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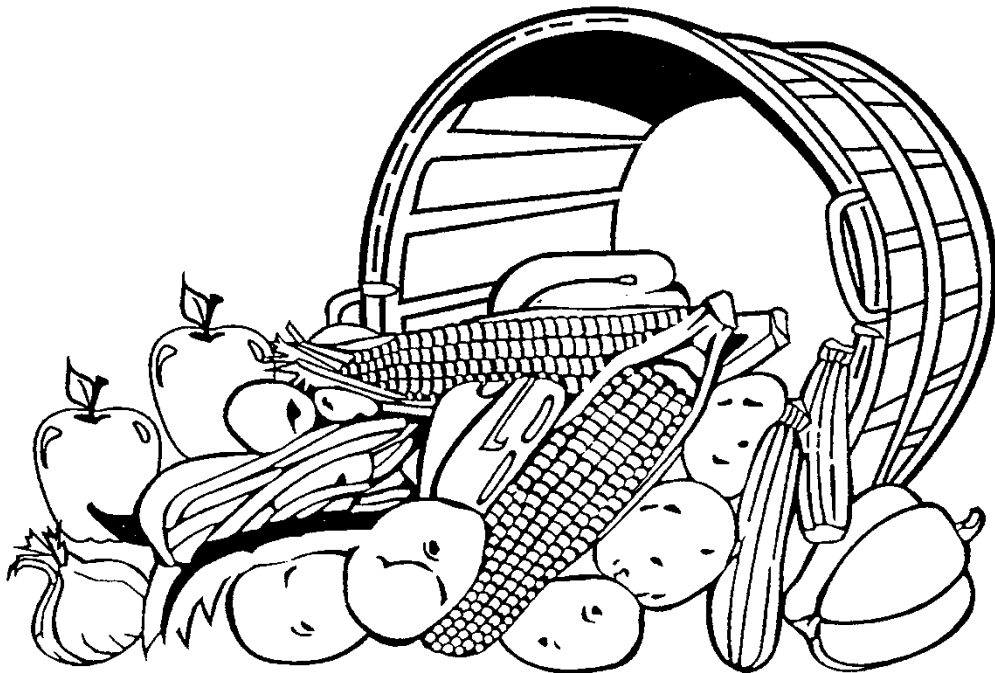
Fruit and
Vegetable
Programs

Fresh
Products
Branch

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Good Agricultural Practices and Good Handling Practices Audit Verification Program

Policy and Instructions



Audit Instructions for GAP & GHP

These audit instructions are specifically developed and designed by the Fresh Products Branch to assist officially licensed auditors in the interpretation and application of the Good Agricultural Practices & Good Handling Practices Audit Verification Program. These instructions do not specifically address the commodity specific audit checklists developed by the Fresh Products Branch. Additional training and instruction is required for commodity specific audits.

These instructions do not establish any substantial rule not legally authorized by official Branch Policy. This publication supersedes any previously issued auditing instructions.

If any questions arise that need further clarification, please contact your Federal Program Manager or the Audit Program Coordinator in Washington DC.

November 2009

******This publication may be not duplicated without authorization from USDA. ******

This handbook replaces instructions dated August 2007

Good Agricultural and Good Handling Practices Audit Verification Program

In October 1998, the U.S. Department of Agriculture and U.S. Food and Drug Administration jointly issued a guidance document for the fresh fruit and vegetable industry that provided general guidelines for reducing the possibility of contamination of fresh produce by microbial organisms. The document, *“Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables,”* provides discussion about high risk areas for contamination and how to avoid or reduce the possibility of such contamination. Shortly thereafter, many wholesale produce companies began requesting their suppliers to provide assurance that the supplier was following Good Agricultural Practices (GAP) and Good Handling Practices (GHP) that the document recommended.

As a result of requests from shippers and growers in various States to provide some type of service to satisfy the wholesalers’ needs, the Association of Fruit and Vegetable Inspection and Standardization Agencies (AFVISA) began investigating the possibility of providing a national audit service in cooperation with USDA to satisfy the shippers and growers needs. In August 2001, USDA approved the program and a draft auditor checklist. In January 2002, the USDA implemented the GAP&GHP audit verification program. Additional information and a copy of the current checklist may be found at www.ams.usda.gov/gapghp.

This program is an audit based service. It is provided in order to assess a company’s efforts to minimize the possibility of contamination of fresh fruits, vegetables and nuts by microbial pathogens. It does not assure that the product is free from microbial contamination. Audits are intended to occur on a scheduled basis at a minimum of once a year. The responsibility for continuing product safety and the continued observance of practices leading to a minimized possibility of microbial contamination rests with the company.

These instructions are specifically developed by the Fresh Products Branch to assist officially authorized auditors in the application of auditing principles and practices, the use of an official checklist and define GAP&GHP terms in order to conduct audits for GAP&GHP program compliance.

These instructions do not establish any rule or regulation.

The mission of the program and the intent of these instructions are to provide a uniformly applied national auditing program for the U.S. fresh produce industry for purposes of verification with GAP&GHP.

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AUDIT INSTRUCTIONS

GENERAL INFORMATION

The USDA Good Agricultural Practices and Good Handling Practices Audit Verification Program (GAP&GHP) is established for the fresh produce industry to verify good agricultural and good handling practices in the preparation of fresh produce for sale in national and international markets. This is an audit based program using a checklist developed and designed according to recommendations from *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables* (The Guide), commodity specific guidelines developed in conjunction with the Food and Drug Administration (FDA), and specific recommendations from the scientific and academic sources.

USDA recognized employees, either Federal or Federal-State licensees, must receive a minimum amount of approved auditor and GAP & GHP training in order to provide this service. This is discussed in Auditor Criteria section below.

The following pages provide a guide to auditor and auditing processes, completing the approved checklist and provide definitions for terms used. USDA authorized auditors must follow all safe food handling procedures or practices prescribed by the auditee.

AUDITOR CRITERIA

The Fresh Products Branch (FPB) shall follow the minimum auditor criteria as outlined by the USDA Agricultural Marketing Service (USDA-AMS) Industry Services Auditing and Accreditation Program (ISAAP). Auditor criteria are outlined in the Fresh Products Branch Directive 701.

GENERAL AUDIT POLICIES

All auditors shall have a clear understanding of all related Fresh Products Branch 700 series Directives and related Bulletins regarding the audit program. In order for an audit to be successful, it will be necessary for the audit team to physically visit the location while the farm/facility is in operation. This means for a farm audit, perform the audit while the crop is actively being grown, a field harvest/field harvesting activities audit shall be performed while the product is being harvested, etc. A desk audit can be used in order for the audit team to become more familiar with the farm/operations' food safety plan. Also it can be used to gather basic information required in order to complete the audit. However, a desk audit does not take the place of the physical visit. The physical visit while the farm/facility is in operation allows the audit team to verify and witness that GAP & GHP are being followed throughout the growing/harvesting/packing operation.

Under no circumstances will USDA perform a desk audit of another auditing firm's results in order to verify conformance to the USDA audit checklist.

Depending on the operation and the scope of the audit, it may be necessary to visit the facility several times. One visit to perform the farm audit, and another visit to perform the packing house audit.

IMPARTIALITY OF AUDITORS

It is the policy of the USDA, Agricultural Marketing Service, Fresh Products Branch that licensed auditors not provide any type of consulting to potential auditees. Specifically, auditors shall not give advice to the auditee on how to conform to any of the specific questions on the audit checklist. Instead auditors shall direct potential auditees to the local cooperative extension agent, university food scientist, or other technical experts in the field of horticultural production/food safety.

This policy is in place to maintain the neutral, unbiased, impartial nature of the services provided by the Fresh Products Branch and the Federal – State Inspection Service, and to avoid any potential conflicts of interest.

AUDIT PHASES

A GAP&GHP audit is made up of several phases: planning and preparation (away from the audit site); an opening meeting; the audit; audit team caucus, an exit meeting; follow-up audit, if necessary, and the unannounced surveillance review. Various activities take place during each of these phases.

Planning, Preparation and Conducting the Audit

Audits must be prepared and planned for in advance. Once assigned by audit management, the lead auditor and members of the audit team should begin preparing for the audit. This phase can take up to several hours depending on the complexity of the audit and the facility. It will lessen in time as auditors become more familiar with their duties and the facility to be audited. Planning and preparation for the upcoming audit should include such items as reviewing the GAP&GHP specifications and the participants written food safety manual, assigning various tasks to the audit team members (including the lead auditor), and specific areas to be audited within the facility.

An effective tool when planning an audit is to review past audit history of the participant. Exercise caution, however, to not prejudge or form bias toward the participant.

The audit plan must be based on the written food safety plan developed and implemented by the auditee, as well as knowledge of previous (past audits) or current problems and corrective actions. This knowledge is vital for identifying the expertise needed by the auditor(s) and for preparing the audit criteria.

Applicable requirements in the auditee's food safety plan, procedural manuals, work instructions, and any auditee generated-specification should be identified. This information should be compared to ensure that there are no obvious conflicts.

A thorough understanding of the audit history is important to the planning and development of the audit. Past problem areas should be evaluated to ensure that corrective action was effective in preventing another occurrence.

