

PrimusLabs.com

Auditee Facility Audit Guidelines

A Guide for Auditees Preparing for PrimusLabs.com Audits

October 2004 Rev 3

For use in conjunction with V03.02 Audits

PrimusLabs.com Facility Audit Guidelines

The document is for guidance only and in no way replaces any Regulatory Legislation or Guidance. The PrimusLabs.com Facility Audit Guidelines are not exhaustive and detail minimum requirements only by means of short statements related to audit questions. There will be variations in applicability to an operation based on the process(es) and commodities involved. PrimusLabs.com accepts no liability for the contents of this document, nor how an individual chooses to apply this document.

This document has been developed to enable facilities to evaluate the food safety risks of storing, processing and/or packing food within their operation. They are intended to help management identify preventative programs that need to be in place and to identify problems that may currently exist.

Used in combination with our self-audit program www.primuslabs.com/fs/self.html a facility can evaluate their food safety programs and prepare for a Third Party Audit.

The expectations are based on the V03 Processing Audit and therefore some specific expectations may not be applicable to all operations e.g. packinghouses, cooling/cold storage operations, storage and distribution facilities. An explanation of deviations from processing operations will be given where possible but it is ultimately the responsibility of the user to determine whether an expectation is applicable to their operation or not. **The numbering system in this manual is also based on the V03 Processing Audit with HACCP Template – the other facility audits (Packinghouse, Cooler etc.) have less of the same questions.**

The expectations are based on:

FDA “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables”

<http://vm.cfsan.fda.gov/%7Edms/prodguid.html%20>

Current Good Manufacturing Practices (GMPs) regulations 21 CFR 100-169

<http://cm.cfsan.fda.gov/%7Elrd/part110t.txt>

Food Code, 2001 edition (FDA/USPHIS) <http://vm.cfsan.fda.gov/%7Edms/fc01-toc.ht>

Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures

Guidance <http://vm.cfsan.fda.gov/~dms/secguid.html>

Guidance on Inspection of Firms Producing Food Products Susceptible to Contamination with

Allergenic Ingredients http://www.fda.gov/ora/inspect_ref/igs/Allergy_Inspection_Guide.htm

Guidelines for Interim Country of Origin Labeling <http://www.ams.usda.gov/COOL/>

Buyer specifications and requirements.

Audit Format and Scoring Guidelines

There are currently 6 Facility Audit Formats. All have at least 2 sections, the GMP Section (Facility Tour) and the Food Safety File Section (Paperwork). Some have HACCP sections added. All audits now have food security and miscellaneous sections – these questions are for information only at this time, i.e. they are not scored.

- **Cooler and Cold Storage Audit.**
This audit is designed to be used for facilities that are receiving goods directly from the fields, orchards etc. after harvest. If there is any packing, repacking, grading etc. occurring on site, then a Packinghouse Audit should be used.
- **Packinghouse Audit.**
This audit should be used for any operation that is grading, packing, repacking, washing whole produce etc. If the item is being sliced, shredded, dried, juiced etc., then a Processing Audit should be used.
- **Packinghouse with HACCP Audit.**
Many buyers are requesting facilities to create and maintain HACCP Systems for their products. PrimusLabs.com offers both it's Packinghouse and Processing Audits with a HACCP Audit section added onto the standard version.
- **Processing Audit.**
This audit should be used for any operation that is washing and slicing, shredding, drying, juicing etc. any item i.e. any "further processed" items.
- **Processing with HACCP Audit.**
Many buyers are requesting facilities to create and maintain HACCP Systems for their products. PrimusLabs.com offers both it's Packinghouse and Processing Audits with a HACCP Audit section added onto the standard version.
- **Storage and Distribution.**
This audit is designed to be used on facilities that are receiving and storing finished goods e.g. regional distribution warehouses. If there is any packing, repacking, grading etc. occurring on site, then a Packinghouse Audit should be used.

The audit format is updated as needed. This may include the layout, the questions themselves and point assignments. The following is the scoring system used for the PrimusLabs.com facility audits:

PRIMUSLAB.COM SCORE SYSTEM FOR ENTIRE AUDIT	
Percentage (%)	Category
95-100	Superior
90-94	Excellent
85-89	Good
80-84	Standard
< 80	Unsatisfactory

POINT SYSTEM FOR INDIVIDUAL QUESTIONS				
Possible Question Points	Full Compliance	Minor Deficiency	Major Deficiency	Non-compliance
15 Point Question	15 points	10 points	5 points	0 points
10 Point Question	10 points	7 points	3 points	0 points
5 Point Question	5 points	3 points	1 point	0 points
3 Point Question	3 points	2 points	1 point	0 points

COMPLIANCE CATEGORIES	
Full Compliance	To be in full compliance of appropriate GMPs, sanitation, pest control, documentation and/or HACCP requirements.
Minor Deficiency	To have minor deficiencies of appropriate GMPs, sanitation, pest control, documentation and/or HACCP requirements. There is little potential hazard to product.
Major Deficiency	To have major deficiencies of appropriate GMPs, sanitation, pest control, documentation and/or HACCP requirements. Potential hazard to product exists.
Non-compliance	To have serious deficiencies of appropriate GMPs, sanitation, pest control, documentation and/or HACCP requirements. Actual hazard to product exists.

Facility Audit Agenda

Audit agenda's do vary, but the normal pattern of events is as follows:

- Opening Meeting. Confirm the appointment details, introduce the auditor(s) and auditee contacts, get some background and history of the operation. Confirm day's agenda.
- **Tour of Operations** – areas depend of the type of facility, but might include raw material storage areas, production, finished goods storage, personnel facilities, maintenance, chemical storage, packaging storage and external areas e.g. where dumpsters are located.
- **Food Safety File** (paperwork section). New auditees must have at least three months worth of paperwork available (unless a short season crop packing facility).
- **HACCP Section (if relevant)**. The auditor might look at the HACCP file in the opening meeting in order to orientate themselves about the site program and CCP's.
- **Food Security Section**. The auditor will have made notes about physical security aspects when carrying out the tour of the operation. This area is scored, but is a separate total percentage from the rest of the rest of the audit.
- **Miscellaneous Questions**. V3.02 questions include Employing Minors, Country Of Origin Labeling and Allergens. These questions are not scored.
- Auditor "quiet" time. Sometimes needed to collate notes before delivering the closing meeting.
- Closing Meeting. Discuss non-compliance points with the auditee team. Please note that PrimusLabs.com auditors are not able to provide either a final score or pass/fail commentary at the end of the audit due to the high number of questions that are asked in the template and the scoring system that is applied. PrimusLabs.com auditors however do expedite audit reports very quickly and auditees should contact PrimusLabs.com if reports have not been received electronically two weeks after the audit has occurred (at the latest).

It is **imperative** that the plant is running product and that a normal compliment of personnel are on site when the audit occurs in order for the auditor to complete a valid assessment. If the plant is not running and/or there are no production staff on site, then the audit will have to be terminated and cancellation charges will be applied or the audit can continue as an educational audit. Please ensure that auditee personnel are available to follow the plant tour and are well versed in the areas that are being inspected.

For further information about the facility audit process and booking facility audits please go to <http://www.primuslabs.com/fs/preaudit.htm>.

Good Manufacturing Practices - Section 1

General Food Safety

1.1.1 There shall be a designated person in charge of the facilities food safety programs including verification of sanitation activities. This person should ideally be a manager within the company.

1.1.2 All chemicals shall be stored in a designated (sign posted), dedicated, locked area away from food and packaging materials and separated from processing areas. Access to chemicals shall be controlled, so that only personnel who understand the risks involved and have trained properly are allowed to use these chemicals. All chemicals must have legible labels of contents including chemicals that have been decanted from master containers into smaller containers. Where chemicals are stored, adequate liquid containment techniques need to be employed (secondary containment, absorbent materials, angled sealed floors, spill kits, etc.) Liquid should not be stored above powders. Chemical storage should be designed to help contain spills and leaking containers. Empty containers must be stored and disposed of correctly

1.1.3 Signs indicating proper GMP requirements shall be posted visibly and in the language(s) of the employees (visual signs allowed) in the following areas:

- Before entering areas that require hair/beard nets and smocks.
- Before areas that prohibit food, tobacco products, chewing gums.
- Bathrooms and break-room(s) should have hand-washing signs as reminders to wash hands before returning to work.

Pest Control

1.2.1 Products and ingredients must be free from evidence or the presence of insects/rodents/birds. **Evidence of contamination constitutes automatic audit failure (in a PrimusLabs.com audit).** This would be considered adulteration of a food product or ingredient and violates section 402(a)(3) of the code of federal regulations. See 1.2.3 for reference to potential indications of pest presence.

1.2.2 Packaging supplies must be free from evidence or the presence of insects/rodents/birds. **Evidence of contamination constitutes automatic audit failure (in a PrimusLabs.com audit).** This would be considered adulteration of a food product or ingredient and violates section 402(a)(3) of the code of federal regulations. See 1.2.3 for reference to potential indications of pest presence.

