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NFPA Supplier Audits for Food Excellence (SAFE)
Audit Checklist

Supplier Information

Facility Name: NFPA Company A
Facility Location/Address: 1350 A Street
 Somewherin, Ne 12345 USA

Parent Organization (if applicable)

Company Name: NFPA Company A
Address: 1350 A Street
 Somewherin, Ne 12345 USA

Audit Information

Audit Date: April 9 - 11, 2003
Auditor Name: PAuditor
Length of Audit: 3 days
Supplier Personnel With Auditor: S. Richards, QA Manager
Exit Interview With: S. Richards, QA Manager; K. Johnston, Director of QA

Overview of site, operation, scope of Product(s) Produced

PRE-AUDIT MATERIALS REVIEWED:

HACCP plans, Quality Manual

AREAS OF THE PLANT EXCLUDED FROM THE AUDIT:

None

Previous Audit Information

Summary of Most Recent Audit: Overall, this is a good facility, with a good management team, and with strong Food Safety and Quality Systems. There is one area in which the facility's programs are not well developed - crisis management.
Date of Last NFPA Audit: 4/14/2003
Follow-up Audit Required: Raw, ready-to-cook refrigerated and frozen pork and poultry products, for further processing, HRI or retail.
When:

Judgement Definitions				
1) Fully Meets	2) Partially Meets	3) Does Not Meet	4) Critical Failure	5) Not Applicable
A world-class system. Meets the intent of the checklist. Beyond practical improvement.	A good, functional system. Some inconsistencies and some non-critical deviations exist.	A system poorly designed or not followed.	Adulterated product is observed being produced and/or shipped.	A system that is not needed or not applicable.

Section Rating Summary

Category	Section	Rating				
		Fully Meets	Partially Meets	Does Not Meet	Critical Failure	Not Applicable
1.0 MANAGEMENT RESPONSIBILITY	1.1 Management Commitment and Review	✓				
2.0 FUNDAMENTALS	2.1 Infrastructure		✓			
	2.2 Sanitation	✓				
	2.3 Pest Control		✓			
	2.4 Chemical Control	✓				
	2.5 Personnel Practices	✓				
	2.6 Training & Education	✓				
	2.7 Handling, Storage & Delivery	✓				
	2.8 Vendor Approval	✓				
	2.9 Control of Materials	✓				
	2.10 Equipment Approval for Use	✓				
	2.11 Packaging Approval for Use					✓
	2.12 Traceability and Crisis Management			✓		
	2.13 Calibration, Measuring and Test Equipment	✓				
	2.14 Food Security	✓				
	2.15 Traffic Control					✓
	2.16 Maintenance	✓				
3.0 FOOD SAFETY & HACCP SYSTEMS	3.1 HACCP Testing	✓				
	3.2 Microbiological Testing					✓
	3.3 Environmental Monitoring					✓
	3.4 Food Allergens & Chemical Sensitivities					✓
	3.5 Foreign Material Control	✓				
4.0 MANUFACTURING QUALITY SYSTEMS	4.1 Conformance to Customer Specifications	✓				
	4.2 Good Laboratory Practices					✓
	4.3 Process Control	✓				
	4.4 Document Control & Record Keeping	✓				
	4.5 Inspection & Test	✓				
	4.6 Control of Nonconforming Materials	✓				
	4.7 Continuing Guarantee					✓
	4.8 Corrective & Preventive Action	✓				
	4.9 Continuous Improvement		✓			

	4.10 Customer Service					✓
	4.11 Internal Auditing		✓			
5.0 REGULATORY CONSIDERATION	5.1 Labeling Approval	✓				
	5.2 Regulatory Compliance	✓				
	5.3 Management of the Regulatory Process	✓				

1.0 - Management Responsibility	
SECTION	RATING
1.1 Management Commitment and Review	Fully Meets

Section 1.1 - Management Commitment and Review	
AUDIT ELEMENT	OBSERVATION
1.1.1 A Quality Policy is documented and communicated to all levels of the organization.	The quality policy is in the Quality Manual and is posted in the employee break room. It states that Quality is the responsibility of all company personnel. It is signed by the President and CEO, Vice President Technical Services & Regulatory Affairs, Vice President Operations and Director of Quality Assurance. There is an identical copy signed by the local Plant Manager and the managers of the following departments: Operations, Maintenance, Accounting, Purchasing, Human Resources, Shipping, Quality Control and Quality Assurance. In addition, superintendents, supervisors, and technicians have all signed agreements that they have read and understood the policy. Employees interviewed indicate they are familiar with the policy.
1.1.2 An organizational chart illustrates positions responsible for compliance to the Quality System.	Published organizational chart and supporting documentation indicates that QA Manager is responsible for overseeing facility compliance to the Quality System. QA Manager reports to Director of QA, who reports to VP Food Safety and Regulatory Compliance, who in turn reports to President and CEO. QA Manager also has a dotted line reporting responsibility to Plant Manager.
1.1.3 Quality System effectiveness reviews are conducted routinely.	Quality System effectiveness is reviewed weekly with all Department heads on Thursday. There are other effectiveness checks including quarterly plant management meetings, weekly QA conference calls between QA Manager, Director of QA, and VP Tech Services and Regulatory Affairs. QA and QC Technicians' performance verification is performed monthly by observation and by physically rechecking product for conformance to specification. The Quality Manual is well documented, complete and detailed, and contains the following programs: Preparation of SOPs, Document Control, Internal Quality Audits, Corrective Actions, Equipment Approval, Foreign Material Control, Lot Release, HACCP, Master Cleaning, Personnel Practices and Pest Control.
SECTION SUMMARY:	Fully Meets There is a well developed, formalized plant quality program, including Quality Manual, Organizational Chart and Quality Policy. There is evidence that plant and corporate management support and encourage attention to quality.

Facility's Response to Auditor's Observations
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2.0 - Fundamentals	
SECTION	RATING
2.1 Infrastructure	Partially Meets
2.2 Sanitation	Fully Meets
2.3 Pest Control	Partially Meets
2.4 Chemical Control	Fully Meets
2.5 Personnel Practices	Fully Meets
2.6 Training & Educational	Fully Meets
2.7 Handling, Storage and Delivery	Fully Meets
2.8 Vendor Approval	Fully Meets
2.9 Control of Materials	Fully Meets
2.10 Equipment Approval For Use	Fully Meets
2.11 Packaging Approval For Use	Not Applicable
2.12 Traceability and Crisis Management	Does Not Meet
2.13 Calibration, Measuring and Test Equipment	Fully Meets
2.14 Food Security	Fully Meets
2.15 Traffic Control	Not Applicable
2.16 Maintenance	Fully Meets

Section 2.1 - Infrastructure		
	AUDIT ELEMENT	OBSERVATION
2.1.1	Plant site and buildings are of suitable size, construction and design to facilitate maintenance and sanitary operations.	Original part of facility was built in 1958 and consists of painted concrete block walls, white metal panels with solid core insulation on ceilings, and resurfaced floors. Facility has been enlarged several times. Production and packaging area ceilings and walls are white metal panels with solid core insulation. Concrete floors are in good condition; floor drains throughout the plant are stainless steel, trench style. There is no evidence of condensation issues in exposed product areas. Unused support structures and pipes have been removed from ceilings. There is no written sanitary design program, but all facility changes must be approved by Plant Manager. Large scale changes must also be approved by corporate management.
2.1.2	Grounds and parking lots are maintained in a condition that protects against the contamination of food or facility.	Grounds are well-groomed and consist of cut lawn at entrance in front of building and paved driveway and parking areas. There are no pest harborage sites near the building. Grounds are graded to slope away from the building. There is no evidence of standing water issues. The property is bounded by residential areas on three sides and an interstate highway on one side. Plant equipment boneyard is a separate shed more than 100 feet from facility.
2.1.3	Building exterior is protected from rodent and pest entry.	Exterior entry / exit doors and dock doors are properly sealed to prevent pest entry when closed. One pedestrian exterior door had no air curtains or other means of preventing flying insects from entering while open - this was converted to emergency exit during the audit. Outside perimeter along base of building is either paved

		<p>or lined with gravel approximately two feet wide. There is rodent flashing below all dock doors. Dock plate levelers have brushes and close completely. Trash is removed through a designated hallway and dock door to compactor. Roof has no unprotected openings - exhaust fans have self-closing louvers which close when fan is turned off. All windows are sealed or have intact screens. Product waste trailer is inside truck bay with closed overhead door, which reduces its ability to attract pests - especially flying insects.</p>
2.1.4	<p>There are appropriate environmental controls. (Adequate lighting, controlled temperature, air, etc.)</p>	<p>Ventilation is adequate in facility. Forced air ventilation in facility during sanitation shift is from roof-mounted exhaust fans which create negative pressure in processing areas.</p> <p>HVAC system is adequate to control temperature for employee comfort in production areas and prevent decomposition of materials in dry storage areas. Humidity is not controlled. Air filters are included in MP2 software (see section 2.16) and are changed regularly. Temperatures in three storage coolers, one ingredient freezer, and one storage blast freezer are recorded continuously. Readouts are initialed and verified daily by comparison to a calibrated thermometer (see item 2.13.2).</p> <p>Lighting in processing areas is adequate and consists primarily of halogen bulb fixtures with shatterproof plastic shields; additional lighting in other areas consists of fluorescent tube fixtures with shatterproof bulbs and/or shatterproof plastic shields with end caps.</p>
2.1.5	<p>All food contact surfaces are made of materials appropriate to the application (i.e., stainless steel vs. aluminum)</p>	<p>There is no written policy on food contact surfaces, but all new equipment would be approved according to "Equipment Approval Procedure" (see section 2.10). Food contact surfaces are mostly made of stainless steel and food grade high density polyethylene. One piece of fabric-based belting material was observed in the packaging area; it was frayed and replaced during the audit. There are numerous instances of improper seam and spot welding on food contact surfaces which result in seams and crevices which are not sanitary. No dead legs were observed in product or CIP lines.</p>
2.1.6	<p>Facility and equipment maintenance ensures safe manufacture of wholesome foods.</p>	<p>Pre-operational inspections are conducted after sanitation and before startup daily - inspection records are complete. A procedure dated 1-24-03 states that QA is responsible for monitoring all emergency maintenance to equipment and product contact surfaces during production - repair needs must be communicated to QA by production supervision. After emergency maintenance occurs, production personnel are responsible for cleaning and sanitizing. QA conducts visual check of sanitation, and any unacceptable finding is documented on SSOP violation log. The shift manager is responsible for filling out the corrective actions section of the log. There are currently no records maintained of emergency repairs unless an SSOP violation occurs. During the audit, this procedure was changed to include an "inspection log for areas requiring maintenance" to maintain these records.</p> <p>Utility drops through metal ceiling panels in the production area are not sealed to prevent pest harborage and reduce the potential for foreign material contamination. Pedestrian walkways over</p>