Initial Audit

The initial audit is the annual announced audit that verifies the farm/facilities compliance with the requirements of the USDA Voluntary GAP&GHP Audit Verification Program. Prior to performing the initial audit, the lead auditor should verify there is a signed contract between the auditee and the Fresh Products Branch as outlined in FPB Directive 625.

After the scope of the audit has been established to encompass specific areas, development of an organized audit plan should proceed. Organization of the specific audit plan should follow a systematic audit path. A predetermined plan related to the checklist should be established and used to formulate the auditor's opinions and judgments. An audit should start with planned objective requirements following a thorough review of applicable procedures, specifications, and regulations. This is accomplished in the planning and preparation phase for each audit.

Opening Meeting

Upon entering the facility, the audit team should make their presence known to the appropriate staff person. The identity of this individual should be apparent through the audit request form FV-237a, review of the food safety plan or previous audit reports. It will likely be the Food Safety Manager, Farm Manager or Farm/Facility Owner.

The lead auditor will conduct the opening meeting. The time necessary to conduct a proper opening meeting will vary depending on the scope of the audit and the familiarity of the auditee with the GAP&GHP program. The lead auditor will reiterate the audit purpose, inform the participant's management of the audit scope, introduce audit team members, request pertinent records/documentation, and inquires about the availability of a participant-provided escort. It is also at this time that the lead auditor will request a private meeting area for the audit team and access to telephone and copier services at the facility. The lead auditor should also establish who the responsible person(s) at the farm/facility is to ensure all necessary personnel are available so they may report the audit findings at the exit meeting.

Audit Implementation

The actual audit may take several hours or longer, depending on the complexity of the audit and the facility. Auditors need to know their particular assignment and perform their assigned duties; keep notes, make observations, examine product, etc. Each auditor should have note paper and a copy of an audit checklist for reference. The

team should also have access to a controlled copy of the auditee's implemented food safety plan. Details of an observation or finding should always be documented at the time of discovery. Before leaving the area, auditors should ask the person(s) responsible in the area of concern to review and confirm the finding whenever a non-conformity is observed.

Another important part of audit implementation is process verification. This consists of asking questions and observing the practices of the auditee's employees or contracted staff to determine if their actions are in compliance with the specified requirements. Observations should not be limited to items on the checklist; they should also include areas of consideration such as work site, rules as applied to employees, safety regulations, etc. If special training, education, experience, or certification is required, the status of these must be verified for each applicable employee.

At the completion of this audit phase, the audit team shall reconvene for a team caucus. The purpose is to discuss audit findings, determine severity of non-conformities, make supporting telephone calls, identify necessary documentation, write the audit report and make copies of the report and all supporting documentation.

The product of an audit is the written report. The completed checklist, scoresheet and corrective action reports are all part of the audit report. The audit report shall include an explanation to all questions for which a NO or N/A answer was noted in the checklist. If applicable, the audit team shall initiate a corrective action report. (For specific instructions, refer to the NON-CONFORMITY and CORRECTIVE ACTION POLICY section). A copy of the audit report shall be given to the auditee upon completion of the audit at the exit meeting. This multi-part form provides documentation that highlights the questions that were answered NO or N/A, and affords the auditee an opportunity to address them at the exit meeting.

Exit Meeting

The exit meeting is generally the last phase of the audit, with the duration varying due to the complexity of the facility, the audit and the findings. The primary purpose of the audit is to verify compliance with the criteria in the audit checklist and auditee's food safety plan, and highlight the need for corrective action on non-conformities revealed during the audit. In this phase, the lead auditor discusses the audit, presents the findings, issues the audit report plus any supporting documents and supplemental records, and allows the auditee an opportunity to address corrective actions, if non-conformities exist. At the discretion of the lead auditor, individual audit team members may present issues that they noted during the audit. The exit meeting provides the auditee an opportunity to ask questions about any aspect of the audit. Information discussed during this meeting may also have a bearing on the auditee's response to the non-conformity report.

A responsible person at the facility is provided a copy of the audit report and all associated paperwork. If a corrective action report is initiated by the auditor, it shall be reviewed and provided to the responsible party. (For specific instructions, refer to the

NON-CONFORMITY and CORRECTIVE ACTION POLICY section.) It is entirely the responsibility of the auditee to formulate and implement a corrective action plan.

The exit meeting also provides an opportunity for the lead auditor to enquire how long the auditee will be in operation. Based on the outcome of the audit, the lead auditor shall begin making preparations for a follow-up or unannounced surveillance review.

FOLLOW-UP AUDIT

A follow-up audit is performed if either the farm/facility's initial audit or unannounced surveillance review does not meet the minimum passing score or receives an automatic unsatisfactory, and the auditee wants to continue on the GAP&GHP program. The follow-up audit must include all audit phases, such as planning and preparation, opening and closing meeting, etc. Preparation for a follow-up audit would include a review of the previous audit report and corrective action report. It is important that a corrective action report has been submitted and there has been adequate time to implement it before scheduling a Follow-up audit. (For specific instructions, refer to the NON-CONFORMITY and CORRECTIVE ACTION POLICY section.)

Determining which scopes will be audited on the follow-up audit will depend on why the initial or unannounced audit failed, either by automatic unsatisfactory or below the minimum passing score.

- The follow-up audit must consist of all scopes originally requested when the audit fails due to an automatic unsatisfactory.
- When the audit fails to meet the minimum passing score for one or more scopes, only those scopes which failed and the General section must be completed on the follow-up audit.

UNANNOUNCED SURVEILLANCE REVIEW

An unannounced surveillance review is performed to verify that a farm/facility is still in conformance with the requirements of the USDA GAP&GHP program. The audit is conducted at some point after the auditee has successfully passed an initial or follow-up audit.

Procedures for conducting the unannounced surveillance review are outlined in the Fresh Products Branch Directive 702.

NON-CONFORMITY and CORRECTIVE ACTION POLICY

A Corrective Action Report (CAR) is required for any GAP&GHP audit that fails because of non-conformities due to a specific "automatic unsatisfactory" or because a particular scope fails to meet the minimum passing score. This report must be submitted to the

lead auditor or State audit program supervisor prior to a Federal or Federal-State auditor conducting a follow up audit of the farm/facility.

Observing an Automatic Unsatisfactory

When an “automatic unsatisfactory” is observed on an audit, the auditor shall write a detailed observation of the practice or procedure that caused the failure, including time, location, individual who witnessed it and the specific question or item that was noted as a non-conformity. The observation causing the failure shall be reported verbally and in writing to the person who oversees the Food Safety Program for the auditee.

The same procedure shall be followed when a particular scope fails to meet the minimum passing score, i.e., a corrective action report must be completed for the non-conformities noted.

Evaluating Corrective Actions

When the lead auditor or State audit program supervisor receives the corrective action report from the auditee, it should be evaluated for the following items (not all may apply for every non-conformity):

- Short Term Corrective Actions – Does it include the details of the failures(s) and an immediate solution to the issue? Does it show who at the farm/facility is responsible for verifying the corrective action(s) has been implemented? Does it appear to be a reasonable solution to the problem; does the corrective action conform to policies or Standard Operating Procedures (SOP’s) listed in their food safety plan?
- Root Cause Analysis – When necessary, does it include long term actions needed to address the issue? Usually a root cause analysis requires a change in SOP’s or a policy of the food safety plan. Has this been included?

When the corrective action report has been reviewed and the actions taken appear to be reasonable and appropriate, the lead auditor or State audit program supervisor will notify the auditee that the corrective actions were reviewed and will be verified during the follow-up audit. If however, the actions seem lacking or do not address the issue, notify the auditee and request that they review the corrective actions again, revise and resubmit for approval. It is important to remember that the corrective actions are not approved as effective until they are verified during the follow-up audit. If there are questions regarding evaluating corrective action reports, contact your Federal Program Manager or the Audit Program Coordinator (APC) in Washington DC.

Verifying Corrective Actions

During the follow-up audit of the farm/facility, the audit team must review the results of the corrective action plan to determine that the actions were implemented and that they achieved the desired results. The audit team should verify the corrective actions through the use of observation, records, and document reviews. Follow-up audits

should not be performed the same day as the initial audit. Auditors must allow sufficient time for corrective actions to be implemented.

PROCESSING AUDIT SCORESHEET

Scoresheet Information

Auditors should take care to write all information on the scoresheet clearly and correctly. The same scoresheet will be used to document scopes completed at a later date and to document unannounced reviews. This will ensure that the contact information remains consistent. Errors should be corrected with a single line through the error and initialed.

- The Facility name shall be legibly recorded as the legal business name the auditee wants listed on the certificate and website. In case of cooperatives or similar operations examples would be:
ABC Produce – XYZ Farms
Rock Family Farm, a Member of Good Foods Cooperative.
- The address shall be listed as the legal main address for the farm/facility. Any other farm or packing locations that are covered by the audit shall be listed under the “legal description” line of the checklist.
- The appropriate blocks of the “Scopes Requested” column should be marked. This should be confirmed with the Facility Representative before the audit begins and during the opening meeting.
- The Facility Representative should sign the scoresheet after all scopes applied for have been completed.

Audit Scopes Performed During the Same Time Period

The auditors shall fill out the audit checklist and scoresheet according to current instructions. The “All Scopes Completed” block in the bottom right corner of the scoresheet shall be checked only after all scopes applied for in the original request have been completed. The checklist and scoresheet shall be forwarded to the appropriate reviewing official.