1.2.3 All areas must be free of reoccurring/existing internal pest activity. Specifically there shall be:

- No reoccurring/existing rodent activity and/or bird nesting observed around the interior perimeter or the facility.
- No evidence of live animals observed inside the facility such as cats, dogs, deer, etc.
- No evidence of excreta/pellets
- No evidence of pests including insects, spiders/webbing, rodents, lizards, ants or birds in the facility.
- No evidence of gnawed bags/sacs or rodents on stored stock or numerous excreta on the floor/shelves of any storage area.
- No decomposed rodent(s) or other animals (frogs, lizards, etc.) in traps. The interior traps shall be checked often and the dead rodent(s) or other animals removed.
- Glue boards shall be free of significant insect build up and/or dust.

1.2.4: All areas shall be free of reoccurring/existing external pest activity. Specifically there shall be:

- No reoccurring/existing rodent activity (significant burrows, trails, excreta, tracks), animal spoor and/or bird nesting observed around the exterior perimeter of the facility (within 20 feet or 6 meters).
- No decomposed rodent(s) or other animals (frogs, lizards, etc.) in bait stations or along perimeter.

Findings of a few “fresh” rodents and/or evidence of rodents feeding in the external traps is not viewed as a problem.

1.2.5 Pest control devices shall be placed so that there is no threat of contaminating product, packing or raw materials. This includes the following restrictions:

- Bait stations must only be used outside the facility.
- Indoor pesticide applications shall only be used if necessary and must meet all legal requirements. Applications must be carried out by a licensed applicator and fully documented.
- Domestic fly sprays (aerosols) shall not be used within production and storage areas.
- Block bait shall be used in bait stations and be properly secured. Pellet or grain bait must not be used
- If used, electric fly killers or insect light traps shall be regularly cleaned out (kept free from a build-up of insects and debris, which has the potential for “spilling over”).
- If used, electric fly killers or insect light traps must be at least 10 feet (3 meters) from product, equipment, or packaging material. Electric fly killers or insect light traps shall not be located above dock doors (potential for forklift damage and attracting insects into the facility). Hallways where product passes through are exempt from these distances as long as product does not stop or is not stored in the hallway.
- If used, insect trap bulbs shall be replaced annually (and recorded) preferably in the spring time.
- Fly swatters shall not be used in production or storage areas.
- No bait shall be found outside bait station.
- Snap traps can only be used when monitoring traps e.g. tin traps show that there is a serious problem and eradication steps are required. Snap traps should be checked daily (and recorded). Snap traps should not use allergen containing baits e.g. peanut butter. Snap traps are only allowed as a short term eradication solution since they present several risks

1.2.6 Pest control devices shall be maintained in a clean and intact condition and marked as monitored on a regular basis.

- If **non-toxic** glue boards are used, they shall be changed frequently ensuring that the surface has a shiny glaze with no build up of dust or debris.
- If mechanical wind-up traps are used, they must be wound. Winding is checked by triggering the spring device to operate the trap. The trap must be rewound after testing.
- Interiors of traps and bottom of glue boards shall have service labels dated and initialed (unless using a barcode system) after each check by the trained operators.
- **Traps and bait stations** shall have service labels dated and initialed (unless using a barcode system) after each check by the licensed PCO.
- Bait in bait stations shall be secured inside the bait station on a rod above the floor of the station or the bait station is designed so bait cannot be removed by a rodent or “float away” in heavy rain.
- Bait stations shall be tamper resistant.
- Bait stations shall not be missing entire bait.
- Bait shall not be old or moldy.
- Bait stations and traps shall not be fouled with weeds, dirt, and other debris.
- **Pest control devices should be checked at least monthly (checking more frequently is an ideal situation).**

Local regulations may exceed the above guidelines. At all times, local regulations must be met.

1.2.7 Interior, exterior of the building perimeter and land perimeter pest control devices shall be adequate in number and location

As a **guide** to number and placement of traps and bait stations:

- Traps shall be positioned at a maximum of 30 feet (9 meters) around the inside perimeter of all rooms. If a wall is less than 30 feet (9 meters) long, it shall have at least one device.
- **Inside the facility, only mechanical traps shall be placed within 6 feet (about 2 meters) of both sides of all outside exit/entry doors. This includes either side of the pedestrian doors. Effort shall be made to avoid placing traps on curbing. .**
- Bait stations or live traps shall be positioned at a maximum of 50 feet (15 meters) intervals around the exterior of the building perimeter and within 6 feet (about 2 meters) of both sides of all outside exit/entry doors, except where there is public access (public access is defined as access easily gained by the general public such as parking lots or sidewalks, school areas or areas of environmental concern).
- Bait stations or live traps should be positioned at a maximum of 100 feet (30 meters) intervals along the fencing of the facility property, except where there is a public access.
- Outside packaging storage must be protected by an adequate number of pest control devices.

1.2.8 All pest control devices shall be identified by a number or other code (e.g. barcode) and a coding system shall be in place to identify the type of device on a map. All traps shall also be located with a wall sign.

1.2.9 Bait stations shall be secured to minimize the movement of the device and be tamper resistant. Bait stations shall be secured with either a ground rod or chain, or glued to the wall/ground, or secured onto patio blocks. If bait stations are secured to patio blocks, then associated wall signs are mandatory. Bait stations must be tamper resistant (screws, latches, locks, etc.). Live traps must be positioned so that the openings are parallel with and closest to, the wall. Efforts shall be made to avoid placing traps on curbing. If used, **electric fly killers** must be at least 10 feet (3 meters) from product, equipment or packing material. **Electric fly killers** shall not be located above doors through which product passes. Hallways where product passes through are

exempt from these distances, as long as product does not stop or is not stored in the hallway (see 1.2.5).

Storage Areas & Packing Materials

1.3.1 All ingredients, products and packaging shall be stored off the ground (i.e. on racks, pallets, shelves, etc.). Materials shall be properly protected during storage to prevent contamination. Ideally, raw materials, finished product and packaging materials should be stored in separate areas to prevent cross contamination. When separate room storage is not possible, it is permissible to store them together, but far enough apart to prevent contact. Raw unprocessed items should not be able to contaminate finished washed/processed items. Packaging storage, especially dust from cardboard storage should not contaminate produce items. If mixed food items are stored on site then there should be controls to prevent contamination issues e.g. raw eggs should not be stored above raw produce, glass items should be kept in a separated area and always stored near ground level. Wet product must not be stored above dry product. Wet product stored in racking must not be allowed to drip onto exposed product underneath.

1.3.2 The storage areas for product and packaging shall be enclosed and pest proof. Main doors should be kept closed unless in use. Food contact packaging should not be stored outside. Non-food packaging e.g. cardboard outers should be stored inside if possible, but if necessary (will result in a minor down score) to store outside (e.g. insufficient space for indoor storage) the packaging must be covered with a waterproof and dust proof shroud and included in the pest control program.

1.3.3 Only food, food contact products and items related to the process shall be stored in the facility main storage areas. Sanitation chemicals and maintenance equipment storage should have their own dedicated storage areas.

1.3.4 All storage racks shall be properly designed for proper drainage of water and to permit air circulation.

1.3.5 Products and raw materials should free from spoilage, adulteration and/or gross contamination. Where legislation exists (e.g. USDA Grading Standards) then contamination should be viewed against this standard. Spoilage or adulteration would include any physical, biological or chemical contamination e.g. glass, trash/litter in products. Adulteration of ice shall not be permitted and water used for ice for product cooling must be potable. **Any observation of gross contamination of ingredients, product or product contact surface will qualify as an automatic failure (in a PrimusLabs.com audit).**

1.3.6 All products that are being rejected or are awaiting final disposition (on hold) shall be stored in a way that avoids accidental use of these materials in the production process (unless they have been cleared for use). The rejected or on hold items must be tagged as such, with a date showing when the product was placed on hold/rejected and the reason for being on hold/rejected. The tagged product must not be commingled with other goods in such a way that their disposition is not clear. A designated hold area and using disposition logs are commendable practices.

1.3.7 All storage areas shall be clean and well ventilated and protected from condensation, sewage, dust, dirt, toxic chemicals or other contaminants. Ledges and drains (if relevant) shall be clean and free of debris. Products and packaging must be clean and free from dust, debris and out of place materials, etc.

1.3.8 All ingredients, products and packaging shall be properly marked with receipt dates and/or tracking information (lot numbers, code dating) for traceability and stock rotation.

1.3.9 All ingredients, products and packaging shall be rotated using FIFO (First In First Out) policy to ensure items are used in the correct order they are received within their allocated shelf life. Commodities that undergo ripening treatments are exempt. Packaging rotation may be affected by market forces.

