Nestlé North America

Nestlé

ATE: January 15, 2006

TO: [redacted], North York, Purchasing
[redacted] Glendale, Purchasing
[redacted] Director Quality Management, Prepared Foods Division
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CC: [redacted] Director Central Audit
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Audit Team Members
Other Auditor(s)

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From:	[redacted]@us.nestle.com
Audit Type:	**NQS Level 1 – Food Safety Audit Report**
Name of Facility:	**Peanut Corporation of America**
Audit Date:	**January 5, 2006**

Holding Company:	**Peanut Corporation of America**	
Address:	PO Box 10037 Lynchburg, Virginia 24506	Phone: [redacted] FAX #: [redacted]

Facility Type:	**Raw Material Supplier**	
Address:	3601 North I-27 Plainview, Texas 79072	Phone: [redacted] FAX #: (xxx) xxx-xxxx

☐ **Other locations manufacturing for Nestlé. [Reference Supplier Co-manufacturer Quality Survey]**

Status:	☐ Active	☒ Potential	
Nestlé Factory Locations Supplied:	London		
Product(s):	Diced or granulated peanuts		
Application(s):	Drumstick Ball Top Cones		
Risk Level Assigned:	High		
Nestlé Businesses:	**Nestlé USA:** ☐ Beverage ☐ Confection & Snacks ☐ PetCare ☐ Prepared Foods ☐ Food Services ☐ Nutrition ☐ Foreign Trade ☐ Nestlé-USA Distribution Co	**Nestlé Canada:** ☐ Beverage ☐ Confection & Snacks ☐ PetCare ☒ Prepared Foods ☐ Food Services ☐ Nutrition ☐ Foreign Trade ☐ Nestlé-USA Distribution Co	**Other Market (s):** List the other Nestlé Markets supplied by this facility. ☐ Beverage ☐ Confection & Snacks ☐ PetCare ☐ Prepared Foods ☐ Food Services ☐ Nutrition ☐ Foreign Trade ☐ Nestlé-USA Distribution Co

Final Assessment

	Complying	Complying with Major Improvement Needed	Not Complying
NQS Level 1 – Food Safety	☐	☐ Improvement required within __days.	☐ Disqualified Manufacture of Nestlé product / material is suspended until corrective action measures have been fully implemented, and verified by Nestlé.

Corrective Action / Follow-up Plan Due Date:	Facility is not approved at this time. Response to concerns noted with action plans and timetable should be sent to Dennis Cline by February 10, 2006

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NQS Level 1 - Food Safety Audit Report
Peanut Corporation of America, Plainview, Texas
January 5, 2006

NQS Audit Conclusion:

An audit of the Peanut Corporation of America (PCA) facility, in Plainview, Texas was completed on January 5, 2006. The facility does not currently meet NQS Level 1 requirements and would not be qualified from a plant audit standpoint to supply chopped peanut pieces to Nestlé. It was communicated to PCA that a follow up audit by Nestlé would be necessary to verify completion of items requested needing corrective actions.

The key food safety issues noted during this audit are the weakness of the pest control program, the lack of any pathogen environmental monitoring program, and concerns noted in the handling raw and further processed (roasted, blanched) peanuts in a common processing area. Without physical isolation and proper airflow for the post-roasted and roasted peanut operations, there is a potential for microbiological cross contamination.

The audit conditions and deficiencies are outlined in the Key Findings and Key Issues Summary sections of this report. PCA management expressed an understanding and recognition of identified issues, and agreed that each item needed to be brought to closure as soon as possible. It is noted that the gaps identified in the audit should be relatively easy for PCA personnel to resolve and none are beyond their capability to resolve. None of the items identified would require significant capital investment to resolve. It is requested that the facility respond in writing to this report within the timetable as listed below. The response should address all issues identified in the Key Findings and Key issues Summary of this report. The response must address the root cause, identify corrective actions, and provide timelines for correction. The plant is asked to complete the "NQS Audit Corrective Action Response or CAR" Excel spreadsheet at the end of this report and send electronically to the auditor per the above timetable.

It appears as if PCA employees and management have an understanding and commitment to quality, food safety, and customer satisfaction. Plant management staff was very open and cooperative during the audit and expressed a desire to work with customers such as Nestlé to meet expectations.

NQS Level 1 Food Safety Elements	Complying	Complying with Major Improvement Needed	Not Complying
Training	☒		
Documentation	☒		
GMP – Housekeeping	☒		
GMP – Sanitation	☒		
GMP – Pest Control			☒
GMP – Other		☒	
Allergen	☒		
Bio-Security		☒	
HACCP		☒	
QMS	☒		
Pathogen Monitoring of the Production Environment			☒
Formal Release / Status Control System		☒	
Lot Traceability, Lot Identification, Coding / Recall & Crisis Management		☒	
Instrument Calibration / Laboratories and Test Method		☒	

NQS Level 1 - Food Safety Audit Report
Peanut Corporation of America, Plainview, Texas
January 5, 2006

Background Information:

Size of Facility:	About 48,000 square feet	Number of employees:	About 35
Age of Facility:	About 45 years	Number of production lines:	1

A Nestlé Quality System Level 1 audit was conducted at the Peanut Corporation of America (PCA), facility in Plainview, Texas, on January 5, 2006 by Dennis Cline. Stewart Parnell, President, Stewart Adams, Technical Director, Danny Kilgore S.E. Operations Manager, Jim Booher, Plant Manager, and Stan Januta, QC Manager, accompanied the auditor throughout the audit.

The purpose of this audit was potential qualification of the Plainview facility to supply chopped roasted peanut pieces initially to the Nestlé London plant, and then eventually to other Nestlé facilities. The Plainview facility consists of a shelled peanut receiving operation whose end product is dry roasted chopped peanut pieces or blanched peanut pieces for the institutional domestic markets. For the purposes of this audit, the entire facility and operation were audited were reviewed.

PCA is part of the Peanut Corporation of America company, Lynchburg, Virginia, and currently supplies peanut products produced in one of three plants (Tidewater, Virginia, Blakely, Georgia, and Plainview, Texas) to the domestic industrial and retail markets.

PCA has supplied product to Nestlé in the past with product processed in the Blakely, Georgia facility,

he Plainview facility was originally constructed in the late 1960's and operated as a Jimmy Dean hog slaughter and processing operation. The facility was later sold to the Sara Lee Company, and then Bean Time (pinto bean processor), and then sat idle for about 5 years until PCA purchased the building and property and began renovations just over 1 year ago. Microbiological and environmental studies were conducted in the building and the grounds as part of the purchase negotiation requirements by PCA. The results of these studies were not reviewed as part of this audit, but it was understood that there were no issues noted. The facility is located in Plainview, Texas, a rural area about 40 miles north of Lubbock, Texas. There is easy access to major highway from this location. The plant currently processes on a 16 hour 5 to 6 days a week schedule. Cleaning operations are conducted during the non-processing hours. The plant only processes roasted and / or blanched peanut products,

The facility has been inspected by the Texas Department of Agriculture (TDA) for organic certification, United States Department of Agriculture (USDA) for blancher approval, and kosher. There have been no independent 3rd party audits of this facility.