- The reviewing official will review, sign and forward the scoresheet to the Branch’s Audit Program Coordinator.
- A certificate will be generated only when a signed scoresheet is received in Headquarters with the “All Scopes Completed” block checked.
- The information will be posted to the USDA website.

Audit Scopes Performed During Different time Periods

- A scope that has been requested on the original application (and checked on the scoresheet) but is audited on a later date will show the scores and date passed/failed on the original scoresheet.

- The “Date and Time Audit Began” shall be the date and time of the first visit and opening meeting. The “Date and Time Audit Completed” shall be when all requested scopes have been completed.
- The auditor must assess the General Questions each time a scope is audited at the farm/facility. The auditee must always pass the General Questions in order to pass any individual scope. EXCEPTION: If Part 7 is performed as standalone audit, then the General Questions do not apply. When audit scopes are completed on different dates, the general questions need to be completed for that scope(s) and the auditor shall record the date in the column on the scoresheet labeled “General Questions.”
- Once the auditor fills out the checklist and scoresheet for the scopes covered for that date, it shall be forwarded to the appropriate reviewing official. The reviewing official will review the scope(s) audited and initial and date the appropriate scope(s) in the column labeled “Reviewing Official,” but will not sign the scoresheet until all scopes requested have been completed. The initialed scoresheet will be returned to the lead auditor and forwarded to APC for processing and posting to the USDA website. A certificate will not be generated until all scopes are completed.
- This process shall be repeated until all requested scopes have been audited. The information will be posted to the USDA website as it is received by the APC; however, a certificate will only be issued after all the scopes requested are audited and the scoresheet is received with the “All Scopes Completed” block checked.
- If for any reason the information listed on the scoresheet has changed from the time of the initial audit, such as company name, address, commodities covered by the audit etc., a separate attachment shall be sent in with the scoresheet explaining why a change is being made.

CHARGING FEES FOR AUDITS

Hourly Fee

Effective October 1, 2008, a uniform fee for Fruit and Vegetable audit, survey and verification services was established by AMS Fruit and Vegetable Programs. Fees are charged at the established Federal rate unless a different fee has been established by special agreement. State supervisors shall make Federal/State licensees aware of any special agreements. Federal Employees shall charge the established Federal rate regardless of where the audit is performed. The current audit fee is \$92.00 per hour per auditor assigned to perform the audit.

The hourly fee covers all travel time, preparation time and audit time for each auditor participating in the audit. The fee is intended to cover mileage, per diem and lodging costs. When audits are performed within the continental United States, there should be no additional charges. Follow-up audits performed due to failure are considered new

audits and the hourly fee should be applied similarly. Overtime may be charged at an additional rate of one-half (1/2) the hourly rate when overtime is incurred on site performing an audit. Overtime should not be charged for travel time. For services performed outside of the Continental United States, the fee will be the standard hourly fee plus all associated costs. This shall include travel and per diem, sufficient to recover the costs for delivering these services.

Administrative Fee

Fresh Products Branch policy requires an Administrative Fee for GAP & GHP audits In addition to the hourly fee. The administrative fee is charged to cover the costs incurred by the FPB in reviewing the audit, issuing and delivering the certificate, posting the audit results to the USDA website and maintaining the audit database. The administrative fee shall be charged on an annual basis for each audit requested regardless of the outcome of the audit. Do not charge an additional administrative fee for unannounced surveillance reviews.

For example, in instances where an audit is split up by scope over several different dates, the administrative fee will only be charged when all scopes requested have been completed and the audit scoresheet is submitted with the “all scopes completed” box marked. However, if the auditee requests additional scopes after the initial scopes have been completed, this is considered a new audit and a new administrative fee will be charged. The current administrative fee is \$50.00.

APPEALS, COMPLAINTS & DISPUTES

The Fresh Products Branch policy regarding appeals, complaints and dispute procedures are outlined in the Fresh Products Branch Directive 703. These policies are based on AMS Industry Services Audit and Accreditation Programs (ISSAP) guidelines outlined in document AMS 2 Section 7.

AUDIT SCOPE

The auditee shall designate which scopes of the checklist shall be audited prior to the audit date. However, it may be helpful for the field office or lead auditor taking the request to discuss the purpose of the audit in order to assist the auditee in choosing the correct sections. For example, there are specific sections that the USDA Commodity Procurement Branch and the Food Quality Assurance Section (FQAS) requires before it will accept product into the domestic feeding programs. Additionally, there is a client specific audit checklist used on audits performed for Sysco Corporation. It is important that the auditor verify before the audit which checklist is to be used.

Generally a GAP audit consists of Parts 1 and 2, while a GHP audit consists of Parts 3 and 4. A wholesale distribution center or terminal warehouse is covered for GHP by Part 6.

AUDIT DEFINITIONS

The following definitions for GAP & GHP terms are from various sources and are provided to assist auditors in completing independent agricultural program reviews.

Accredited	That which is formal and/or recognized.
Adequate	That which is sufficient to meet a specific requirement in keeping with good agricultural and/or handling practices.
Agricultural Water	Water used in the growing environment (for example, field, vineyard, or orchard) for agronomic reasons. <i>It includes water used for irrigation, transpiration control (cooling), frost protection, or as a carrier for fertilizers and pesticides. Occasionally a more specific term may be used, such as "irrigation water." Typical sources of agricultural water include flowing surface waters from rivers, streams, irrigation ditches or open canals; impoundments (such as ponds, reservoirs, and lakes), wells, and municipal supplies.</i>
Clean	Surfaces are washed, rinsed and visually free of dust, dirt, food residues, trash and other debris.
Cold Chain	The maintenance of proper cooling temperatures throughout the food system (farm to fork) for fruits and vegetables to assure product safety and quality.
Composted Manure	A managed process in which animal manure is digested aerobically or anaerobically by microbial action, or exposed to documented minimum time/temperature requirements.
Contaminate	To transfer impurities or harmful microorganisms to food surfaces or water.
Control	(a) To manage the conditions of an operation in order to be consistent with established criteria, and (b) To follow correct procedures and meet established criteria.
Control Measure	Any action or activity that can be used to prevent, reduce, or eliminate a microbiological hazard.
Documentation	A written procedure or record of a task being completed.

Facility	The buildings and other physical structures used for or in connection with the harvesting, washing, sorting, storage, packaging, labeling, holding, or transport of fresh produce.
Food-Contact Surfaces	Those surfaces that contact fresh produce and those surfaces from which drainage onto the produce or onto surfaces that contact the produce may occur during the normal course of operations. <i>“Food-contact surfaces” includes equipment, such as containers and conveyor belts that contact fresh produce, used in harvesting, post harvesting, and packing operations. It would not include tractors, forklifts, hand trucks, pallets, etc., that are used for handling or storing large quantities of contained or packed fresh produce and that do not come into actual contact with the food.</i>
Food Safety Plan	A documented set of policies, procedures, and guidelines that a farm/facility implements in order to meet the objectives of minimizing microbial hazards of fresh fruits, vegetables, and other specialty crops. A food safety plan is written and developed after a hazard analysis of the operation has been performed. The known risks are then managed by the implementation of policies and procedures that mitigate the hazards.
Fresh fruits and vegetables (as defined by The Guide)	Fresh produce that is likely to be sold to consumers in an unprocessed or minimally processed (i.e., raw) form. <i>Fresh produce may be intact, such as strawberries, whole carrots, radishes, and fresh market tomatoes, or cut during harvesting, such as celery, broccoli, and cauliflower. The guidance in this document is also applicable to “fresh cut” produce, such as pre-cut, packaged, ready-to-eat salad mixes. However, some fresh produce specialty items, such as fresh cut produce, may be subject to additional processing steps and/or handling that may warrant consideration of specific good manufacturing practices in addition to the good agricultural and management practices covered in this guidance document.</i>

Good Agricultural Practices (GAPs)	The basic environmental and operational conditions that is necessary for the production of safe, wholesome fruits and vegetables.
Good Management Practices or Good Handling Practices (GHPs)	General practices to reduce microbial food safety hazards. <i>The term may include both “good agricultural practices” used in growing, harvesting, sorting, packing, and storage operations and “good handling practices” used in sorting, packing, storage, and transportation operations.</i>
Good Manufacturing Practices (GMP)	General practices used in sorting, packing, storage and transportation of manufactured products. <i>Fresh fruits and vegetables are not considered a manufactured product, however, minimally processed fruits and vegetables (fresh-cut) and nuts are considered manufactured. In general, GMP’s are mandated and are a part of Section 21 of the Code of Federal Regulations (21 CFR) established by the Food and Drug Administration (FDA).</i>
Harvesting Zone	The area where food products grow and where harvesting occurs. <i>This would include the area under trees and vines or in the rows where crops are grown.</i>
Lot	The food produced during a period of time indicated by a specific code.
Microbial Hazard	Occurrence of a microorganism that has the potential to cause illness or injury.
Microbially Safe Water	Agricultural water which meets the microbial requirements of the EPA drinking water standards. <i>This water is not to be used for hand washing or drinking purposes. These uses must use potable water.</i>
Microorganisms	Yeasts, molds, bacteria, protozoa, helminthes (worms), and viruses. <i>Occasionally, the term “microbe” or “microbial” is used instead of the term “microorganism.”</i>