Operational Practices

1.4.1 There shall be no generation of condensation, dust or spillage from equipment. Limited spillage to the floor is permitted provided it is frequently cleaned away and does not result in build-up or potential cross contamination. Fixtures, ducts and pipes shall be installed in a manner that avoids contaminating the product, packaging or equipment.

1.4.2 Process flow, facility layout, employee control and utensil control shall ensure that processed products are not contaminated by raw (unprocessed) products. Raw products should not come into contact with processed products, especially processed products that have been washed, cut or thermally treated. Staff who handle raw products must not then handle processed products without first ensuring that they are free of raw material contaminants. This must include hand washing, glove change etc., but might also include changing into a new set of garments. Ideally staff should be dedicated to handling raw or processed goods, but not both within a shift. Utensils should not be allowed to be vectors for cross contamination; ideally dedicated coded utensils should be provided for raw and processed goods, failing this, there should be a utensil sanitation step between uses. Note that anti-microbial washes are not kill steps, but they are microbial reduction steps.

1.4.3 Ceilings and/or any overhead fixtures shall be free from condensation or dust. Ladders or walkways above exposed product or packaging material shall have kick plates at least 3 inches high. Forming condensation (above process, product or packaging) must be wiped before the condensate drips.

1.4.4 There shall be sufficient space provided for proper storage and operation to permit traffic flow and daily operations without likely cross contamination. In processing plants, the flow should be such that raw product shall not cross contaminate the processed finished product.

1.4.5 Production/packing areas shall be inside the facility i.e. enclosed by walls and roof. Production/packing should also be physically separated from storage areas. In some cases a physical barrier between production/packing and storage areas might be required – this will depend on the type of product being produced and the items being stored.

1.4.6 All re-work shall be handled correctly. Rework includes product that has come directly from the line or perhaps returned from a customer but of good quality. Rework will vary from one product to another. GMPs must be followed and cross contamination issues must be considered when handling rework. Re-work areas in coolers must adhere to all required GMP's. In a cooler where the re-packing is a daily routine event, then a packinghouse audit template should be used. Traceback details of the product must be transferred correctly.

1.4.7 Raw ingredients or products shall be examined for damage, insect or rodent infestation, temperature abuse, tampering, etc. before use.

1.4.8 All products shall be appropriately labeled, identified and possess lot numbers and/or code dating information. On bulk product, the coding should be on the carton or RPC tag; on bagged, clamshell and other prepacks, the coding should be on the pack itself and also on the cartons.

1.4.9 Foreign material control method(s) shall be in place and where necessary tested to ensure proper operations. The frequency and types of testing shall be established in a written program and the frequency is adhered to by QA personnel and documented. Foreign material controls include detectors, traps, visual, sieves, filters and magnets. Metal detection is a must for products that have been cut, sliced, diced or shredded using an automated cutting machine e.g. an Urschel Slicer. Continuous visual inspection is acceptable for whole products.

1.4.10 The strength of sanitizers (product and cleaning) shall be checked on a regular basis and recorded. Test strips or test kits for checking the concentrations of the sanitizers (dip stations, wash water, etc) should be in use. Solutions that are too weak will be ineffective, while those too strong may be harmful to employees or product. Where necessary, pH of solutions should also be checked.

1.4.11 Hand washing stations shall be located where needed e.g. hand washing stations in restrooms, after dressing/changing rooms/before entering the processing/packing area, inside processing/packing area, etc. Ideally hand-wash stations should be located in full sight in order to observe discipline (especially in ready to eat plants). Enough stations should be provided to ensure efficient staff flow. Hands-free is an optimum system for food establishments.

1.4.12 Bathrooms (toilets, restrooms) shall be adequate in number and convenient in location:

- Bathrooms should be located within a reasonable distance from the employees' workstation.
- Bathrooms should be readily available to male and female employees.
- There should be one toilet for every 20 employees.
- Hand wash stations should be clean and functioning.
- At least one wash sink or equivalent should be provided for each ten persons up to 100 persons.
- Each individual toilet facility must be able to be locked from inside.
- Each toilet facility must be maintained, well lighted and ventilated to outside air.
- Each individual toilet facility shall occupy a separate compartment with a door and walls sufficient to assure privacy.
- In the toilet room, the floor and side walls shall be watertight. The sidewalls shall be watertight to a height of at least five inches.
- The floors, walls, ceiling, partitions and doors of all toilet rooms shall be made of a finish that can be cleaned easily.
- Doors to toilet facilities must not open into areas where food is exposed to airborne contamination, i.e. in processing and packing areas. Double doors or a positive airflow system may be acceptable.
- Doors to restrooms that do open into the production facility, i.e. not located in the amenity area or office area, must be kept closed at all times e.g. a spring loaded door.
- Restrooms should be properly stocked with scentless soap, paper towels and toilet rolls.

1.4.13 All hand wash stations should have warm water (>85°F, 30°C) available for use within 10 seconds. Warm water is more effective in hand washing because it facilitates the removal of oil and dirt from hands and encourages employee usage.

1.4.14 Hand dip and/or hand gel and/or alcohol spray stations shall be adequate in number, convenient in location and properly maintained. Secondary hand sanitation is required for fresh-cut operations, for operations producing washed ready-to-eat products (e.g. tomatoes) that have edible skins/peels and for unwashed, potentially ready to eat items e.g. blueberries. Hand dips, gels or sprays do not replace hand-washing requirements. Hand dips should contain a USDA approved food grade sanitizer at a determined and regularly monitored concentration

1.4.15 Foot (boot) stations (foot dip mats) shall be located in processing areas when crossing into a "clean" zone from an area of potential contamination e.g. raw storage to packaging, from bathrooms

to processing, etc. Foot dips are not required in packinghouses but might be considered as an additional control.

1.4.16 Single service containers shall be used for their intended purpose only i.e. food contact use and shall not be reused. An exemption for reuse of boxes in tomato, citrus, etc. re-pack operations shall be permitted only if there are measures in place to re-inspect the containers, FIFO rotate and correct box transfers in place. If a single service container is used for any other reason than the storage and distribution of food it must be clearly differentiated for this purpose.

1.4.17 In-house reusable containers shall be labeled or color-coded to clearly indicate their designated purpose. Returnable plastic crates (RPC's, also totes) should be used and stored properly e.g. stored shrouded within a pest proofed building, kept off the floor and only used for storage and shipping finished goods to the customer.

1.4.18 All pieces of measuring equipment e.g. scales, thermometers, pH probes, etc. shall be functioning properly.

Employee Practices

1.5.1 Employees must wash their hands before starting work, after using the restroom and after breaks. Hand washing signs in appropriate languages should be posted at hand wash stations, in restrooms and break areas.

1.5.2 Employees who have exposed boils, sores infected wounds or any other source of abnormal microbial contamination shall not be allowed to work in direct contact with food or food contact surfaces. All bandages must be covered with a non-porous covering such as latex or plastic gloves.

1.5.3 Employees (including maintenance staff and visitors) shall wear hair restraints and beard nets (when applicable) appropriately. Hairnets are not necessary in operations manufacturing bulk products that are not ready to eat (i.e. requires cooking) and products with inedible skins or peels, however, long hair must be tied back for safety reasons (no metal clips or pins). Handlers of items that may be "ready to eat" e.g. green onions, stone fruit, tomatoes, etc. must wear hair restraints. Hairgrips must not be worn outside hair restraints.

1.5.4 Employees shall not wear jewelry (earrings, necklaces, bracelets, rings with stones) or watches in the facility; plain wedding bands are an exception. False eyelashes and false fingernails shall not be permitted.

1.5.5 An outer garment policy considering potential cross contamination and foreign material risks shall be established. Suitable garments include smocks, aprons, gloves, sleeves (where appropriate) and suitable footwear. Unless wearing gloves, fingernail polish shall not be permitted. If worn, gloves must be replaced when soiled, torn or when otherwise necessary and must not replace hand washing requirements. Smocks must be laundered in-house or by contract laundering agency and should not be taken home by employees.

1.5.6 Protective outer garments (smocks, aprons, gloves, sleeves) shall be removed when employees leave the work area (i.e. restroom, break room, outside, etc.).

1.5.7 There shall be a designated area for employees to leave protective outer garments (smocks, aprons, gloves, sleeves) when they leave the work area. Employees should not leave outer garments on floors, worktables, equipment or packaging materials.

1.5.8 Smoking, chewing tobacco, chewing gum, drinking and eating shall only be permitted in designated areas that are away from facility food products and packaging materials. Water shall be

accessible to employees at all times but location and consumption must not affect the product safety.

1.5.9 Outside pockets above the waist shall not be used to store employees' personal items e.g. pens, tools, probes, etc. Ideally top pockets shall be sewn up or non-existent.

Equipment

1.6.1 Processing and packing equipment and auxiliary supporting equipment shall be free of flaking paint corrosion, rust and other materials (e.g. tape, etc.). Food contact surfaces shall be made of non-toxic, non-porous materials. Surfaces shall be maintained in good condition.