		product conveyor belts in all areas are properly shielded with toe plates to protect product from potential contamination.
2.1.7	The quality of water, ice, steam and gases used in food applications is known suitable for intended use. All food contact water is determined to be from a potable source and is controlled for its use.	Water is from municipal supply (Somewherin, NE) and passes through a screen filter. Water supply line to ice house goes through 23 micron filter. Water going into chiller passes through 10 micron sock filters - one of these filters was observed with holes during the audit. All filters are included in MP2 maintenance scheduling program. Additional filters are used for ingredient water - they are changed monthly. Water report from municipality is obtained quarterly, and includes test results for aerobic plate count, coliforms, trace metals and pesticides. Tests for total coliform and E. coli are conducted at least twice a year on water samples collected at three point-of-use locations in facility. Last test was performed 2-3-03; all results were "none detected". Ice is checked for foreign material using melt test hourly during production. Records are not kept unless foreign material is found, in which case the Corrective Actions program is used. No food contact gases are used.
2.1.8	All water systems are protected against back flow.	Backflow prevention device on water supply line located behind maintenance shop is checked annually by a certified tester - last test was performed 10-20-02. There are no records of checks for four backflow prevention devices at points-of-use in production and packaging areas. These devices will be placed on annual testing frequency as well. No employee practices potentially causing backflow problems were observed.
2.1.9	There are hand-washing facilities for restrooms, break areas and manufacturing areas.	Main break room and restrooms/locker rooms are well maintained with foot-operated handwashing sink, hot water, soap, paper towels, and trash cans. Four handwash facilities in production and packaging areas are likewise equipped and functional. Women's restroom stalls do not have covered receptacles for sanitary items. Restrooms have self-closing doors and do not open into production area. Handwashing signs are posted inside restrooms, at entrances to processing areas and at handwash facilities. Observed employees were using handwash stations as required by Personnel Practices program.
	SECTION SUMMARY:	Partially Meets Building and infrastructure are generally well maintained. There were several observations which indicate that the systems are not fully effective: no air curtain at one exterior door to exclude flying pests; no covered sanitary receptacles in the women's restroom stalls; numerous instances of insanitary welds on equipment; no record of checks for backflow prevention devices in production and packaging areas; torn sock filter for chiller water; and utility drops not sealed where they pass through the ceiling in production area.

Facility's Response to Auditor's Observations

Section 2.2 - Sanitation		
	AUDIT ELEMENT	OBSERVATION
2.2.1	There is a written and comprehensive plant and equipment sanitation program.	The current revision of the Master Cleaning program is signed by Operations Manager and dated 1-24-03. Operations Manager has direct on-site responsibility for implementation of SSOPs;

		Sanitation Manager is responsible for carrying out the program in accordance with the SSOPs. QA Manager is responsible for verification of SSOPs performance. The SSOPs are written to cover both operational and pre-operational sanitation activities, and include a written master sanitation schedule for other than daily tasks. Training program consists of on-the-job training under supervision, with a supervisor's sign-off that training for specific plant areas was conducted annually.
2.2.2	There are written operating procedures or work instructions.	Sanitation SOPs include disassembly and cleaning procedures by equipment, chemicals to be used, concentrations, contact time, temperatures, frequency, rinsing procedures, re-cleaning, and inspection by sanitation personnel before pre-op inspection. Work instructions are complete. CIP procedures specify temperature of 140 degrees F and cycle time requirement of 45 minutes. Records indicate that water temperature is frequently not 140 degrees F, however visual inspections have not noted insufficient cleaning.
2.2.3	Brushes and utensils used for cleaning food contact surfaces are controlled and clearly identified.	Green scrub pads are primary utensils used for cleaning - no other color may be used. They are issued daily to employees, then returned after cleaning activities are complete to be thrown out. One white brush is maintained for special cleaning tasks, and is stored in a bucket inside the chemical storage room. Black brush is used for drains. Scrub pads for custodial purposes must not be green in color. Color code system is posted in production and packaging areas and is included in annual training of employees. No deviations from the program were observed during the audit.
2.2.4	A Master Sanitation Schedule is maintained.	A Master Sanitation Schedule outlines each task, minimum frequency of cleaning, and departmental manager responsible. While the entire Master Cleaning program is the responsibility of the Operations Manager, various other departmental managers and shift managers are responsible for control and implementation of the master cleaning program. There are sign-off records of all Master Cleaning activities; records reviewed were up to date and complete. Overheads, walls, and floors in facility were clean. No equipment cleaning issues were observed. Good operational sanitation was maintained throughout facility during the audit.
2.2.5	Measures are in place to verify and monitor the effectiveness of cleaning methods.	Trained QA technicians randomly select equipment to be inspected in each area of the plant prior to production. Personnel select a minimum of 7 pieces of equipment from production area, and 3 pieces of equipment in packaging area. A 100% visual check is done on remaining equipment, as time allows. Personnel visually inspect the equipment selected, and record results on pre-op checklist form. Deficiencies result in immediate corrective action by sanitation personnel and a reinspection. When sanitary conditions are achieved, the equipment is released. Verification activities include random visual rechecks by QA Manager. Microbiological swab testing is done on product contact surfaces only, as described in audit item 3.2.1. Review of pre-op checklists indicates that when the need for recleaning becomes repetitive, corrective action includes re-training.
2.2.6	For dry processing areas, procedures are in place to clean equipment and structures.	Not applicable - there are no dry processing areas at this facility.

SECTION SUMMARY:	Fully Meets Facility has a well documented plant and equipment sanitation program. Observations and records indicate that programs and SSOPs are performed as written.
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Facility's Response to Auditor's Observations

Section 2.3 - Pest Control		
	AUDIT ELEMENT	OBSERVATION
2.3.1	A documented pest control program is in place.	A written Pest Control program outlines required activities of outside contractor and in-house personnel. The program administered by outside contractor No-Bugs Pest Control provides for twice-monthly service of bait stations, rodent traps, and chemical applications as needed. Insectocutors are serviced in-house; they are numbered but have no service records attached. The program records include a schematic device map for rodent devices dated 1-31-03 (no device map was available for insectocutors); copy of pest control business license for contractor; contractor service reports (which include any pesticide applications); and QA inspection reports, which include inspection and maintenance of insectocutors. No signs of pest activity were noted during the audit. Insectocutor pans were clean.
2.3.2	The pest control program includes frequent inspections.	The rodent device schematic lists 54 bait stations (all exterior) and 123 interior rodent traps (located around external walls and in storage areas). There are several intervals between bait stations which exceed 50 feet. There are no rodent traps along the walls of the break room, and there are several intervals between interior traps which exceed 25 feet around interior walls of the supply room. Insectocutors are located near all external entryways. One of these devices was within 10 feet of covered food packaging storage area - it was removed during audit. Facility QA personnel conduct weekly inspections of rodent bait stations and traps and insectocutors.
2.3.3	Deficiencies are documented and corrective action taken.	Service reports include applicator's name, date, chemical name and concentration used, amount, and recommendations to facility management. EPA registration numbers are used to reference chemicals. Service reports are available for at least 2 years. Most recent service reports were dated 3-25-03 and 4-8-03. Most recent QA inspection report was dated 4-7-03; weekly reports were present for at least last 6 months. Pest activity is noted on inspection reports where applicable, as well as recommendations for management action. There are graphical trend reports of activity for all devices. Records indicate infrequent rodent activity inside facility. Repetitive catches in the receiving area were handled as a Corrective Action project; report indicates that root cause was attributed to a dock door being open for extended periods. After receiving personnel were cautioned to keep the door closed, catches virtually ended at that location.
2.3.4	"Restricted Use" pesticide applications are performed by a certified pesticide applicator or a licensed pest control contractor or under direct supervision of the same.	According to QA Manager, all restricted use pesticides are applied by No-Bugs Pest Control technician, Mr. Chemicals. Mr. Chemicals is not certified, but per letter faxed during the audit from P.C. Owner, No-Bugs Pest Control owner/operator, Nebraska law only requires that he work under the supervision of

		a local office with a certified applicator. In-house files include a copy of Mr. Owner's State of Nebraska structural pest control business license, which expires 10-31-04, and copy of liability insurance, which expires 7-12-03.
2.3.5	The supplier maintains and enforces written procedures for the application of pesticides.	Not applicable - all pesticide applications are the responsibility of outside contractor No-Bugs Pest Control.
2.3.6	All chemicals used in pest control are accurately labeled and stored securely.	There are no pest control chemicals stored at this facility. Labels and MSDS for pesticides used by contractor are maintained in file.
	SECTION SUMMARY:	Partially Meets Pest control program at this facility is well documented and records indicate procedures are followed. No pest activity was noted during the audit. However, intervals between exterior rodent bait stations and interior rodent traps are greater than accepted food industry standards, and internal rodent activity has been noted in records. Also, an insectocutor was located near protected food packaging materials - this was moved during the audit.

