Food Safety Evaluation

Company: Iowa Premium, LLC **Audit Date:** January 14, 2016

Facility Physical Address: 3337 L Avenue Tama, IA 52339

Company Contact / Title: Mike Gager

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Est #, and/or FDA #: 8 **FSNS Evaluator:** Justin Derington

Previous Audit Date: 1/9/2015 **Previous Audit Score:** 96%

Audit Number: 5160009

Audit Information

Total Audit Points	602
Total Audit Percentage	96%
Total Food Safety Points	251
Total Food Safety Percentage	97%
Audit Outcome (pass/fail):	Pass
Re-audit Required?	No

Has the establishment registered with FDA according to "The Public Health Security and Bioterrorism Preparedness and Response Act of 2002"?	FSIS Establishment, not required

Food Safety Evaluation

Facility Description:

Iowa Premium Beef was located in a rural area just outside Tama, IA and was surrounded by planted farmland. The facility was previously owned and operated by Tama Packing. The company began operations in November 2014 and currently staffed 400 employees. The plant currently harvested and processed approximately 650 head daily at a line speed of 80 head per hour.

Products Produced at this Location:

Products produced are as follows:

- Products produced are as follows:
- Beef primal cuts
- Trimmings
- Variety meats

Meeting Attendees:

Name	Title	Entrance Meeting	Closing Meeting
Mikel Gage	Quality Assurance Manager	Present	Present

FSNS® CERTIFICATION AUDIT

Food Safety Evaluation -- Score Summary

Section	Points		Section Average
	Received	Available	
Company Commitment	30	30	100%
Regulatory Non-Compliance and 3rd Party Audit Review	25	25	100%
* Sanitation & Hygiene Total	139	145	96%
General Sanitation	45	45	100%
Pre-operational Sanitation	42	45	93%
Operational Sanitation	20	20	100%
Employee Hygiene	32	35	91%
* HACCP	72	75	96%
Allergen Control and Management	0	0	100%
* Crisis Management	40	40	100%
Facility Security	33	35	94%
Pest Control	65	65	100%
Process Controls	40	50	80%
Maintenance / Construction & Design	143	150	95%
QA/QC Program	15	15	100%
TOTAL SCORE	602	630	96%

*** Identifies the sections that comprise the Food Safety Score.**

Minimum Total Score Needed to Pass: 90%
Minimum Food Safety Sections Score Needed to Pass: 90%
Minimum Other Sections Score Needed to Pass: 80%

Sections not meeting minimum required score will be highlighted in yellow.

Audit Findings – Summary of Deficiencies

Section Letter	Item Number	Comments
C	16	The facility had implemented an ATP and microbiological testing program. APC testing was performed as outlined in the Pre-operational Micro Sampling program. This program required 13 areas be swabbed in fabrication per week and 10 areas in slaughter per week. The ATP results from the week of December 14, 2015 were reviewed. A reswab for a failed test of a sanitizer was not available. Additionally, the APC tests were to be performed weekly, however, no data was available between December 8, 2015 and Decemeber 31, 2015.
C	30	During the plant tour, drinks and empty drink containers were observed in the box make-up area. This was not consistent with company GMPs.
D	12	Verification activities included pre-shipment review of records performed daily, direct observation performed once per shift and calibration of thermometers. The verification procedures did not address the pressure gauge used to monitor hot water wash pressure.
G	1	Security arrangements implemented at the facility were outlined in the Food Defense Program. The Food Defense Program ou;tlined security arrangements for general security, restricted areas, visitors and guests, trucks and trailers, mail and new personnel. Evidence of a risk assessment having been carried out was not available for review.
I	2	The Receiving Inspection SOP outlined the requirements receiving packaging materials and chemicals at the facility. The facility was not currently documenting that incoming goods were inspected and trailers were acceptable.
I	10	Document retention requirements were not defined.
I	11	The Shipping Inspection SOP outlined procedures for ensuring trailers were clean, precooled and in adequate condition prior to being loaded. Trailer inspections were documented on the Outbound Form. However, this form did not include verifying that trailers were cooled below 45 F as required in the written program.
J	6	The facility was currently performed monthly SPS internal audits in the fabrication areas. This program had not been extended to the entire facility as of the time of the audit.
J	19	During the plant tour spray paint and other non-food grade greases were observed being stored in the box make-up area. Additionally, Food grade and non-food grade greases were observed stored together in the in the box make-up area and fabrication maintenance shop.

Food Safety Evaluation

The following has been issued as guidance for scoring the questions contained within the Food Safety Evaluation. The evaluator may impress his/her judgment and/or experience to this guidance as needed or required.

Point Scale	Basis for Assigned Point Value
5	Program is well written, and documentation is available, and process is implemented and operating as described.
4	Program is missing an item or a step could be enhanced, or minimal (few) errors in documentation exist, or observe process not operating as described.
3	Program is relayed verbally with no formally written program, or the task is being performed as relayed in the verbal program, or obvious and consistent errors exist in the documentation.
2	Staff is not educated on the entire program with difficulty in verbalizing it, or documentation contains multiple errors, or minimal items are in place and operating as designed.
1	Attempts at having a written program located throughout multiple documents; some type of documentation; minimal portions are in place and operating.
0	No written program; no documentation; no implementation or execution.
N/A	Item not applicable to the facility.