1.6.2 Non-food contact surfaces shall be free of flaking paint, corrosion, rust and other materials (e.g. tape, etc.). The surfaces shall be made of smooth materials that can be cleaned and sanitized easily.

1.6.3 Equipment shall be suitable for current use and design and condition (e.g. smooth seams, non-porous, no dead spots, non-toxic materials) and must facilitate effective cleaning and maintenance. There shall be no metal to metal contact. Equipment design should allow access to all areas to facilitate cleaning.

1.6.4 All chemicals (food grade and non-food grade) shall be handled and stored in a controlled manner. Food grade and non-food grade chemicals shall be stored apart. Grease guns should indicate which are for food grade grease and which for non-food grade grease. Non-food grade materials shall not be left in the production/storage areas.

1.6.5 Independent thermometers or temperature recorders shall be present in all coolers and freezers. If thermostat probes are used there should be more than one probe in each room monitored.

1.6.6 All thermometers shall be non-glass and non-mercury in design. If glass/alcohol thermometers are used, these shall be properly shielded to prevent product or packaging contamination in the event of breakage.

1.6.7 All repairs shall be completed without the use of string, cardboard, wire, duct tape or other improvised materials.

1.6.8 If temporary repairs are necessary then these shall be dated with the date the temporary repair was made. Temporary repairs can be documented (logged). Temporary repairs shall be permanently repaired within a specified time period.

Equipment Cleaning

1.7.1 All equipment surfaces that make contact with product shall be kept in a clean condition to avoid cross contamination.

1.7.2 All non-food contact equipment surfaces shall be kept in a clean condition to prevent potential cross contamination.

1.7.3 Bins, boxes, hoppers, barrels, baskets, etc. used for the storage of product, or ingredients shall be kept in a clean state. The storage of these items should ensure that they remain clean and uncontaminated.

1.7.4 During cleaning products, ingredients and packing shall be protected or removed from the area. Cleaning operations should be carried out in a manner that prevents contamination i.e.

excessive spray from high-pressure water or air hoses. Cleaning should not contaminate already cleaned equipment.

1.7.5 All coils in coolers and freezers shall be cleaned on a routine basis. There should be no build-up of dust, mold or other contaminants.

1.7.6 All fan guards shall be clean. There shall be no build-up of dust or other materials on the fan guards.

1.7.7 All equipment that is not used on a daily basis shall be stored clean, with food-contact surfaces protected. Stored equipment should be clean.

1.7.8 All tools and utensils not being used shall be stored clean and in a manner to prevent contamination (off ground, etc).

1.7.9 Safety equipment shall be provided for the sanitation crew. Safety and cleaning equipment storage shall be organized and segregated from food and packaging materials and secured to prevent unauthorized use.

1.7.10 All items used for sanitation shall be appropriate for their designated purpose (no steel wool, straw or metal bristles, etc).

1.7.11 Cleaning equipment shall be area specific and coded to prevent cross contamination. Separate restroom, outdoor, maintenance and production brushes, mops, etc. in this manner. If allergens are used, separate coding for allergen management should be considered.

1.7.12 Excess lubricants and greases must be removed from equipment and there shall be no evidence of leakage or drips. Where drive motors are mounted over product zones catch pans shall be installed with drainage via hosing to the floor.

General Cleaning

1.8.1 All spills shall be cleaned up immediately in order to prevent microbial growth and the attraction of pests, reduce cross contamination and maintain a sanitary environment.

1.8.2 Waste and garbage shall be frequently removed from all areas. Garbage containers shall be included in a regular cleaning schedule.

1.8.3 The areas under storage racks shall be kept clean and free of spills, garbage, waste or any other material. Sanitation practices shall include the periodic cleaning of the areas under the racks to assure that acceptable levels of sanitation are maintained and spills are taken care of as promptly as possible.

1.8.4 All facility floor drains, including covers and internal channels shall be kept clean and free of decayed or old material. All facility floor drains must be free of odors and there shall be no overflow or excessive standing water in the floor drains. Drains in wet production (packinghouse and processing) and wet storage facilities should be cleaned daily.

1.8.5 Sanitation practices shall include the scheduled cleaning of overhead pipes, ducts, fans, ceilings, etc. There must be no evidence of aged ice build-up in freezers or condensation leaking in coolers or refrigerated production areas. Fans, ducts and pipes shall be free of excessive dust and spider webs.

1.8.6 All facility plastic strip curtains shall be clean, free of mold/mildew and off odors, black discoloration, etc. Curtains must be installed so that the tips are just off the ground and broken strips must be replaced when damaged.

1.8.7 Cleaning equipment shall be stored away from the food and operational areas in a designated storage area for the cleaning equipment. Access to cleaning equipment should be restricted to trained staff. There should be an adequate supply of cleaning equipment (as per procedures employed).

1.8.8 Bathrooms (restrooms, toilets) and hand-washing stations shall be maintained in a clean and sanitary condition:

- Bathrooms shall have a drainage installation that allows the waste to be flushed and disposed properly.
- Bathroom fixtures shall be in good operating condition and clean.
- No offensive odors shall be evident.
- Soiled toilet tissue must be placed in the toilet (not on floor or in trash cans).
- Toilet stalls in female bathrooms shall have sanitary napkin disposal receptacles.
- Drainage system must function properly
- Trashcans shall be available for hand wash paper towels.
- Hand wash signs (in the appropriate languages) shall be posted

1.8.9 Employee locker and lunchroom shall be kept in a sanitary condition. Sanitation practices include the periodic cleaning of this area (includes inside microwaves, inside and behind refrigerators, behind and on top of all vending machines, tops of lockers) to assure that acceptable levels of sanitation are maintained. Food should not be kept in employee locker facilities. Temperature sensitive food must be kept in chillers or chill boxes. Vending machines should be visibly clean inside, maintain the desired temperature and items be within expiration date codes.

1.8.10 The maintenance shop shall be kept clean and organized. Sanitation practices shall include the periodic cleaning of this area in order to avoid pest harborage conditions that may contaminate the product, materials or equipment. Maintenance shops should not be located near or in production areas and product/packaging storage areas. Maintenance shops should employ a “clean as you go” policy with respect to metal filings and chips generated when metalworking.

1.8.11 Internal transport vehicles (forklifts, hand trucks, etc.) used to transport food shall be in a good state of repair, clean, odor free, free of personal food items, and free of rodents and insects. A sanitation program for internal transport vehicles shall be established to assure proper sanitation levels.

1.8.12 Trucks and/or trailers used to transport food and packaging shall be in a good state of good repair, clean, odor-free, and free of rodents and insects. Trucks must be appropriate for the product being transported.

1.8.13 Dock levelers shall be clean, pest free and in good repair. Gaskets (bristle strips) around dock levelers should fit tightly to prevent pest entry.

Buildings and Grounds

1.9.1 All glass lights in the facility that can contaminate finished products, raw materials, equipment, or packaging shall be shielded to protect product contamination in the event of breakage (safety type glass is acceptable). This includes, but is not limited to items such as light bulbs, emergency lights, truck loading lights (dock lamps), insectocutors, forklift lights, clock faces, thermometers, gauges, watches, eye glasses, computer monitors, office window glass, etc.

Precautions should be taken to prevent glass contamination in the event of glass breakage. Windows and computer monitors in packing areas should be covered with a plastic film to prevent shatter. Plastic coated shatterproof light bulbs are also acceptable without further protection. Inside light coverings should be clean, free of algae, insects and excessive dirt.

1.9.2 Items that have the potential to become foreign material contaminants shall be eliminated from the facility. Examples include, pins in sign boards within the facility, staples, paperclips, using “snappable” blades instead of one piece blades, broken and brittle plastic issues on re-useable totes and uncontrolled glass items like coffee pots, computer screens etc. in production areas.

1.9.3 All equipment shall be made of sanitary, food grade material that can be easily cleaned. Efforts should be made to eliminate wood equipment from facilities including tool and utensil handles, tables, ladders, platforms, storage containers, etc. “Wet” facilities should not be constructed of unsealed wooden walls or ceilings. Dry packinghouses may have wooden walls and floor supports. Wood pallets are acceptable and should be dry and in good condition. Use of slip-sheets between uncovered, double-stacked pallets is required. Wooden bins should not be used for potentially ready to eat products (apples, stonefruit etc.).

1.9.4 Adequate lighting shall be made available in all areas where food and packaging is examined, processed, or stored and where equipment or utensils are cleaned. This includes process areas, storage areas, hand-washing area, locker rooms, and restrooms. The lighting should be strong enough to allow employees to see clearly so that they can conduct their work in an unobstructed manner. Lighting should also be strong enough to conduct proper sanitation and facility inspections.

1.9.5 The facility shall have a good ventilation system that will minimize odors and vapors (including steam and noxious fumes e.g. gasoline powered forklifts) in areas where they may contaminate (taint) product, ingredients or packaging materials. There should be no dust or condensate present in areas that can contaminate product or processing equipment or packaging supplies. Ventilation equipment shall be maintained to provide an adequate air exchange rate.