Municipal Biosolids (Biosolids)	The by-product of human waste treatment by local government that may be used as fertilizer or as a soil amendment.
Nonpotable Water	Water that is not safe to drink. <i>Nonpotable sources of water may include lakes, ponds, rivers, and stream water that has been polluted by human sewage or animal waste runoff, or contaminated with pest-control chemical runoff from agricultural fields or residential lawns.</i>
Nonwater Carriage Toilet Facility	A toilet facility not connected to a sewer.
Operation	A facility with buildings pertinent to receiving, handling, packing or holding food items or a field location where food handling activities such as harvesting, loading or packing food items occurs. <i>This may also include cooling, icing, sorting or shelling (nuts). See Wholesale Distribution Center.</i>
Operator	The person or persons who have day-to-day responsibility for the production, harvesting, washing, sorting, cooling, packaging, shipping, or transportation of fresh fruits and vegetables, and responsibility for management of all employees who are involved in each of these activities.
Pathogen	A microorganism capable of causing disease or injury.
Personal Service Room	A room used for activities not directly connected with the production or service function performed by the establishment. <i>Such activities include, but are not limited to, first-aid, medical services, dressing, showering, toilet use, washing, and eating.</i>
Pest	Pest refers to any animal or insect of public health importance including, but not limited to, birds, rodents, cockroaches, flies, and larvae that may carry pathogens that can contaminate food.
pH (Acidity/Alkalinity)	pH is the measure of the acidity or alkalinity in a food product. <i>It is expressed on a scale from 0 to 14, with 7 being neutral. Below pH 7 is considered acid (e.g., citrus fruits) while above pH 7 is defined as alkaline (e.g., peas and corn).</i>

Plant	<i>The building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.</i>
Potable Water	<ul style="list-style-type: none"> • <i>Clean water that is safe to drink;</i> • <i>Water which meets the quality standards prescribed in the U.S. Public Health Service Drinking Water Standards, published in 42 CFR part 72, or water which is approved for drinking purposes by the State or local authority having jurisdiction.</i> <p><i>NOTE: In the context of reducing microbial contamination, it is understood that water must be within the limits of acceptable microbial populations. The EPA ‘Total Coliform Rule’ calls for water tests showing an absence of total coliforms including E. coli. However, the water may contain or be treated with other chemicals or additives that would help to reduce any microbes introduced during the produce packing or washing process.</i></p> <p>For more information see: http://www.epa.gov/safewater/disinfection/tcr/pdfs/qrg_tcr_v11.pdf</p>
Processing Water	<i>Water used for post-harvest treatment of produce, such as washing, cooling, waxing, and product transport.</i>
Product Flow Zone	<i>The area through which food products pass during the packing and storage processes. This would include conveyors and overhead areas where product is moved to and/or stored.</i>
Quality Control Operation	<i>A planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the Act (Section 201 of the Federal Food, Drug, and Cosmetic Act).</i>
Raw Manure	<i>Manure is considered raw unless it can be documented the manure has reached designated minimum time and temperature as defined by a process authority, which may include but not limited to; extension specialists, university researchers or regulatory personnel. Aged manure shall be considered as raw manure because there is no documentation that it was exposed to the minimum time/temperature requirements.</i>

Rinsing	<i>Removal of residues, soil, grease, soap, and detergents from surfaces by flushing with potable water.</i>
Risk Assessment	<i>The overall process of identifying all the risks and assessing the potential impact of each risk.</i>
Sanitize	<i>To treat clean produce by a process that is effective in destroying or substantially reducing the numbers of microorganisms of public health concern, as well as other undesirable microorganisms, without adversely affecting the quality of the product or its safety for the consumer.</i>
Sanitize (food contact surfaces)	<i>To adequately treat clean food contact surfaces by a process that is effective in destroying or substantially reducing the numbers of microorganisms of public health concern, as well as other undesirable microorganisms, without adversely affecting the quality of the involved product or its safety for the consumer. It means the application of cumulative heat or chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, is sufficient to reduce populations of representative microorganisms by 5 log or 99.999%.</i>
Sanitizer	<i>A chemical compound designed to kill microorganisms. Two of the most commonly used sanitizers are chlorine bleach and quaternary ammonium compounds (“quats”). A sanitizer solution is made by mixing a small, measured amount of the sanitizer with potable water according to the directions given by the manufacturer or by agencies that deal with farms and food.</i>
Shall	<i>Used to state mandatory requirements.</i>
Should	<i>Used to state recommended or advisory procedures or identify recommended equipment.</i>
Source water	<i>The origin of the water being used in the operation. (Municipal, well, stream, pond, etc.)</i>
Supplier	<i>The source of the product. This includes any intermediary handlers that have or had the produce in their physical possession. It does not include brokers or commercial transporters.</i>
Terminal Warehouse	<i>See Wholesale Distribution Center.</i>

Terminal Warehouse Receiver	A warehouse in a Wholesale Distribution Center that receives produce or other produce related food items from a shipping area or from another produce warehouse. <i>This would include domestic and imported products.</i>
Toilet Facility	A fixture maintained within a toilet room for the purpose of defecation or urination, or both.
Toilet Room	A room maintained within or on the premises of any place of employment, containing toilet facilities for use by employees.
Traceback	The ability to trace a fruit or vegetable back to its field of origin. A common practice used by health officials to investigate food borne illness outbreaks.
Transporter	The operator of a conveyance such as a truck, railcar, vessel, or aircraft used to transport fresh produce from grower to market.
Well Head	<ol style="list-style-type: none"> 1. The part of a water well that is present at the surface. 2. Any and all components of a wellhead and related equipment from the top of the outermost casing string (the casing bowl connection) up to but excluding the flow line valve.
Well Head Protection Area	<ol style="list-style-type: none"> 1. The surface and subsurface area surrounding water wells. 2. An area declared by an official entity consisting of a designated radial setback distance around a potable water well where ground water is provided the most stringent protection measures to protect the ground water source for potable water well and includes the surface and subsurface area surrounding the well. 3. The surface and subsurface area surrounding a water well, well field or spring supplying a public water system, through which contaminants are reasonably likely to move toward and reach such water well, well field or spring.
Wholesale Distribution Center or Terminal Warehouse	Wholesale Distribution Centers or Terminal Warehouses are generally located away from the packing house or production area. These may be located near a large city or may be located at a "Port of Entry" to the US for storage prior to entering the U.S. marketing channels. Initial packing or storage immediately after packing does not usually occur at these locations. However, repacking of previously packed product may occur.

SCORING GUIDELINES

All questions covered by the scope of the audit shall be answered by the auditor as either YES, NO, or N/A. **With the exception of the client requested checklist Part 7, in no case shall partial points be awarded for a partially completed or minimally acceptable procedure.**

Identifying a Question As N/A

Because the USDA checklist is generic that can be used for any commodity and operation, there may be situations where a particular question does not apply to the specific operation being audited. If the question is “not applicable” (N/A) to the situation, then “N/A” may be used. In such situations auditors must provide a brief explanation of the details as to why the “N/A” designation was used for each individual question in the comments section. There are questions throughout the checklist which cannot be answered as “N/A” and are indicated as such on the checklist.

Care must be used to not overuse “N/A” throughout the checklist. For clarification regarding the use or preventing the overuse of “N/A,” auditors should review the situation with their Federal Program Manager or the Field Operations Section.

Checklist Questions Requiring Documentation

Where documentation is required, as indicated by a bold type “**D**,” “**R**,” or “**P**” in the *Doc* Column, auditors must ask for and review the requested documentation. When a question is identified as needing documentation, the auditor should review written company procedures or policies within the company’s Food Safety Plan and the records maintained as evidence of the procedure or policy being performed. **Procedures** show what will be done. **Records** show that the process has been completed. In some instances, the documentation requirement may also call for a review of records, checklists, and/or work/service logs. A record is the written company verification of the task being completed.

A “**D**” indicates that a document(s) is required to show conformance to the question. A document may be a combination of standard operating procedures outlining company policy as well as a record indicating that a particular action was taken. A “**R**” indicates that a record is required to be kept showing an action was taken. A “**P**” indicates that a policy/standard operating procedure (SOP) must be documented in the food safety plan in order to show conformance to the question.

Review of Records

It is important to remember that auditors may have to review records to verify a particular question, even though documentation is not indicated as required. The majority of questions identified with a “D,” “R,” or “P” are identified as such to remind auditors to review policies and documented procedures established by the organization.

As you review this handbook, you will notice that particular questions have been designated (in the handbook) to help auditors identify which questions they should review; either policy manuals, records, or both.

For example:

- **Review company policies; documented procedures.** This question has been identified to remind the auditor to review the organization’s policies/documented procedures explaining what the company’s policies are for specific situations, current work instructions, etc.
- **Review records/schedules/checklists.** This question has been identified to remind the auditor to review the organization’s records (schedules, work logs, checklists, service records, billing forms, etc.) to verify that specific situations are being adhered to regarding the company’s policies. The additional purpose is to assist the auditor in verification of answering YES to particular questions as an additional form of verification.
- **Review company policies, standard operating procedures (SOPs) and review records.** This question has been identified to remind the auditor that this particular question requires the verification of both a written policy and a review of records verifying adherence.

