamination? (i.e., there are kick plates that are at least 4 inches wide, covers, or other shields installed where necessary)	10		10				
Equipment/ Containers/ Utensils	2.11.3*	1. Are equipment, containers, and utensils: a. in good repair? (e.g., no rust and/or peeling paint present) and being used for their intended purpose(s), b. able to be cleaned and sanitized? (i.e., wooden equipment, utensils and/or wooden product surfaces are prohibited) 2. Are product contact surfaces made of smooth, non-absorbent, sealed, durable, non-corrosive, nontoxic materials, easily cleanable product contact surfaces that are sloped to drain freely, and are they able to withstand the environment in which they are used? 3. Are seams on product contact equipment or surfaces smoothly bonded?	10		10				
Temporary Repairs	2.11.4	Are materials such as string, tape, wire, and/or cardboard that might have potential to contaminate the product or that cannot be properly cleaned and sanitized, not being used for temporary repairs on product contact equipment?	7		7				
Vehicles/ Equipment	2.11.5	Are vehicles and/or equipment, which are used for moving raw materials, finished products, and packaging throughout the facility, cleaned and maintained in good condition?	4		4				
P.M. Program	**(b)**	**Preventive Maintenance Program**							
P.M. Program	2.11.6	1. Is there a documented procedure on preventative maintenance program, which includes methods and responsibilities? (preventive maintenance schedule on equipment, utensils, floors, walls, ceilings, roof and building fabrications)	7		7				
P.M. Program	2.11.7	Are records kept for ordered maintenance work or repairs, which are signed off when the work is completed?	7		7				
		*product Safety Section Total Points	30		30	0	0	0	30
		Other Section Total Points	25		25	0	0	0	25
Sub Category	**2.12**	**Receiving, Storage and Distribution**							
Receiving, Storage & Distribution		**General Expectation: Compliance with 21CFR 110.93.**							
Receiving	**(a)**	**Receiving: In-bound Inspection**							
Receiving	2.12.1*	1. Are incoming raw materials and packaging materials inspected for potential product safety hazards during receiving? 2. Are findings from incoming raw materials inspections documented and available for review?	10		10				

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Receiving	2.12.2*	If liquid or dry raw materials and other ingredients are received in bulk, are adequate transfer procedures in place to protect product from contamination? (e.g., transfer procedures, maintenance of transfer hoses, connection ports, etc.)		x					Bulk materials are not received.
Receiving	2.12.3	Are temperatures of refrigerated and frozen products documented at the time of receiving?		x					Refrigerated/frozen products are not received.
Receiving	2.12.4*	1. Does the company have practices for the inspections of incoming trucks and are inspections (e.g., cleanliness, temperature) documented, and available for review? 2. Do incoming trucks, trailers, or transport containers that are used for transporting product appear to be clean and in good condition?	10		10				
Storage	**(b)**	**Storage**							
Storage	2.12.5*	1. Are storage room temperatures maintained within a defined acceptable range? 2. Is storage room humidity maintained within a defined acceptable range? (Applicable only if humidity control is in place)		x					Temperature and humidity control are not required.