1.9.6 The floor surfaces in the facility shall be suitable for the type of operation being conducted. It should be constructed in such a manner that it may be adequately cleaned and kept in good repair. Floors should be smooth without deep cracks or seams, or exposed aggregate. Drains should be adequate for the facility operations. Carpeting on stairs or walkways is not a suitable surface, particularly in wet environments.

1.9.7 All doors to the outside shall be protected from rodents and flying insects entering the facility. Gaps should be no greater than 1/8 inch (3 mm). Air curtains are acceptable, provided they are operating properly. Personnel doors to the outside should be loaded so that they close properly.

1.9.8 Dock doors shall be fitted with buffers to seal against trucks. Seals should be clean and in good repair.

1.9.9 Exterior walls shall be maintained. They should be free of holes and deep cracks that could harbor pests. All pipes on the exterior walls should have caps to prevent rodents and others pests from entering the facility. Vents and air ducts should also be protected to prevent entry of pests. Any screens on the exterior walls should have mesh size of no greater than 1/8 inch (3 mm).

1.9.10 Interior walls shall be maintained to be free from holes, and large cracks that can harbor insects and other pests. Exposed insulation can be a contaminant – with heat and water this becomes an ideal breeding ground for microbes.

1.9.11 Employees shall have a designated area for storing personal items such as coats, shoes, purses, etc. Lockers are desirable. Food should not be stored inside lockers as it can attract insects and other pests. Gloves, hairnets, smocks or aprons should not be stored in the lockers because they can be contaminated from other items brought from home. If lockers are used, they should be maintained in a clean condition with no storage on top of lockers allowed (ideally with sloping tops). Areas set aside for employee personal items should be far enough away from stored raw or finished products, packaging materials, processing equipment or processing lines to prevent contamination. Personal items should not be kept directly on the floor. Temperature sensitive food must be kept in chillers or chill boxes, not in ambient conditions.

1.9.12 All storage areas shall maintain an 18" (46 cm) distance between the stored items and the wall. Each row of stored items should maintain a 14" (36 cm) space between every other row. In coolers and freezers an 18" (46 cm) clearance of the bottom rack from the floor is an alternative. This space is necessary to prevent harborage of pests, to allow proper monitoring of pest activity and for employees to perform their cleaning duties. Staging areas are not required to conform to these requirements.

1.9.13 Facility grounds shall be maintained in a clean and orderly condition to prevent attraction of insects, rodents and other pests. Weeds and grass should be maintained in order to help avoid pest harborage. There should be no standing water or foul smelling odor. Designated outside smoking areas must have a disposal can for cigarette butts and all areas (including car parks) should be free from litter, cigarette butts, etc.

1.9.14 Outdoor storage of equipment (bone yards) shall be stored in a manner that will prevent the harborage of pests. Pipes should have the ends capped. Equipment on pallets should not have direct contact with the dirt. All items stored should be at least 4 inches above the dirt. This area should be away from the building perimeter, be included in the pest control program and be maintained to prevent build-up of obsolete equipment.

1.9.15 Pallets shall be maintained in a clean, intact condition, free from mold, pests, or any evidence of pests, food residues, harmful odors, chemical spillage, etc. Broken and/or dirty pallets should be separated for cleaning, repair or return. Washed pallets should be dried prior to use. Broken or dirty pallets should not be used.

1.9.16 The area around the dumpster/cull truck shall be maintained in a clean condition. There shall be no spillage on the ground or standing water/liquid seepage around the dumpster/cull truck and no foul odor present. The dumpster/cull truck should be cleaned on a regular basis.

1.9.17 All dumpsters (except dry non-food waste e.g. paper cardboard) and garbage receptacles shall be kept covered to prevent the attraction of insects, rodents and other pests.

1.9.18 The facility shall show proof that there is back-flow protection from, or cross-connection between, piping systems that discharge waste water or sewage. Back flow protection from facility tanks and systems back into the main water system shall also be present.

1.9.19 Drains shall be constructed in such a manner that they provide adequate drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor. Construction should be such so that the distance from high point to the drain should never exceed 15 feet. Drains should be cleaned on a regularly scheduled basis.

Food Safety File Requirements – Section 2

General File Requirements

All logs shall be kept on file in an easily retrievable manner.

2.1.1 There shall be a written trace back program. Grower packers/processors and packers/processors who buy from growers should be able to trace back to growing field(s). Packers and processors who buy indirectly should be able to traceback (by lot) to where they purchased and should ideally purchase from companies who can themselves traceback to the grower and field(s). Coolers and storage facilities are expected to have systems that are able to track product from shipping back through to receiving (and vice versa). [Recording batches of packaging is required for some products where packaging recalls might occur e.g. modified atmosphere packaging, juice bottles etc. Recording packaging batches is not required for packaging that is not usually the cause of a recall e.g. cardboard boxes.](#)

2.1.2 There shall be a written recall program. This should include basic recall procedures and responsibilities, current facility contact listing with alternates, out of hours contact numbers, description of Class I, II and III recalls and details of the coding system(s). There should be contact listings for suppliers and customers – if these listings are viewed as confidential, then there should be a referral to where these listings are maintained, in the recall procedure. Contact listings for and storage facilities might have no direct communications with suppliers and/or customers, but in any event, they should at least have contact listing for their clients.

2.1.3 A “mock” recall shall be performed at least annually. Documentation should include the date and time the mock recall was initiated, the scenario, the product chosen, amount of product produced, affected lot ID’s, date code(s), lot code(s), etc. amount of product located, and percentage located. Mock recall documentation should include copies of documentation that supports the traceback and notes of any “lessons learned”. The mock recall should be completed within two hours with 100% of chosen product located to the first external customer(s).

2.1.4 There shall be written procedures for employees to follow when regulatory agencies (e.g. FDA, USDA, OSHA, Health Department, etc.) inspect the facility. The procedures should include rules for accompanying inspectors, sampling protocol (i.e. duplicate samples) and company policy on taking photos. Key personnel, including receptionists should be aware of the policy.

2.1.5 There shall be a written glass policy, which should include:

- Where glass is prohibited and where glass is allowed.
- An overall statement of intent with respect to glass on site.
- If certain glass items are allowed, then a glass register should exist. Note the glass register should only list items that could not be replaced with a less dangerous material.
- Glass breakage procedure including requiring recording what happened, recording what happens to potentially affected product, recording future preventative actions and especially where to record the incident details e.g. in the NOCUA log.

Chemicals

2.2.1 Material Safety Data Sheets (MSDS) shall be available for all chemicals (e.g. pesticides, cleaning, maintenance, sanitizing, etc.) currently used in the facility. MSDS shall be located in the appropriate departments, accessible at all times, indexed and filed in an organized way for quick reference.

2.2.2 Specimen labels shall be available for all chemicals (e.g. pesticides, cleaning, maintenance, sanitizing, etc.) that are decanted out of their original containers (e.g. rodent bait, cleaning

chemicals, hand dip solutions, etc.). Specimen labels might be kept on file and/or be displayed in an accessible area in the plant, e.g. clipped to hose pipes. Not applicable if all chemicals are used in the presence of the full label on the container.

Chemical usage logs (chemical inventories) shall be on file and in use. Chemicals include cleaners and sanitizers, and chemicals such as chlorine for water flumes, hydrocoolers, etc.). The inventory must take into account the arrival of new stocks.

Pest Control

2.3.1 There shall be a documented pest control program in place. If performed in-house the pest-control operator or State equivalent must be licensed (if handling chemicals) If a service is contracted, the pest control contract service must be licensed, certified and insured. Copies of the service contract, insurance documentation and pest control licenses are required to be on site and up to date for auditing purposes. When certification legislation does not apply e.g. in certain countries, there must be evidence of on-going training.

2.3.2 There shall be a schematic drawing (trap map) on file, current and detailing internal and external traps. All devices (e.g. Ketch-Alls, bait stations, glue boards, insect attractant units) should be numbered and identified (differentiated) on the map. The map should be an accurate representation of the physical placements and be updated as necessary.

2.3.3 Service reports from the contract pest control company and/or complete inspection records if serviced in-house shall be available for review. Record shall include services performed, date of service, chemicals used (including EPA # if in the US), signs of activity and corrective actions.

Self Inspection

2.4.1 There shall be a system in place for dealing with customer and/or consumer complaints. Customer (buyer) complaints might take the form of rejection. Required documentation includes: -

- Date/Time of Complaint/Rejection,
- Who Made the Complaint,
- Contact Information,
- Product Description,
- Where the Product was Purchased,
- Amount of Product,
- Product Code/Date,
- Nature of Complaint,
- Corrective Actions,
- Corrective Actions Taken to Prevent Reoccurrence.

Where there are many (e.g. more than 100 in a year) complaints, a degree of analysis and review is expected.