The general processing steps for processing of dry roasted chopped peanut pieces are below. Shelled peanuts, which are primarily grown in the local southwest region, are received from one of two shellers (Golden or Birdsong). Peanuts are received via truck in 100# burlap bags, cardboard totes, or supersacks. It was understood that the receiving containers were all one-way containers and they are not returned to the shellers to be re-filled.

1. Shelled peanuts are received (supersacks, cardboard totes, or 100# burlap bags)
2. Destoning (Roka de-stoner system)
3. Holding bins
4. Dry roasting (oven) – used if roasting (Aeroglide oven system)
5. Blanching – skin removal
6. Sorting (optical sorting using Sortex 9000)
7. Inspection (visual)
8. Sizing / fines removal
9. Metal detection
10. Pack off into super sacks if for granulation product
11. Short term storage

If granulated, then next steps apply

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12. Holding bins
13. Granulation / chopping
14. Sizing
15. Fines removal
16. Packaging
17. Case Metal detection (not yet installed)
18. Palletizing
19. Storage
20. Distribution

There are currently no specifications for products produced for Nestlé. The plant does have PCA specifications for all products produced.

This auditor would like to thank the facility for their cooperation and positive attitude displayed throughout the audit.

NQS First Priority Level - Key Findings Summary:

Training
Complying

Although training practices are in place, there is no overall documented written training plan, which summarizes the training programs and plant training requirements. A formal written training plan containing plant / company training requirements should be written.

New employee training includes Good Manufacturing Practices (GMP) (program reviewed was dated December 29, 2005), general and job related safety, general HACCP, general allergen, product sampling, and basic plant security information. To acknowledge attendance and participation in training session, each employee and the trainer sign off on a form after the training has been completed.

The GMP training includes hygiene, sanitation; process, and product integrity; receiving and shipping areas; food security; training; and record retention. Training is conducted using video and verbal presentations, and GMP training is conducted in English. All records reviewed in regards to training indicated that the company is following the established procedures.

A temporary employee-training program is followed for the training of any temporary prior to working in the plant. Temporary employees are trained on the same Good Manufacturing Practices as regular full-time plant personal. The temporary employees sign off on a sheet indicating they completed the training.

On going training consists of monthly meeting where topics about GMP and safety are reviewed (same as new hire training). The management team also discusses any incidents / concerns that may have occurred at the plant as a means of continuous improvement.

It is recommended that the plant implement a process by which learning effectiveness is measured. This can be completed by use of short tests following each training session.

Contractors are given GMP and general safety training before entering the plant. The plant GMP and safety rules are reviewed prior to entering the manufacturing areas and a sign off sheet agreeing to these is completed. Contractors, depending on their role, may not be escorted while on site (pest control operator, vending machines, etc.), but all contractors are monitored while on site.

Quality control employees and operators using laboratory equipment are given specific training on how to operate the test equipment.

Overall, employees receive about 8 hours of training annually, with training being spread out over the year. The training starts as a newly hired employee joins the company and continues throughout their employment. The information used for training was reviewed and found to contain sufficient information needed to adequately training employees on safe food handling techniques. All documents and information reviewed was current through today's date.

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mployees observed were following the plant established GMP's.

Documentation
Complying

The following documentation was reviewed: employee training, manufacturing guidelines and specifications, plant quality manual, HACCP plan, operating procedures, hold guidelines, receiving / shipping inspection forms, processing checklists, lab equipment calibration records, inspection checklists, start up checklists, pest control service log and schematics, recall program, master sanitation program, sanitation procedures, traceability guidelines, and glass and brittle plastics policy. Documents exist for recording processing and quality checks completed during processing.

A glass and brittle plastics control policy is documented (dated December 29, 2005). It includes requirements for glass and brittle plastics. The program includes procedures for the shielding and protection of light bulbs as well as the exclusion of glass in the plant, an inventory of glass and brittle plastics, and a daily audit of these same items. This procedure clearly defines cleaning and inspection requirements for broken glass incidents.

A customer complaint procedure is documented (dated December 29, 2005). The president, operations manager, and quality manager review complaint issues.

The plant has a document control practice with most all documents being maintained in a paper format. There is no formal written document control procedure. Each document is titled, numbered, and has a date of issue. Most all documentation has been taken from the sister plant in Blakely, Georgia, and is being adjusted to meet the needs of the Plainview facility. The Plant Manager is the final authority for approval of all documents. It was understood that all documents in the document control program are reviewed at least one time per year. An effort needs to be made to make the final transitions of documentation to meet the needs of the local plant.

he plant should create a written Change Management policy that defines steps to be followed for changes that might take place in manufacturing and documentation.

Forms used to record processing conditions and quality data are also included in the document control system and are used on the production floor as paper copies. These documents are collected following processing and are stored in the quality control or accounting office. These forms are reviewed during and after processing by the production supervision and quality management. All forms reviewed during this audit were found to be in the designated format and were current. Good documentation practices were being followed to complete the forms. For each document and form reviewed, there were no cross outs, no scratch outs or re-writes, no pencil usage on the production floor, and no pre-completed information. Pencils were being utilized in the quality control areas. The facility should put forth an effort to eliminate pencils and use blue or black pens in all areas. The processing and quality data is reviewed during and after operations by production and quality personnel.

All documents reviewed were easy to understand, well formatted, and are utilized by the workforce. Plant personnel followed good documentation practices. A copy of the recently developed quality / food safety manual was given to this auditor.

The processing paperwork reviewed in the plant was complete and satisfactory. The records are current through today's date.

GMPs – Housekeeping
Complying with Major Improvement Needed

There was no housekeeping issues noted in the receiving / shipping, processing, chopping / packaging, and storage areas of the plant. There were small amounts of peanut pieces along the south wall and behind electrical panels in the re-clean room. The chemical storage room, maintenance shop, immediate exterior areas around the north and east ides of the plant, employee break room, and bathrooms were also clean and organized.

The exterior areas on the south and west sides of the plant had large amount of dirt and product debris (skins) scattered in depths for about ¼ inch to about 8 inches.

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There is a remote building on the north side of the plant, which contains what appears to be excess equipment and items removed from the plant. There is a large amount of items stored in piles on the ground. This creates potential harborage areas for insects, rodents, and birds. The building on the southwest corner of the plant used to park the skins collection trailer has unacceptable amounts of product skins accumulated on the floor areas.

Food contact tools and non-food contact tools were separated and appropriately maintained. A number of brooms and shovels have wooden handles. Any tools with wooden handles in the manufacturing areas of the plant should be replaced with non-wooden handled items.