Food Safety Evaluation

A. Company Commitment		Score	Comments
1.	The Mission Statement includes a strong focus on food safety and quality.	**5**	The Iowa Premium Mission Statement outlined the company's commitment to food safety and quality. This mission statement was signed by the CEO and communicated to plant personnel through postings throughout the facility.
2.	The Mission Statement is communicated to all employees?	**5**	The Iowa Premium Mission Statement outlined the company's commitment to food safety and quality. This mission statement was signed by the CEO and communicated to plant personnel through postings throughout the facility.
3.	A training program for new employees and on-going (annual) training is established and records are available (i.e., food safety, allergen, GMP, HACCP training, etc.).	**5**	The facility used the electronic Alchemy system to track training requirements. Training included Company Governing Principles, hazardous communications, food defense, GMPs, handwashing, HACCP and blood borne pathogens. Allergens training was included in the GMP training. Records of employee training were available for review.
4.	Company management understands the risk associated with food safety issues and/or poor quality.	**5**	The management team understood the risks of food safety and quality issues.
5.	A current organizational chart is available.	**5**	The Iowa Premium Beef Organizational Chart outlined the reporting structure of the company. The Food Safety Manager reported to the CEO of the company.
6.	The reporting structure and authority for the Food Safety Department are defined.	**5**	The Food Safety Manager was responsible for ensuring food safety and quality policies were adopted at the facility. The Food Safety Manager reported to the CEO.
	Section A. Total Score	**30**	

B. Regulatory Non-Compliance and 3rd Party Audit Review		Score	Comments
1.	Review the past 12 months of Recent Regulatory Non-Compliances for the facility. Record the numbers of Regulatory Non-Compliances YTD.	The facility received 172 NRs were issued in 2015. The facility was subjected to a for cause Food Safety Assessment (FSA) due to multiple event days. The FSA resulted in a notice of suspension in May, 2015. The abeyance was lifted in December, 2015.	

2.	Facility responds to Regulatory Non-Compliances in a timely manner.	**5**	The facility targeted a 7 day response timeframe. Records from the months of August and September were consistent with this goal.
3.	The appropriate personnel are involved in responding to the Regulatory Non-Compliances.	**5**	The Food Safety Manager and the operations manager in the effected area.
4.	A tracking system for Regulatory Non-Compliances is established with a timely review and assessment by the management team.	**5**	NRs went into a tracking log that was reviewed for trends on a monthly basis.
5.	Review any additional regulatory agency enforcement activity.	**5**	The facility was subjected to a for cause FSA in May of 2015. The suspension and abeyance was lifted in December.
6.	Previous 3rd Party Audit deficiencies have been corrected or plans put in place to address the issues.	**5**	Non-conformities from the previous audit had been addressed.

Section B. Total Score **25**

C. Sanitation and Hygiene		**Score**	**Comments**
	GENERAL SANITATION		
1.	Development of the SSOP meets the following requirements: (a) describe all procedures an establishment will conduct daily, before and during operations to prevent product contamination; (b) signed and dated by the official with the overall on-site authority and the document is maintained as described; (c) procedures to be conducted prior to operations are identified and address cleaning of product contact surfaces; and (d) the frequency at which each procedure is to be conducted is specified and the responsible individual is identified.	**5**	The Sanitation Standard Operating Procedures outlined the activities to be performed prior to and during operations to ensure a sanitary facility is maintained. This program included the responsibilities of key personnel, frequency of activities to be performed and was signed by the Food Safety Manager on 9/1/15.

2.	The facility routinely evaluates the effectiveness of the SSOP and revises the procedures as necessary to prevent product contamination.	**5**	The SSOPs were revaluated on an annual basis with the most recent review occurred on 9/1/15.
3.	SSOP Corrective Actions documented and contain the following: (a) appropriate disposition of product that may be contaminated; (b) restoration of sanitary conditions; (c) measures to prevent recurrence of direct product contamination; and (d) the re-evaluation of the SSOPs and any necessary modifications to them occurs as required.	**5**	Corrective actions included disposition of potentially contaminated product, restoration of sanitary conditions, preventive measures and re-evaluation of SSOPs.
4.	Records are maintained on a daily basis and are sufficient to document the implementation and monitoring of the SSOPs and any corrective actions taken. These records are signed and dated by the responsible individual.	**5**	The facility maintained pre-operational and operational SSOP inspection records. These records were dated and initialed at the time the inspection was completed.
5.	All cleaning chemicals and sanitizers have been approved by the appropriate regulatory agency and they are properly stored. MSDS and labels are available for review.	**5**	Cleaning and sanitizers used at the facility were approved by USDA for use. SDS were available for review for the chemicals used.
6.	A training program is established for the sanitation crew. Training is performed on an on-going basis (annually) and records are maintained and available for review.	**5**	Sanitation personnel received training upon hire and annually. Training included general sanitation practices, hygiene requirements and training on task-specific procedures. Training records from 7/31/15 were reviewed during the audit.
7.	The vehicles used to transport or deliver food (i.e., tubs, gondolas, plastic bins, etc.) are easily cleanable and in good repair.	**5**	Tubs and gondolas used at the plant were stainless steel or food grade plastic. These items were kept clean and observed to be well maintained.