If a corporate office/sales department handles complaints there should be a summary report communicated to relevant personnel, to indicate the types of complaints and frequencies.

2.4.2 Records of any prior regulatory inspections and/or contracted inspections company responses and remedial actions (date of response, action taken, and signature) shall be on file. Inspections include regulatory (Federal and State), Third Party (inc. last PrimusLabs.com audit) and Second Party (e.g. Buyers).

2.4.3 There shall be appropriate logs in use for all process monitoring activities. The records include corrective actions to be filled in when process is outside the established limits.

There shall be a log sheet for evaluating the hand and/or foot dip (where appropriate) stations. The log sheet should include target sanitizer concentration (ppm) and frequency of verification. Foot dips are required in fresh cut processing audits (see 1.4.15). If a packinghouse operation or a dry area processing plant elects to have foot dips, then required monitoring records should be kept.

2.4.4 Food handling departments shall be inspected daily before operation begins. This should be a start up check of all the potential issues as opposed to a repeat of the daily sanitation completion record. This should include: -

- Time of check and name of inspector.
- Examination of equipment to verify cleanliness.
- General housekeeping of storage and production areas.
- Checking that the production line is ready to start.
- Checking that all personnel meet GMP requirements.
- Corrective actions in case of non-compliance.

2.4.5 Equipment for monitoring purposes (e.g. scales, thermometers, metal detectors, ORP meters, pH meters, etc.) shall be calibrated regularly to ensure correct and accurate operation. These calibrations shall be documented.

2.4.7 There shall be program for periodic facility/GMP inspections and records shall be maintained along with corrective actions. These internal inspections shall occur at least monthly. In a large facility it may be necessary to divide the facility into smaller sections and inspect more frequently so that the entire facility will still be inspected monthly.

2.4.8 Incoming goods shall be inspected for quality, defects and food security. Sampling procedures shall be written and followed. Where issues are rare e.g. packaging, issues may be noted as deviation incidents and recorded as unusual occurrences. Product inspection data is not required if own product (e.g. in-house grown) is being packed.

2.4.9 There shall be written specifications detailing acceptable standards for raw produce materials, ingredients and packaging. Written specifications for products are not required if own product (e.g. in-house grown) is being packed.

2.4.10 There shall be a third party audit certificate(s) or letter(s) of guarantee from packaging and product suppliers to indicate that the material supplied meets agreed specifications. Letter(s) of guarantee for products are not required if own (e.g. in-house grown) product is being packed.

2.4.11 There shall be written records (separate log or noted on bills of lading, etc.) of incoming truck inspections. Designated personnel are responsible for inspecting the vehicles to ensure:

- Interior is clean, free from off-odors, pest free and in good condition (free from holes, etc.).
- Refrigerated vehicles are in compliance with specified temperatures.
- Damaged, dirty and infested transports are not unloaded until management approves acceptance or rejection. Disposition or acceptance of material is fully documented.

Not applicable if flatbeds are used. Truck cleaning certificates are acceptable for the sanitation section of the question but these must be for each load for brokered trucks and on a regularly frequency for in-house trucks. Even with certificates, the trucks must be checked for cleanliness. Packaging supply trucks can be recorded by exception or on the routine monitoring log.

2.4.12 There shall be a log or report detailing deviations or incidents. Unusual occurrences (e.g. foreign objects, chemical spills, rejected packaging, etc.) shall be detailed in this summary log along with corrective actions. This log is sometime referred to as a NUOCA Log (Notice of Unusual Occurrences and Corrective Actions Log).

2.4.13 There shall be records showing product final temperatures after processing and/or prior to dispatch.

Maintenance and Sanitation

2.5.1 There shall be a formal preventative maintenance program. The maintenance program should schedule routine inspections, lubrications, part replacements, etc. at appropriate frequencies (weekly, monthly, etc.). There should be preventative maintenance completion records.

2.5.2 There shall be a log for repairs/maintenance service orders/work orders and completion of work. May include: date/ time, targeted equipment/ area, reason for service required, who is requesting, who is being informed, observations; date & signature when repair is completed.

2.5.3 There shall be records of all maintenance work and signature of a designated employee to confirm that the equipment has been sanitized after maintenance work has been completed and before being used again. If the equipment has been worked on in the production area (as opposed to being transferred to the maintenance shop), then the area surrounding the recently maintained equipment should also be sanitized (records of this sanitation should be maintained).

2.5.4 There shall be a master sanitation program that covers the entire area of the facility including equipment. The schedule states what is to be cleaned and when (how often). Areas include where applicable, processing, packing, product storage, dry storage, waste areas, restrooms and break areas. Within these listings there should be details such as floors, walls, light covers, pipes, ceilings, named equipment and equipment parts and surfaces. Infrequent schedules e.g. weekly, monthly, quarterly, annually, etc. are required for several reasons e.g. cleaning areas and equipment that are not cleaned daily, using a different cleaning technique/chemical than what is used on a daily schedule and/or doing a more “in depth” clean on equipment.

2.5.5 There shall be written sanitation/cleaning procedures for all equipment and areas. These procedures are often referred to as Sanitation Standard Operating Procedures (SSOP's). Procedures should match details found on the master sanitation schedule. These procedures should include: -

- Frequency
- Safety precautions (tag outs, personnel safety with respect to chemicals (e.g. PPE) etc.)
- Detailed cleaning /sanitation steps (especially with respect rinsing off chemical and using terminal sanitizers)
- Chemicals (name, dilution and water requirements) and utensils used
- Responsible person
- Special instructions with respect to cleaning
- Logs that need to be filled out

2.5.6 There shall be sanitation logs that cover the entire area of the facility and equipment. These logs shall cover the operations noted of the master sanitation schedule. Logs should include:

- Date
- List of areas/equipment to be cleaned
- Individual accountability and sign-off for each task completed

2.5.7 There shall be a log that indicates that floor drains are cleaned on a daily basis in wet and fresh-cut areas; such as the master sanitation schedule, sanitation logs and/or pre-operation inspection log where daily cleaning of floors and drains is indicated. Wet storage areas benefit from daily cleaning. Dry packinghouse drains and dry storage should be cleaned at least weekly.

2.5.8 Records shall be available to show that cooling units are serviced and cleaned on a scheduled basis (at least annually).

Personnel

2.6.1 The company shall have a current list of the food safety committee members. The committee should be multidisciplinary. This committee may have joint responsibilities to general safety also. If an operation has a HACCP Plan, the HACCP team may also look after the Food Safety Issues.

2.6.2 There shall be logs and minutes/notes of meetings addressing food safety topics. Meetings should occur at least quarterly.

2.6.3 There shall be logs of orientation (new hire) training, with topics covered, trainer, materials used and materials given to new hires. Training materials given to employees must include a copy of the company personnel GMPs. GMP Training materials and presentations should be provided in the relevant language(s) of the workforce.

2.6.4 The company shall have logs of food safety training and related topics (must include GMPs) with topics covered, trainer and materials used/given. There shall be logs of employees who attend training

2.6.5 There shall be a procedure for documenting employee non-compliance/discipline and corrective actions.

Microbial Tests

2.7.1 Equipment microbial testing shall be required for products that are considered potentially ready-to-eat (items that can be eaten raw, items that might undergo a wash step, items that might be stored in high humidity cooling, including hydrocoolers and ice injectors) or where buyer requires equipment testing. Testing is done on a regular, scheduled basis. Not applicable for products that require cooking and/or have inedible skins e.g. potatoes, oranges, etc. If out of specification results are detected, then full details of corrective actions must be noted.

2.7.2 Facility microbial testing shall be required for products that are considered potentially ready-to-eat (items that can be eaten raw, items that might undergo a wash step, items that might be stored in high humidity cooling, including hydrocoolers and ice injectors) or where buyer requires equipment testing. Testing is done on a regular, scheduled basis. Not applicable for products that require cooking and/or have inedible skins e.g. potatoes, oranges, etc. If out of specification results are detected, then full details of corrective actions must be noted.

2.7.3 Product microbial testing shall be required for products that are considered ready-to-eat (e.g. fresh-cut items, produce consumed in a raw state and with the peel or skin) and may also have gone through a wash step. Other “known issue” items should also be tested e.g. cantaloupe, cilantro, spring onions, mushrooms and washed tomatoes. If out of specification results are detected, then full details of corrective actions must be noted.

2.7.4 There shall be an annual microbiological test on potable water used in the facility. The water sample must be taken from the operation (either by the company itself or the local water company). Water samples taken from the site take account for of sites piping, holding tanks etc. Results of water sample testing must meet the US EPA drinking water microbiological specification <http://www.epa.gov/safewater/mcl.html#mcls>. If out of specification results are detected, then full details of corrective actions must be noted.

2.7.5 There shall be a letter of guarantee and/or test results from the supplier(s) of ice, or of internal tests of ice manufactured or procured by the company. Results of ice sample testing must meet the US EPA drinking water microbiological specification <http://www.epa.gov/safewater/mcl.html#mcls>. If out of specification results are detected, then full details of corrective actions must be noted.