Employees were continually sweeping the floor areas around equipment as needed during the audit.

All packaging materials (cartons, totes, liners, etc.) were covered as appropriate and stored in a designated warehouse area. All items observed stored in the warehouse areas (ambient) were stored on pallets in floor locations.

There was no idle equipment stored in the warehouse areas of the plant.

There was a designated perimeter painted white about 18 inches wide maintained around the warehouse areas. This perimeter was free and clear of product storage, equipment storage, and any other unwanted dirt or debris. Along the exterior southwest wall of the pre-clean room, the concrete at the floor / wall juncture is eroded to a depth of 1 to 2 inches. This area was collecting dirt and debris and is not readily cleanable.

Brooms and other cleaning tools were observed stored hanging on designated racks in designated areas when not in use.

The plant GMPs state that food, beverage, gum, and tobacco products are acceptable in designated areas and are not allowed in the processing and / or warehouse areas of the plant. There were no food, beverage, gum or tobacco items observed in any areas of the plant other than the designated area observed.

There are hand-sanitizing stations located at the entryways to the production areas.

GMPs – Sanitation
Complying

The general overall sanitary condition of the interior of the plant was good. There was minimal product build up on the overhead piping and walls in the pre-clean room. Any product accumulation provides a good environment for potential food source and harborage areas for pests, and a potential foreign material source for any product or equipment that might be located below it when it sloughs off.

The plant is both dry and wet cleaned. Hand tools, brooms, etc., and portable vacuums are used in the facility for some of the dry cleaning requirements. Sanitizer is applied for food contact surfaces after dry cleaning. For wet cleaning, there are no CIP systems in this facility. Some equipment is disassembled and washed in a COP tank.

The plant has established basic cleaning procedures and instructions for the pieces of equipment in the operation. These procedures are developed only for the major tasks. The cleaning standard operating procedures (SOPs) need to be developed throughout the plant to address all wet and dry cleaning. SOPs should be written to outline each task, the cleaning frequency, who is responsible for cleaning, chemicals to be used, chemical concentrations, personal protective equipment, tools needed to complete the task, and anything other information the plant personnel might need for these tasks.

The Master Cleaning Schedule is very basic, and does not include a number of items in the plant such as walls, ceilings, air vents, electrical panels, floor drains, etc. All exterior areas of the plant should be added to master cleaning schedules as poor conditions can lead to potential infestations issues. All of these items should also have procedures developed as described above.

The plant maintains a pre-operational inspection of the processing lines and equipment to assure cleanliness and functionality. Equipment operators are responsible for the sanitation of the equipment they operate. Production supervisors and operators are responsible for ensuring equipment is clean and properly set up prior to start-up.

There are no bulk chemicals for cleaning received at this site.

Janitorial supplies are on hand for cleaning the office area and facility restrooms. These are stored in a designated location away from the production areas.

Overall, good sanitation was evident throughout the interior of the facility.

GMPs – Pest Control
Not Complying

The facility uses a 3rd party pest control service – McIlroy's Pest Control – for pest control services. The plant has a basic pest control policy (dated December 29, 2005) around which the 3rd party program is designed. There is a pest control manual in which the business license, PCO certification, device schematics, services reports, and MSDS sheets are contained. There is no written description of the service that McIlroy's is to provide. McIlroy provides service every 2 weeks. All pest control devices are inspected each service. The frequency of device inspection may be increased if determined necessary. A site map, service reports with general or vague inspection comments, PCO certification, company business license, and chemical MSDS sheets are all in order and current. The plant quality control manager is the primary contact for the pest control operator, before, during, and following each service call.

The pest control operator (PCO) is certified in Texas, and has license number 22365 PTLW, which expires March 23, 2006.

The pest control program is supplemented by an in-house warehouse-fogging program utilized during the warmer season. This program consists of routine fogging of the plant warehouse areas utilizing a central system applying Entech Fog 5 (pyrethrum). This pesticide is stored in a locked cage within the maintenance shop. This locked cage area also contains some maintenance items. The pesticide storage area needs to be separated from a routine maintenance use and storage area.

The plant utilizes 36 multi-catch traps (and glue boards) on the interior of the building, and 36 rodent bait stations on the exterior of the building. Pheromone monitors are utilized for stored product pests in the warehouse areas of the plant during the warmer season. Each device is inspected by the PCO during the site visit. All results are documented on the service reports. The plant should work with the PCO to develop a sheet that documents pest activity in a manner that trends can easily be seen. The sheets should be able to easily indicate problem areas or areas of concerns.

The pest control logs for the past 10 months were reviewed with varying levels of rodent activity noted on every report. The activity was primarily noted on the exterior of the building, but there were also concerns in the interior areas of the building. The pest control reports indicate that the plant has an on-going concern with rodent activity occurring at varying levels. The number of devices originally utilized in the service program were doubled after about 5 months of service. The service reports reviewed also say, "seal all voids around doors to prevent pest entry", without noting for which door is a concern. The PCO has utilized a straight line out to indicate some of the devices are being inspected. Each and every device that is inspected should be marked on the log sheet with an individual mark.

The plant maintains asphalt / concrete perimeter on all sides of the building. This area was completely clear except for the pest control devices that had been installed, and the dirt and product debris referenced in the sanitation section above. The paved portions of the property around surrounded by vacant fields. The fields currently contained minimal vegetation and dirt.

During the audit of the exterior of the building, the following was observed:

1) A bait box on north side of building near ramp was missing the top. The rodenticide was on the ground about 2 feet from the stations. There was another bait station installed about 4 feet away from the damaged bait station.
2) The partition walls around the exterior compressor room on the south west corner of the building are constructed of 2 layers of metal with about 3 inches of space in-between the layers. The area inside of this wall was easy viewed (due to the way they had been cut off) contained about 8 to 10 inches of dirt, product debris (skins), and mice carcasses.
3) Mouse carcass lying near bait station #10.
4) 3 mice carcasses and burrows under the grating located near on the wall near the shipping doors.
5) 3 mice carcasses in varying stages of decay lying near bait station #11.

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6) 4 mice carcasses in varying stages of decay lying near bait station #12.
7) > 14 mice carcasses in varying stages of decay lying near bait station #13.
8) 5 mice carcasses in varying stages of decay lying near bait station #14.
9) > 10 mice carcasses in varying stages of decay lying near bait station #15.
10) 1 mice carcass in varying stages of decay lying near bait station #18.
11) 3 mice carcasses and 1 rat carcass in varying stages of decay lying near bait station #20.
12) 5 mice carcasses and 1 rat carcass in varying stages of decay lying near bait station #21.
13) 1 mouse carcass in the foam insulation near the corner of the building (area near emergency exit door on the south wall for the pre-clean room).
14) Numerous burrows along area on south side of plant where asphalt ends and dirt begin.
15) A dead pigeon was lying on the ground near the peanut-receiving door.
16) 4 pigeons roosting on the iron support structure inside the skin collection building. The doors to this outside building where hanging open, as the trailer was not completely backed into the building. Based on the feces observed, and by building design, it appears as if bird activity is a problem (and a potential problem) for this building.
17) A lot rodenticide was scattered loosely on the ground on the south and southwest exterior of the building.