8.	Review all Regulatory Non-Compliances for SSOP violations. Record the number of SSOP related Regulatory Non-Compliances YTD. Record the number of Regulatory Non-Compliances linked or trended as repeat failures YTD.	**5**	The facility had received seven NRs related to sanitation. None of the seven had been linked.
9.	Facility and equipment are designed and engineered with concern for food safety issues.	**5**	The facility was constructed and engineered with concern to food safety. No apparent food safety risks were observed to be present by the structure or design of the facility.

General Sanitation Score 45

PRE-OPERATIONAL SANITATION			
10.	Cleaning is done by in-house or contract employees?	Contracted to Qvest	
11.	A master sanitation program identifies all areas to be cleaned, responsibilities and the frequency. Documents verifying the completion of the MSP are available for review.	**5**	A master sanitation schedule had been developed which outlined the frequency for cleaning those areas that were cleaned less than daily. This schedule identified weekly, monthly, quarterly and bi-annual activities to be carried out and included documentation of when each item was cleaned.
12.	The Sanitation Department has an SOP that provides detailed guidance on how to clean each piece of equipment in the plant. This includes equipment requiring CIP.	**5**	Documented cleaning procedures were defined in the Standard Sanitation and Operations Procedures Manual. The procedures were defined for each piece of equipment and included the step-by-step cleaning procedures and chemicals to be used.
13.	Cleaner and sanitizer concentrations and applications comply with the master sanitation program and are approved for use in a food manufacturing facility.	**5**	The facility used titration test strips to verify the concentration of the sanitizers used. This was documented on the Chemical Titration Log. The concentration of cleaning chemicals was not currently being verified.
14.	Sanitation procedures and practices are designed to prevent cross-contamination.	**5**	Sanitation was performed at the end of the production shift after product, raw material and packaging materials were removed from the area.

15.	The Sanitation Manager/Supervisor is involved in monitoring the adequacy of the pre-operational sanitation.	**5**	The sanitation manager from the contracted company was involved in monitoring the effectiveness of the sanitation procedures.
16.	Microbiological testing and/or bioluminescence are utilized to monitor the effectiveness of cleaning and sanitizing procedures (contact surfaces and non-contact surfaces). Feedback of results is established.	**2**	The facility had implemented an ATP and microbiological testing program. APC testing was performed as outlined in the Pre-operational Micro Sampling program. This program required 13 areas be swabbed in fabrication per week and 10 areas in slaughter per week. The ATP results from the week of December 14, 2015 were reviewed. A reswab for a failed test of a sanitizer was not available. Additionally, the APC tests were to be performed weekly, however, no data was available between December 8, 2015 and December 31, 2015.
17.	An environmental monitoring program is developed and established for the processing environment.	**5**	Non-contact areas were included in the pool of potential swab areas to be included in the micro or ATP swab locations.
18.	A pre-operational inspection program is established and documented. Records including any Corrective Actions are available for review and are current.	**5**	The facility performed daily per-operational inspections. Pre-operational inspection records and necessary corrective actions from the week of December 11, 2015 were reviewed during the audit.
19.	The facility has developed and implemented a rotational sanitizer program.	**5**	The facility rotated between quaternary ammonia and sodium hypochlorite every other day.

Pre-operational Sanitation Score 42

OPERATIONAL SANITATION			
20.	Production managers are involved with monitoring their people to see that personal hygiene practices prevent contamination.	**5**	Production supervisors were responsible for monitoring employee compliance with hygiene requirements.
21.	Management and employees are trained to check that traffic (people, equipment, product) is controlled to prevent potential cross contamination or minimize the risk.	**5**	Employees and supervisors were trained on appropriate movement patterns to prevent cross contamination.

22.	Condensation is controlled to prevent potential contamination of product and product zones.	**5**	Condensation was not observed during the audit.
23.	Food is protected from dust, dirt and other contaminates while being transported or delivered.	**5**	Products were vacuum sealed and placed in a covered combo during storage or transportation.

Operational Sanitation Score 20

EMPLOYEE HYGIENE

24.	A GMP/ Personal Hygiene Policy is established and implemented. The policy includes employee hygiene, hand washing requirements, jewelry restrictions, policies for use of hair nets/ beard nets, and provisions for use of gloves when handling product. Personal items are stored away from the processing area. Eating is not allowed in the locker rooms.	**5**	The Good Manufacturing Practices Procedures outlined the hygiene and employee practice requirements to be implemented at the facility. This policy included hairnets, bear nets, hand washing, prohibition on jewelry with the exception of a plain wedding band, eating drinking and the use of tobacco products, glove requirements and storage of personal items.
25.	Employees, visitors and contractors are complying with the Personal Hygiene Policy.	**5**	No violations of the GMP policy were noted during the audit.
26.	An outer garment policy is established and followed. It includes provisions for above-the-waist pockets.	**5**	The Good Manufacturing Practices Procedure outlined the outer clothing requirements for the facility. Frocks did not have pockets above the waist.
27.	Hand washing facilities and boot washes / dips are adequate and utilized per the company policy.	**5**	Hand wash stations were located at the entrance to the production areas and observed being used per company policy.
28.	The Personal Hygiene Policy addresses excluding personnel with medical problems from potentially contaminating products.	**5**	The Good Manufacturing practices procedure included excluding personnel suffering from a communicable disease or medical problem which could potentially effect product.