Storage	2.12.7*	1. Is temperature and/or humidity monitored regularly via continuous recording device or manually? 2. Are records and corrective actions available for review?		x					
Transp & Distrib	**(c)**	**Transportation and Distribution**							
Transp. & Distrib.	2.12.8	Is there a documented procedure on inspection of incoming and outgoing trucks, which includes methods and responsibilities?	7		7				
Transp. & Distrib.	2.12.9*	1. Does the company have practices for the inspections of outgoing trucks? 2. Do outgoing trucks, trailers, or transport containers that are used for transporting product appear to be clean and in good condition? 3. Are inspections (e.g., cleanliness, temperature) documented, and are inspection records and corrective actions available for review?	10		10				
Transp. & Distrib.	2.12.10	Are perishable products maintained in their appropriate temperature range if staged and/or stored in shipping areas (outside the coolers) to prevent temperature degradation of products?		x					
		*product Safety Section Total Points	30		30	0	0	0	30
		Other Section Total Points	7		7	0	0	0	7
HACCP PLAN		**SECTION B: HACCP PLAN AND PROCESS PRACTICES**							
HACCP PLAN		**General Expectation: An accurate and documented Hazard Analysis Critical Control Points (HACCP) Plan is developed and implemented. The HACCP Plan complies with Codex Alimentarius Commission and National Advisory Committee for Microbiological Criteria for products' definitions for HACCP. The plan addresses physical, chemical, and biological hazards. Frequency of checks and required record keeping are documented. Verification procedures document that the HACCP Plan is working and is continuously effective.**							
	1.0	**MANAGEMENT RESPONSIBILITY**							
Sub Category	**1.1**	**Management Commitment and Review**							

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Mgmt. Commitment	1.1.1	Does management appear to be committed to executing an adequate HACCP/Hazard Prevention product safety management program?	7		7				
		Other Section Total Points	7		7	0	0	0	7
	2.0	**FUNDAMENTALS**							
Sub Category	**2.1**	**HACCP/Hazard Prevention Program/Risk Based Preventive Controls for Human Food**							
HACCP	2.1.1	Is food safety plan prepared in accordance with the steps identified in the Codex Alimentarius Commission or NACMCF HACCP guidelines?	7		7				
HACCP	2.1.2	Does the facility operate under a government regulated HACCP program (FDA or USDA)?			FDA				IHA Codex and FDA FSMA PC Plan.
HACCP	2.1.3	1. Is there a HACCP team identified and documented? 2. Is the HACCP team comprised of employees with diverse responsibilities and does it include a competent HACCP Team Leader?	4		4				
HACCP	2.1.4	1. Does the HACCP team meet periodically to address product safety issues and/or review the HACCP program? 2. Are records of the meetings kept on file and available for review?	4		4				
		General Expectation: Are there documented HACCP or Risk Based Preventive Controls program(s), detailing the 7 principles, and is it established, up-to-date, and available for review? The HACCP Plan or PCP Plan must be developed following the required steps: 1) Conduct a hazard analysis. 2) Determine the critical control points or preventive control points (yes/no). 3) Establish critical limits (if any CCPs or PCPs). 4) Establish monitoring procedures (if any CCPs or PCPs). 5) Establish corrective actions (if any CCPs or PCPs). 6) Establish verification procedures (if any CCPs or PCPs). 7) Establish record-keeping, documentation, and validation procedures (if any CCPs or PCPs).							
HACCP	**(a)**	**Product Description(s), Process-Flow Diagram(s), Hazard Analysis Worksheet(s)**							
Product Description(s)	2.1.5	Are product descriptions, intended uses, shelf life, customers, documented and are they accurate?	7		7				
Process-Flow Diagram(s)	2.1.6	1. Are process-flow diagram(s) current for all HACCP plan(s), and are they accurate? 2. Are critical control or control point(s) identified on the process-flow diagram(s)?	7		7				
Hazard Analysis Worksheet(s)	2.1.7*	Do Hazard Analysis Worksheet(s) exist and do they identify biological, chemical, and physical hazards, and consider the severity and likelihood of occurrence?	10		10				
Preventive Controls-Hazard Analysis Worksheet(s)	2.1.8*	Applicable to FSMA: Do Hazard Analysis Worksheet(s) exist and do they identify biological, chemical, and physical hazards, and consider analysis of hazards and risk-based preventive controls? Note: Preventive controls: Are these measures required to ensure that hazards requiring a preventive control will be minimized or prevented? For example, they include process, food allergen, and sanitation controls, as well as supply-chain controls and a recall plan)	10		10				