Facility's Rspose to Auditor's Observations

Section 2.4 - Chemical Control		
	AUDIT ELEMENT	OBSERVATION
2.4.1	A chemical control program manages the use, storage, and handling of non-food chemicals at the manufacturing facility.	Facility maintains a list of approved non-food chemicals; purchase is only through approved vendors (see section 2.8). Sanitation chemicals from R-Square (Foamight, Dynamic II, RS 520, and RS 1134) are approved for use in a food plant. Approval documentation was not on file - letters were faxed during audit. The chemical storage room is identified, locked, and organized; access is restricted to supervisors and management personnel. Sanitation chemicals are segregated from office and janitorial cleaning supplies. One nonfood chemical stored in maintenance shop area (Royal Purple High Performance Crystal-Pure 68) is approved for use in a food plant.
2.4.2	Chemical cleaners and sanitizers are used according to their label instructions.	Use of cleaners and sanitizers is documented in SSOPs (see section 2.2). Chemicals are used according to manufacturers recommendations. All cleaning chemicals are dispensed by a computerized system into barrels to be brought into processing area. Once there, they are diluted to the proper concentration using calibrated orifices in a wall-mounted pressure wash system. Cleaner and sanitizer concentrations are checked daily using a refractometer and procedure provided by the chemical manufacturer, and are recorded on pre-op checklist. Annual training includes instruction in the use of chemicals, sanitizers and the pressure wash system. Employees interviewed correctly described the procedures.
2.4.3	MSDS sheets are available for all non-food chemicals. (sanitation, boiler and pesticides)	MSDS are maintained by QA Manager; copies are available in chemical storage area and in break room. MSDS were not on file for the sanitizer Casco CS 1500 Sodium Hypochlorite 12.5%, and for the R-Square cleaning chemicals Foamight, Dynamic II, RS 520, and RS 1134. These were faxed during the audit. MSDS sheets were on file for maintenance chemical Shell FM Hydraulic

		Oil 68, Lubemaster Permalube FG grease, and ingredients Rhodia Curafos FG and Morton TFC Purex Salt. Annual training includes MSDS awareness. Employees interviewed knew the purpose and location of MSDS.
	SECTION SUMMARY:	Fully Meets Non-food chemicals in this facility are approved for use and are being stored and used according to established procedures. MSDS were on file, or readily obtained during the audit, for all non-food chemicals observed.

Facility's Response to Auditor's Observations

Section 2.5 - Personnel Practices		
	AUDIT ELEMENT	OBSERVATION
2.5.1	All employees wear, in an effective manner, hairnets and beard covers, in areas where food, products, packaging or ingredients are exposed.	Personnel Practices program requires clean hair nets and beard guards issued by the plant worn to entirely cover all head and facial hair, including long sideburns and mustaches. All observed employees were complying with policy. Auditor was also required to comply.
2.5.2	The wearing of jewelry is controlled to prevent contamination.	Personnel Practices program requires all jewelry, except plain wedding bands, be removed before entering plant. Medic alert identification is exempt from this requirement. If fingernail polish or false fingernails are worn, gloves must cover hands in any production area including box rooms, shipping / receiving, dry storage, product storage. False eyelashes are prohibited. All observed employees were complying with policy. Auditor was required to remove wristwatch before entering production area.
2.5.3	Employees follow proper hygiene practices to prevent contamination of food.	Although all product in plant is raw, ready-to-cook, Personnel Practices program requires employees to maintain a high degree of personal cleanliness to prevent contamination of food products. Hands and fingernails must be kept clean. Employee policy prohibits using hands to touch face or wipe forehead, scratch head or body, or place fingers on/in mouth, nose, or ears. Employees must wash their hands thoroughly with soap when entering processing areas, or when hands/gloves become soiled. All observed employees were complying with policy. There are four hand washing stations in the plant; there are no hand dip sanitizer stations. No materials in the production or packaging areas were observed being handled in an insanitary manner. No personal items were observed stored in production, packaging or storage areas. Break room and locker rooms have shelves for employees' personal items.
2.5.4	Gloves are maintained in an intact, clean and sanitary condition.	Plant issued latex gloves are used for handling food and food contact packaging. Personnel Practices program does not require use of gloves except for covering bandaged wounds, fingernail polish or false fingernails, but requires gloves be maintained intact and in sanitary condition. Annual training includes instructions on use and cleaning of gloves, and instructions to discard any that are damaged or insanitary. All observed employees were complying with policy.
2.5.5	There is no eating, chewing gum, candy and tobacco products in production and warehouse areas.	Personnel Practices program prohibits use of any food, candy, cough drops, or tobacco product in processing areas; also prohibited are holding toothpicks, match sticks or similar objects

		in mouth. Smoking rooms and food storage/consumption areas are designated. There is an additional policy which prohibits the chewing of tobacco in the plant. All observed employees were complying with policy.
2.5.6	Employees with symptoms of illness or open cuts/lesions are excluded from food handling jobs.	Personnel Practices program lists conditions which would exclude an employee from entering a food handling area if there is a likelihood of their contaminating food: persons known, or suspected, to be suffering from, or to be a carrier of a food transmissible disease. Other conditions which should be reported to management so that any need for medical examination and/or possible exclusion from food handling can be considered, include jaundice, diarrhea, vomiting, fever, sore throat with fever, visibly infected skin lesions, discharges from eye, ear, or nose. All wounds must be properly bandaged, then covered with glove before handling product. All observed employees were complying with policy. Supervisors do not receive special training in managing health issues, but all interviewed indicated they know what to look for.
2.5.7	Uniforms are designed in a manner so as not to be a foreign material risk.	Personnel Practices program prohibits pockets above the waist and button closures. Items with clips may not be attached to garment necklines. Objects (e.g., pens, cigarettes) are not allowed to be carried on ears. All observed employees were complying with policy. Visitors, including the auditor, are provided with lab coats to cover outside clothing.
2.5.8	Employee clothing or uniforms are maintained in a clean manner.	Personnel Practices program requires clothing be kept reasonably clean during shift, and that smocks not be worn outside the facility. Carrying garment over arm is permitted. If traveling between two buildings where there is an overhead roof, smocks may be worn. Employees observed wore clean clothes; smocks were all reasonably clean. One employee was observed outside wearing smock. Program does not specify acceptable materials for clothing, but employees interviewed indicated they know what materials are appropriate.
	SECTION SUMMARY:	Fully Meets Facility has implemented an effective Personnel Practices program and, except as noted in items above, all observed employees were in compliance.

Facility's Rspnse to Auditor's Observations

Section 2.6 - Training & Education		
	AUDIT ELEMENT	OBSERVATION
2.6.1	Training and education programs are documented.	All employees receive orientation training in plant safety, MSDS, GMP and food safety, personnel practices and regulatory awareness. Annual refresher training is given in safety, sanitation, personnel practices, GMPs, and food safety. Additional training is conducted according to employee area of responsibility as follows: QA and HACCP - HACCP, GMPs and regulatory awareness. HACCP training is conducted at a level appropriate to level of employee involvement. Sanitation - chemical safety and handling. Laboratory - Good Lab Practices, lab and chemical safety, culture media, and methods. Records are maintained. Training records for two employees were confirmed by interviews

		as accurate and up-to-date. No proficiency testing is performed; training effectiveness is measured by employee adherence to established procedures.
2.6.2	Authorized personnel conduct training.	QA Manager, two QA Supervisors and HACCP Coordinator have received the following - NFPA HACCP Train-the-trainer certification, corporate GMP policy training, corporate sponsored workshops. Also, QA manager has MS in microbiology. Outside instructors are periodically used for specialized training (e.g., MSDS, chemical safety and handling).
	SECTION SUMMARY:	Fully Meets Training appropriate for production, QA, maintenance, and sanitation personnel is conducted according to need by qualified personnel and is documented. Training records are complete.

Facility's Response to Auditor's Observations
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Section 2.7 - Handling, Storage & Delivery		
	AUDIT ELEMENT	OBSERVATION
2.7.1	Inbound, stored and outbound goods are protected from damage, contamination and deterioration.	Written shipping and receiving procedures (revision dated 7-12-02) describe how and by whom products are handled when received, when returned under seal, when returned by a customer, or when returned by a sister facility. Inbound raw materials generally include raw meat, dry materials (e.g., spices and flavorings), vegetables, packaging materials and product returns. Damaged product is placed on hold for disposition by QA manager. Received materials are held in clearly designated areas until after inspection, and are then moved to designated storage areas. No records of these handling procedures are maintained, unless a material is found damaged or non-conforming. Outbound products are held in designated storage areas until ready for shipment. The shipping/receiving manager was very knowledgeable about the procedures.
2.7.2	Temperature-sensitive items are maintained at proper temperatures.	Chilled ingredient and product storage areas are maintained at temperature range of 32 - 38 degrees F, and are monitored continuously on chart recorders. One chilled ingredient storage area chart indicated that the temperature spikes to 50 degrees F every 12 hours, but this is unlikely to cause ingredient deterioration. Separate ingredient and finished product freezers are maintained at 0 degrees F, and are alarmed if temperature exceeds 10 degrees F; records indicate alarms are tested annually. Dry storage area does not have special temperature control. No materials observed were being stored at inappropriate temperatures.
2.7.3	Carriers and warehouse facilities are routinely inspected for acceptability.	All carriers undergo sanitary inspection before product is loaded and before unloading incoming materials. Inspections are documented on "Trailer Temp and Condition Shipping" form. Trailer seals are checked before trailer is opened, and temperature settings on reefer are checked. After opening, trailers are checked for sanitary condition and off-odors, and must hold only food products or packaging materials. Outbound procedures require that trailers are inspected for sanitary conditions and off-odors. Shipping and receiving procedures prohibit use or acceptance of trailers known to have contained non-food