Erroneous or Falsified Records

Records which show errors or which show a deviation from the company procedure should be copied and will become a part of the audit report. In this case, the documentation will not likely support the question. It must be answered NO. If the documentation includes personally identifiable information this information may not be copied. A statement to this fact referencing the specific document will be included in the report.

If at any time during the audit, proof of falsified records has been identified by the audit team, the audit should be stopped and the lead auditor should contact their Federal Program Manager or the Field Operations Section in Washington, DC for further instructions. Falsification of records is considered an egregious offense, and will lead to an automatic failure of the audit.

CHECKLIST INFORMATION

Questions: The following questions are for general information during the audit and to provide future information for audits and/or operations review. This will help the auditor to determine the scope and extent of the audit.

Each must be answered as requested, unless otherwise noted. Please write legibly so that anyone looking at the scoresheet and checklist can read and understand it.

- **Firm Name:** List the name of the company being audited. This should appear exactly as the company wants their name to appear on the certificate.
- **Contact Person:** List the person from the auditee who is the main point of contact in reference to the audit.
- **Audit Site(s):** List the actual location of the audit sites, including the State and zip code. Use an additional sheet if necessary.
- **Main Address:** List the main mailing address of the Firm being audited. This may be used to mail the results of the audit and for other future correspondence.
- **State: - Zip: - Telephone No: - Fax: - E-mail:** List the phone, Fax and E-mail.
- **Auditor(s):** All auditors and auditors in training working on the audit must be listed here. This would include official "Observers" asked to accompany the audit team in order to provide special technical help or to observe an audit.
- **USDA or Fed-State Office:** List the office that is performing the audit.
- **Date: - Time Arrived: - Time Departed:** List the date and time of arrival to perform the audit. Show time departed audit site. Add "Date Departed" if audit requires more than one day.
- **Travel Time:** List the amount of time to the nearest 1/4 hour required to travel to the audit site(s). Be specific to show information entered here. No information need be shown if none is available.
- **Person(s) Interviewed:** All persons interviewed during the audit should be listed here. List full names of persons integral to the company's safe food handling practices. List number and duty or duties of workers interviewed. Job titles may also be used. Use an additional sheet if necessary.
- **Audit Scope:** The scope of the audit will cover the initial section titled "General Questions" with the exception of Part 7 Food Security. All audits must begin with and pass the General Questions. These questions are common to completing a farm review (Part 1), activities pertaining to harvest and field packing (Part 2), packing within a permanent structure (Part 3), storage and transportation processes (Part 4) and terminal warehousing and receiving (Part 6). When auditors are completing a multiple scope audit, the General Questions shall be answered and considered for each section of the audit covered. It is important to

- remember that on a multiple scope audit, if the General Questions results are acceptable for one scope, but not another, then audit does not pass. All scopes within the audit must pass the General Questions.
- **Products/Acres:** The auditor shall list all commodities covered by this audit in this section. For Parts 1 and 2, auditors shall also record the number of acres of commodities grown.
- **Auditors Signature:** All auditors and auditors in training who served on the audit team shall sign the checklist upon the completion of the audit. An audit checklist that is unsigned shall be considered incomplete. Only the lead auditor is required to sign the scoresheet.

COMPUTING AUDIT POINTS

To tabulate the score for a specific part of the checklist follow these instructions.

- Add all the points given for questions answered “yes” and enter it on the line labeled “Total points for Section X.”
- Add all of the points assigned to the questions answered N/A and enter it on the line labeled “Less N/A.”
- Subtract the “Less N/A” points from the total possible points for the section to figure out the adjusted total points.
- Multiply the adjusted total by 80% to calculate the minimum passing score.
- Compare the minimum passing score to the total points earned for the section; if the total points earned are equal to or greater than the minimum passing score, the section passes, if it is less than the minimum passing score the section fails.

.....

EXAMPLE:

Total points earned for General Questions 120

Total Possible	=<u>180</u>	<i>The total number of points possible for this section.</i>
Subtract “N/A”	-<u>35</u>	<i>Enter the additive number of N/A points (+ points) here.</i>
Adjusted Total	=<u>145</u>	<i>Subtract the N/A points from the Total possible points.</i>
X .8 (80%)	145x.8	<i>Multiply the Adjusted Total by .8 and show it as the Passing Score.</i>
Passing Score	<u>116</u>	<i>Total Possible points less N/A points times 80%.</i>

In this example, the total points earned by the applicant were 120. The total possible points for this section if all questions had been answered, was 180. The auditor had marked several questions “N/A” that totaled 35 points.

When subtracting the 35 N/A points from the total possible points results in an adjusted total of 145 points. To calculate the minimum score required to pass the section, take the adjusted total points 145 and multiply by eighty percent (.80). This results in a minimum passing score of 116. The total points earned for the section 120 was higher than the minimum passing score 116, therefore the company passed this section.

AUTOMATIC “UNSATISFACTORY” CONDITIONS

The following areas must be observed throughout the course of the audit. If during the course of the audit, it can be shown without a doubt that the infraction has occurred, the operation will fail the audit until it can be shown that the problem has been satisfactorily corrected and it is evident that the problem will not again occur. (See Corrective Action Policy.)

The following five bullets are considered automatic unsatisfactory conditions. These are not the only examples that may occur, and additional examples or further explanations may be provided along with the discussion of individual questions.

- **An immediate food safety risk is present when produce is grown, processed, packed or held under conditions that promote or cause the produce to become contaminated.**

Auditors should assess this part of the audit throughout the review process. If it becomes evident that the conditions in the process being reviewed have led to contamination of the product or such conditions are likely to cause a contamination, the operation will not meet the minimum requirements of the Audit Program. Examples of this would be the initial use of non-potable water in the product washing process or a leaky sewer pipe in the production or storage area.

Auditors should review 21 CFR, part 110.110 and the appropriate Food Defect Action Levels for the appropriate product in the Appendix Section.

- **The presence or evidence of rodents, an excessive amount of insects or other pests in the production area during packing, processing or storage.**

Evidence of working infestations of rodents, birds or other mammal type pests or feces from various pests in the production or storage area would be cause for an immediate failure.

- **Observation of employee practices (personal or hygienic) that jeopardize or may jeopardize the safety of the produce.**

Such employee practices would include putting eaten/partially eaten product back into the product flow zone, spitting on product or into product flow zones or disposing of

used toilet tissue on the floor or in containers in the toilet room, which causes an unsanitary condition. Employees that use the toilet facilities and do not wash their hands would be an unsafe hygienic practice.

- **Falsification of Records.**

If at any time during the audit, proof of falsified records has been identified by the audit team, the audit should be stopped and the lead auditor should contact their Federal Program Manager or the Field Operations Section in Washington, DC for further instructions. Falsification of records is considered an egregious offense, and will lead to an automatic failure of the audit. An example of records falsification would be a temperature log filled out in advance of the current date or time.

- **General Questions P1 and P2.**

Any working food safety program shall have a documented food safety program and a designated person to oversee the program. Any auditee that does not have a documented food safety program and a designated person to oversee the program is not showing a commitment to food safety. Therefore, the USDA will not verify a company's GAP&GHP program without a documented program.

All operations wishing to be reviewed shall have some type of written food safety program in place and have various parts of it documented with records showing that the procedure was carried out. A documented food safety program addressing the GAP or GHP specifications would include written standard operating procedures (SOP's), standard sanitary operating procedures (SSOP's) or other written procedures for cleaning or treating areas where it is possible to reduce or eliminate the possibility of microbial contamination. Operators should also have records for specific actions that are taken, such as regular cleaning of food contact surfaces, refrigeration areas or transportation machinery.

General Questions

IMPLEMENTATION OF A FOOD SAFETY PROGRAM

- ***Did the auditee participate in GAP&GHP training?***

Yes / No /

GAP&GHP training for producers could include Cooperative Extension Service training, formalized classes attended, Good Agricultural or Manufacturing Practices seminars or other professional training that may include Water, Manure/Biosolids, Worker Health & Hygiene, Sanitary Facilities, Field Sanitation, Packing Facility Sanitation and/or Transportation issues.

- ***Is there a map that accurately represents the farm operations?***

Yes / No /NA /

Producers should have some type of map showing their growing areas. Large operations will have several maps of their operations. In many cases, the maps will show products being grown in specific locations. This information is always required when the scope covers Farm Review and Field Harvest & Field Packing Activities (Parts 1 & 2). It is also important to have accurate information available when reviewing Traceback.

- ***Legal Description/GPS/Lat.-Long. Of Location:*** _____

A legal description, such as a County issued parcel number (APN) or a Township and Range, may be available for the operation(s). If the audit site is different from the main address listed on the front of the scoresheet, the address of the audit site(s) shall be listed here. It may be useful to research for information about wells, locations of former landfills near or on the property, for future audits or for producer record for a particular audit.

- ***Are all crop production areas located on this audit site?***

Yes / No / NA /

Crop production areas may or may not be located on contiguous or adjacent acreage. This information is required in order to properly assess questions under Farm Review (Part 1) and Field Harvest and Field Packing Activities (Part 2). Sites which are separate will have to be separately visited in order to verify all aspects of the audit scope at each location. When the operation has production areas other than on the audit site, the auditor must review farming and/or harvesting practices and determine if different practices are followed at different sites. One site which fails to meet minimum audit requirements would be enough to disqualify the entire operation.