There were no insects or rodent activity observed in the interior areas of the plant during the audit.

From my observations during the audit walk through and from the pest control program records, plant management needs to review and revise the current program to incorporate more Integrated Pest Management techniques. This plant has a serious on-going problem with rodents on the exterior portions of the building must be resolved. Although there were no observations of rodents or rodent activity in the interior of the plant noted during this audit, the levels of dead rodents observed, coupled with voids noted around some doorways, indicate there are potential concerns for the interior areas of the plants.

Overall, the current pest control program appears to be less than effective and is unacceptable.

GMPs - Other
Complying with Major Improvement Needed

All areas of the plant observed are in age appropriate condition and maintained in an acceptable manner. Floors (concrete), walls (concrete / metal siding) and ceilings (drop, concrete, metal) were mostly in good repair, with no major cracking or breaks noted. There were no open holes observed in the walls or floors from previous installations, however there were several pipe penetrations through interior walls in the pre-clean room that had not yet been sealed around. Some of the concrete flooring was cracked and broken. This was in particularly poor condition were previous existing walls had been removed. The concrete at the floor / wall juncture on the west side of the pre-clean room was eroded to a depth of 1 – 2 inches.

The paint is peeling on the walls in the pre-clean room. The areas in the corners of the room seem to be in the worst condition.

All manufacturing equipment viewed was in acceptable condition, of sanitary design, and was appropriately clean. A number of pieces of equipment had been transferred to this location from the Blakely facility. No poorly constructed on inadequately designed pieces of equipment were observed. All equipment observed was permanently installed (bolted to floor or a platform), and appropriately sealed with caulking material. There were no poorly welded areas on the equipment observed. The weld on the chute at the peanut dump station in the pre-clean room was broken and in need of repair. No opened ended unused conduits or piping was observed.

All hoppers for peanut storage and transport are open top vessels. There were no areas of dirt of debris accumulated on overhead piping or conduits above any of this vessels noted during this audit. The conveyor above the #13 Roka de-stoner had been equipped with a cardboard top held on with duct tape to attempt to control product from blowing into the air and out of the conveyor. This conveyor had also been labeled as #1 using paper and duct tape. This was noted on several different pieces of equipment in the facility. It was understood that these were used as equipment identification markers during installation and were being replaced with metal tags.

A delron guide rail cover above the bucket elevator near the raw nut dumper was damaged and coming loose from the equipment.

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ll sides of exterior of the building are surrounded by asphalt. The areas along the south and west sides of the plant had significant amounts of dirt and product debris piled up along the building. This creates a potential food source and harborage for insects and rodents and should e maintained clean.

All exterior doors were closed with marginal seals in place. There were a number of small gaps noted in the seals of a number of the doors. Each emergency exit door is maintained closed but not locked. Each door utilized for access by plant employees is equipped with a mechanical lock and is of a self-closing design.

There were hand-sanitizing stations located in the production areas of the facility. There are hand-washing facilities in the employee bathrooms. No employees were observed wearing gloves while working in this operation. No gloves were noted stored in non-designated locations.

Items requiring maintenance attention are noted during daily inspections of the equipment. There was no preventive maintenance database reviewed. The plant needs to consider developing a formal program which includes a complete list of items requiring maintenance, tasks by item, frequencies, issuance of work schedules, input of maintenance work performed, maintenance history, inventory of equipment, etc., and parts and control of stock in maintenance stores.

The plant restrooms and break room were clean and no issues were noted. Employees currently wear their own clothing and shoes to work in all areas of the facility. Employees wear hairnets and beardnets when in the plant. The plant needs to institute a written uniform policy where no employee street clothes would e exposed to product. The plant should also implement a plant designated shoe program with provisions for keeping the shoes in the plant. Employee clothing and shoes could potentially ring unwanted microorganisms, dirt, and debris into the operation. It was understood that most employee's leave their shoes are the plant when not in use. The plant should define guidelines requiring that all plant shoes be kept at the plant when not in use. No employees where observed carrying items that could become potential foreign material in pockets above the waist. As a visitor, I was required to wear a hairnet.

There are currently no written plant guidelines for traffic control from raw to further processed. These requirements should include traffic patterns, uniforms requirements (needs, changes, etc.), hairnet requirements, shoe requirements, fork truck controls, etc. It was understood that the operators typically work in one area.

The operator in the sizing room that was operating the filler was observed touching the product and then handling the exterior of the new boxes to be filled. The employee was touching product to help top of the box to attain the correct weight. This employee should wear clean gloves to touch product, or an appropriate tool should be designated for this operation.

The pre-clean room was of negative air pressure to the further processing areas.

All areas of the product handling areas of the plant were adequately lighted with lights that were shielded or contained shatterproof bulbs.

Two wire brushes were observed near the blanchers (34 B / 34 A) roaster and under the hoppers in the pack out room. Wire brushes can be an excellent source of metal foreign material in a process and should be eliminated.

No non-cleaning chemicals items observed in the plant. The plant does not have a policy for these types of items. All approved non-cleaning chemicals should be included in a written control program that lists the item, the usage point (and amount if appropriate), and the storage location when not in use. Compliance to this should be part of the on-going internal plant inspections. There were no non-cleaning chemicals observed in locations they did not belong.

There were no temporary repairs of tape, wires, strings, etc., observed, but tape was used in the operational areas as mentioned above. There should be minimal use of tape in the operating areas and when used, it should be controlled – dated of application, inspected regularly for condition, and a plan of action to eliminate its need. With the exception of 1 electrical transfer / control panel in the pre-clean on the south wall with parts stored on top of it, I did not observe any items being stored in or on locations they did not belong (electrical cabinets, control panels, etc.)

Wooden handled brooms and other cleaning tools were observed in the plant operating areas. Efforts need to be made to eliminate wood from the product processing areas.

The plant operators conduct daily inspections of equipment and areas prior to starting up, and throughout operations.

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lant supervisors and managers conduct monthly internal audits. The entire plant interior and exterior is audited each month. These audits cover GMPs, housekeeping, operations, and sanitation. Any concerns are documented and corrective actions are assigned. Follow up occurs during future audits.

The granulation or sizing room is a separate room located adjacent to the finished product warehouse and has plastic strip curtain doors. Product is granulated and packed into finished product packages in this area. The airflow in the room was positive to the warehouse. There was some peeling paint observed on the housing of the bucket elevator by the sifter in this room.