		chemicals, but no records are required. Temperatures are documented for customer-specific requirements. Normal facility policy in the absence of customer requirements is to maintain trailer temperature at 34 degrees F for fresh product and 0 degrees F for frozen product. Outbound trailers must be sealed with a HACCP seal - the number is recorded on the bill of lading. Chilled storage, freezers and dry storage areas are inspected informally (no records) daily by warehouse supervisor for cleanliness and orderliness, and annually during audit.
2.7.4	Bulk raw materials are protected against contamination during unloading and loading.	Not applicable - no bulk materials are received at this facility.
2.7.5	Inbound materials are properly identified.	Vendors identify incoming material with lot numbers, purchase order numbers, pallet serial numbers, and other information. Materials are verified against purchase orders, and COAs as appropriate, during inspection. Date received is recorded on Bill of Lading, which is filed in shipping/receiving office. For dry goods and packaging material, date received is written on one container per pallet. All observed ingredients and packaging materials were identified.
2.7.6	A schedule of inbound materials includes condition of storage and shelf life.	There is no schedule of inbound materials. Raw, non-frozen meats reportedly have a chilled shelf life of less than 7 days from receipt; frozen and dry storage shelf life is not controlled. There is no shelf-life requirement for product shipment. Chilled products are usually shipped within one day of production, frozen products are shipped FIFO, typically within a few days.
2.7.7	Materials are used, and shipped with a suitable rotation to prevent degradation.	Written procedures require raw materials to be used by FIFO whenever possible. There is a written procedure for suitable finished product rotation to ensure oldest released product is shipped first. Daily inventories, including product status and date of manufacture, are maintained in a computer database and are used to select product lots for shipment. Trailer inspection and temperature requirements are described in item 2.7.3. As noted above, it is unusual for product to be held more than a few days before shipping. All records reviewed indicated product was 3 days old or less when shipped. No products are exported from this facility.
2.7.8	Returned goods are handled in such a manner to protect their contamination or the contamination of other goods.	When finished goods are returned, the Returned Goods/Hold Product Procedure requires QA to tag product and record the following information either on Hold tag or on incoming product forms: Date, time, type of product, code, quantity, whether product is under USDA seal, temperature, disposition of containers, temperature recorder load date and time, pallet number, lot number, and other information. Product is immediately placed on QA/Production Hold, until disposition is made by QA manager or designee. Based on disposition other than condemned, normal tracking procedure must be followed to maintain traceability. If product is reworked into another product code, lot tracking form retains information necessary to maintain traceability. Product returns are unusual; no recent records were available for review.
	SECTION SUMMARY:	Fully Meets Facility has an effective and generally well documented system for material handling, storage, and delivery. Records and in-plant observations verify compliance with the program.

Facility's Response to Auditor's Observations

Section 2.8 - Vendor Approval		
	AUDIT ELEMENT	OBSERVATION
2.8.1	There is a Vendor Approval Process for ingredients, food contact packaging, and services affecting food safety and quality.	The Vendor Approval Process is managed through corporate purchasing. The "approved vendor list" is generated by corporate and distributed to local facilities. However, when facility purchasing manager submits a request for a new vendor, the request is reviewed by corporate, who either disapproves or adds vendor to the approved list. Corporate also assigns a vendor ID number to be used in computer system for generating purchase orders. Written specifications and COAs are only required for selected raw materials (i.e., certain dry ingredients and packaging materials).
2.8.2	An "Approved Vendor List" is utilized for all raw material purchases.	Facility receives a hard copy of "approved vendor" and "approved product" lists from corporate purchasing department. Only vendors and specified products on list can be purchased by facility purchasing manager. Most recent lists were both dated 3-31-03. A recently received lot of salt was approved on both lists. A pallet of plastic wrap was also identified as approved on both lists.
2.8.3	Vendors provide a process for traceability for incoming goods and materials.	Vendors identify all incoming materials as described in item 2.7.5. All Bills of Lading reviewed and observed pallets in warehouse contained the expected identification information.
2.8.4	A Vendor Performance evaluation is in place.	No local program for continuing vendor performance evaluation is in place. Facility may communicate concerns directly to vendors, and corporate is copied on this. Corporate maintains and implements the performance evaluation system; the information provided by the local facility may have influence in their decisions. Corporate is ultimately responsible for either maintaining or revoking a vendor's approved status.
2.8.5	There are provisions for buying from "non-approved" sources, in the case of emergency situations.	Corporate document "Vendor Approval Program" (dated 2-12-00) states that, in emergency situations, supplies will be located in the following order: original supplier, a sister facility, another vendor as necessary. There is an emergency provision for a local facility to over-ride the requirement for only issuing POs to an approved vendor, but this option can only be exercised if plant shutdown is imminent, and must be justified; this option has not been used at this facility. In all other instances, corporate must approve new suppliers at local request during emergency situations. No records of purchase from non-approved suppliers were available.
2.8.6	Vendors are approved by "facility" location (vs. company name).	Corporate policy is that vendors may be approved by company or by facility location.
	SECTION SUMMARY:	Fully Meets Although facility has input into vendor approval process, it is managed at the corporate level. Records indicate facility practices are in full compliance with the corporate program.

Facility's Response to Auditor's Observations

Section 2.9 - Control of Materials

	AUDIT ELEMENT	OBSERVATION
2.9.1	Incoming materials are verified as conforming to written specifications.	Ingredients and packaging materials are not verified as conforming to written specifications by the local facility. A few materials must be accompanied by Certificates of Analysis, and these are compared against written specifications. Many ingredients and packaging shipments are accompanied by COAs, but it is the responsibility of corporate to verify conformance to specification. Monthly correlations are reportedly conducted at corporate headquarters during which raw material, packaging material, and finished product specifications are verified. The facility is notified only if material specifications are not met.
2.9.2	A process to change or modify customer specifications is documented.	Not applicable - the process which controls customer specifications is managed by corporate.
2.9.3	There are control procedures for rework products.	Attempts are made to rework and release any returned, in-process or finished product that fails to meet specifications. Rework procedures for specific nonconformances are documented in the Returned Goods/Hold Product Procedure. Nonconforming product is placed on QA Hold using bright green stickers with consecutive serial numbers. Information attached includes the time and date of tagging, shift, reason, production code, line number, quantity, and signature of QA technician issuing Hold. After rework is complete, QA re-checks the product for conformance with product specifications. All rework is recorded on the Product Rework Log, which is used for traceability and for Continuous Improvement. If product is reworked into another lot, rework identity is recorded for traceability. No products contain allergens, so this is not a restriction, but procedures require reworking only like into like. No nonconforming or returned product was being reworked during the audit. Several batch records were observed with rework. Examples were checked on the Product Rework Log; rework release and traceability procedures were followed.
	SECTION SUMMARY:	Fully Meets Control of incoming materials is very limited, and generally under corporate control. Rework procedures are well documented, and records indicate compliance with procedures.

Facility's Response to Auditor's Observations

Section 2.10 - Equipment Approval for Use

	AUDIT ELEMENT	OBSERVATION
2.10.1	New equipment design is approved for sanitary design considerations.	There is an "Equipment Approval Procedure" to ensure the sanitary design of equipment that may contact product directly or indirectly. New equipment prior to being purchased or constructed must be approved by Maintenance, Sanitation, and QA Managers. Equipment bought from outside vendors must be accompanied by information on sanitary design and cleaning capabilities, or a letter of guarantee. When equipment is made in-house, Maintenance, Sanitation, and QA Managers are responsible for ensuring equipment has met all criteria for cleaning and sanitary conditions - the criteria are not defined. There are no references to industry standards of sanitary design

		or construction. Records for a recently installed packaging machine were examined; purchase approvals were present, signed and dated 12-13-02.
2.10.2	Equipment installations are approved to ensure sanitary operating conditions.	Prior to the installation of equipment, the Maintenance and Quality Managers or designees will perform a visual inspection of machinery and area of installation, to ensure that the installation of the new equipment will not affect the overall ability and effectiveness for the equipment to be maintained in a sanitary condition during use, and that the ability to perform adequate sanitation during cleanup will not be hindered. No industry standards for installation are used. Maintenance manager verifies installation by either reviewing equipment manual, letter of guarantee, observation of cleaning tasks, or by performing the task of cleaning the equipment. Procedures require all deficiencies to be corrected and documented prior to equipment use. Records for the packaging machine include approval signatures of both Maintenance and Quality Managers.
2.10.3	Equipment is validated for sanitary design prior to use.	Prior to equipment use, the QA, Maintenance, and Sanitation Managers must sign a letter stating that newly installed equipment is constructed of acceptable materials, performs satisfactorily, and can be maintained in good sanitary condition. The letter for the packaging machine was present, signed and dated 3-31-03. The packaging machine had not yet been placed in production at the time of this audit.
	SECTION SUMMARY:	Fully Meets The facility has an excellent system for equipment review and approval prior to purchase, during installation and prior to use. Records indicate the program is followed.

Facility's Response to Auditor's Observations

Section 2.11 - Packaging Approval for Use		
	AUDIT ELEMENT	OBSERVATION
2.11.1	Packaging materials are purchased according to written approved specifications.	Corporate maintains control over the packaging material suppliers and specifications. Any changes are communicated to facility purchasing manager who maintains hard copy file. Letters of Guarantee are maintained at corporate. Packaging can only be purchased from the corporate-approved sources. Records indicate that the procedure is followed.
	SECTION SUMMARY:	Not Applicable Packaging materials are purchased strictly from corporate-approved vendors. No testing of packaging materials is conducted at this facility.