29.	All equipment and utensils are handled and stored in a sanitary manner. Materials used as food contact surfaces are smooth, non-toxic and non-absorbent (i.e., no wooden handles allowed in the processing areas, no rust present on equipment, etc.).	**5**	Equipment and utensils were observed during the audit were constructed of appropriate material and well maintained.
30.	Eating, chewing gum, drinking and use of tobacco products are not allowed in the processing areas.	**2**	During the plant tour, drinks and empty drink containers were observed in the box make-up area. This was not consistent with company GMPs.
	Employee Hygiene Score	**32**	
	Section C. Total Score	**139**	

D. HACCP		**Score**	**Comments**
1.	A cross-functional HACCP Team is established and at least one member of the team has formal HACCP training.	**5**	A multi-functional HACCP team had been established which consisted of the VP of Operations, Food Safety Manager, Quality Assurance Manager, QA/FS Supervisors, Harvest Manager, Fabrication Manager, Plant Manager and the Maintenance Manager. Five members of the team had received formal HACCP training.
2.	The HACCP Team meets on a scheduled basis.	**5**	The HACCP team met a minimum of annually to review and reassess the HACCP plan. Records of meetings were maintained in the HACCP Reassessment Log. The most recent reassessment occurred on 9/21/15 for the harvest/variety meats plan.
3.	Employees performing HACCP functions are trained on an annual basis and records are kept to document the training.	**5**	Employees responsible for implementing the HACCP plan received training upon hire and annually. Training from 12/21/15 was reviewed during the audit.
4.	The flow chart accurately represents the process and is verified and signed. CCPs are identified on the flow chart.	**5**	A flow diagram, dated 9/21/15, was available for each of the two HACCP plans. The flow diagrams accurately outlined the product flow associated with each process and identified CCPs.
5.	Process Category descriptions are complete and accurate.	**5**	The product description included the common name, intended use, packaging type, labeling instructions and special distribution requirements.

6.	The Hazard Analysis (HA) is complete and addresses each step in the flow chart. The HA identifies biological, chemical and physical hazards.	**5**	A hazard analysis had been conducted for each of the HACCP plans during which each step identified in the flow diagram was analyzed for potential chemical, physical and biological hazards. Biological hazards identified included: *E. Coli O157:H7* , NonO157 STEC, Salmonella, SRMs, parasites. Chemical hazards included antibiotic residues and cleaning chemicals. Physical hazards included buckshot and needles.
7.	Critical control points (CCP's) and Critical Limits (CL) are clearly defined and consistent with the 7 HACCP principles.	**5**	The facility identified three CCPs in the harvest plan and one CCP in the fabrication plan. CCPs were clearly defined and consistent with the 7 principles of HACCP. CCPs included the following: CCPh1 - Zero tolerance inspection of carcasses and offal - 5 carcasses and 10 pieces of each offal type were inspected once per production hour. CCPh2 - Hot water carcass wash. Critical limit of water being 196 F or higher and applied at a pressure of 12 psi or greater. This CCP was monitored once every hour of production CCPh3 - Variety Meat freezing and storage. This CCP had a critical limit of product being chilled to 44.6 F or less within 24 hours. This was monitored once every 24 hour period with a minimum o 13 boxes checked. CCPF 1 - Product temperature below 44.6 F during packaging. This CCP was monitored once per production period.
8.	The Hazard Analysis, CCP's, and Critical Limits are clearly identified and scientifically validated. Monitoring and verification activities have been validated with scientific and in-plant data. All are well documented.	**5**	The critical limits, monitoring procedures and verification requirements were clearly defined and validated. Validation information for the hot carcass wash and temperature control requirements were reviewed during the audit.
9.	Corrective action procedures are identified and adhered to when CL are not met.	**5**	Corrective action procedures were defined and were consistent with 9 CFR 417.3

10.	The corrective actions include: (a) cause of the deviation is identified and eliminated; (b) the CCP will be under control after the corrective action is taken; (c) measures to prevent recurrence are established; and (d) no product that is injurious to health as a result of the deviation enters commerce. Records are thorough and available for review.	**5**	Corrective action procedures included identifying the cause of the deviation, bringing the CCP back under control, corrective actions implemented to prevent reoccurrence and disposition of potentially contaminated product. A completed corrective action for a zero tolerance failure on 12/31/15 was reviewed during the audit.
11.	A CCP deviation file is maintained and utilized to allow early detection of possible linkages and potential systems failure.	**5**	The facility maintained a file where HACCP deviations and corrective actions were maintained.
12.	The verification frequency and responsibility is defined and validated, and records are complete. Verification activities includes calibration of monitoring devices.	**2**	Verification activities included pre-shipment review of records performed daily, direct observation performed once per shift and calibration of thermometers. The verification procedures did not address the pressure gauge used to monitor hot water wash pressure.
13.	The pre-shipment review is documented and complete.	**5**	Per the documented verification procedures, the facility performed a pre-shipment review of records prior to products being shipped.
14.	Reassessment is conducted at least annually and proper documentation is available for review.	**5**	The HACCP team met a minimum of annually to review and reassess the HACCP plan. Records of meetings were maintained in the HACCP Reassessment Log. The most recent reassessment occurred on 9/21/15 for the harvest/variety meats plan.
15.	Employees performing the monitoring and/or verification activities of the CCP(s) understand the CL and corrective actions.	**5**	Employees interviewed during the audit understood the CCPs, critical limits, monitoring procedures and corrective action protocols.
16.	No actual or potential instances of failure of the HACCP Plan or product contamination/ adulteration were observed.	**No**	No actual or potential HACCP failures were noted during the audit.

