

Audit Criteria for Food Contact Packaging Materials, Food-Related Items, and Personal Care (Contact) Products

Company Information	Audit Information
Facility: C0087690 - Address: China Contact: Title: Phone: Fax: Email:	Audit# - Visit#: 825888 - 590254 Audit Type: PKG - Audit Criteria for Food Contact Packaging Materials, Food-Related Items, and Personal Care (Contact) Products Template Version: 2 Audit Category: REAUDIT Auditor: Rong Liang Audit Start Time: 28-DEC-2012 09:00:00 AM Audit End Time: 28-DEC-2012 05:00:00 PM Prior Audit Date: 10-JUL-12 Prior Audit Score: 90.55%

Audit Result: Needs Improvement

Facility and Operating Profile	
No	Question/Notes
1	Facility and Operations Description:
2	Auditor's Notes: The company area is approximate 2700 square meters in this location. The production building is just one floor including warehouse, processing area and packaging room. The manufacturing facility has approximate 80 employees, injection position working with 3 shifts and packaging position working with one shift, 5 days a week. Was the audit Announced or Unannounced?
3	Announced Products made at this facility:
4	See notes Disposable PLA or PSM material fork, spoon and knife products for food service The following departments and individuals participated in the audit process:
Section Notes :	See notes GM; Quality Manger Purchase Manager

Score Summary By Section	
Section Name	Section Score
Section A - Administration and Regulatory Compliance	95.00%
Section B - HACCP Management	95.00%
Section C - Facilities and Equipment	89.00%
Section D - Sanitation, Housekeeping and Hygiene	90.00%
Section E - Rodent and Pest Control Management	89.00%
Section F - Approved Suppliers, Receiving and Inventory Control	95.00%
Section G - Process and Product Evaluation	89.00%
Section H - Packaging and Labeling	95.00%
Section I - Storage and Shipping	92.00%
Section J - Training Requirements	95.00%
Section K - Laboratory Support	95.00%
Section L - Product Defense	93.00%
Food Safety, Quality and Food Defense Audit Average Score:	92.67%

Category Scoring Guide

95% - 100% = Meets or Exceeds Audit Expectations

85% - 94.99% = Needs Improvement

75% - 84.99% = Needs Significant Improvement

<75% = Critical

Automatic Audit Failure (Denoted as a "Critical" item in the audit report)

- Product Contamination and/or adulteration
- Significant deviation from identified CCP in the HACCP Plan
- Mislabeled or misbranded product
- Record falsification
- Significant deviation from specification
- Facility is not operating in compliance with stated regulatory requirements

Overview	
No	Question/Notes
	<p>Notes from the auditor:</p> <p>See Notes</p> <p>The facility focused on manufacturing biodegradable cutlery product made of PSM or PLA material. PP materials were observed in raw material warehouse. The company stated that PP materials were just used for cleaning interior of injection equipments.</p> <p>The product contact surface connected with injection equipments were made of wood and covered with aluminum foil bag. Products were put into the plastic container and were covered with lids during the storing. The plastic container would be cleaned routinely in this plant.</p> <p>For PLA material made products, products would be passed through the machine for increasing strength. After that, products were inspected and packaged in the packaging room. The appearance of product was inspected by packaging employee one by one before packaging. The packaging desks were made of stainless steel. The employee wore the clean outer garment and their hairs were restrained properly in this audit. The facilities and equipments were kept clean and orderly as well.</p> <p>The HACCP plans for disposable biodegradable cutlery product was established and the raw material incoming inspection was identified the CCP. The raw material must be accepted from approved suppliers. The suppliers' COAs were available for each lot of raw material.</p> <p>The annual training schedule was available and the training topics included orientation training, related regulations, HACCP, prerequisite program and personal hygiene. The training on above topics was conducted monthly. The training comprehension was verified by oral question in this facility.</p>
Section Notes :	