Facility's Response to Auditor's Observations

Section 2.12 - Traceability and Crisis Management		
	AUDIT ELEMENT	OBSERVATION
2.12.1	Raw materials are traceable into finished products.	Ingredients and packaging materials are tracked using vendor's lot numbers through batch records to finished products. Finished

	- Finished goods are traceable through distribution to the point of the first customer.	products use bar code identification and computer-assigned lot code number on primary packaging, casing and pallet tag. During the audit, a designated lot of raw poultry meat (10,000 lbs) was traced through to finished products (3 lots) and on to first external customers within one hour forty five minutes, with 100% of product accounted for. Facility expectations for product forward traceability is 100% in less than 2 hours. Records used included Bill of Lading, batch records, and shipping records in computer database. Traceability of rework is described in 2.9.3.
2.12.2	The effectiveness of traceability is tested regularly. Traceability performance is documented in the audit report.	Corporate requirements are to conduct a mock recall at least twice a year, including after normal business hours, and a test of alternate personnel listed. The type (raw material forward / lot code backward / lot code forward) of mock recall for each exercise is determined by corporate and carried out at the local facility. A mock recall involving both lot code backward and raw material forward was conducted 12-2-02. A finished product was identified and traced back to raw material components including flavoring ingredients, which were then traced forward again to first external customer. 100% recovery was achieved within one hour and forty minutes. A mock recall involving lot code forward was conducted 2-7-03. Records indicate a finished product lot was traced through to first external customer within ten minutes, with 100% recovery.
2.12.3	A recall/crisis management program is documented and includes emergency contact information.	Recall / recovery plan is limited to traceability. Crisis management is expected to be handled by corporate. No crisis management action plan has been developed and no crisis management team has been identified, although it is understood that QA Manager, Director of QA and Plant Manager would be involved. No emergency contact information is available except for corporate. No actual recalls have occurred at this facility.
	SECTION SUMMARY:	Does Not Meet Traceability procedures are documented and practiced. Trace exercise performed during the audit resulted in 100% recovery within 2 hrs. No crisis management program exists beyond traceability and product recovery; expectations are that crisis management would be handled by corporate.

Facility's Rspnse to Auditor's Observations

Section 2.13 - Calibration, Measuring and Test Equipment		
	AUDIT ELEMENT	OBSERVATION
2.13.1	A system for laboratory and process equipment identification is in place.	All process equipment is identified and listed in the MP2 computer database system - this list is maintained for maintenance and calibration scheduling and parts inventory purposes. Critical equipment (scales, temperature recorders, metering devices, metal detector) are highlighted. Equipment due for calibration is highlighted in the database until closed out. Lab equipment is numbered and listed on a master checklist. Lab equipment which require periodic calibration are designated on the checklist. All equipment requiring calibration have stickers which indicate equipment name or number, date of last calibration, and date when next calibration is due. Maintenance personnel perform all process equipment calibrations except for metal detector

		(performed by certified outside vendor). QA is responsible for scheduling lab equipment calibrations.
2.13.2	Calibration or maintenance frequency is determined based on the critical nature of the measurement.	Calibration frequencies are based on manufacturer recommendations or in-house experience. MP2 database includes calibration frequencies and instructions for all equipment calibrated in-house. Outside calibrations are performed by corporate-approved vendors. All equipment observed were within current calibration according to calibration stickers. Records for a process check weigher and metal detector were requested and indicated that calibrations had been completed within prescribed frequencies since installation. Periodic checks of scales (daily), temperature recorders (daily) and metal detector (4 times daily) are performed and recorded by production personnel.
2.13.3	Reference standards are identified for critical test equipment. (e.g., calibration test weights)	Maintenance uses certified standards or test equipment for all in-house calibrations. Standards are re-certified by outside vendors according to frequencies in the MP2 database. Maintenance personnel performing in-house calibrations have been trained by manufacturers or on-the-job. In-house calibration performance is periodically verified by Maintenance Manager; records indicate all calibration personnel have been observed at least once in the past 12 months.
2.13.4	A corrective action process is in place when an "out of calibration" result is identified.	Equipment found to be out-of-calibration is taken out of service until calibrated. Critical equipment work orders have instructions to notify QA if equipment is beyond specified calibration limits. QA has no written procedures for actions to be taken, but it is understood that production records would be reviewed for equipment that is checked daily (see 2.13.2) and the extent of out-of-calibration would be assessed for impact on product safety and integrity and scope of product affected. Reportedly, no such events have occurred, so no records were available for review. No calibration records observed showed equipment outside of specified calibration limits.
	SECTION SUMMARY:	Fully Meets Maintenance has a thorough, well implemented program for process equipment calibration. Personnel performing calibrations are well trained or outside, corporate-approved vendors. Records are complete, and indicate adherence to prescribed frequencies. QA does not have written procedures for assessing product in case of severe out-of-calibration, but described procedures sounded appropriate.

Facility's Response to Auditor's Observations

Section 2.14 - Food Security	
AUDIT ELEMENT	OBSERVATION
2.14.1 The facility has conducted an analysis and implemented food security risk control measures.	A copy of the FSIS Security Guidelines for Food Processors is on file. Bob Protekt has corporate responsibility as Security Manager for both food and physical security. He conducted a preliminary survey to assess security at this facility on 3-13-02 and again on 7-24-02 and made comments to management. The checklist was developed internally, based on the FSIS guidelines. Most of the measures described were already in place, or have been implemented since the surveys. Security measures were added to

		internal audit checklist in 2002.
2.14.2	Security is sufficient to ensure access to the facility is only for authorized personnel.	Facility grounds are protected by a 6 foot chain link fence topped with 2 feet of barbed wire. Some exterior doors are not locked, but there is only one entrance to grounds protected by barriers and a guard station. Written procedures require that all employees and visitors must present picture ID before entrance is permitted. In addition, there is a sign-in and -out sheet at the guard station. All visitors must wear ID badges issued by guard and be accompanied by employee at all times. This auditor was required to show picture ID and sign in and out. Several video cameras continuously record outside the facility - one records license tags of all vehicles passing guard station - and video cameras also monitor several areas inside facility. 12-hour tapes are archived. Truck drivers are required to remain in their trucks, designated lounge, or employee break room; instructions are posted in shipping/receiving area next to interior doors. Background checks have not been performed on employees; apparently, this is currently under discussion at corporate.
2.14.3	Food security and GMP policies and procedures are reviewed with contractors and visitors prior to access to the facility.	A written procedure restricts access to the facility and requires contractors and visitors to be accompanied by member of management. The procedure does not require a review of GMP policies, but this auditor was required to sign a 1-page "Visitor GMP Checklist", thereby agreeing to follow all GMP policies and rules. GMP policies are posted in the break room areas and near all entrances to processing areas.
	SECTION SUMMARY:	Fully Meets A food security survey has been performed and improvements to the program are under development. Non-employee access is restricted by written procedures and in practice. Visitors must sign a GMP checklist before entering plant.

Facility's Response to Auditor's Observations

Section 2.15 - Traffic Control		
	AUDIT ELEMENT	OBSERVATION
2.15.1	Product segregation is adequate to prevent cross-contamination between raw and cooked products.	Not applicable - this facility produces only raw and ready-to-cook products.
2.15.2	Control measures are in place to reduce the potential of cross-contamination in micro-sensitive areas.	Not applicable - this facility produces only raw and ready-to-cook products.
	SECTION SUMMARY:	Not Applicable This facility produces only raw and ready-to-cook products.

Facility's Response to Auditor's Observations

Section 2.16 - Maintenance		
	AUDIT ELEMENT	OBSERVATION
2.16.1	A corrective and preventive maintenance program is in place and is effective. The	List of all food process equipment is maintained in the MP2 computer database system. Preventive maintenance tasks are

	<p>program includes:</p> <ul style="list-style-type: none"> - a list of food handling equipment; - maintenance frequencies; - training for maintenance personnel; - accountability for corrective and preventive maintenance; - maintenance records; - logging of emergency maintenance; - records retention for the shelf life of the product; and - inventory control for maintenance parts to ensure that there is an accounting for parts prior to production. 	<p>automatically printed out at the required frequency for each task or piece of equipment. In the case of simultaneous tasks, the database prioritizes equipment designated as "critical" (see item 2.13.1). A work order, generated by the database, is completed by mechanic when work is done and includes the mechanic's signature and date. Work orders require sign-off by mechanic for parts/tools reconciliation. Equipment requiring cleaning/sanitation after maintenance are so noted in work orders. Upon completion of maintenance, the information is entered into MP2 system for permanent records storage. The paper copy is archived; records are kept for the life of the equipment. Maintenance tasks are periodically verified by Maintenance Manager, but verification is not recorded. Replacement parts are noted in work orders or in equipment manuals, and are listed in parts inventory database; no preferred vendor list is used, but practice is to obtain parts from equipment manufacturer. Temporary repairs are permitted at the mechanic's discretion, but work order is not closed out until permanent resolution is made. Equipment due for preventive maintenance is highlighted in the system until closed out. The database indicated no open work orders older than current week. No temporary repairs were observed during the audit. Several electric motors in processing area had small amounts of rust; there is an ongoing program of replacing them with stainless steel units if near a food contact area. If not, then they are being repainted.</p>
	SECTION SUMMARY:	<p>Fully Meets Preventive maintenance program is well managed, using a computer-driven database to notify when equipment is due for maintenance, issue work orders, identify and inventory parts, and indicate when work is closed out. Records are kept electronically and on paper; records reviewed were complete.</p>

Facility's Response to Auditor's Observations

3.0 HACCP and Food Safety Programs	
SECTION	RATING
3.1 HACCP Systems	Fully Meets
3.2 Microbiological Testing	Not Applicable
3.3 Environmental Monitoring	Not Applicable
3.4 Food Allergens & Chemical Sensitivities	Not Applicable
3.5 Foreign Material Control	Fully Meets