Temperature Controlled Storage & Distribution

2.8.1 For temperature controlled packing and/or processing areas there shall be temperature logs or recording thermometer printouts on file and signed by a supervisor on a daily basis. Automated probe measurements must be independent of the thermostat probe(s), unless there are more than three probes in a room for crosschecking. If recorded manually the log should note the time interval of readings taken.

2.8.2 For temperature controlled storage areas there shall be temperature logs or recording thermometer printouts on file and signed by a supervisor on a daily basis. Automated probe measurements must be independent of the thermostat probe(s), unless there are more than three probes in a room for crosschecking. If recorded manually the log should note the time interval of readings taken.

2.8.3 There shall be records of truck temperature checks (prior to loading). Refrigerated items should not be loaded on trucks operating outside of the required temperature range. Not applicable if products are not temperature controlled in transit e.g. onions.

2.8.4 There shall be sanitary condition logs for shipping trucks detailing cleanliness and/or any off-odors. Corrective actions shall be detailed. This may be indicated on the bill of lading. Truck cleaning certificates are acceptable for the sanitation section of the question but these must be for each load for brokered trucks and on a regularly frequency for in-house trucks. Even with certificates, the trucks must be checked for cleanliness.

2.8.5 Shipping logs shall be available and organized (either by date or any other filing system).

2.8.6 Procedures shall exist detailing the tagging and recording systems for controlling product that has been rejected or placed "on hold". The SOP should include details on how the affected product lot(s) is separated from other lots in terms of tagging systems and any other physical separation. The SOP should also note how the affected product is recorded in terms of why it was rejected and/or placed on hold, where the product is located, what will happen or what has happened to the product (re-work, disposal etc.) and any preventative actions arising from the rejection and/or on hold incident. Documents should show names of those staff placing product on hold and names of those responsible for releasing product from hold.

HACCP Program – Section 3

If a HACCP program is in place and/or is required by a buyer.

Management Support of HACCP

3.1.1 There shall be a group of people responsible for the development and maintenance of the HACCP program. Ideally, the group shall be comprised of individuals from different areas of the company such as maintenance, sanitation, QC, etc. One member of the team should be designated the HACCP Coordinator. If the company is too small to have a HACCP group, one individual should be designated as the HACCP coordinator. That individual will be responsible for the implementation and any changes or updates to the HACCP program.

3.1.2 All employees shall be trained to understand the principles of HACCP and the plan implemented in the facility. Training should be scheduled on a regular basis and documented. The training should be tailored to the people within the company. The HACCP coordinator and other key staff should either be formally trained e.g. a HACCP Alliance Course and/or be very experienced. Management, QA and CCP should have a thorough HACCP training (in-house or external). CCP operators should be specially trained for their function. All other site staff should receive basic overview training i.e. what is HACCP, the 7 principles and what are the CCP's on site. Basic training should be repeated at least annually. Basic training might form part of the new hire orientation package. Senior management should receive training (HACCP requires "buy in" from all levels).

3.1.3 All HACCP training shall be properly documented. Documentation should include date of training, time of training, topics covered, name of instructor and signature of all in attendance.

3.1.4 When any changes to the HACCP plan are made, the HACCP coordinator must inform all employees involved. Re-training or educational sessions may be necessary.

3.1.5 At a minimum, self-audits of the HACCP program should be done on a yearly basis. Self audits will ensure that the process flow, hazard analysis and HACCP chart reflect reality and that the program has captured any changes to the process (form of verification). Whenever changes are made to the program i.e. new equipment added to the facility, new critical control points added to the plan, new limits added, new packaging is required, etc., then the plan needs to be re-evaluated by a self-audit to make sure it is working properly (form of verification). Self-audits should be fully documented with corrective action taken

3.1.6 An individual (or group) shall be assigned the responsibility of receiving HACCP records daily, reviewing the records, noting discrepancies, and making sure that the records are stored in a secure place. Plans must be in place to ensure records are maintained when the responsible individual(s) are absent e.g. on vacation, sick leave, etc.

3.1.7 All HACCP records shall be maintained in a designated area where they can be readily retrieved. These records should be well organized.

3.1.8 All HACCP records shall be kept in a secured area. A locked cabinet or locked room is preferred with access to authorized individuals only.

3.1.9 All HACCP records shall be held for a minimum of one year regardless of the production item's shelf life. Any records required by law to be kept longer than one year should be kept the legally mandated period.

Review of the Written HACCP Plan

3.2.1 There shall be a product description for each product produced indicating the materials and raw ingredients, how the product is intended to be produced/processed, how the product is intended to be used by the customer (e.g. to be washed, peeled, cooked, etc.), shelf life, storage requirements and any potential risk associated with the product.

3.2.2 There shall be a flow chart for each process showing each step of the process and including any holding times, temperature regimes and tagging. Flow charts should be dated. The flow charts should cover all the products produced on site under the HACCP Program.

3.2.3 A detailed, documented hazard analysis for each process shall be conducted and documented. The hazard analysis should look at the severity and likelihood of any potential hazard that the process might create, and then decide if there is an adequate control step for this potential risk.

3.2.2 Critical control points (CCPs) shall be developed to control hazards identified in the hazard analysis step. CCPs should be developed with adequate detail and defined parameters. A CCP must be controllable and must be able to eliminate or reduce the risk to acceptable “safe” levels.

3.2.4 Monitoring requirements and frequencies shall be determined for the CCPs and include responsibilities for conducting the monitoring activity. Monitoring procedures shall be effective and frequent enough to demonstrate that the CCP is under control.

3.2.5 There shall be a clear, detailed action plan for operators to follow if the CCP limits are exceeded. It shall describe plans to adjust the process back into control and withhold out of compliance products if necessary. The corrective action details should note what happened, what corrective actions were carried out, including what happened to potentially affected product and also how the process was “repaired” or “amended” in order to get the process back to the required control level. The HACCP Plan Corrective Action sections should state where the corrective action details are to be recorded.

3.2.6 There shall be records developed for monitoring CCPs, identifying the CCP number and showing the CCP parameters. The records must match the details noted in the HACCP plan.

3.2.7 Specific responsibilities shall be assigned for the monitoring, recording and corrective actions of each CCP. The responsibilities should be indicated on the HACCP chart.

3.2.8 Verification plans and schedules shall be developed for each CCP. Verification activities include checking paperwork (CCP checks), checking signatures, testing, customer complaints and any other information that CCPs might help generate. The data from CCP verification and validation should be used to update the program along with the self audit and external audit findings.

Execution of the HACCP Plan on the Plant Floor

3.3.1 All documents noted in the HACCP plan shall be in place for real time monitoring of the CCPs.

3.3.2 CCP monitoring activities and frequencies shall be in compliance with those stated in the HACCP plan.

3.3.3 CCP operators shall be aware of basic HACCP principles: specifically CCPs in their area and their responsibilities for taking appropriate actions should limits be exceeded.

3.3.4 The use of “correction fluid” (white out”) shall not be permitted to make corrections on CCP records. Corrections should be made by crossing out so that the original information is still legible. The operator making the change should initial it.

3.3.5 CCP records shall be maintained in ink and signed by operators. Pencil must not be used. Operators must sign their work (the record should include a date).

3.3.6 Corrective actions shall be detailed in writing when the failure of a CCP occurs. The CCP failure shall be noted in the correct records, detailing what happened, when, what was done to correct the issue and if there were any preventative actions.

3.3.7 CCP records shall be reviewed and signed off daily by the quality control [supervisor or manager](#). Therefore records will have been signed off at least twice, once by the CCP operator and then signed again as a check.

Verification of the HACCP Plan

3.4.1 Verification, monitoring, feedback and other HACCP information from the HACCP program shall be reviewed and discussed at management level meetings with notes and documentation.

3.4.2 An action plan shall be created, followed and documented when there is a problem with the HACCP plan. Problems might be identified from the CCP verification programs e.g. paperwork checks, testing results, complaints etc. Problems might also be located when carrying out internal and external audits.

3.4.3 There shall be a self-audit program in place with an annual external audit of the HACCP program. This should include internal verification of the HACCP plan. Internal audits are covered by 3.1.5.

Additional Questions for Cooling/Cold Storage Audits

1.3.2 All product shall be stored at the correct temperatures. Products are stored in separate chambers if they require different optimum storage temperatures.

1.4.3 If re-work/ re-packaging occurs at the cooling/cold storage facility (e.g. damaged product from the field) reworked product must be handled properly, as per any product being packed in a packinghouse this includes facility and personnel GMP's. Reworking in Coolers and Cold Storage Facilities should be a rare occurrence. Examples of specific rework control include: -

- Packaging opened with clean knives.
- Employees emptying packaging are following proper GMP's (equivalent to packinghouse).
- Re-work area is meet's required facility GMP's (equivalent packinghouse).
- Outside of packaging does not touch the re-work as they being emptied.
- The traceback details are transferred correctly.