Non-Compliance Summary		
No	Question/Notes	Answer
Section C /5	<p>Handwashing Facilities</p> <p><i>Warm water was not available from faucet for hand washing in this audit. It is recommended that the handwashing stations must deliver tempered water (90-105°F) within 10 seconds.</i></p>	Needs Improvement*
Section C /7	<p>Plant Lighting and Protection</p> <p><i>The lights equipped on the ceiling were protected with shields in this audit. However the lights equipped on the injection machine were not protected. It is recommended that all glass lights must be completely enclosed in shatter-resistant protective shields or manufactured with shatter-resistant materials to prevent glass contamination of product.</i></p>	Needs Improvement*
Section D /2	<p>Standard Sanitation Operating Procedures and Monitoring</p> <p><i>There were three cisterns for cleaning product storage container in a room beside production workshop. The water in one cistern was dirty and mops were stored in this room in this audit. It showed the mops were likely cleaned in this cistern. It is recommended that floor cleaning tools such as mops and brooms must be not cleaned in cisterns for cleaning product container.</i></p>	Needs Improvement*
Section E /3	<p>Inside Premises Management</p> <p><i>Traps were not equipped at interior side of doorway in raw material warehouse. It is recommended that exterior opening doorways must have traps on both sides of the interior side of the doorway.</i></p>	Needs Improvement*
Section E /4	<p>Pest Tight Doors and Entrance Closures</p> <p><i>The gap was present between the floor and doorjamb in finished product warehouse. It is recommended that all doors must be tight closing with no visible light observed between the floor and doorjamb.</i></p>	Needs Improvement*

Section G /1	<p>Process Control and Documentation Procedures</p> <p><i>Several stickers showing different production date were on one in-process product storage container in this audit. It can not show the production date of in-process product accurately. It is recommended that identification for in-process products shall be improved in this plant.</i></p>	Needs Improvement*
Section G /3	<p>Routine Calibration of Operational Equipment and Measuring Devices (such as thermometers, scales, flow meters, counters, metal detectors, etc.)</p> <p><i>There was just one scale used for weighing product in this plant. The scale was not calibrated in this year. It is recommended that key process control devices shall be calibrated annually.</i></p>	Needs Improvement*
Section I /3	<p>Storage Facility and Dock Maintenance</p> <p><i>Product cartons were stored close to the wall in warehouse in this audit. It is recommended that wall perimeters must be maintained in a clear and clean manner and allow for pest management inspections and sanitation/housekeeping requirements.</i></p>	Needs Improvement*
Section L /2	<p>Human Element</p> <p><i>The employees were not identified with their name in this plant and auditor was not provided the visitor recognition card when entering. It is recommended that there must be a documented and implemented system for the positive identification and recognition of all employees entering the facility.</i></p>	Needs Improvement*