- ***Total acres farmed (Owned, leased/rented, contracted, consigned):***_____.

This information is only required when the audit covers or includes Farm Review (Part 1). Knowing this information provides the auditor with information to determine what will need to be personally reviewed. This would include all acreage coming under the use of the company being audited.

- ***Does the company have more than one packing facility?***

Yes / No / NA /

Multiple packing facilities under the same name can be reviewed separately or all as one audit. The auditee must designate how they want to be audited prior to the start of the audit. However, where the audit covers all facilities, one failing facility would cause the remainder to fail. When separate audits cover each of the facilities, a problem in one facility would not affect the final audit of the other facilities. When listing the separate locations under multiple reports/audits, the normal street address or a different name must be used as the separating reference. This would include multiple growers or grower locations that may be contracted under an individual packing facility.

- ***Is there a floor plan of the packing house facility indicating flow of product, storage areas, cull areas, employee break rooms, restrooms, offices?***

Yes / No / NA /

A floor plan of the facility will be useful for the auditor to locate and identify such areas listed and to help point out problem areas. This information should be obtained when the scope covers House Packing Facility (Part 3) and/or the Storage Facility (Part 4).

- ***Is any product commingled prior to packing?***

Yes / No /

It is common in some produce facilities and in some commodity programs to commingle product from different growers. This may occur at the storage level prior to packing, during a pre-grading and pre-sizing process or at the time of packing. The knowledge of commingling is important in order to properly answer questions regarding Traceback.

Questions P-1 and P-2 must be answered **YES** in order to continue, if the questions cannot be answered **YES**, the audit will be reported as an “automatic unsatisfactory.”

Questions		Points	YES	NO	N/A	Doc
P-1	A documented food safety program that incorporates GAP and/or GHP has been implemented.					D
P-2	The operation has designated someone to implement and oversee an established food safety program. Name _____					D

Question P-1 requires that the auditor review documentation which indicates that, at a minimum, a GAP & GHP program has been established for the scope or scopes of the audit being completed. Documentation may include a Food Safety Manual or plan, various published Standard Operating Procedures (SOP's), and/or documentation that a program is implemented and being followed. It may also contain information or references pertaining to internal or self audits of the program (not a requirement). Other similar documentation may also be applicable and acceptable if it indicates that a formally established program is in place.

Question P-2 indicates that there is a person in the operation that will implement and oversee a food safety program. Operations which are serious about following established food safety programs will have a designated person whom is responsible for ensuring that the program is being followed.

Auditors should interview the designee in order to determine their knowledge of the program. Designees should be able to show procedures and records and knowledgeably answer questions about the program they are responsible for.

Traceability

Traceback is the ability to track food items back to their source. A system to identify the source of fresh produce cannot prevent the occurrence of a microbiological hazard that may lead to an initial outbreak of food borne disease. However, the ability to identify the source of a product through traceback can serve as an important complement to good agricultural and management practices intended to prevent the occurrence of food safety problems. Information gained from a traceback investigation may also be useful in identifying and eliminating a hazardous pathway.

The Guide also recommends that producers have the ability to track product forward throughout the marketing chain. This would include through retail channels to the consumer. Auditors should consider any and all reliable methods that an operation may use to track product.

It is common practice in some commodity groups to commingle various growers' product prior to the time it is packed. This may occur with tree fruit, tomatoes and potatoes, etc. When comingling occurs, auditors should assess whether or not the product can be traced to a reasonably sized group of growers and/or harvest dates. For these groups, reasonably sized would be considered approximately 5 to 8 tree fruit growers or 3 to 5 vegetable growers. A group of harvest dates is considered reasonable when the interval is no longer than seven days.

Questions		Points	YES	NO	N/A	Doc
G-1	A documented traceability program has been established.	15				D

All facilities or operations shall have a traceability program that, at a minimum, allows a traceback investigation to follow the product both forward and backward at least to the next level in the marketing chain. The program shall be used for all fresh produce listed in the audit and handled at the facility or operation. Documents may be paper or electronic and must be accessible both during the audit and in case of a traceback investigation. There are many commercially available traceability programs that auditees may utilize for their traceability program.

On the farm:

- The operation shall be able to track the product to grower and the production area from which it came.
- The production area may be one, or a group of orchards or fields.
- There must also be records for crops that are held in storage before packing.
- Production records shall have the grower, production area and year.
- Harvest dates (or group of dates) must be documented.
- If a product is comingled during or after harvest, all growers, production areas and dates regarding the comingled product shall be included in the traceability program.
- Crop production records, farm maps, transportation bills, weight tickets and storage records may provide documentation.
- The traceability program must also provide documentation regarding where a product has been sent once it leaves the facility.

At the packing stage and forward in the marketing chain:

- The product and/or packages and containers shall have markings that allow them to be traced to a packing house. In most cases, the company label or other identification will allow tracking.
- If a company has multiple packing facilities, the product or container must be uniquely marked identifying the packing facility the product originated from.
- All packed containers must be identified with a date of pack. This may be imbedded into a lot code or unique ID number and does not need to appear as 10/1/09 or August 13, 2009, etc. In the case of wholesale or master containers the pack date may be on the outer container and may or may not appear on the individual consumer unit.
- The pack date should correspond to the farm traceback information.

Product or container markings must be reliably applied and easily read or deciphered up and down the marketing chain. A method of identification that can only be deciphered by one part of the marketing chain will not meet the requirements of a traceability program. This question cannot be answered N/A.

Questions		Points	YES	NO	N/A	Doc
G-2	The operation has performed a “mock recall” that was proven to be effective.	10				R

The guide indicates that all facilities should work with their suppliers and customers to track the path the product takes from the farm to the consumer. This will provide a readily available trail in case there is a need to determine where product originates and to where it was shipped.

A “recall” is a means to return marketed product to its origin; to remove it from the market place. A “mock recall” is a practice exercise that is used to determine where product is shipped and whether or not it can be returned to the origin or removed from the marketing chain.

**** If the audit is only for Farm Review and/or Harvest, a mock recall is not required for the first year in the program. Field pack and packing house operations must have some documented evidence of completing at least one mock recall within the 12 months prior to the audit. If the audit is performed within approximately 10 days of start of packing, documents from the previous season may be used. Documents must indicate the customers contacted, the amount of product remaining from the original shipment and the disposition of product which could not be effectively recalled. Such disposition may include sales to customers, reshipment to a subsequent customer that could be contacted if a recall were necessary, or destruction of product. The auditor must review recall records and assess the practice. ****

Worker Health and Hygiene

Any question with a shaded box in the “NO” column must be answered “YES.” If the question cannot be answered “YES” then the audit will be reported as an “automatic unsatisfactory.”

Questions		Points	YES	NO	N/A	Doc
G-3	Potable water is available to all workers.	10				R

**** It is intended that this question applies to water being used in the operation by workers to drink and wash hands or other body parts in order to reduce contamination. It will be necessary for auditors to review documentation, such as testing records, in order to verify that the water is potable. The water test does not need to specifically show “Meets Drinking Water Standards” or similar language in order to award points for this question. Water tests for drinking water should show that the microbial contents are within the EPA, State or local guidelines. If the permitted amounts are not shown on the water test, the auditors should familiarize themselves with what is permitted. The EPA “Total Coliform Rule” has a zero tolerance for coliforms, including E. coli. ****

Potable water is clean water that is safe to drink. Under the Department of Labor, OSHA regulations (29 CFR, Part 1910), this means water which meets the quality standards prescribed in the U.S. Public Health Service Drinking Water Standards, published in 42 CFR Part 72, or water which is approved for drinking purposes by the US Environmental Protection Agency, State or local authority having jurisdiction.

**** Municipal water supplies are regulated by law and are required to be potable. Well water may or may not be potable. Testing determines if water is potable. Surface water is subject to various uncontrollable influences and should not be considered potable without further testing or treatment to show that the water is potable. ****

In some instances, operations may add chlorine or other acceptable agents to potable water in order to further reduce the possibility of contamination during hand washing. Although this water may not be suitable for drinking, it shall be acceptable for hand washing. This question cannot be answered N/A.

Questions		Points	YES	NO	N/A	Doc
G-4	All employees and all visitors to the location are required to follow proper sanitation and hygiene practices.	10				P

Proper sanitation and hygiene practices for food processing establishments are described as GMP's under 21 CFR 110.10. Not all such GMP's under 21 CFR 110.10 may be appropriate in every operation, however operations should establish and follow those that apply. Fresh produce handling operations should stress that both visitors and employees must follow the established sanitation and hygiene practices, including hand washing.

For visitors, establishments may require them to check-in and enter the premises through a specific door or through the office. There may be signs posted indicating that visitors must follow a specific policy or policies. Some companies may ask visitors to sign-in before entering. Each of these is an indication that the facility requires certain hygiene and sanitation policies.

In addition, requirements must be continually stressed through periodic reviews of employee/visitor habits, training sessions, required attire/uniform dress code or other means. A minimal statement by company management at orientation, in an employee handbook or posting of signs in various locations and no continual review or follow-up will not be sufficient to be considered as a "required process."