Section 3.1 - HACCP Systems	
AUDIT ELEMENT	OBSERVATION
<p>3.1.1 HACCP Team: A HACCP team is in place and they are responsible for developing and modifying the HACCP plan and implementing and maintaining the HACCP system.</p>	<p>The HACCP team at this facility consists of the Plant Manager, QA Manager, production superintendents, First and Second Shift managers, QA supervisors, HACCP Coordinator and the assistant HACCP coordinator. HACCP coordinator has attended train-the-trainer course for HACCP. Plant manager, Shipping Manager, Operations Manager, and assistant HACCP coordinator have attended a NFPA Basic HACCP course. Team meets twice a year</p>

		unless there is change in the process or product at this facility - records are kept. Last meeting was 1-8-03.
3.1.2	<p><u>HACCP Plan:</u></p> <ul style="list-style-type: none"> - <u>A HACCP preliminary steps were conducted prior to developing the HACCP plan.</u> - <u>A HACCP plan is documented for each product/process.</u> 	<p>HACCP preliminary steps have been taken and documented, including product descriptions, intended distribution and use, and flow charts (last verified 1-6-03). Products are grouped into raw processed bulk, raw processed retail frozen, raw processed retail refrigerated, and ready-to-cook retail. The same HACCP plans cover poultry and pork products. HACCP plans are in accordance with USDA requirements. Flow charts and HACCP plans are present for each group. Flow chart for raw processed retail were observed and verified during the audit.</p>
3.1.3	<p><u>Content of the HACCP Plan:</u></p> <ul style="list-style-type: none"> - <u>A hazard analysis, including identification of hazards and associated control measures, is documented for each product/process.</u> - <u>Critical Control Points are determined and critical limits are established to prevent, eliminate or reduce hazards to acceptable levels.</u> - <u>Monitoring procedures are established to assess whether a CCP is under control and to produce an accurate record.</u> - <u>Corrective action procedures are documented in the event that monitoring indicates a loss of control at the CCP.</u> - <u>Verification/validation procedures are documented that will ensure the validity of the HACCP plan and that the HACCP system will operate according to the HACCP plan.</u> - <u>Record-keeping and documentation procedures are established to document the safety of the foods produced.</u> 	<p>Hazard analysis and HACCP plan are documented for each group. Hazard analysis includes assessment of likelihood of occurrence, but not severity. In all four HACCP plans, hazards identified as requiring CCPs included pathogens from raw meat (and vegetables, as appropriate) and metal from raw materials and in-process equipment. CCPs include temperature and condition of meat at receipt (monitored each receipt), temperature of cold storage areas (monitored continuously, verified daily), temperature of shipping trailer (recorded each shipment), and operational metal detector (checked 4 times daily). Critical limits were developed in discussion with USDA in-plant inspector. All monitoring activities are recorded. Written corrective actions exist for each CCP, and are in accordance with 9 CFR 417. Verification activities include calibration of temperature sensors and metal detector, records review by HACCP Coordinator, weekly observation of monitoring activities by a QA technician and at least annual reassessment of HACCP plan. HACCP records are kept on-site for 1 year for refrigerated product, 2 years for frozen.</p>
3.1.4	<p><u>Implementation of the HACCP System:</u></p> <ul style="list-style-type: none"> - <u>Copies of the HACCP plan in use are current and approved by management.</u> - <u>Monitoring procedures are conducted according to the procedures and frequencies specified in the HACCP plan.</u> - <u>Corrective actions are conducted according to the procedures specified in the HACCP plan.</u> - <u>Verification procedures, including calibration of HACCP instruments and equipment, record reviews, and HACCP system audit/review procedures, are conducted according to the procedures specified in the HACCP plan.</u> - <u>Validation procedures, including comprehensive reviews of the hazard analysis and HACCP plan, are conducted as specified in the HACCP plan.</u> - <u>HACCP records are readily available and provide evidence that the HACCP system is being implemented and maintained to</u> 	<p>A copy of the current HACCP plan was requested on arrival; it was the same version (signed 1-13-03 by Plant Manager) as reviewed prior to the audit. Monitoring records were scanned for each CCP; records reviewed were complete, initialed by the monitor, and signed/dated by both Shipping Manager and HACCP Coordinator. Three Corrective Action Reports were in the file - two for raw meat receipt temperature and one for faulty metal detector - and were complete and signed. Calibration records were present for all HACCP-designated instruments. A memo describing the most recent HACCP plan reassessment was present (dated 1-10-03) and indicated no changes to the plan. Historical HACCP plans are maintained in a file, and there is a revision history which explains the rationale for plan changes over time. There is a validation procedure described in the "Lot Release Procedure" dated 3-28-02 which involves a review of all HACCP records including the preshipment review and sign-off by Shipping Manager. This activity is independent of the HACCP plan and constitutes both a validation step and a positive release mechanism for all finished product at this facility. No other procedures are written for managing the HACCP program, but practices and records indicate compliance with the plan and USDA requirements.</p>

	ensure food safety.	
3.1.5	Personnel demonstrate knowledge of and take specified actions regarding the CCPs, critical limits, monitoring procedures, corrective actions, verification, validation and record-keeping procedures identified in the HACCP plan that are under their area of responsibility.	HACCP Coordinator is very knowledgeable about HACCP and USDA requirements. HACCP technician was interviewed and demonstrated accurate knowledge of CCP1 (raw meat receiving), including critical limits, monitoring procedures, corrective actions, verification and record-keeping. Other employees demonstrated appropriate knowledge of HACCP implementation as it related to their area of responsibility. Monitoring records at each CCP were reviewed during the in-plant inspection; all appeared to be filled out appropriately, no record keeping issues were observed.
	SECTION SUMMARY:	Fully Meets The facility operates under USDA inspection, and must comply with 9 CFR 417. HACCP Coordinator is very knowledgeable about HACCP; other HACCP team members are also trained. HACCP documents, procedures, and records are well developed. CCPs were developed based on the hazard analysis and discussions with USDA inspector. Records and in-plant inspection indicate HACCP plan is being performed as written and in compliance with the regulation.

Facility's Response to Auditor's Observations

Section 3.2 - Microbiological Testing		
	AUDIT ELEMENT	OBSERVATION
3.2.1	Microbiological testing is in place, where applicable.	There is a written procedure for product contact surface testing for Total Plate Count. It requires swab samples be taken after sanitation is complete. Five samples in the processing area and two in the packaging area are randomly selected for collection on Mondays and Fridays. Since all products are raw, no corrective actions are required; these data are being assembled for trend analysis. Swab samples are sent to MicroTest, a local testing laboratory.
3.2.2	Employees are trained in procedures for microbiological sampling, evaluation and management of data.	Sample collections are performed by trained QA employees. They are trained in proper technique by QA Manager who has MS in microbiology. Test results are received and reviewed by QA Manager.
3.2.3	Microbiological testing is completed in accordance with recognized or validated equivalent methods.	Testing laboratory was selected because of its proximity to the plant. MicroTest reports indicate that tests are performed using 3M Petrifilm method.
3.2.4	Microbiological testing includes in-process and finished products, ingredients, and the environment as appropriate to products manufactured.	The only microbiological testing performed is on post-sanitation product contact surfaces, as described in 3.2.1.
3.2.5	Where appropriate, a pathogen control program is in place to prevent the presence of <i>Listeria</i>, <i>Monocytogenes</i>, <i>Salmonella</i>, and <i>E. coli O157:H7</i> in manufacturing and storage environments.	Since all products are raw, no pathogen control program is in place. No pathogen testing is used in the HACCP plan.
3.2.6	All results for testing are within microbiological specifications.	Test results are being used to determine a baseline for post-sanitation levels. These will ultimately be used to determine trends and opportunities for continuous improvement.
3.2.7	An appropriate sample size is used for	Swab samples each cover approximately a one inch square area.

	microbiological testing that is representative to the lot or area being evaluated.	
3.2.8	If Certificates of Analysis (COA) are used in lieu of microbiological testing, appropriate verification procedures are in place.	The few COAs used for raw material control do not include specifications for microorganisms. COAs generated for products do not include testing for microorganisms.
3.2.9	All products tested for pathogens are placed on hold pending acceptable results. Status of products tested for pathogens is dependent on results.	not applicable - no pathogen testing is performed.
	SECTION SUMMARY:	Not Applicable The only microbiological testing performed is on post-sanitation product contact surfaces to measure cleaning/sanitation effectiveness. Since all product is raw, no product testing is performed.

Facility's Response to Auditor's Observations

Section - 3.3 Environmental Monitoring		
	AUDIT ELEMENT	OBSERVATION
3.3.1	Environmental testing is performed for monitoring the presence of pathogens.	Not applicable - all products at this facility are raw, not cooked. There is no environmental testing for pathogens.
3.3.2	An appropriate corrective action plan is in place and effective.	Not applicable.
3.3.3	If product contact surfaces are tested for pathogens, the appropriate product lot(s) are placed on hold pending results.	Not applicable.
	SECTION SUMMARY:	Not Applicable All products at this facility are raw, not cooked. There is no environmental testing for pathogens.

Facility's Response to Auditor's Observations

Section 3.4 - Food Allergens & Chemical Sensitivities		
<small>(Allergens and sensitive chemicals are defined as peanuts, tree nuts, eggs and egg products, milk and other dairy products, shellfish, fin fish, soy protein, wheat and sulfites.)</small>		
	AUDIT ELEMENT	OBSERVATION
3.4.1	Food allergens and sensitizing chemicals are clearly identified in the facility.	The hazard analysis during development of the facility HACCP plans and subsequent reassessments considered the potential for allergens and allergen sources. The hazard analysis included spice blends and flavorings. No sources of the eight major allergens have been identified in the facility. No sulfites or Yellow No. 5 is used in the facility or ingredients.
3.4.2	Procedures are in place to prevent the cross contact of products with an undeclared allergen. The procedures include process change control.	Not applicable - no allergens identified at this facility.
3.4.3	Labeling and packaging procedures exist	Not applicable - no allergens identified at this facility.

	to ensure that only correct labels are used. Labels are verified to be correct relative to the appropriate allergens.	
	SECTION SUMMARY:	Not Applicable The HACCP plan hazard analysis includes an assessment of allergen hazards. No sources of allergens are identified at this facility.