Section A. Administration and Regulatory Compliance		
No	Question/Notes	Answer
1	<p>Organization and Responsibilities <i>The current plant management organization chart was dated and signed by GM. It shows the reporting structure of the plant operating departments. Quality manager is responsible to GM in this plant. A clear documentation of the responsibilities and authorities of the Quality department was available. The control and release of withheld and retained product was designated as the responsibility of the Quality Manager.</i></p>	Acceptable
2	<p>Policies and Procedures Manual <i>Documented quality, product safety and security management system was established in this plant. Documented policies, procedures and pre-requisite programs that address relevant product safety, quality and security requirements for the receiving, handling, manufacturing and shipping of product were available.</i></p>	Acceptable
3	<p>Management Awareness and Commitment <i>Management commitment and active support was showed through training program and financial resources for product quality and safety system in this plant. Equipments and facilities were in proper condition in this plant. GM was in attendance during the opening and closing meetings in the audit.</i></p>	Acceptable
4	<p>Product Identification, Traceability and Recall Plans and Procedures <i>Documented product identification and traceability management procedure was established in this plant. Product identification codes and lot definition including raw materials, product contact packaging materials and finished products was documented. Traceability from raw material and product contact packaging to finished products and shipping records was achievable. Lot numbers of finished products were shown on shipping documents. Written products recall procedure was established in this plant. It addressed the criteria of recall initiating, the process of product recall and responsibilities of each department involved. The list of recall team was available and the recall coordinator was identified. 24/7 contact information for each team member was included. Traceability exercises were conducted twice to the first level of distribution in last twelve months. Management assessment of each traceability exercise was conducted and documented. A balance sheet of total quantity of product produced subject to the exercise vs. product shipped, product on hand and product otherwise documented (damaged, lost, samples, etc.), product unaccounted for, a calculated percent recovery was available. The assessment report showed percent recovery of traceability exercise achieved at a 100% level within 4hours.</i></p>	Acceptable
5	<p>Regulatory Compliance <i>The file of regulatory actions, visits, reports or other notifications received from any regulatory agency was maintained in this plant. Written responses with appropriate corrective actions were documented.</i></p>	Acceptable
6	<p>Document and Records Management <i>The document and records management procedures were established and it addresses document creating process, the control of document issue and revise, document filing, specific time limits for holding files and proper disposition of outdated documents and records. All documented procedures were identified the current revision status. Locations for the storage of documents and records were designated. Records were indexed and easily retrievable in this plant.</i></p>	Acceptable
7	<p>Change Management <i>Change management procedure was established and it described the process of communication, approval and training for changes in key management personnel, specifications, policies and procedures.</i></p>	Acceptable
8	<p>Documentation to Track Effectiveness of Policies <i>Management review for evaluating the level of conformance to quality and product safety management system was conducted in this year and documentations were available for review during this audit.</i></p>	Acceptable
9	<p>Crisis and Natural Disaster Management <i>A crisis management team was assembled and included a sufficient number of members representing the necessary department to handle and resolve critical situations such as recall, product defense issue and emergency situations. A list to outline the responsibility of each member with 24/7 telephone number was available. Quality Assurance was responsible for evaluating the status of ingredients, in-process materials and finished product involved in an emergency and making sure they were acceptable prior to the start of production or shipping.</i></p>	Acceptable

Section A. Administration and Regulatory Compliance		
No	Question/Notes	Answer
10	Customer/Consumer Complaints (Policies, Follow Up and Response) <i>Customer complaint management procedure was established in this plant. It addressed department responsibility, the handling process for a complaint including investigation of complaint, response to customer, taking corrective actions and tracing the effectiveness. The company stated that customer complaint did not happen in this year.</i>	Acceptable
Section Notes :		

Section B. HACCP Management		
No	Question/Notes	Answer
1	Preliminary HACCP Tasks <i>Preliminary HACCP tasks were accomplished in this facility. HACCP team was assembled and team member responsibilities were clearly identified. The flow diagram outlining each step involved in the process was available and CCP was identified on it.</i>	Acceptable
2	Hazard Analysis (HACCP Principle 1) <i>Hazard Analysis document was available in this plant. The chemical, physical and biological hazards that may be reasonably expected to occur at each step from raw material, processing and distribution were taken into account by HACCP team. Evaluation included all ingredients, equipment, processing steps and packaging.</i>	Acceptable
3	Critical Control Points (HACCP Principle 2) <i>Documentation for determining a step or process as a CCP or not was clear and thoroughly explained, defining the hazards and the specific controls that eliminate or reduce the hazard. Raw material incoming inspection was identified the CCP. The raw materials must be received from approved suppliers.</i>	Acceptable
4	Critical Limits (HACCP Principle 3) <i>The critical limits were established, specified and validated for each CCP. Critical limits were measurable. Process capabilities were documented to demonstrate that established CCP limits were compatible with the plant process and that limits were attainable.</i>	Acceptable
5	CCP Monitoring (HACCP Principle 4) <i>Monitoring procedure for each CCP was established and the frequency of monitoring was sufficient to assure the CCPs in control. Monitoring data were documented on the HACCP records and evaluated by a designated person with knowledge and authority to carry out corrective actions with indicated.</i>	Acceptable
6	Corrective Actions (HACCP Principle 5) <i>Corrective actions were developed for each CCP and included instructions with the necessary actions to take to secure product and bring the CCP under control in the event a critical limit was exceeded.</i>	Acceptable
7	Verification and Validation (HACCP Principle 6) <i>The verification of HACCP system was included in the internal audit in this year. It included review of the HACCP system and plan and its records, confirmation that CCP was properly monitored and kept under control and product testing.</i>	Acceptable
8	Documentation and Record Keeping (HACCP Principle 7) <i>HACCP procedures were documented with detailed corrective actions and product dispositions. Documentations and records including hazard analysis, CCP determination, CCP monitoring etc were kept properly. Deviations from the HACCP plan were thoroughly documented with detailed corrective actions and product dispositions. Final records were in ink, signed by the operator, supervisor and HACCP reviewer and without missing data or blanks. Records were securely stored and easily retrievable.</i>	Acceptable
Section Notes :		