Auditors should review company procedures and policies to determine whether or not there is an established policy and what the policy covers. Auditors must be held to the same standard as a visitor. They should be asked to go through the same procedures that are required of other visitors. If they are not, this is a good indication that such practices are not required or are not stressed. This question cannot be answered N/A.

Questions		Points	YES	NO	N/A	Doc
G-5	Training on proper sanitation and hygiene practices is provided to all staff.	15				D

All personnel should understand the impact of poor personal cleanliness and unsanitary practices on food safety. Good hygiene not only protects the worker from illness, but it reduces the potential for contaminating fresh produce which, if consumed by the public, could cause a large number of illnesses. In 21 CFR, Part 110.10, subparagraphs B (1 through 9), there is information about GMP's which may be applicable to various situations in fresh produce packing operations.

Excerpts from Good Manufacturing Practices for food processing establishments from 21 CFR 110.10 state:

(b) Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:

(1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.

(2) Maintaining adequate personal cleanliness.

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.

(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

(9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

(c) Education and training. Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

(d) Supervision. Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

Each operator should develop a sanitation training program for their employees. Depending on the situation, formal presentations, one-on-one instruction, or demonstrations (example, hand washing) may be appropriate. Depending on the workers' job requirements, periodic refresher or follow-up training sessions may be needed.

It is the auditee's responsibility to train and educate their employees about GAP's & GHP's. They may wish to design and implement their own program or to contract such a program from some other party. Auditors should review records of training, when it occurred, whether or not there have been any follow-ups and whether or not all employees handling the produce attended the training.

Adequate training would include documentation and be sufficiently suitable for the number, experience and job of the employees. There must be a positive attempt to provide training.

A simple statement to the employees at the beginning of the season that they should follow safe food handling practices is not sufficient. A written company policy in an employee orientation or policy manual is not sufficient.

Auditors should question auditee employees and staff, observe any training being completed at the time of the audit and review documentation and/or records in order to determine that adequate training is being completed. This question cannot be answered N/A.

Questions		Points	YES	NO	N/A	Doc
G-6	Employees and visitors are following good hygiene/sanitation practices.	15				

This statement relates to the previous two statements. Auditors must observe various visitor and employee practices throughout the course of the audit. Observations can only be made on those people present at the site during the audit. Everyone must be following the acceptable or company required practices in order that this question be answered YES. This question cannot be answered N/A.

Questions		Points	YES	NO	N/A	Doc
****	G-7 Employees who handle or package produce are washing their hands before beginning or returning to work.	15				

Thorough hand washing before commencing work with produce and after using the toilet is very important. Many of the diseases that are transmissible through food may be harbored in the employee's intestinal tract and shed in the feces. Contaminated hands, including poorly cleaned fingernails and cuticles, can also transmit infectious diseases.

Food handling operations should stress that hand washing with soap and/or other sanitizing agent(s) is required. It should be noted that sanitizer use alone is not an acceptable practice and points should not be awarded for this question if this is the case. This can be completed by regular and periodic reviews of employee habits, training sessions or other means. A minimal statement by company management at orientation, information printed in an employee handbook or a simple company policy statement, with no continual review or follow-up will not be sufficient to be considered as a "required process."

The recommended hand washing procedure is as follows:

- Wet hands with clean, warm water, apply soap, and work up a lather.
- Rub hands together for at least 20 seconds (sing the ABC song to yourself – that takes about 20 seconds).
- Clean under the nails and between the fingers. Rub fingertips of each hand in suds on palm of opposite hand.
- Rinse under clean, running water.
- Dry hands with a single-use towel.

This question may only be indicated as N/A where the workers are not working directly with the produce, such as pruning or other similar field work. In cases where a supply of toilet facilities is not mandated, hand washing facilities are required under this statement whenever employees are handling food products. This question can also not be answered NO. If a worker who handles produce does not wash their hands before beginning and returning to work, and there are no immediate corrective actions taken by the auditee, this would be considered an automatic unsatisfactory condition.

Questions		Points	YES	NO	N/A	Doc
	G-8 Readily understandable signs are posted to instruct employees to wash their hands before beginning or returning to work.	10				

Many operations post signs in or near the bathrooms to remind/require employees to wash their hands after they use the toilet facility. Some operations post signs in various places and require washing before going/returning to work.

GMP's under 21 CFR, Part 110.37 require the posting of signage instructing employees handling food or food containers to wash before going to work or after any activity away from the work site. Hand washing may also be stressed as a part of the employee orientation and/or regular safety meetings.

21 CFR, Part 110.37, subparagraph (e) (5) reads as follows:

(5) Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, of food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.

Auditors should look for signs near the hand washing stations. The signs should require that employees wash hands before going to work or before returning to work from some activity (breaks, meal breaks, etc.) other than handling the produce. Where there are non-English speaking employees on the staff; signs must also be posted in the native language of the workers. However, it is not necessary that signs be posted in all the languages of the workforce at the location. Signs should be posted in the native language of the predominant number of workers. Graphic signage demonstrating and reminding workers of the requirement shall be acceptable.

Auditors should question and observe to determine whether or not this is being followed. Signs that are not posted in close proximity to the hand washing stations will not be considered as adequate. This question may only be answered N/A when there are no requirements for bathroom/toilet facilities, such as when there are less than the minimum number of workers present or in home toilets used only by family members.

Questions		Points	YES	NO	N/A	Doc
G-9	All toilet/restroom/field sanitation facilities are clean. They are properly supplied with single use towels, toilet paper, and hand soap or anti-bacterial soap and potable water for hand washing.	15				

The following statements include portions of GMP's, under 21CFR, 110.37 which apply to horticultural production facilities:

(d) Toilet facilities. Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:

(1) Maintaining the facilities in a sanitary condition.

(2) Keeping the facilities in good repair at all times.

(e) Hand-washing facilities. Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:

(1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.

(2) Effective hand-cleaning and sanitizing preparations.

(3) Sanitary towel service or suitable drying devices.

(4) Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.

(6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

f) Rubbish and offal disposal. Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

Hand washing facilities with soap and towels may be located within or outside of the toilet facility. They must be located near the toilet facility that food handling employees would have ample opportunity to wash before returning to work.

Auditors should review all toilet/restroom facilities pertinent to the operation being audited. Any single toilet facility within the operation that does not meet minimum requirements would prevent this statement from being answered YES for the entire operation.

Toilet facilities do not need to be sparkling clean with polished sinks and water supply fixtures in order to be considered clean. Auditors must consider the number of people using a facility, the time of day that the observation was made (just after a break/meal period vs. at the beginning of the work period), the cleaning schedule and the overall appearance of the facility. A few pieces of paper here and there would be acceptable, whereas a pile of used paper towels spilling out of a trash receptacle onto the floor or scattered about the floor would not be acceptable.

During the audit, it may be observed that a hand washing facility has run out of drying towels or a toilet facility is out of paper. Auditors should not simply fail the operation on this one observation, as the facility may have been properly stocked before the audit began. Several hand washing stations or toilet facilities in the operation must be observed, observations might be made several times during the audit and a factual conclusion made as to whether or not there is an ongoing effort to keep the stations properly supplied.

In some locations of the country, it may be found that employees will dispose of dirty/used toilet tissue in a box or other receptacle in the toilet room. Dirty/used paper may also be observed to be disposed of on the toilet room floor. This is not an acceptable practice. Used toilet tissue that is disposed of on the toilet room floor or into a container in the toilet room causes an unsanitary condition and will be cause for an automatic unsatisfactory to be issued. All dirty toilet tissue must be flushed into the sewer or septic system. However, it will be acceptable for the disposal of feminine hygiene products to be made into a lined and closed receptacle in the toilet room.

This question can only be answered N/A when toilet facilities are not required and are not present.

Questions		Points	YES	NO	N/A	Doc
G-10	All toilet/restroom/field sanitation facilities are serviced and cleaned on a scheduled basis.	10				R

Records shall be examined to check the cleaning schedule of the toilet/restroom/field sanitation unit facilities. A cleaning schedule should be specified in the company's food safety plan. Many field sanitation units are contracted out and cleaning services are part of the contract.

This question can only be answered N/A when toilet facilities are not required and are not present.

Questions		Points	YES	NO	N/A	Doc
G-11	Smoking and eating are confined to designated areas separate from where product is handled.	10				P

GMP's under 21 CFR, 110.10 state:

“Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.”

Such activities must be separated from the area where food handling is being carried out.

Contamination of food may occur in any step of the food handling operation. In field handling activities, smoking and eating shall be confined to vehicular drive areas away from the production/growing area. This would be at the edges of the field out of the harvesting zone or in the drive areas between fields.

In a packing or storage facility, this would be a designated area separate from the packing or receiving/loading product flow zones. This could be in the general area of

the packing or receiving/loading area, but would be located a sufficient distance from the flow zone area in order to minimize contamination. Such areas shall be designated and separated by painted lines or by partitions in order to encourage employees to confine the activities to the specifically designated area.

Auditors must review the activities in relation to where the food packing and storage is being completed. It is assumed that all employees may need to drink some liquid from time to time during the work period. This would be to reduce dehydration, especially in hot, dry locations. Bottled water use is acceptable in the work area provided it is stored in closed plastic containers away from the product flow zone when not being used. Any other signs of eating, drinking, smoking or any presence of food or tobacco items in a food handling or storage area will be cause for answering this question NO.