The plant is in the process of adding an oil roasting line. The roasting equipment observed is in one corner of the finished product warehouse and the bulk infeed dump station (is same room as and) is about 30 feet from the pack-off station for blanched or roasted nuts. This process will need to be reviewed very closely prior to any start up to be sure that raw nuts are isolated from further processed nuts – this includes air flow, traffic flow, etc.

The plant has no documented supplier approval program. There are very few raw materials and packaging materials used in this facility. The plant sources raw materials and packaging materials from supplier that have long-term relationships with PCA and the other operating facilities.

The plant water is sourced from a municipal system. Water is primary for sanitation in this plant. The water is test annually by the city of Plainview for compliance to national drinking water standards. No testing results were reviewed as part of this audit. No additional testing is conducted on this water.

There are no bulk liquid ingredients received or utilized at this facility.

Allergen Control
Complying

The plant has an allergen statement in place and recognizes peanuts as allergens. The allergen statement is a general overview of allergens and includes a list of the top 8 allergens. Only peanuts are processed in this facility.

PCA would be responsible to notify Nestlé if there are any potential changes to the allergen status.

Bio-Security
Complying with Major Improvement Needed

The plant does have a brief general plant safety policy. The plant has not completed any formal assessment of the site for bio-security. A formal assessment should be completed of the site and appropriate action taken against concerns noted.

The plant is located in a rural agricultural area about 40 miles north of Lubbock, Texas.

The site is fenced one 3 sides with the front of the building not being fenced. The front of the building has one entry door. There is one main gate for entering the fenced shipping and receiving areas. An employee must manually open this gate. The gate was noted standing open during the audit. The plant indicated a truck had just entered the site and the supervisor was going to close the gate. The supervisor was noted closing gate a few minutes later.

There are no security camera systems monitoring any areas of the building or grounds.

Employees and visitors must enter the building through one front door. Once in the building, you must walk past the plant offices to gain access to the production areas.

lo employee is issued any type of identification badge, and there are no electronic locks. All visitors are escorted while on site.

All plant access doors were closed and not locked during the audit. Truck drivers may enter the building near the shipping / receiving office and must stay in this area.

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There are emergency exit doors to the outside of the plant. These doors were found to be closed and not locked during the audit. The doors are equipped with handles on the exterior side and are self-closing.

The plant has a seals program, and there are seal's utilized on all inbound and outbound loads of raw material or finished product. It was understood that the plant would reject any raw material received without an intact numbered seal that is matched to the shipping documentations.

A trailer inspection program is in place to document the conditions of each trailer and load of materials received, and empty trailers prior to loading for shipment. The incoming and outgoing forms contain sufficient information to insure trailers are being inspected adequately.

There are no liquid bulk ingredients or chemicals received or stored at this location.

HACCP (Hazard Analysis Critical Control Point)
Complying with Major Improvement Needed

A documented HACCP plan (dated December 29, 2005) based on the plan for the Blakely, Georgia plant has been developed. The plan was developed by the operations manager, quality manager, and technical director. The HACCP plan included process flow charts, CCPs, and corrective action plans. It was understood that a HACCP plan review is completed whenever there is a change to existing equipment, or when new equipment is added to the existing process line. The plant maintains a revisions history and log to track all changes to the HACCP plan. All paperwork that contains a CCP check is reviewed by plant and quality supervision.

Management has limited training in HACCP, but understands the basic principles of food safety related hazards. It is recommended that someone in management attend a certified HACCP training course to better understand food safety hazards that potentially occur through the entire product process flow from raw peanuts to finished roasted peanuts. Once complete, the HACCP program can be further reviewed and risk re-assessed. Risk assessment includes safety hazards related to microbiological, physical, and chemical (includes allergens) hazards. Currently the food safety concerns are centered on the physical presence of raw peanuts being handled in the peanut roasting area (microbiological).

The HACCP plan needs to include the following: risk assessment of processes and materials, process flow charts, CCPs, corrective action plans, meeting notes from HACCP discussions that might provide rationale for decisions (plan history), documentation of the process validation steps for CCPs, calibrations requirements, and documented outcomes of HACCP reviews.

A foreign material protection plan includes the following: a plant glass and brittle plastics policy is maintained, destoning equipment, in line screens / sifters, magnets, metal detectors, visual inspection of equipment prior to start up, and visual inspection of process of the operating condition and equipment during production.

The plant has 1 CCP for product that might be produced for Nestlé:

- CCP 1 – roaster conditions. The dry roaster is operated such that peanuts are roasted at > / = 300 F for about 25 minutes.

The metal detection check was verified during this audit with no concerns noted. The system viewed was verified using 2.0 stainless steel, 2.0 non-ferrous, and 1.5 ferrous standards.

Metal detector monitoring procedures are established and include action in case of deviation. The systems are checked at least one time per hour by the quality control technician. .

Comments / concerns related to HACCP and the current plant design / usage related to concerns for potential microbiological cross contamination with the raw and finished nuts. These items need to be reviewed by the plant / company HACCP authorities.

- The storage, dumping, and cleaning of raw nuts takes place in the pre-clean room. This room has a negative air pressure to the other areas of the plant. The room has a doorway entering into the roasting room, but no door is installed. What check is in place to be sure air pressure is maintained?

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- All peanut pieces are moved through the processing equipment via open top conveyors and bucket conveyors. All storage bins and conveyors are designed without any tops. The concern is for potential foreign material to easily enter the product flow.
- Employees wear their street clothes in all areas of the operation. At a minimum, a smock or outer garment should be provided by the plant to create a barrier between the employee clothes and the product being processed.
- There are informal traffic patterns and practices for moving vehicles and plant personnel, but no documented plant guidelines. A formal written control plan for the movement of personnel and equipment for the prevention of raw / further processed product contamination needs to be developed. This should include requirements for work assignments and personnel movement, uniform control / changes, hair net usage / changes, glove requirement, cleaning requirements, footwear treatments, etc.
- Raw and blanched peanuts are roasted and / or blanched on specific equipment that has been installed on a shared line. The roaster is used to transport peanuts to the blanchers when the plant is blanching, and the blanchers are by-passed when roasting. The conveyors after these are share pieces of equipment. No microbiological studies have been completed to show that no risk is present on these shared pieces of equipment.
- No environmental sampling program is in place or has been completed to provide information on the potential microbiological risks or concerns in the further processing areas.
- The plant is in the process of installing an oil roasting system in a corner of the finished product warehouse. The peanut dumping station for the oil roasting system is being installed in the corner of the roasting / blanching room about 30 feet from the pack-off station for roasted / blanched nuts. By design, blanched only raw nuts will have to be transported to, and then dumped, in the roasting / blanching room.