Section C. Facilities and Equipment		
No	Question/Notes	Answer
1	Potable Water, Ice, Backflow Prevention, Steam and Waste Water Management <i>Potable water was from municipal water system. It was sampled in plant and tested by a certified laboratory annually and the test report showed that potable water conformed to potable water specification.</i>	Acceptable

Section C. Facilities and Equipment		
No	Question/Notes	Answer
2	Plant Construction and Design <i>The construction of the facility is such that it facilitated the manufacture of quality products and that it meets the GMP requirements. Exterior of plant and grounds are covered with cement pavement and lawn to minimize dust. There was no evident standing water in this plant. Walls and floors were constructed with hard, smooth and easy cleaning material. A glass and brittle plastic program was in place.</i>	Acceptable
3	Plant Condition (Walls, Ceilings, Floors, etc.) <i>Plant facilities including walls, ceilings, floors etc. were properly maintained in orderly and clean conditions. The ceiling surfaces and overhead structures such as piping were clean, in good repair and free of flaking paint. Ceiling panels, framework and supports were properly secured with no missing or damaged parts.</i>	Acceptable
4	Employee Facilities <i>Locker room for personnel was adequate, convenient and physically separated from production areas in this plant. Toilet facilities were available and it was well lit, clean and properly ventilated.</i>	Acceptable
5	Handwashing Facilities <i>Warm water was not available from faucet for hand washing in this audit. It is recommended that the handwashing stations must deliver tempered water (90-105°F) within 10 seconds.</i>	Needs Improvement*
6	Equipment Layout, Design and Conditions <i>Processing equipments were installed in such a manner as to permit proper operation and access for clean and inspection. Equipments were made of smooth, impervious, non-toxic, non-absorbent and corrosion-resistant material where it had direct product contact and were free of flaking paint, rust and cracks.</i>	Acceptable
7	Plant Lighting and Protection <i>The lights equipped on the ceiling were protected with shields in this audit. However the lights equipped on the injection machine were not protected. It is recommended that all glass lights must be completely enclosed in shatter-resistant protective shields or manufactured with shatter-resistant materials to prevent glass contamination of product.</i>	Needs Improvement*
8	Maintenance Standard (Support of GMPs, Housekeeping, Lubricants) <i>Documented preventative maintenance program that cover all food contact production equipment and facilities was in place in this plant. Equipments and facilities were maintained per the preventative maintenance schedule and documented. Temporary repairs were not observed in this plant.</i>	Acceptable
Section Notes :		