Section D. Total Score 72

E. Allergen Control and Management		Score	Comments
1.	The facility uses an allergen(s) in the production of its product(s). List allergen(s) utilized.	Allergens were not handled at the facility.	
2.	An Allergen Control program is developed and implemented.	**N/A**	Allergens were not handled at the facility.
3.	The allergen program includes rework and carryover controls and verification to maintain compliance.	**N/A**	Allergens were not handled at the facility.
4.	The Allergen program includes identification and segregation of allergens from receiving, storage, processing and finished product.	**N/A**	Allergens were not handled at the facility.
5.	Cleaning validations are conducted on lines containing allergens.	**N/A**	Allergens were not handled at the facility.
6.	Labels with allergen ingredients are reconciled and verified for accuracy and content. Labels with allergens are verified at point of use/ application.	**N/A**	Allergens were not handled at the facility.
7.	Production scheduling is used for controlling changeovers. Describe the process.	**N/A**	Allergens were not handled at the facility.

Section E. Total Score **0**

F. Crisis Management		Score	Comments
1.	A written Crisis Management (Recall / Traceability) Program is established and implemented; responsible parties are assigned.	**5**	The Recall Program outlined actions to be taken in the event of a recall. This policy defined the recall team and assigned responsibilities to each person.

2.	Procedures are established for identification and accountability of all raw materials, packaging and finished products from all suppliers.	**5**	Procedures for identifying and tracking raw material (cattle) and packaging materials were defined. Carcasses were identified with a carcass tag, applied on the kill floor, which identified the carcass by lot and was traceable back to the supplier. Cattle was tracked to the fabrication floor using the cold scale data. Finished products were identified with a time stamp so that the facility would have a rough idea as to which cattle were utilized for specific finished products.
3.	An annual Mock Recall is conducted on raw materials, finished product and packaging materials and completed within 2 hours of initiation. Documentation and corrective actions are available for review. Include information from the most recent Mock Recall.	**5**	The facility performed a minimum of two mock recalls per year. The most recent audit traceability exercise was conducted on 1/12/16 during which time the facility traced a lot of packaging material forward to the finished product and first level of distribution. Additionally, the facility traced a lot of finished products backward to the raw materials on 1/6/16. Records of these exercises were available for review.
4.	For all products, finished product label controls are implemented and verified. Labels are verified at point of application/ use at a frequency that demonstrates control.	**5**	The facility verified product labels once per production hour during hourly box audit checks.
5.	A written rework and work in process (WIP) program is established and documented. All rework and WIP is segregated and clearly identified. The rework and WIP policy includes procedures for handling rework and WIP's containing allergens.	**5**	Rework was generated in the form of damaged boxes in the warehouse. Rework was tracked in using Rework Sheets.
6.	A system for tracking customer complaints is established and reviewed on a routine basis.	**5**	Customer complaints were logged into the company's customer complaint log. This log was reviewed for trends by the Quality Assurance Manager once per month.
7.	Finished product labeling for every product is defined and implemented. Describe methods used (i.e., code dating).	**5**	Finish products were identified with the product code, product name and production date.

8.	A returned goods policy is written and implemented. Records are maintained and available for review.	**5**	Returned products were handled as outlined in the Returned Product SOP. This policy stated that returned goods were to be inspected and approved by management personnel who was responsible for determining disposition. Returned goods were to be tracked on the Returned Goods Form.
9.	A program for control of Imported Goods (raw material or packaging material) exists and is implemented. Records are maintained and available for review.	**n/a**	Imported goods were not used.
10.	A program for control of labels at a Co-packer is written and implemented. Records are maintained and available for review.	**n/a**	Co-packers were not used.

Section F. Total Score 40

G. Facility Security		**Score**	**Comments**
1.	A risk assessment has been conducted to determine potential risks within the organization (i.e., based on FSIS Self-Assessment Checklist). Should include action plan(s) if security is compromised.	**3**	Security arrangements implemented at the facility were outlined in the Food Defense Program. The Food Defense Program outlined security arrangements for general security, restricted areas, visitors and guests, trucks and trailers, mail and new personnel. Evidence of a risk assessment having been carried out was not available for review.
2.	Access to the facility, production and non-production areas, is restricted to authorized personnel only.	**5**	Access to the facility was restricted to authorized personnel through a perimeter fence, closed circuit camera system and on site security personnel.
3.	The visitor/contractor policies include plant security items that are reviewed prior to allowing visitors into the facility. Visitors are escorted at all times by company personnel.	**5**	Visitors and contractors were required to sign in upon arrival and were escorted while on site.
4.	The company has implemented a procedure for screening all potential employees and may include reference checks, drug screening and criminal background checks.	**5**	Prospective employees were screened using reference checks and drug tests.