Facility's Response to Auditor's Observations

Section 3.5 - Foreign Material Control		
	AUDIT ELEMENT	OBSERVATION
3.5.1	Procedures or devices are in place for foreign material control.	Corporate policy document titled "Foreign Material Control Points" dated 6-27-02 outlines possible routes for foreign material contamination based on examination of company-wide consumer and customer complaint history, and suggests methods for controlling or reducing this hazard. This is the basis for development of in-plant procedures addressing foreign material control including accountability of thermometers, stopwatches, and calculators issued to employees as needed for job performance, but not pens or markers. Objects may not be placed in pockets above the employee's waist. Wooden pallets are inspected for broken pieces, debris, and sanitary condition; their use is restricted in the facility. Overhead maintenance work involving welding, grinding, or cutting performed during non-production hours requires prior notification to the sanitation manager or designee and either the QA manager or startup shift QA supervisor. Maintenance is responsible for cleaning up parts and loose debris; maintenance procedures require reconciliation of parts and tools; sanitation is responsible for cleanup; QA is responsible for releasing during pre-operational inspection, and for documenting any deficiencies and corrective actions on pre-op SSOP forms. No screens, sifters or magnets are used.
3.5.2	Corrective action is taken if a metal detector or other foreign material detection device is found to be non-operational.	The three metal detectors on packaging lines are CCPs. The HACCP plan requires that all are tested with 1.5 mm ferrous, 2.0 mm non-ferrous and 3.0 mm stainless steel wands at least 4 times daily when the packaging lines are in operation. Corrective action requires that, if a metal detector is not operational (i.e., does not detect and trigger kick-out for any of the test wands), product back to the last good check is segregated, held, and run through a functioning metal detector before release. If the detector signals metal in product at any time, the product is retained, inspected and, if an object is found, an attempt is made to identify the source. Interview of the packaging operator confirmed her knowledge of the procedure, and her ability to test the metal detector according to procedure. One corrective action report for metal detector failure was reviewed, and indicated that procedure was followed.
3.5.3	There are effective procedures for the prevention of glass contamination, breakage, and management.	Facility has located all glass-containing light fixtures in the facility on a schematic map; this is used during self-audits to identify the location of any device in need of repair. "Guidelines Against Glass and Brittle Plastic in Processing Plant" dated 1-27-03 outlines procedures used to ensure that all glass is shielded or

		shatterproof, all light bulb purchases are of shielded or shatterproof type and involve the purchasing manager, glass breakage incidents are handled appropriately, maintenance technicians will inspect meters daily for condition, and QA and/or HACCP Coordinator will perform monthly inspections for compliance to this guideline. There is a list of all equipment meters or lenses which use glass and brittle plastic in the processing plant, including fork lift head lights. Glass breakages require preparation of a Glass Incident report, which is kept on file by QA. Incidents are rare - only five were in the file, going back five years. Guidelines do not include procedures for routine glass bulb changing or for broken glass disposal in the event of a breakage incident.
3.5.4	Lubricants and process aids used are food grade.	Certified Lubemaster Permalube FG grease is approved for use in a food processing plant. Approval documentation was not on file, but was faxed during the audit. No equipment bearings are located over exposed product areas. No conditions were observed potentially leading to product contamination with lubricant.
	SECTION SUMMARY:	Fully Meets Potential sources of metal contamination have been well thought out and procedures implemented to minimize potential. Metal detectors are CCPs in HACCP plan. Glass, brittle plastic and wood are controlled; records indicate glass breakage incidents are rare. The only lubricant observed was food grade. No opportunities for product contamination with lubricant were observed.

Facility's Response to Auditor's Observations

4.0 Manufacturing Quality Systems	
SECTION	RATING
4.1 Conformance to Customer Specifications	Fully Meets
4.2 Good Laboratory Practices	Not Applicable
4.3 Process Control	Fully Meets
4.4 Document Control & Record Keeping	Fully Meets
4.5 Inspection & Test	Fully Meets
4.6 Control of Nonconforming Materials	Fully Meets
4.7 Continuing Guarantee	Not Applicable
4.8 Corrective & Preventive Action	Fully Meets
4.9 Continuous Improvement	Partially Meets
4.10 Customer Service	Not Applicable
4.11 Internal Auditing	Partially Meets

Section 4.1 - Conformance to Customer Specifications		
	AUDIT ELEMENT	OBSERVATION
4.1.1	Products are evaluated and confirmed to meet customer-specific specifications.	All customer-specific requirements and specifications are supplied from corporate office and maintained within the computer database system that generates batch records. All changes to

	customer specifications, including capability issues from the facility, are routed through corporate (see item 4.4.2). All finished product is evaluated for conformance to customer specifications. Product must pass all specification tests and pre-shipment review of HACCP records before release. Records, and interview of Shipping Manager, indicate this procedure is followed. If product does not meet the specifications, it is put on QA Hold as described in audit item 4.6.1.
SECTION SUMMARY:	Fully Meets Customer specifications, including changes and capability issues, are managed through corporate. All finished products are evaluated for conformance to customer specifications before release.

Facility's Response to Auditor's Observations

Section 4.2 - Good Laboratory Practices	
AUDIT ELEMENT	OBSERVATION
4.2.1 Laboratory procedures follow recognized and/or official methodology for all tests for which such a standard exists.	The only test procedures are performed by QC, to verify products meet customer specifications. No microbiological testing is performed on site (see section 3.2).
4.2.2 Laboratory methods are validated for accuracy and analyst proficiency is verified periodically.	Not applicable - no microbiological testing is performed at this facility.
SECTION SUMMARY:	Not Applicable The only test procedures are performed by QC, to verify products meet customer specifications. No microbiological testing is performed at this facility.

Facility's Response to Auditor's Observations

Section 4.3 - Process Control	
AUDIT ELEMENT	OBSERVATION
4.3.1 Process control procedures ensure conformance to specifications.	Process control is accomplished by extensive in-process and finished product testing to meet customer specifications for net weight, % lean, and other physical attributes. Well documented sampling plans assure that critical parameters are maintained in a tight range throughout the process. Records reviewed during the in-plant inspection verified that procedures are followed.
4.3.2 Current procedures are available for operators for all prescribed process and quality checks.	Clear, written operating instructions are present for in-process and finished product sampling, testing, and data analysis. Results reviewed by this auditor indicate that procedures are being followed and results are being acted upon when needed. Some tests that were once laboratory responsibilities have been successfully moved to the operator. Overall, the process control systems in place are very well conceived and executed.
4.3.3 Statistical process controls are utilized.	Specification ranges are based on customer requirements. A 2001 continuous improvement project introduced statistical techniques to determine whether internal operating ranges can be successfully tightened beyond customer requirements, resulting in

		a more uniform finished product. The low frequency of non-conforming product demonstrates the success the facility has had with this effort.
4.3.4	Processes operate to a target versus a maximum or minimum value.	Most specifications only include ranges and not specific targets. However, it is to the plant's advantage to target the center of the range in order to minimize the risk of non-conforming product.
	SECTION SUMMARY:	Fully Meets Process control systems are well documented and strictly followed. Personnel responsible for execution of program are well trained and motivated. Specification ranges are established by the customer, however, the facility has continually improved many processes to the point where the operating parameters are much tighter than the required specs.

Facility's Response to Auditor's Observations

Section 4.4 - Document Control and Record Keeping		
	AUDIT ELEMENT	OBSERVATION
4.4.1	Systems are in place for managing and controlling all Quality System documentation data and records.	The Quality Manual provides a very detailed policy/procedure for creating new or modifying existing SOP's or specifications. The process is to send a draft of the document to the Quality Systems Documentation Manager who sends copies to QA, the Plant Manager and possibly Purchasing for review and approval. When the document is approved it is entered into the Quality Manual, automatically replacing earlier versions, if any. These documents include title, number, date, electronic signature, page number (page of total pages) and the document being replaced. All Quality Manual documents are maintained in an electronic file, which is password protected and backed up regularly off-site. Only the QA Manager or higher is authorized to issue quality and food safety documentation. Except for refrigerated products records (1 year), all documents are retained for at least 2 years, 3 years for regulatory inspection reports, per company policy, but most are kept until storage room becomes limiting.
4.4.2	The supplier changes customer specific documents only with prior approval and authorization.	Customer approval of specification changes is routed through corporate. Change are implemented only after written (hard copy, fax or email) approval is received. Three examples from the last 6 months were reviewed - for example, one was for a change in flavoring supplier - all three were signed and dated as approved by corporate Manager Customer Relations. Batch records for all three indicate that batches were not produced until approval was received.
4.4.3	Records are reviewed prior to product release to customers.	Finished products are held until testing is completed; product is not shipped until records are reviewed and signed by Shipping Manager. Copies of COAs for two days' production were requested. COAs were present for all products produced on those days; COAs indicated that customer specifications were met, and were signed and dated by QC Manager on the date of shipment. COAs and inspection reports were requested for two receivals that require COAs; both were present and COAs matched the material lot number received and material specifications.
	SECTION SUMMARY:	Fully Meets Quality Manual documents are well controlled and organized.

Customer specification changes are managed through corporate, but are not implemented until written (letter, fax, email) confirmation is obtained. Product shipment is under positive release by Shipping Manager review of COAs and HACCP records. Examples reviewed indicate the procedures are followed.