If re-work is actually being performed on a routine basis for whatever reason, then for auditing purposes, a Packinghouse Audit Template should be used.

Additional Question for Storage & Distribution Audits

1.3.2 All product shall be stored at the correct temperatures. Products are stored in separate chambers if they require different optimum storage temperatures.

Food Security Section – Section 4

Food security questions are currently for survey purposes only for now and do not effect the audit score. Food security questions shall be completed if there is a buyer involved or, if there is no buyer involved but the auditee would like the service.

Facility Security

4.1.1 The facility should be surrounded by a continuous security fence. The fence should be designed to exclude intruders e.g. height (maybe 6ft or greater), thick gauge wire and topped off with barbwire. The facility might use a brick wall perimeter and the top of the wall has barbed wire or an alternative deterrent.

The company should have printed material (educational) on food security i

4.1.2 The facility should have various security systems in place to prevent and deter intruders, as well as alert the staff to the presence an intruder. These may include swipe cards, keys, combination numbers and other locking devices and alarm systems. Security systems should be used correctly and part of facility discipline.

4.1.3 Cameras should be placed strategically to monitor key entrances and key areas of the facility. Cameras fitted with recording systems are ideal.

4.1.4 Security staff should be employed to provide a deterrent against and reaction to security issues. Security staff may check all incoming personnel and visitors. Security may be a random, roving type unit that may be on site permanently or when the site is closed.

4.1.5 All food items should be stored inside or within a secure compound.

4.1.6 All processing materials should be stored in secure areas with controlled access. Processing materials include sanitation chemicals, product-washing chemicals, product coatings etc. Empty containers should also be stored securely until they are either collected or disposed of properly.

4.1.7 All packaging material (cartons, wrap film, fruit cups, etc.) should be stored in secured areas with controlled access.

Employee Security

4.2.1 Background checks (e.g. social security numbers, INS details, previous job references, felony crime checks, etc.) should be conducted on critical personnel?

4.2.2 All personnel should be required to store "carry-in" material (including bags, purses, chill boxes etc.) in designated areas. These items should not be taken into the production and storage areas.

4.2.3 The company should provide secured storage for employees' carry-in material

4.2.4 Staff should attend either external or in-house training on food security issues. Records should be kept. Training might include checking raw materials, facility security, handling visitors etc. Training might also include formal Operational Risk Management Training.

4.2.5 The company should have a documented food security policy that outlines the operation security controls. These should include policies covering personnel, visitors, contractors, raw material receipt (product and packaging), trucks (incoming and outbound) etc. There might also be a requirement to ensure that suppliers have proper food security programs.

4.2.6 All employees should be issued non-reproducible identification badges with personal identification details linking them to the company. The ID's should have the employee's number, photo and position within the organization (without being potential product contaminants).

4.2.7 All visitors including contractors should be provided with identification badges that are valid only for the time that these visitors are on site. The identification cards should be collected when the visitors leave the site. Badge issue and return should be recorded, e.g. in the visitors sign in book. Ideally each badge should have a unique number and this number is recorded in the logbook

4.2.8 Visitors (including contractors) should be required to "sign in" and sign out" in a visitors logbook and should be issued with identification badges. Badge issue and return should be recorded, e.g. in the visitors sign in book. Contractors, whether long term or short term should also be covered by the site security procedures.

Chemical Security

4.3.1 Chemical usage logs and/or chemical inventories should be on file. Chemicals include cleaners and sanitizers, and chemical such as chlorine for water flumes, hydrocoolers, etc. The inventory must take into account the arrival of new stocks. If chemical use records are maintained, then an occasional inventory check will be required to reconcile the stock versus what has been used.

Testing Security

4.4.1 Water sources should be tested on a periodic basis. [The water sample should be taken from the operation \(either by the company itself or the local water company\)](#). Tests should be carried out to check to ensure that the water meets the full EPA requirements (see <http://www.epa.gov/safewater/mcl.html#mcls>) [including looking for microbial, chemical and heavy metal contaminants](#). If out of specification results are detected, then full details of corrective actions must be noted.

4.4.2 Packaging should either be tamper evident or tamper proof. Tamper systems could be sealed bags or security tape on boxes.

Transport Security

4.5.1 Seals are required and fitted to inbound trucks of raw material product and packaging. Seal numbers are recorded. [If locks are used, then this question is N/A.](#)

4.5.2 Seals should be fitted to outbound trucks of finished goods. Seal numbers are recorded. [If locks are used, then this question is N/A.](#)

4.5.3 Locked trucks should arrive at the auditee's facility, which are unlocked just prior to unloading. [If seals are used, then this question is N/A.](#)

4.5.4 Trucks should be locked after being loaded, before leaving the site. [If seals are used, then this question is N/A.](#)

4.5.5 Trucks should be fitted with tracking devices e.g. [Global Positioning Systems \(GPS\)](#) ideally. [If GPS is not used, then some sort of two way communication e.g cell phones.](#)

Miscellaneous Survey Questions – Section 5

Employing Minors

5.1.1 Under age employees (minors, children) should not be employed if below the National and/or State Legal Minimum Age. If minors are employed, then their employment must meet both Federal and State Laws in terms of types of work and hours spent working.

5.1.2 If Minors are employed records of hours of employment must meet National and/or State Laws (both in and out of school time)

5.1.3 If Minors are employed they should be prohibited from doing certain jobs restricted by law (e.g. restricted to light work, safe conditions, day shift).

Country of Origin Labeling

5.2.1 Correct country of origin labeling shall be indicated on retail product packaging i.e. bags, clamshells etc. Food service products are exempt. The new proposed rule includes indicating the USA as a county of origin. Note that marketing origin labels e.g. California Grown, Washington Apple etc. are not accepted as country of origin labeling.

5.2.2 Correct country of origin shall be indicated on the cartons i.e. the boxes, cartons, returnable plastic crates etc. that are used to carry the products (whether bulk product or bagged/prepacked product. Food service products are exempt.

5.2.3 Records shall show the country of origin of the product and help prove that the label of the finished cartons and bags are correct. Records that might prove country of origin labeling include delivery notes, production records and shipping manifests.

5.2.4 Adequate steps shall be taken in the storage and production process to ensure that there is no commingling of materials from different countries (unless product will be labeled as such). This includes ensuring that batches are processed separately and there is clear differentiation when switching batches with different countries of origin.

Allergens

5.3.1 If the production process includes the handling of allergen containing materials, then the allergen questions will be completed. **The key concerns are Wheat, Eggs, Milk, Soybeans, Crustaceans (Shellfish), Peanuts, Treenuts and Fish. Other allergens that would need investigating further are Sulfites and Artificial Color FDC N^o. 5.**

5.3.2 Allergen materials and allergen containing materials must be stored in a manner that avoids cross contaminating all other materials. Separated areas are ideal and never storing allergens above other materials is a must. Allergens should tagged as usual (rotation and lot coding), but also should be identified as allergens.

5.3.3 Ideally facilities shall have separate production line(s) for allergen containing ingredients. If no separate production line is used then there shall be written procedures to avoid allergen cross contamination. These procedures may include specific order of producing allergen containing products and special sanitation SOP's.

5.3.4 All utensils (including cleaning equipment, paddles, shovels etc.) and work in progress storage containers must be clearly identified for allergen use only in order to prevent allergen cross contamination

5.3.5 Rework of allergen containing products must be strictly controlled. Allergen rework product must be clearly labeled. Allergen rework must be stored separately to non allergen rework, raw materials and product. Allergen rework should only be used when a similar allergen containing product is being ran. Even the outside of allergen containing condiment packs might be a risk to the food e.g. romaine lettuce, that the condiment pack was touching and this food e.g. romaine lettuce should only be re-used for the allergen containing product. Like all rework, the traceability should be maintained which means that the use of rework materials is being properly recorded.

5.3.6 Employees shall be trained and aware of what allergens are, the effects of allergens on allergy sufferers, the actual allergens handled on site and the facility controls to prevent allergen cross contamination. Training should include personnel practices, like hand washing, changing protective garments and gloves etc., when moving around the production area. Key operators like warehouse personnel, production personnel, label designers etc. should receive specific training. Training must be recorded.

5.3.7 Allergen containing products should clearly show on the label the allergens that are associated with the product. If the allergens form part of condiment inclusion packs, these allergens should still be indicated on the main product label. If an operation is producing allergen containing products that will be used as an ingredient by a subsequent manufacturer, the documentation that goes with the product must underline the allergen contents and also ideally the bag and cartons should indicate the allergen contained within the product. If non-allergen containing products are produced on a site where allergens are used, the management must consider the chance of allergen cross contamination and if satisfactory controls to prevent such contamination are in place. If there are any doubts that the adequacy of these controls (GMP's), then the management should have considered using a "may contain" clause of the non-allergy containing products (this is a last resort and should not replace proper GMP's).