QMS (Quality Monitoring Scheme)
Complying

lthough a program formally called "QMS" does not exist, procedures and policies, manufacturing parameters, quality-testing targets with ranges, specifications, corrective actions, and product/customer specific requirements are in place.

Results from quality testing are recorded throughout production on designated paperwork. Quality testing is completed throughout processing by quality control and production operators. The quality technicians are responsible to calibrate all equipment utilized for quality testing on a daily basis. Production and quality employees and supervisors are continually monitoring the quality of products through visuals inspections.

Typically, routine product testing includes visual, odor, microbiological, and analytical before, during and after manufacturing. The results can be included on a Certificate of Analysis (COA) as requested by each customer. Testing of the products produced is based on customer requirements. Testing typically includes:

- Analytical – color, salt content, granulation or particulate sizing, odor, flavor may be informally tested
- Organoleptic - aroma, appearance, and occasionally, flavor may be informally tested
- Microbiological – aerobic plate count, yeast, mold, e. coli, salmonella, and coliforms – completed by an outside microbiological laboratory. Aflatoxin results are included on the COA, but these testing results are transferred from the information provided by the incoming results from the sheller.

All tasks and specifications are defined and completed for each lot produced. Additional customer specific testing requirements can be discussed and added if determined necessary.

The factory employees and management personnel I talked too were well aware of the product specifications, HACCP CCPs, and quality testing parameters.

Information is provided by the shellers for the incoming raw, shelled nuts. The results are from USDA parameters and testing for peanut grading. For testing purposes, a 75,000-gram samples is drawn across about 200, 000 pound lots.

- Slot screen sizing
- Percent other types of kernels
- Split or broken kernels
- Damaged or unshelled kernels
- Minor defects
- Foreign material based on 8, 012.60 grams.

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- Moisture
- Aflatoxin (typically by J. Leek & Associates)

Pathogen Monitoring of the Production Environment
Not Complying

There is currently no environmental pathogen-monitoring plan. There has been no pathogen-monitoring plan completed to provide historical information to justify the discontinuance of an environmental monitoring program for the operating areas of the facility.

A plan needs to be developed and implemented. If needed, Nestlé can provide recommendations for an appropriate sampling plan.

Formal Release / Status Control System
Complying with Major Improvement Needed

All product currently produced in the facility is subject to a release practice. If products are processed according to the designated parameters, including a review of the CCPs, and they meet the testing requirements, they are considered ready for shipping. There are no computer transactions or paperwork processed to let the shipping areas know that the product has been checked and is ready for release. There is no documented "formal" release system in place; however, practices appear to be in place to prevent any out of compliance materials from being shipped.

It is recommended that a formal release system be create with an appropriate procedures and a formal release checklist utilizing testing and monitoring that is currently performed. A finished product microbial test is a good test to use as a finished product release criteria.

. was understood that all finished product is tested for pathogens prior to distribution.

A certificate of analysis (COA) is generated for every lot of product shipped.

A written procedure is in place for the holding of non-conforming goods. The procedure reviewed was dated December 29, 2005. Non-conforming product would be tagged with a hold tag and moved to a designated area of the warehouse. The QA Manager has product disposition authority, but in some cases, may discuss these matters with the plant manager and company president.

Lot Traceability, Lot Identification, Coding / Recall & Crisis Management (Mock Recall)
Complying with Major Improvement Needed

A recall, mock recall, and crisis management procedure are documented and readily available. The recall procedure (dated December 29, 200) was reviewed during this audit. The procedure lists necessary steps in the event of a product recall and includes 24-hour emergency contact information.

It was understood that the plant conducted a mock recall during 2005, but no documentation was completed. No documentation is equal "did not happen". This does not meet Nestlé requirements.

PCA needs to develop and implement a workable protocol for conducting mock recalls and then it on a regular basis. The requirement is to be able to accurately locate and account for any lot of raw material or primary packaging material used from receipt through usage and finished product and on to the transfer of ownership of the finished goods. To be in compliance this must be completed within 2 hours. Further, a program must be in place to perform mock recalls and traces yearly and to analyze the results of the tests.

`ased on paperwork reviewed, I believe that products and ingredients can be traced forward to orders and backward to .ncoming raw material.

The plant does not have a written rework procedure to describe how rework product (when and if used) should be handled and tracked during manufacturing.

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finished product label is printed in house and contains the following information:

Product name
Item number
Lot number T6005
T – Texas,
6 – year
005 - Julian day of manufacturing
Manufacturing date 1/5/06 (month/day/year)
Net weight

Instrument Calibration (for CCPs) / Laboratories and Test Method
Complying with Major Improvement Needed

There is a quality control laboratory with equipment utilized for analytical product testing. No microbiological testing is completed at this site. All laboratory equipment is calibrated on a daily basis by the quality control technician. Calibration logs maintained for each piece of equipment were reviewed during the audit and found to be complete through today's date.

Plant scales are calibrated on an annual basis by Buffalo Gap Scale Company. The scales were last inspected on August 11, 2006. All scales are verified on a daily basis by the quality control and production operators.

The time/temperature recording devices and the thermocouples for the roasting line should be on a minimum annual calibration verification program by the vendor. These devices were originally calibrated by the manufacturer and have been operating for about 9 months. A written program needs to be established to be sure these devices are inspected / calibrated at leas annually, or as needed.

The metal detection systems for the roasting / granulation lines should be on a minimum annual calibration verification program by the vendor. These devices were originally calibrated by the manufacturer and have been operating for about 9 months. A written program needs to be established to be sure these devices are inspected / calibrated at least annually, or as needed. The quality control technicians verify the operation of these units prior to start up each day and then on an hourly basis throughout operations.

The magnets for the roasting line should be inspected annually for pull strength. A written program needs to be established to be sure these devices are inspected / replaced annually, or as needed as indicated by test results.

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Key Issues

Training
Complying

Although training practices are in place, there is no overall documented written training plan, which summarizes the training programs and plant training requirements. A formal written training plan containing plant / company training requirements should be written.

It is recommended that the plant implement a process by which learning effectiveness is measured. This can be completed by use of short tests following each training session.

Documentation
Complying

The plant should create a written Change Management policy that defines steps to be followed for changes that might take place in manufacturing and documentation.

Pencils were being utilized in the quality control areas. The facility should put forth an effort to eliminate pencils and use blue or black pens in all areas.

GMPs – Housekeeping
Complying with Major Improvement Needed

There were small amounts of peanut pieces along the south wall and behind electrical panels in the pre-clean room.

The exterior areas on the south and west sides of the plant had large amount of dirt and product debris (skins) scattered in depths for about ¼ inch to about 8 inches.

There is a remote building on the north side of the plant, which contains what appears to be excess equipment and items removed from the plant. There is a large amount of items stored in piles on the ground. This creates potential harborage areas for insects, rodents, and birds. The building on the southwest corner of the plant used to park the skins collection trailer has unacceptable amounts of product skins accumulated on the floor areas.