Facility's Rspose to Auditor's Observations

Section 4.5 - Inspection & Test		
	AUDIT ELEMENT	OBSERVATION
4.5.1	In-process and/or finished products are inspected and tested to ensure conformance to specifications and customer requirements.	All customer-specific requirements and specifications are supplied from corporate office and maintained within the computer database system. All finished product is evaluated for conformance to customer specifications. No finished product taste panels are performed (product is raw). No finished product samples are retained.
4.5.2	Records are available to show evidence of inspection and test results.	Finished product inspection and test results (hard copy and electronic notation of approval) are maintained for one (refrigerated) or two (frozen) years. Observation of records file indicates this procedure is followed, although it was not possible to confirm that records for all product lots were present.
4.5.3	Procedures dictate that customers are consulted regarding nonconforming materials prior to shipment.	Non-conforming products are not shipped unless cleared by fax or email by corporate. No test records were observed indicating non-conforming product was produced. No recent (one year) examples of non-conforming product shipments were available for review.
	SECTION SUMMARY:	Fully Meets All finished products are verified through inspection and test to meet customer specifications prior to release. Any nonconforming products would have to be released through corporate, although there were no recent examples of this.

Facility's Rspose to Auditor's Observations

Section 4.6 - Control of Nonconforming Materials		
	AUDIT ELEMENT	OBSERVATION
4.6.1	Nonconforming product is segregated and controlled from inadvertent shipment.	Nonconforming product is tagged with a numbered green QA Hold tag, then placed into a designated area in the ingredient freezer or chill area, as appropriate. Production supervisor for the area or product affected is notified of the failure. Production must notify QA before rework begins, and QA monitors the rework process. When all rework is complete, QA rechecks product. Once product meets requirements, QA Hold tag is removed. Only QA may remove tag. Production is notified of release. All records of hold tag numbers, personnel and product involved, and dispositions are maintained in master hold log. Nonconforming product cannot be shipped because of positive release procedure requiring review and sign-off of finished product records by Shipping Manager. There were no recent examples of

		nonconforming product, so no records were reviewed.
	SECTION SUMMARY:	Fully Meets According to Lot Release procedure, nonconforming product is segregated in temperature controlled areas until released by QA. Product cannot be inadvertently shipped because of positive release procedure requiring review and sign-off of finished product records by Shipping Manager.

Facility's Response to Auditor's Observations

Section 4.7 - Continuing Guarantee		
	AUDIT ELEMENT	OBSERVATION
4.7.1	Where applicable, a continuing guarantee is supplied to customers indicating that materials shipped comply with all applicable laws and regulations.	Not applicable - corporate is responsible for supplying customers with continuing guarantees.
	SECTION SUMMARY:	Not Applicable Corporate is responsible for supplying customers with continuing guarantees.

Facility's Response to Auditor's Observations

Section 4.8 - Corrective & Preventive Action		
	AUDIT ELEMENT	OBSERVATION
4.8.1	The corrective and preventive action process is defined and includes: - identification of the issue; - investigation of root cause; - timely corrective action; and - follow-up to confirm implementation and effectiveness.	The corrective action program is described in the Quality Manual. The corrective action process involves filling out a Corrective Action Request form describing the problem and required corrective action and assigning responsibility for the corrective action. Completion of the corrective action is documented on the form as is acceptability of the corrective action by the requestor. The CARs are entered into a computer database and a monthly report is published listing outstanding CARs. QA Manager has responsibility for monitoring that CARs are closed out in a timely manner. A review of several CARs indicated timely corrective actions that were documented as satisfactory to the requestors. CARs are reviewed with plant management at quarterly meetings.
	SECTION SUMMARY:	Fully Meets A well documented Corrective Action program exists and is utilized. Review of several example indicates procedures followed. Management reviews reports at quarterly meetings.

Facility's Response to Auditor's Observations

Section 4.9 - Continuous Improvement		
	AUDIT ELEMENT	OBSERVATION
4.9.1	Quality data are reviewed and improvements designated.	A continuous improvement program is practiced but not documented. The Quality Assurance Business Plan sets quality

	objectives for the year. At quarterly meetings, plant management reviews progress against these objectives. A combined measure of conformance quality and consumer feedback is updated on a weekly basis to track facility performance. Trends are evaluated and specific teams are assigned to work on various aspects of the improvement program. The introduction of statistical process control was example of the process (see item 4.3.3). However, records indicate progress of the 2002 improvement initiatives were not tracked. No progress reports or status updates were present for initiatives identified in the last management review.
SECTION SUMMARY:	Partially Meets A continuous improvement is not written, but is practiced, utilizing multi-departmental teams and key performance indicators. However, records indicate that consistency in performance of this program has diminished in the past year.

Facility's Response to Auditor's Observations

Section 4.10 - Customer Service		
	AUDIT ELEMENT	OBSERVATION
4.10.1	Procedures are in place for complaint handling.	Complaint handling procedures are not documented at the facility. All complaints are handled at corporate and communicated down to the plant. The interface between plant QA and corporate consumer affairs is a good one. Complaints are addressed in a timely manner and generally resolved quickly.
4.10.2	Responses to complaints regarding a customer's product are directed to the customer in a timely manner.	Corporate customer relations receives complaints and forwards them to the appropriate person at the affected plant. The plant contact person assigned the particular complaint responds to customer relations team which then contacts customer. Policy dictates that complaining customers should be contacted with resolution within 3 days of their initial communication.
	SECTION SUMMARY:	Not Applicable The customer service system is handled by corporate. In practice, there is a close collaboration between the corporate customer relations department and plant quality assurance, and complaints are generally resolved quickly.

Facility's Response to Auditor's Observations

Section 4.11 - Internal Auditing		
	AUDIT ELEMENT	OBSERVATION
4.11.1	An internal audit program is in place and effective.	A documented internal audit program is in place at this site and is effective in identifying internal issues and improvement opportunities. Internal auditors have been trained by working with more senior auditors, and may be accompanied by corporate auditors. Audits are scheduled on a regular basis in different areas, such that all parts of the facility and programs are audited at least annually. Internally prepared checklists are used. Audit reports are presented to the supervisors responsible for the areas audited. However, internal audit results are not systematically

		reviewed by the management team. Audit reports for 2002 were reviewed, and were often 'closed out' without a definitive documented resolution of defects identified.
	SECTION SUMMARY:	Partially Meets An internal auditing program is documented and dedicated, trained staff perform audits such that the entire facility is audited at least annually. Audit reports are complete, but follow-up actions are not always performed. Management review of the audit reports was not consistent in 2002.

Facility's Rspose to Auditor's Observations

5.0 Regulatory Considerations	
SECTION	RATING
5.1 Labeling Approval	Fully Meets
5.2 Regulatory Compliance	Fully Meets
5.3 Management of the Regulatory Process	Fully Meets

Section 5.1 - Labeling Approval		
	AUDIT ELEMENT	OBSERVATION
5.1.1	There is a documented process and procedure to develop, review and approve labels.	Not applicable - labels are developed, reviewed, and approved only by the corporate Regulatory Affairs department.
5.1.2	Labels are verified before use on the manufacturing line as appropriate for the product being run.	Labels are computer-generated as needed for production, and are specific and unique to each product code. QA technicians perform an on-line label verification check of label alignment, correct product code, visual sharpness of wording on label, correct pack date, correct sell by date if applicable, and USDA logo. Labels in use during the audit were verified as matching the product.
	SECTION SUMMARY:	Fully Meets Labels are developed and approved by corporate, and generated as needed by the computer system. Labels are checked several times during production to ensure they are correct.

Facility's Response to Auditor's Observations

Section 5.2 - Regulatory Compliance		
	AUDIT ELEMENT	OBSERVATION
5.2.1	The facility processes, products, training, and records comply with applicable state, local, and Federal regulations.	Director of QA and corporate VP Technical Services and Regulatory Compliance are responsible for monitoring regulatory requirements. This facility operates under continuous USDA-FSIS inspection as an approved meat/poultry processing plant. All applicable federal regulations in 9 CFR are followed, as well as applicable state and local regulations. Facility demonstrates compliance by successfully implementing regulatory programs such as HACCP and SSOPs; records for all program activities are maintained. There are also records of corrective actions and

		preventive measures in response to USDA Noncompliance Reports.
	SECTION SUMMARY:	Fully Meets Plant and corporate management are responsible for monitoring regulatory requirements. The plant operates under continuous inspection by USDA. Review of Noncompliance Reports indicate no recurring regulatory issues.

Facility's Response to Auditor's Observations

Section 5.3 - Management of the Regulatory Process		
	AUDIT ELEMENT	OBSERVATION
5.3.1	Management ensures that employees are trained to manage the regulatory inspection process.	There is a corporate procedure dated 7-2-02 which addresses FSIS-USDA inspections, citations, and postings. It details the actions to take for a routine compliance inspection, "special emphasis" program inspection, USDA employee complaint, or follow-up inspection to check abatement of previously cited violations. All visitors must sign in and are subject to the requirement to be accompanied by a member of management. Senior management must be notified. The plant receptionist was aware of the procedure, and had 24 hour contact numbers for Plant Manager, Director of QA and corporate VP Technical Services and Regulatory Compliance.
5.3.2	Customers are notified if their product is not in regulatory compliance.	Customers are only notified in the event of a product recall, and would be notified by corporate. No mechanism exists at the facility to contact customers directly.
5.3.3	Duplicate samples are taken when any regulatory samples of product are taken.	Per "Visitor and Contractor Access Control Procedure", all samples taken during a compliance visit must be split between plant and regulatory agency. Corporate would notify customer if their product was sampled.
5.3.4	Duplicate copies of any documents given to regulatory authorities concerning a customer's product are made.	As stated in the FSIS-USDA inspection procedure, the inspector may review any programs or procedures available, but copies are not to be given to the inspector without authorization from corporate Loss Prevention or Legal. No examples of this procedure were available for review.
	SECTION SUMMARY:	Fully Meets A corporate procedure is in place which addresses procedures to be followed during routine and non-routine USDA FSIS inspections. Customer contact would be made by corporate.

Facility's Response to Auditor's Observations