Section D. Sanitation, Housekeeping and Hygiene		
No	Question/Notes	Answer
1	Master Sanitation Schedule and Monitoring <i>Master sanitation schedule was established in this plant. It covered operational areas, equipment, warehouse, storage, maintenance, employee support areas and other plant areas. Monitoring documentations for completion of scheduled cleaning tasks were available during this audit.</i>	Acceptable
2	Standard Sanitation Operating Procedures and Monitoring <i>There were three cisterns for cleaning product storage container in a room beside production workshop. The water in one cistern was dirty and mops were stored in this room in this audit. It showed the mops were likely cleaned in this cistern. It is recommended that floor cleaning tools such as mops and brooms must be not cleaned in cisterns for cleaning product container.</i>	Needs Improvement*
3	Cleaning Chemical and Sanitizer Control <i>All containers for cleaning chemicals and sanitizers were properly labeled and they were securely stored during periods of non-use in this plant. There was a separated area from production areas for storage cleaning chemical and sanitizer. The entrance was locked and MSDS for chemical was available on site.</i>	Acceptable
4	Pre Operational Monitoring and Corrective Action <i>A pre-operational checklist was used to check plant and equipment were clean and sanitary prior to daily operation. Deficiencies were noted and corrective actions taken.</i>	Acceptable
5	Verification of Cleaning Effectiveness <i>Sanitation effectiveness was monitored visually prior to production in this plant.</i>	Acceptable

Section D. Sanitation, Housekeeping and Hygiene		
No	Question/Notes	Answer
6	Operational Housekeeping and Monitoring <i>During this audit, it was observed all areas of the plant were kept clean, orderly and free from accumulation of litter. Garbage, trash and waste materials were accumulated in identified containers and disposed of properly.</i>	Acceptable
7	Personal Hygiene and Good Manufacturing Practices <i>Written GMP document was established in this plant. During this audit, it was observed that GMP requirements were followed in this plant. Employees wore clean clothing and hair was restrained properly. No personnel wore fake fingernails, fingernail polish jewelry, rings or watches, etc.</i>	Acceptable
8	Internal Audits and Corrective Actions <i>Internal audit for quality and product safety system was conducted in this year. It assessed facility, maintenance, pest control, production, sanitation, and housekeeping conditions and personnel hygienic practices for systematic effectiveness and to initiate corrective actions for deficiencies.</i>	Acceptable
Section Notes :		

Section E. Rodent and Pest Control Management		
No	Question/Notes	Answer
1	Documented and Specific Pest Control Program <i>Documented pest management plan was established in this plant. Mechanical traps and insect light traps were equipped at interior of production facility. Sites map for pest control device was available. The pest control devices were inspected daily in this plant.</i>	Acceptable
2	Outside Premises Management (Grounds, Waste Disposal Areas) <i>The buildings exterior and grounds were well maintained and no pest harborages were observed. Adequate trash and waste disposal facilities are available and no standing water on the premises that could attract pests was observed.</i>	Acceptable
3	Inside Premises Management <i>Traps were not equipped at interior side of doorway in raw material warehouse. It is recommended that exterior opening doorways must have traps on both sides of the interior side of the doorway.</i>	Needs Improvement*
4	Pest Tight Doors and Entrance Closures <i>The gap was present between the floor and doorjamb in finished product warehouse. It is recommended that all doors must be tight closing with no visible light observed between the floor and doorjamb.</i>	Needs Improvement*
5	Secure Storage and Documentation of Pest Related Chemicals <i>Pesticide was not used in this facility.</i>	Acceptable
6	Detailed Activity Reports with Corrective Actions <i>Pest control devices were inspected daily in this plant. The inspection documentations were available in this audit. It included the pest type and numbers trapped in devices.</i>	Acceptable
Section Notes :		