HACCP Plan(s) & CCPs	**(b)**	**HACCP Plan(s)/Risk Based Preventive Controls for Human Food**							

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
HACCP Plan(s) CCPs	2.1.9*	Does CCP plan(s) include: a. names of CCP(s) that control hazards; b. critical limits; c. monitoring procedures and frequency; d. corrective actions taken if critical limits are violated; e. plan verification procedures; and f. record keeping and documentation procedures.	10		10				
Preventive Control Plan(s) and PCPs	2.1.10*	Applicable to FSMA: Does PCP plan(s) include: a. names of PCP(s) that control hazards; b. critical limits; c. monitoring procedures and frequency; d. corrective actions taken if critical limits are violated; e. plan verification procedures; and f. record keeping and documentation procedures.	10		10				
Monitoring	**(c)**	**Monitoring Procedures**							
Monitoring-CCPs	2.1.10*	1. Is each critical control point as specified in CCP Plan, monitored at scheduled intervals, documented, and records reviewed? 2. Are CCP records signed and/or initialed by the individual performing the task? 3. Are CCP records signed and/or initialed by the individual reviewing the records? 4. Are records accurate and legible?	10		10				
Monitoring-CCPs	2.1.11*	Are CCPs in compliance with the critical limits stated?	10		10				
Monitoring-PCPs	2.1.12*	Applicable o FSMA: 1. Is each preventive control point as specified in PCP Plan, monitored at scheduled intervals, documented, and records reviewed? 2. Are PCP records signed and/or initialed by the individual performing the task? 3. Are PCP records signed and/or initialed by the individual reviewing the records? 4. Are records accurate and legible?	10		10				
Monitoring-PCPs	2.1.13*	Applicable to FSMA: Are PCPs in compliance with the critical limits stated?	10		10				
Corrective Actions	**(d)**	**Corrective Actions**							
Corrective Actions-CCPs	2.1.12*	1. When critical limit(s) are not met, are identified corrective actions as specified on the CCP Plan(s) implemented to bring critical control point(s) under control? 2. Are deviations and corrective actions properly documented and reviewed (initialed and dated)? 3. Are records accurate and legible?	10		10				
Corrective Actions-PCPs	2.1.13*	Applicable to FSMA: 1. When preventive control limit(s) are not met, are identified corrective actions as specified on the PCP Plan(s) implemented to bring critical control point(s) under control? 2. Are deviations and corrective actions properly documented and reviewed (initialed and dated)? 3. Are records accurate and legible?	10		10				
Corrective Actions	2.1.14*	Is disposition of non-compliant products documented?	10		10				
Verification	**(e)**	**Verification Procedures**							
Verification-CCP Plan(s)	2.1.15*	Are CCP or PCP Plan(s) signed and/or initialed and dated by the Food Safety Manager and/or another member of HACCP team?	10		10				
Verification-HACCP Plan(s)	2.1.16*	1. Were HACCP plan(s) or PCP Plans in use during the audit current and up-to-date? 2. Do these documents provide the date of last assessment?	10		10				

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Verification-CCP /PCP Plan(s)	2.1.17*	Are verification procedures, example on calibration, testing, measuring, which determine the validity of the CCP or PCP plan and product safety management practices, defined in a written document?	10		10				
Verification-CCPs/PCPs	2.1.18*	Is direct observation conducted by an authorized personnel to ensure that work instructions are followed when verifying CCP(s) or PCPs and the CCP or PCP Operator is aware of corrective actions to be taken during deviations?	10		10				
Verification-CCPs/PCPs	2.1.19*	Were all CCPs or PCPs verified by the auditor during inspection and were all CCPs in compliance with the CCP Plan(s)?	10		10				
Validation	**(f)**	**Validation Procedures**							
Validation HACCP/PCP	2.1.20*	1. Are audits or reviews of HACCP or PCP program conducted on a regular basis to ensure they are executed according to the facility's plan? 2. Are records available for review?	10		10				
Validation HACCP/PCP	2.1.21*	Has the facility validated all critical limits or preventive control points or key elements, and is support documentation maintained and available for review? (e.g., process authority, validation study, cite number and dates of in-house study, scientific reference, regulatory requirements)	10		10				
Validation HACCP/PCP	2.1.22*	1. Are CCP or PCP deviations trended and assessed for improvement? 2. Is root cause analysis conducted on repeat occurrences?	10		10				