5.	Raw materials are inspected for product integrity and the condition of the trailer seals.	**5**	Packaging materials and chemicals received at the facility were inspected for integrity and seals verified upon arrival.
6.	All trailers are sealed or secured while at the facility.	**5**	Trailers were required to be sealed upon arrival or departure.
7.	Procedures are established and followed for mail handling.	**5**	Mail was received by the company's front office, sorted and distributed to relevant departments.
8.	External vessels (i.e., silos, tanks, rail cars, etc.) are secured at all times.	**N/A**	External vessels were not used.

Section G. Total Score 33

H. Pest Control		**Score**	**Comments**
1.	A written Pest Control Program is established and implemented. The program is designed to sufficiently maintain a pest-free environment.	**5**	The Scope of Services from the contracted third party company. The interior of the facility was to be serviced on a weekly basis and the exterior was serviced monthly.
2.	MSDS's are on file for all pesticides used in the facility.	**5**	MSDS were maintained and available for chemicals used at the facility.
3.	Pest Control Operator (PCO) is licensed, insured and certified.	**5**	The PCO was licensed and insured with a certificate of insurance valid through 12/31/16 and applicator license valid through 12/31/16.
4.	In-house or contract service?	Contracted to Ecolab.	
5.	Pesticides are approved by the regulatory agency and handling procedures are on file.	**5**	Pesticides in use at the facility were approved by the EPA for use.
6.	All pesticides are labeled and properly stored in a secure area.	**N/A**	Pesticides were not stored at the facility.
7.	PCO service reports and usage logs are current per the stated frequency and available for review.	**5**	Service reports were current per the stated frequency with the most recent service occurring on 1/13/16.
8.	Pest control devices are properly located so as not to contaminate product, packaging or equipment.	**5**	The position of pest control devices did not appear to pose a significant risk to product safety.

9.	There is no evidence of pests in the interior or exterior of the facility.	**5**	No evidence of pests were observed in the production areas.
10.	A map listing all traps, bait stations and insect control devices is available and current. The map is currently dated and reassessed a minimum of once per year.	**5**	Site maps. Dated 1/6/16, were available for review which outlined the location and type of the pest control devices present throughout the facility.
11.	There are an appropriate number of interior pest control devices (typically placed 20–30 ft. apart). Doorways and entrances to the outside should have an interior pest device located on either side of the doorway or entrance.	**5**	The facility had implemented 47 interior catchall traps which were serviced weekly. These devices were located on each side of the doorways and located so as not to pose a significant to product safety.
12.	There are an appropriate number of exterior pest control devices (typically placed 30-50 ft. apart). The stations are tamper resistant, secured and properly identified. The bait is anchored inside the station.	**5**	Forty-five bait stations were present around the exterior perimeter of the facility. Bait stations were tamper resistant, identified and a bait was secured in place.
13.	Insect control devices may be used at exterior entrances. The devices are located 30 ft. from exposed product, packaging or equipment and 10 ft. from covered product.	**5**	Ten fly lights were performed in the employee breakrooms and near the restrainer at the entrance to the kill floor. Insect lights were protected against breakage and located as to not present a significant risk to product safety.
14.	All pest control items are functioning properly.	**5**	Pest control devices observed during the audit were functioning properly.
15.	All traps, stations and insect devices have a label signed and dated by the PCO at each service or bar coded for electronic recording.	**5**	Traps and bait stations were equipped with bar code scanners that were scanned at the time of service.

Section H. Total Score 65

FSNS® CERTIFICATION AUDIT

I. Process Controls		Score	Comments
1.	All containers are properly labeled or color-coded (i.e., white oil, sanitizer, lubricants, food contact items, inedible items, trash, etc.).	**5**	A color coding system was in place for barrels and tubs. Grey was designated as trash, green on the kill floor was edible and white on the fabrication floor was considered edible. Red was used to designated 30+ cattle and yellow was used for under 30 SRM.
2.	A receiving program for raw materials, packaging materials, and ingredients is established and implemented for all suppliers. Items are stored in appropriate conditions (i.e., perishable goods are refrigerated.).	**2**	The Receiving Inspection SOP outlined the requirements receiving packaging materials and chemicals at the facility. The facility was not currently documenting that incoming goods were inspected and trailers were acceptable.
3.	A QA Hold Program is established and implemented. A written protocol for control of QA Hold Tags is followed. Records are available and current. Documentation include disposition of held product.	**5**	Non-conforming product was identified and placed on hold as defined in the Hold Program. Products were identified with orange HOLD tags and placed in a dedicated areas. The reason items were placed, corrective actions taken and the disposition of product were tracked and documented in the QA Hold Tags log.
4.	Procedures are established for the calibration and accuracy of key testing equipment associated with food safety. Documentation of these activities is on file and available for review.	**5**	Thermometers were calibrated as outlined in the Thermometer Calibration. Thermometers were calibrated on a daily Tel-Tru dry well. Calibration records were maintained in the in the form of the Thermometer calibration Log. Thermometers were calibrated to 40 F and 160 F, depending on the intended use of the thermometer.
5.	Effective foreign material controls (e.g. metal, foreign and extraneous materials, etc.) are in place. Written procedures including monitoring frequency, standards and corrective action are available and implemented.	**5**	The Foreign Material Policy outlined procedures for controlling foreign material at the facility. This policy included a list of glass and brittle plastic materials within the facility and required monthly audits of these items. Additionally, this policy also addressed the use of sharp metal objects and outlined control measures. A metal detector had been implemented for beef trimmings. These metal detectors were monitored once per production hour using a 4.5 mm ferrous, 5.0 mm non-ferrous and a 6.5 mm stainless steel standard.
6.	An annual validation of finished product microbiological data is established.	**5**	The facility performed carcass swabs with one in every three hundred carcasses being swabbed and tested for APC. Additionally, trim and beef components intended for raw use were sampled using either N60 Plus or traditional excision procedures and tested for E. coli O157:H7.