A number of brooms and shovels have wooden handles. Any tools with wooden handles in the manufacturing areas of the plant should be replaced with non-wooden handled items.

There was a designated perimeter painted white about 18 inches wide maintained around the warehouse areas. This perimeter was free and clear of product storage, equipment storage, and any other unwanted dirt or debris. Along the exterior southwest wall of the pre-clean room, the concrete at the floor / wall juncture is eroded to a depth of 1 to 2 inches. This area was collecting dirt and debris and is not readily cleanable.

GMPs – Sanitation
Complying

The plant has established basic cleaning procedures and instructions for the pieces of equipment in the operation. These procedures are developed only for the major tasks. The cleaning standard operating procedures (SOPs) need to be developed throughout the plant to address all wet and dry cleaning. SOPs should be written to outline each task, the cleaning frequency, who is responsible for cleaning, chemicals to be used, chemical concentrations, personal protective equipment, tools needed to complete the task, and anything other information the plant personnel might need for these tasks.

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The Master Cleaning Schedule is very basic, and does not include a number of items in the plant such as walls, ceilings, air vents, electrical panels, floor drains, etc. All exterior areas of the plant should be added to master cleaning schedules as poor conditions can lead to potential infestations issues. All of these items should also have procedures developed as described above.

GMPs – Pest Control
Not Complying

Each device is inspected by the PCO during the site visit. All results are documented on the service reports. The plant should work with the PCO to develop a sheet that documents pest activity in a manner that trends can easily be seen. The sheets should be able to easily indicate problem areas or areas of concerns.

The pest control logs for the past 10 months were reviewed with varying levels of rodent activity noted on every report. The activity was primarily noted on the exterior of the building, but there were also concerns in the interior areas of the building. The pest control reports indicate that the plant has an on-going concern with rodent activity occurring at varying levels. The number of devices originally utilized in the service program was doubled after about 5 months of service. The service reports reviewed also say, "seal all voids around doors to prevent pest entry", without noting for which door is a concern. The PCO has utilized a straight line out to indicate some of the devices are being inspected. Each and every device that is inspected should be marked on the log sheet with an individual mark.

During the audit of the exterior of the building, the following was observed:

1) A bait box on north side of building near ramp was missing the top. The rodenticide was on the ground about 2 feet from the stations. There was another bait station installed about 4 feet away from the damaged bait station.
2) The partition walls around the exterior compressor room on the south west corner of the building are constructed of 2 layers of metal with about 3 inches of space in-between the layers. The area inside of this wall was easy viewed (due to the way they had been cut off) contained about 8 to 10 inches of dirt, product debris (skins), and mice carcasses.
3) Mouse carcass lying near bait station #10.
4) 3 mice carcasses and burrows under the grating located near on the wall near the shipping doors.
5) 3 mice carcasses in varying stages of decay lying near bait station #11.
6) 4 mice carcasses in varying stages of decay lying near bait station #12.
7) > 14 mice carcasses in varying stages of decay lying near bait station #13.
8) 5 mice carcasses in varying stages of decay lying near bait station #14.
9) > 10 mice carcasses in varying stages of decay lying near bait station #15.
10) 1 mice carcass in varying stages of decay lying near bait station #18.
11) 3 mice carcasses and 1 rat carcass in varying stages of decay lying near bait station #20.
12) 5 mice carcasses and 1 rat carcass in varying stages of decay lying near bait station #21.
13) 1 mouse carcass in the foam insulation near the corner of the building (area near emergency exit door on the south wall for the pre-clean room).
14) Numerous burrows along area on south side of plant where asphalt ends and dirt begin.
15) A dead pigeon was lying on the ground near the peanut-receiving door.
16) 4 pigeons roosting on the iron support structure inside the skin collection building. The doors to this outside building where hanging open, as the trailer was not completely backed into the building. Based on the feces observed, and by building design, it appears as if bird activity is a problem (and a potential problem) for this building.
17) A lot rodenticide was scattered loosely on the ground on the south and southwest exterior of the building.

From my observations during the audit walk through and from the pest control program records, plant management needs to review and revise the current program to incorporate more Integrated Pest Management techniques. This plant has a serious on-going problem with rodents on the exterior portions of the building must be resolved. Although there were no observations of rodents or rodent activity in the interior of the plant noted during this audit, the levels of dead rodents observed, coupled with voids noted around some doorways, indicate there are potential concerns for the interior areas of the plants.

Overall, the current pest control program appears to be less than effective and is unacceptable.

GMPs - Other

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Complying with Major Improvement Needed

There were no open holes observed in the walls or floors from previous installations, however there were several pipe penetrations through interior walls in the pre-clean room that had not yet been sealed around.

Some of the concrete flooring was cracked and broken. This was in particularly poor condition were previous existing walls had been removed. The concrete at the floor / wall juncture on the west side of the pre-clean room was eroded to a depth of 1 – 2 inches.

The paint is peeling on the walls in the pre-clean room. The areas in the corners of the room seem to be in the worst condition.

The weld on the chute at the peanut dump station in the pre-clean room was broken and in need of repair.

All hoppers for peanut storage and transport are open top vessels. There were no areas of dirt of debris accumulated on overhead piping or conduits above any of this vessels noted during this audit.

The conveyor above the #13 Roka de-stoner had been equipped with a cardboard top held on with duct tape to attempt to control product from blowing into the air and out of the conveyor. This conveyor had also been labeled as #1 using paper and duct tape. This was noted on several different pieces of equipment in the facility.

A delron guide rail cover above the bucket elevator near the raw nut dumper was damaged and coming loose from the equipment.

All sides of exterior of the building are surrounded by asphalt. The areas along the south and west sides of the plant had significant amounts of dirt and product debris piled up along the building. This creates a potential food source and harborage for insects and rodents and should e maintained clean.

All exterior doors were closed with marginal seals in place. There were a number of small gaps noted in the seals of a number of the doors. Each emergency exit door is maintained closed but not locked. Each door utilized for access by plant employees is equipped with a mechanical lock and is of a self-closing design.

Employees currently wear their own clothing and shoes to work in all areas of the facility. Employees wear hairnets and beardnets when in the plant. The plant needs to institute a written uniform policy where no employee street clothes would e exposed to product. The plant should also implement a plant designated shoe program with provisions for keeping the shoes in the plant. Employee clothing and shoes could potentially ring unwanted microorganisms, dirt, and debris into the operation. It was understood that most employee's leave their shoes are the plant when not in use. The plant should define guidelines requiring that all plant shoes be kept at the plant when not in use.

There are currently no written plant guidelines for traffic control from raw to further processed. These requirements should include traffic patterns, uniforms requirements (needs, changes, etc.), hairnet requirements, shoe requirements, fork truck controls, etc. It was understood that the operators typically work in one area.