Validation HACCP/PCP	2.1.23*	1. Is annual internal audit conducted on HACCP or PCP program? 2. Are findings corrected and documented?	10		10				
Validation	2.1.25*	Are targeted sampling and testing conducted on products, and is it documented as required in the verification procedures?	10		10				
Record Keeping	**(g)**	**Record Keeping**							
Record Keeping-CCP/PCP	2.1.26*	1. Are CCP or PCP records maintained for a specified number of years (shelf life 1 year, customer requirements, , regulatory requirements)? 2. Are all records accurate and legible?	10		10				
		*Product Safety Section Total Points	220		220	0	0	0	220
		Other Section Total Points	29		29	0	0	0	29
Sub Category	**2.2**	**Allergens**							
Allergens		**General Expectation: Develop food allergen program based on a. the eight food groups, b. food additives, c. color additives, d. allergens used in the products (refer to 21 CFR 117)**							
Allergens	2.2.1	Is there a list indicating all allergens and/or sensitizing chemicals stored in the facility? (e.g., eight major allergens recognized by the USDA and Codex include: proteins from peanuts, tree nuts, dairy, egg, soy, wheat, finfish, and crustacea. Sensitizing chemicals include: sulfites, and some food colorings such as Yellow 5)	7		7				
Allergens	2.2.2	Are there written procedures on management of allergen-containing products?	7		7				

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Allergens	2.2.3*	Are allergens stored in a manner that protects other non-allergenic materials from inadvertent contamination?	10		10				
Allergens	2.2.4*	Are containers, equipment, and/or utensils used in handling allergens identified to prevent cross contamination from allergens to non-allergen containing products?		x					Facility does not process allergens.
Allergens	2.2.5*	Are proper product handling procedures in place to prevent cross contamination from allergens to non-allergen containing products? (e.g., production sequencing and equipment sanitation [i.e., nonallergen-containing product is produced first], or sanitation protocols are followed to ensure that equipment used for the production of allergen-containing products is strictly used for its purpose)	10		10				
Allergens	2.2.6*	Has validation study conducted on sanitation practices by using specific allergen swabs?		x					
Allergens	2.2.7 *	a. Are effective sanitation procedures practiced to prevent cross contamination from allergen to non-allergen containing products or during change-overs? b. Is cleaning documented when switching from allergen to non-allergen containing products and are the equipment, containers, and/or utensils checked for removal of potential allergenic-product residue?		x					
Allergens	2.2.8*	Rework or Work in Progress (WIP): Are there written procedures on proper handling of rework or WIP material (if applicable)?		x					Not applicable.
Allergens	2.2.9*	Is the policy enforced to prevent cross contamination from allergens to non-allergen containing products and also to ensure that rework or WIP is only incorporated into similar products?		x					Not applicable.
Allergens	2.2.10	Are labeling and packaging procedures for products containing allergens, documented?	7		7				
Allergens	2.2.11*	a. Are labels reviewed for accuracy upon receipt or printing and upon use and is review process documented? b. Are all allergens declared on the label using common terms as dictated by the FDA Food Allergen Labeling and Protection Act?	10		10				
Allergens	2.2.12*	Is there an established verification program to ensure allergen control procedures are in compliance?	10		10				
		*Food Safety Section Total Points	40		40	0	0	0	40
		Other Section Total Points	21		21	0	0	0	21
Doc. Control	**3.0**	**SECTION C: DOCUMENT CONTROL**							
Document Control	3.1.1.	Is there a documented procedure on document control to maintain current documented procedures and forms?	4		4				
Document Control	3.1.2	1. Are procedures in place to control document transmission, changes and removal of obsolete documents? 2. Are changes and reasons for changes documented?	4		4				
Document Control	3.1.3	Is there an authorized person to issue product safety documents?	4		4				
Document Control	3.1.4	Do document control procedures ensure customer confidentiality?	4		4				
Document Control	3.1.5	Does a document control system protect physical and electronic documents against loss and unauthorized access?	4		4				
Document Control	3.1.6	Is there a records retention policy for product safety related documentation, data and records?	4		4				

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
		Other Section Total Points	24		24	0	0	0	24