7.	Temperature control measures in the facility are implemented and documented for receiving, storage, processing and shipping areas/processes as applicable.	**5**	The Temperature Monitoring Program for Product Storage Areas outlined procedures for ensuring temperature control requirements were implemented. This program stated that the cooler and freezer areas were to be monitored once every two hours during product time periods. However, the facility was currently using an electronic system to monitor these areas. The QA department verified, with a calibrated handheld thermometer, the accuracy of the electronic system once per week. This was documented on the Weekly Cooler/Freezer Thermometer Calibration Log.
8.	If an internal laboratory is used, facility and personnel adhere to Good Laboratory Practices (GLP) which are documented and understood by all personnel responsible for lab testing. GLPs consist of, but are not limited to: storage of media and testing agents, applicable test methods, SOPs for calibration of equipment, proficiency testing program, reporting of results, use of positive controls, etc.	**N/A**	Microbiological testing was contracted to a third party laboratory.
9.	Necessary controls are in place to prevent cross contamination of the processing area(s) and product from the on-site laboratory and respective personnel.	**N/A**	Microbiological testing was contracted to a third party laboratory.
10.	A program for Document Retention is developed and implemented, including electronic records.	**0**	Document retention requirements were not defined.
11.	Transport vehicles (refrigerated trailers) are clean, in good repair, and show no signs of pest activity prior to loading. Refrigerated goods are loaded onto a pre-cooled trailer. Documentation of this review and pre-cooling are available for review.	**3**	The Shipping Inspection SOP outlined procedures for ensuring trailers were clean, precooled and in adequate condition prior to being loaded. Trailer inspections were documented on the Outbound Form. However, this form did not include verifying that trailers were cooled below 45 F as required in the written program.

12.	A program for use of materials and ingredients, like First In First Out (FIFO), is written and implemented. Documentation is maintained and available for review.	**5**	The facility used an electronic inventory system to ensure finished products were shipped on a first in, first out program.

Section I. Total Score 40

J. Maintenance / Construction and Design		**Score**	**Comments**
1.	A written Maintenance Policy for Food Safety exists and implementation is verified. The policy addresses items such as: cleaning and sanitizing of repaired equipment or newly installed equipment, guidelines for maintenance activities, tool accountability and cleanliness, etc. Documentation of this policy is maintained and available for review.	**5**	Maintenance policies and procedures for food safety were included in the Process and Control section of the GMP policy. The policy included assessment of new equipment prior to purchase and provided guidelines for repairs or maintenance work during operations. Repairs were monitored by production supervisors. Tool accountability and equipment sanitation was recorded on Operational SSOP monitoring forms.
2.	Facility has implemented food-safety minded facility interventions / improvements (e.g. door foamers, conveyor belt spray bars, microbial interventions in the facility structure, etc.) in the design and maintenance of the facility.	**5**	The facility had implemented organic acid carcass wash cabinets, doorway foamers and peracetic acid spray bars on trim lines.
3.	A program for Backed-Up Drains is implemented.	**5**	Backed up drain procedures were defined in the Sanitation Standard Operating Procedures. This policy included removing product from the area, unclogging the drain and cleaning and sanitizing the area prior to resuming production.
4.	A preventative maintenance program is utilized and appropriate. Records are maintained.	**5**	Preventive maintenance was planned and scheduled using an electronic system. Completed preventive maintenance records for euthanasia equipment used in the harvest process were available.

5.	A program is in place for reporting needed work on equipment or in production areas to the Maintenance Department. Documentation is maintained and available for review.	**5**	Maintenance work was requested on a Work Request for Maintenance form. Completed work orders were available and reviewed during the audit.
6.	A periodic Housekeeping and Facility Inspection program is implemented and records are maintained. Each area is inspected monthly and remedial actions are required.	**3**	The facility currently performed monthly SPS internal audits in the fabrication areas. This program had not been extended to the entire facility as of the time of the audit.
7.	Manufacturing, processing, packaging and storage operations are in an enclosed, pest-proof building, which protects food, equipment and utensils from dust, dirt, rodents and other sources of contamination. All doors and openings are pest resistant.	**5**	The facility was adequately sealed to minimize potential pest and contaminate entry into processing areas.
8.	The facility has adequate lighting in all areas.	**5**	Lighting was adequate for operations, sanitation and inspections.
9.	Lighting fixtures in or over product, packaging, or storage areas are shielded or equipped with safety “shatter proof” bulbs. A written Glass and Hard & Brittle Plastic Policy is maintained.	**5**	Glass and hard plastics were covered in the Foreign Material Policy. Light audits were conducted monthly. Cleanup procedures for breakages outlined the stoppage of production, notification of QA, gathering of pieces, and changing of employee clothing. Lighting was shielded or shatterproof.
10.	Production areas are vented to reduce fumes, vapors and odors.	**5**	Fumes, vapors or odors were not detected during the audit.
11.	Paper and packaging materials are adequately stored raised from the floor and away from the walls with sufficient room to facilitate proper cleaning of the area.	**5**	Packaging materials were properly stored with sufficient space allowed for cleaning and inspections.
12.	Employee welfare areas are well-maintained, conveniently located and properly ventilated.	**5**	Employee locker rooms, restrooms and lunch rooms were well maintained and allowed direct access to processing areas.