The operator in the sizing room that was operating the filler was observed touching the product and then handling the exterior of the new boxes to be filled. The employee was touching product to help top of the box to attain the correct weight. This employee should wear clean gloves to touch product, or an appropriate tool should be designated for this operation.

Two wire brushes were observed near the blanchers (34 B / 34 A) roaster and under the hoppers in the pack out room. Wire brushes can be an excellent source of metal foreign material in a process and should be eliminated.

No non-cleaning chemicals items observed in the plant. The plant does not have a policy for these types of items. All approved non-cleaning chemicals should be included in a written control program that lists the item, the usage point (and amount if appropriate), and the storage location when not in use.

With the exception of 1 electrical transfer / control panel in the pre-clean on the south wall with parts stored on top of it, I did not observe any items being stored in or on locations they did not belong (electrical cabinets, control panels, etc.)

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Wooden handled brooms and other cleaning tools were observed in the plant operating areas. Efforts need to be made to eliminate wood from the product processing areas.

The granulation or sizing room is a separate room located adjacent to the finished product warehouse and has plastic strip curtain doors. There was some peeling paint observed on the housing of the bucket elevator by the sifter in this room.

The plant is in the process of adding an oil roasting line. The roasting equipment observed is in one corner of the finished product warehouse and the bulk infeed dump station (is same room as and) is about 30 feet from the pack-off station for blanched or roasted nuts. This process will need to be reviewed very closely prior to any start up to be sure that raw nuts are isolated from further processed nuts – this includes air flow, traffic flow, etc.

The plant has no documented supplier approval program. There are very few raw materials and packaging materials used in this facility. The plant sources raw materials and packaging materials from supplier that have long-term relationships with PCA and the other operating facilities.

Bio-Security
Complying with Major Improvement Needed

The plant does have a brief general plant safety policy. The plant has not completed any formal assessment of the site for bio-security. A formal assessment should be completed of the site and appropriate action taken against concerns noted.

No employee is issued any type of identification badge, and there are no electronic locks.

HACCP (Hazard Analysis Critical Control Point)
Complying with Major Improvement Needed

Management has limited training in HACCP, but understands the basic principles of food safety related hazards. It is recommended that someone in management attend a certified HACCP training course to better understand food safety hazards that potentially occur through the entire product process flow from raw peanuts to finished roasted peanuts. Once complete, the HACCP program can be further reviewed and risk re-assessed. Risk assessment includes safety hazards related to microbiological, physical, and chemical (includes allergens) hazards. Currently the food safety concerns are centered on the physical presence of raw peanuts being handled in the peanut roasting area (microbiological).

Comments / concerns related to HACCP and the current plant design / usage related to concerns for potential microbiological cross contamination with the raw and finished nuts. These items need to be reviewed by the plant / company HACCP authorities.

- The storage, dumping, and cleaning of raw nuts takes place in the pre-clean room. This room has a negative air pressure to the other areas of the plant. The room has a doorway entering into the roasting room, but no door is installed. What check is in place to be sure air pressure is maintained?
- All peanut pieces are moved through the processing equipment via open top conveyors and bucket conveyors. All storage bins and conveyors are designed without any tops. The concern is for potential foreign material to easily enter the product flow.
- Employees wear their street clothes in all areas of the operation. At a minimum, a smock or outer garment should be provided by the plant to create a barrier between the employee clothes and the product being processed.
- There are informal traffic patterns and practices for moving vehicles and plant personnel, but no documented plant guidelines. A formal written control plan for the movement of personnel and equipment for the prevention of raw / further processed product contamination needs to be developed. This should include requirements for work assignments and personnel movement, uniform control / changes, hair net usage / changes, glove requirement, cleaning requirements, footwear treatments, etc.
- Raw and blanched peanuts are roasted and / or blanched on specific equipment that has been installed on a shared line. The roaster is used to transport peanuts to the blanchers when the plant is blanching, and the blanchers are by-passed when roasting. The conveyors after these are share pieces of equipment. No

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microbiological studies have been completed to show that no risk is present on these shared pieces of equipment.

- No environmental sampling program is in place or has been completed to provide information on the potential microbiological risks or concerns in the further processing areas.
- The plant is in the process of installing an oil roasting system in a corner of the finished product warehouse. The peanut dumping station for the oil roasting system is being installed in the corner of the roasting / blanching room about 30 feet from the pack-off station for roasted / blanched nuts. By design, blanched only raw nuts will have to be transported to, and then dumped, in the roasting / blanching room.

Pathogen Monitoring of the Production Environment
Not Complying

There is currently no environmental pathogen-monitoring plan. There has been no pathogen-monitoring plan completed to provide historical information to justify the discontinuance of an environmental monitoring program for the operating areas of the facility.

A plan needs to be developed and implemented. If needed, Nestlé can provide recommendations for an appropriate sampling plan.

Formal Release / Status Control System
Complying with Major Improvement Needed

There is no documented "formal" release system in place; however, practices appear to be in place to prevent any out of compliance materials from being shipped.

It is recommended that a formal release system be create with an appropriate procedures and a formal release checklist utilizing testing and monitoring that is currently performed. A finished product microbial test is a good test to use as a finished product release criteria.

Lot Traceability, Lot Identification, Coding / Recall & Crisis Management (Mock Recall)
Complying with Major Improvement Needed

It was understood that the plant conducted a mock recall during 2005, but no documentation was completed. No documentation is equal "did not happen". This does not meet Nestlé requirements.

PCA needs to develop and implement a workable protocol for conducting mock recalls and then it on a regular basis. The requirement is to be able to accurately locate and account for any lot of raw material or primary packaging material used from receipt through usage and finished product and on to the transfer of ownership of the finished goods. To be in compliance this must be completed within 2 hours. Further, a program must be in place to perform mock recalls and traces yearly and to analyze the results of the tests.

Instrument Calibration (for CCPs) / Laboratories and Test Method
Complying with Major Improvement Needed

The time/temperature recording devices and the thermocouples for the roasting line should be on a minimum annual calibration verification program by the vendor. These devices were originally calibrated by the manufacturer and have been operating for about 9 months. A written program needs to be established to be sure these devices are inspected / calibrated at leas annually, or as needed.

The metal detection systems for the roasting / granulation lines should be on a minimum annual calibration verification program by the vendor. These devices were originally calibrated by the manufacturer and have been operating for about 9 months. A written program needs to be established to be sure these devices are inspected / calibrated at least annually, or as needed. The quality control technicians verify the operation of these units prior to start up each day and then on an hourly basis throughout operations.

The magnets for the roasting line should be inspected annually for pull strength. A written program needs to be established to be sure these devices are inspected / replaced annually, or as needed as indicated by test results.

Reference attached Detail Findings List for specific points noted during the audit.

"NQS AUDIT CAR SHEET v4.xls"