Section F. Approved Suppliers, Receiving and Inventory Control		
No	Question/Notes	Answer
1	Supplier Approval Policies and Procedures <i>Supplier approval procedure that identifies criteria for approving suppliers was established in this plant. Approved supplier list was available and all ingredients and packaging materials were purchased from approved supplier. Certificate of Analysis (COA) or Continuing Letters of Guarantee was current and available for all ingredients and packaging materials.</i>	Acceptable
2	Incoming Vehicle Inspection and Documentation <i>Written inspection program describes acceptable and/or unacceptable conditions for all inbound carriers. All inbound carriers were inspected for product safety, quality and security related concerns at the time of receiving.</i>	Acceptable
3	Release Criteria for Ingredients <i>All materials were maintained in a secure fashion and released for use against defined program.</i>	Acceptable

Section F. Approved Suppliers, Receiving and Inventory Control		
No	Question/Notes	Answer
4	Storage and Handling Policies and Practices <i>Procedures for the storage and handling practices of ingredients and supplies were established to assure they did not become a source of contamination. Receiving areas and storage locations were maintained in a clean and sanitary manner and ingredients and supplies were held under conditions necessary to maintain product integrity.</i>	Acceptable
5	Bulk Receiving Systems Sanitation and Monitoring <i>There was no bulk material in this facility.</i>	Acceptable
6	Restricted and/or Sensitive Ingredient Control, Including Chemical Compounds <i>Restricted ingredients, sensitive ingredients, allergenic materials and potentially toxic chemicals are stored separately and maintained under strict control. Toxic chemicals and flammable solvents are stored in secured and restricted areas. Usage records and inventories are maintained for toxic materials and Material Data Safety Sheet (MSDS) are readily available for all chemical compounds in the facility.</i>	Acceptable
Section Notes :		

Section G. Process and Product Evaluation		
No	Question/Notes	Answer
1	Process Control and Documentation Procedures <i>Several stickers showing different production date were on one in-process product storage container in this audit. It can not show the production date of in-process product accurately. It is recommended that identification for in-process products shall be improved in this plant.</i>	Needs Improvement*
2	Specification and Formulation Control and Accuracy <i>Specifications that define acceptable product attributes were established in this plant. Test protocols and frequencies were followed as identified in the specification. Records were available that demonstrate compliance to product formulations and finished product specifications.</i>	Acceptable
3	Routine Calibration of Operational Equipment and Measuring Devices (such as thermometers, scales, flow meters, counters, metal detectors, etc.) <i>There was just one scale used for weighing product in this plant. The scale was not calibrated in this year. It is recommended that key process control devices shall be calibrated annually.</i>	Needs Improvement*
4	Foreign Material Control <i>PSM or PLA granule was extruded into products in this plant. Metal foreign material was not likely to exist in products.</i>	Acceptable
5	Application of Statistical Control <i>Statistical control was not used in this plant.</i>	Acceptable
6	Allergen and Sensitive Ingredient Controls <i>Allergen or sensitive materials were not used in this plant.</i>	Acceptable
7	Specification Compliance Documentation <i>Records are maintained to document that product is manufactured according to specification. Finished products are inspected and tested. Product is not shipped until all parameters meet specification and approved by management.</i>	Acceptable
8	Rework and Carryover Products <i>The lot number of rework product used was documented in the blending sheet in this plant.</i>	Acceptable
9	Analytical Records Management <i>Records management procedure was established and analytical documents, reports and records were properly stored and retrieved.</i>	Acceptable
Section Notes :		

Section H. Packaging and Labeling		
No	Question/Notes	Answer
1	Label Accuracy and Regulatory Compliance <i>Procedures and policies are in place to assure proper labeling of products and that labels meet regulatory requirements.</i>	Acceptable
2	Documented Net Weight or Count Compliance Policy and Performance <i>The quantity was counted by operator when packaging. And the product quantity was inspected by weighing and documented before shipment.</i>	Acceptable

Section H. Packaging and Labeling		
No	Question/Notes	Answer
3	Clear Manufacturing Codes on Individual and Cased Product <i>Lot number was printed clearly on the outer carton to afford easy legibility in this plant.</i>	Acceptable
4	Package Integrity and Function <i>Product cartons were proper function for distribution in this plant.</i>	Acceptable
5	Label Security and Obsolete Label Controls <i>Written label security control procedure was established and it described the security measures for labeling materials to prevent unauthorized or accidental use and to prevent the use of obsolete labels.</i>	Acceptable
Section Notes :		