13.	Doors to the restrooms are self-closing.	**5**	Restroom doors were self closing.
14.	Signs requiring hand-washing are posted at all hand-wash facilities in restrooms.	**5**	Signs requiring handwashing were present at the entrance to the production floor and in the restrooms.
15.	Pallets are maintained in a sanitary manner and properly stored while in production/ processing areas.	**5**	Pallets were observed to be neatly stacked and in good condition.
16.	The shipping and receiving docks/areas are neatly organized and clean. Dock doors have bumpers in good repair and dock levelers are in place and properly set.	**5**	The shipping dock was well constructed and maintained.
17.	Adequate hand wash facilities are provided in restrooms and are convenient and easily accessible in production areas.	**5**	Hands free hand wash sinks were present in restrooms and readily accessible throughout processing areas.
18.	Suitable and adequate trash containers with covers are located in appropriate areas; this includes containers inside the facility as well as outside of the facility.	**5**	Trash containers were adequate and were covered where required. The compactor was enclosed.
19.	Hazardous materials are secured and stored away from product and packaging material. Food grade substances are stored separate from hazardous materials.	**0**	During the plant tour spray paint and other non-food grade greases were observed being stored in the box make-up area. Additionally, food grade and non-food grade greases were observed stored together in the in the box make-up area and fabrication maintenance shop.
20.	All walkways and conveyors are protected to prevent product contamination.	**5**	Walkways and conveyors were properly protected to prevent contamination.
21.	Floors are sloped to the drain to prevent pooling of water.	**5**	Floors sloped to drains. Pooling water was not observed.

22.	Overheads are free of rust and clutter. There are no signs of roof leaks.	**5**	Overheads were well maintained. Roof leaks were not evident.
23.	Walls, ceilings and floors are made of a material that is easy to clean and is kept in good repair. Paint is minimized or kept in good repair.	**5**	Most walls were covered with Kemlite or stainless steel panels that were easily cleanable. Floors were sealed concrete and in good condition. Painted walls were well maintained.
24.	Forklifts and batteries are well maintained and properly stored.	**5**	Forklifts and batteries were well maintained and stored in a designated area of the shipping department.
25.	Maintenance areas exhibit good housekeeping and are well organized.	**5**	Maintenance shops were organized and generally well kept.
26.	Water potability testing is conducted at least annually. List date of last test performed and the source of water used for processing.	**5**	The facility used well water that was pumped by in-house wells. Water testing was performed once per week. Water samples were sent to a third party laboratory for chlorine, total coliforms and E. coli. Records from the month of December, 2015 were reviewed during the audit.
27.	The quality of ice, steam, and gases that come into contact with the food products must be approved for use as such and/or a COA on file from the supplier, and/or tested on a routine basis.	**5**	The facility used dry ice (CO2) in their processes. The CO2 was received from an approved supplier who provided a COA with each load of CO2 provided to the facility. A COA from 1/14/16 was reviewed during the audit.
28.	Back-flow or siphonage devices are in place and functioning properly where needed. The devices are checked on an annual basis for proper operation.	**5**	Backflow devices were present on the main incoming water lines. These back flow devices were tested by a third party a minimum of annually with the most recent test being performed on 10/10/15.
29.	The grounds surrounding the facility are free of stored equipment, litter, waste, refuse and uncut weeds or grass.	**5**	Exterior grounds could only be partially assessed due to recent snowfall accumulation. Excessive vegetation or litter were not observed. Equipment on site used in on-going construction was well organized.
30.	Equipment stored in outside areas is elevated off of the ground and pipes have end-caps in place.	**5**	Equipment on site used in on-going construction was well organized. Pipes were not observed stored outside.

Section J. Total Score 143

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K. QA/QC Program		Score	Comments
1.	A written QA/QC manual is present that describes the procedures and processes for the facility to produce a high quality product.	5	Procedures for production of quality products were in the FSQA Manual.
2.	The QA/QC procedures identify the Quality Control Points, establish the monitoring procedures, and maintain records of its implementation.	5	Several monitoring forms were used to record quality inspections, including: Boneless Meat Quality Checks for offal, primals and trimmings, Carcass Quality Report, Harvest Process Control (dressing procedures), fat analysis, organic acid interventions, metal Detection Log and Organic Acid Interventions monitoring form.
3.	The QA/QC manual is reviewed and updated as necessary by the facility management team.	5	The manual had been implemented in September 2014 and was scheduled for annual review.
	Section K. Total Score	**15**	

L. Conflict of Interest Declaration

The Auditor declares that he/ she does not have a conflict of interest with this auditee and the audit has been carried out independently and impartially.	I, Justin Derington do not have a conflict of interest with this auditee.