Section I. Storage and Shipping		
No	Question/Notes	Answer
1	Warehouse and Finished Product Management <i>Warehouse conditions were maintained in a manner to assure product integrity. Finished product and packaging materials were stored in separated warehouse. There were no chemical, cleaning products or damaged products observed in warehouse during audit.</i>	Acceptable
2	Retained and Returned Products <i>The documented procedure for non-conformity product control was established in this company. It defined identification, secured segregation, documentation and evaluation for non-conforming retained and returned products. Designated areas are established for retained and returned products and an inventory log is maintained showing current product on hold and the disposition of all released product with proper authorization.</i>	Acceptable
3	Storage Facility and Dock Maintenance <i>Product cartons were stored close to the wall in warehouse in this audit. It is recommended that wall perimeters must be maintained in a clear and clean manner and allow for pest management inspections and sanitation/housekeeping requirements.</i>	Needs Improvement*
4	Transport Condition <i>Outbound trailer inspection program was established and the inspection was documented in this plant.</i>	Acceptable
5	Release Authorization to Ship Product <i>Release authorization documentations were available before product shipment in this plant.</i>	Acceptable
Section Notes :		

Section J. Training Requirements		
No	Question/Notes	Answer
1	New Hire Training (GMP, Food Defense, HACCP) <i>Employee training program was established in this plant. Annual training plan including new hire training was available. New operating personnel received the training in GMP, personal hygiene etc.</i>	Acceptable
2	Training Language <i>Training was provided in the language and presentation format that can be easily and clearly understood by the trainee.</i>	Acceptable
3	Prerequisite Program Training <i>The program included training for pre-requisite training for basic food handling sanitation and for specific critical jobs. There were documented training for all sanitation employees.</i>	Acceptable
4	Refresher Training <i>Employee refresh training in GMP was conducted annually and documented in this plant. Monthly training session covering topics on GMP, pre-requisite training was taken place.</i>	Acceptable
5	Proof of Knowledge <i>Training records showed that training comprehension was verified through oral question.</i>	Acceptable
6	Training Records <i>All employee training records including date, training provider, training agenda and trainees' signature were maintained in this plant.</i>	Acceptable
7	Training Program Review <i>The training program was reviewed annually in this plant.</i>	Acceptable
Section Notes :		

Section K. Laboratory Support		
No	Question/Notes	Answer
1	Laboratory Facility and Staffing <i>There was no laboratory in this plant.</i>	N/A
2	Laboratory Procedures and Documentation <i>There was no laboratory in this plant.</i>	N/A
3	Laboratory Equipment Calibration <i>There was no laboratory in this plant.</i>	N/A
4	Analytical Accuracy Verification <i>There was no laboratory in this plant.</i>	N/A
5	Third Party Laboratories <i>The third party laboratory used in this plant has been authorized the certificate of ISO 17025.</i>	Acceptable
Section Notes :		

Section L. Product Defense		
No	Question/Notes	Answer
1	Management <i>Security management procedure was established. It included the management of the entry and exit of personnel and vehicle.</i>	Acceptable
2	Human Element <i>The employees were not identified with their name in this plant and auditor was not provided the visitor recognition card when entering. It is recommended that there must be a documented and implemented system for the positive identification and recognition of all employees entering the facility.</i>	Needs Improvement*
3	Facility <i>The security guard was present at entrance to this facility and all doors to outside were locked or monitored in this plant.</i>	Acceptable
4	Operations <i>Non-employee drivers and delivery personnel had designated waiting areas in this company. Trucks and/or trailers were inspected before unloading. Vehicles were secured after loading was completed and seal numbers were documented.</i>	Acceptable
Section Notes :		

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* Represents Non-Conformances.

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