Questions		Points	YES	NO	N/A	Doc
G-12	Workers with diarrheal disease or symptoms of other infectious disease are prohibited from handling fresh produce.	15				P

GMP's under 21 CFR, 110.10 state:

“(a) Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.”

Supervisors should be familiar with the symptoms of infectious diseases so that if symptoms are evident, the supervisor can take appropriate steps. Several microbial diseases are able to readily invade and multiply in the human body and to produce severe disease. Any worker showing symptoms of an active case of illness that may be caused by such pathogens shall be excluded from work assignments that involve direct or indirect contact with fresh produce. Workers with diarrheal disease and symptoms of other infectious diseases shall not work directly with fresh produce or the sorting and packing equipment in the packing facility. Operators shall instruct employees to report any active case of illness to their supervisor before beginning work.

Auditors should pose appropriate questions to managers/supervisors to determine whether or not they show knowledge of known symptoms of the infectious diseases. Auditors must also look for indications of worker illness, such as obviously evident prescription or over the counter anti-diarrhea medications or frequent trips to the toilet facilities by individual employees. Some companies may have a written policy to follow when workers show signs of possible illness.

Auditors should question supervisory personnel in order to determine what would be done if a food handling worker showed signs of infectious disease or diarrhea. Such affected persons should not be handling food, food packages or be working around product flow zones. This question cannot be indicated as N/A.

Questions		Points	YES	NO	N/A	Doc
G-13	There is a policy describing procedures which specify handling/disposition of produce or food contact surfaces that have come into contact with blood or other body fluids.	15				P

Blood or body fluids, regardless of the source (human or animal), are possible sources of microbial contamination. Such fluids can contain several infectious microbial organisms. In some States or localities, blood or other body fluids are considered as hazardous substances and must be handled with special equipment and procedures. All food handling operations must have a written plan to properly handle and dispose of any food products and to properly clean/sanitize food contact surfaces that come into contact with blood or other body fluids.

Auditors should review the plan and answer YES or NO as appropriate. This question cannot be answered N/A.

Questions		Points	YES	NO	N/A	Doc
G-14	Workers are instructed to seek prompt treatment with clean first aid supplies for cuts, abrasions and other injuries.	5				P

GMP's under 21 CFR, 110.10 state:

“(a) Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.”

Food handling workers that have any of the above conditions or that are injured on the job, no matter how minor, must seek first aid help. Operators must instruct and stress that workers report any conditions or injuries that could contaminate food products or containers. Minor cuts or scrapes which are incident to a food production environment

are just as serious as major one. All must be properly covered before the person returns to handling food or working around food contact surfaces.

Auditors may verify this statement by reviewing company documents, questioning supervisory personnel or food handlers in what they would do. This question cannot be answered N/A.

Questions		Points	YES	NO	N/A	Doc
G-15	Company personnel or contracted personnel that apply regulated pre-harvest and/or post harvest materials are licensed. Company personnel or contracted personnel applying non-regulated materials have been trained on its proper use.	10				R

Pre-harvest materials include pesticides, growth regulators and fertilizers. Post harvest materials would include waxes, fumigants and fungicides. Personnel in each area being audited should have a working knowledge of the use of these materials, if they are using them. This would include what the application material would be used for (fertilizer, wax, fungicide, etc.), the appropriate strength level, and what to do if there is a spill or the strength is improperly mixed. Applicators who hold current Federal or State licenses will meet the requirements of this question. However, if there are no restricted use materials being used which require the auditee to hold a pesticide license, the auditor should review training documents that proves that the applicators have received training on the proper use of the materials. Auditors may consider the question as N/A only when no pre-harvest and/or post-harvest materials are used in the scope of the operation being audited.

Part 1

FARM REVIEW

Part 1 is the Farm Review scope of the audit. This includes the farming operations pertaining to water usage, sewage and its treatment, presence of animals and livestock, use of manure and biosolids and land use history. All farming operations must be reviewed under these questions. It will be necessary to physically visit each crop production area. The audit shall take place during the growing season. One visit may be sufficient for a crop production area when more than one similar commodity or crop is grown on the farm.

All questions covered in the General Questions Section are applicable to this section. If a passing score is not attained in the General Questions Section as the questions pertain to a Farm Review, then the auditee does not meet the minimum requirements for a Farm Review.

Water Usage

Water use in crop production involves numerous field operations including irrigation, applications of pesticides and fertilizers, cooling, and frost control. Inadequate water quality has the potential to be a direct source of contamination and a vehicle for spreading localized contamination in the field, facility, or transportation environments. Wherever water comes in contact with fresh produce, its quality dictates the potential for pathogen contamination. If pathogens survive on the produce, they may cause food borne illness.

Water can be a carrier of many microorganisms including pathogenic strains of *Escherichia coli*, *Salmonella* spp., *Vibrio cholerae*, *Shigella* spp., *Cryptosporidium parvum*, *Giardia lamblia*, *Cyclospora cayetanensis*, *Toxoplasma gondii*, and the Norwalk and Hepatitis A viruses. Even small amounts of contamination with some of these organisms can result in food borne illness.

The quality of water, how and when it is used, and the characteristics of the crop influence the potential for water to contaminate produce. In general, the quality of water in direct contact with the edible portion of produce may need to be of better quality compared to uses where there is minimal contact. Other factors that influence the potential for contact with waterborne pathogens, and their likelihood of causing food borne illness, include the condition and type of crop, the amount of time between contact and harvest, and post-harvest handling practices.

Produce that has a large surface area (such as leafy vegetables) and those with topographical features (such as rough surfaces) which foster attachment or entrapment may be at greater risk from pathogens, if they are present, especially if contact occurs close to harvest or during post-harvest handling. Some sectors of the produce industry

use water containing antimicrobial chemicals to maintain water quality or minimize surface contamination.

Water usage on the farm includes irrigation and chemical applications of the product. Auditors must consider the water source and usage when assessing the following statements.

- **(1-1) What is the source of irrigation water? (Pond, Stream, Well, Municipal, Other) Please specify:**

_____:

The farm water source should be shown here. When there are multiple sources, all must be listed. If the irrigation source and the source of chemical application spray water is the same, one statement will be sufficient. If the sources are different, auditors must explain.

- **(1-2) How are the crops irrigated? (Flood, Drip, Sprinkler, Overhead, Other) Please specify:**_____:

The irrigation method and the type of crop will have an effect on the potential for microbial contamination. In order to help assess the potential, auditors must list the irrigation method. Be specific and list all methods if the farm uses multiple methods.

Water Quality Risks – Sources, Testing and Treatment

	Questions	Points	YES	NO	N/A	Doc
1-3	A water quality assessment has been performed to determine the quality of water used for irrigation purposes on the crop(s) being applied.	15				D
1-4	A water quality assessment has been performed to determine the quality of water used for chemical application or fertigation method.	15				D

Farming operations must have knowledge of their water quality in order to determine whether or not the product could become contaminated through irrigation or chemical spraying. Water which comes into contact with the product must not be contaminated with microbial organisms.

Drip irrigation methods or those where the water does not touch the crop are less likely to promote potential contamination than flood irrigation methods. Irrigation with sprinkler methods where the water sprinkles or drenches the crop can be the most risky for causing contamination, especially if the water quality is unknown.

Municipal water sources are viewed as the least likely to be contaminated. Well water that is not regularly tested has a medium to high risk of causing contamination. Surface water has the highest risk of contamination.

Municipal water supplies are regulated by law and are generally required to be potable. Well water may or not be potable and may or may not be microbially safe. Surface water is subject to various uncontrollable influences and shall be considered non-potable without further testing or treatment to show that the water quality is adequate for its intended use.

The following further discusses testing schedules for sources of farm water.

- **Municipal water:** Acquire test results from the local water authority **annually**.
- **Well water:** Test at a minimum annually and treat the well if fecal coliforms are present. If the well casing is secure and well-maintained, and if livestock and manure storages are excluded from the well recharge and pumping area, then the risk of contamination is greatly reduced.
- **Surface water:** Test **quarterly in warm climates** such as California, Florida, Texas and other southern states. Test **three times** during the growing season in **northern climates** such as New York, Pennsylvania, and Michigan - first at planting, second at peak use, third at or near harvest.

Auditors need to evaluate many factors when answering these two questions. It is never the intent that potable or microbially safe water should be used in every water application on the farm. Chemical applications or irrigation that occur prior to the crop being planted or if the crop is dormant (such as tree fruit) does not require potable water. However chemical or irrigation applications that occur just prior to the crop being harvested must use microbially safe water.

Auditors must review the irrigation and spray methods and determine whether or not the auditee has performed a risk assessment regarding the suitability of the spray or irrigation water. Questions 1-3 and 1-4 shall be answered N/A if no irrigation or spray applications are made on the crop.

	Questions	Points	YES	NO	N/A	Doc
1-5	If necessary, steps are taken to protect irrigation water from potential direct and non-point source contamination.	15				

**** The assessment and evaluation of internal and external sources of contamination made for the above questions will determine if steps are needed to protect water. Farms should look at the production areas in terms of their proximity to surrounding land uses that pose a potential for polluted runoff, and take steps to minimize the pollution from contaminating their water source, by use of berms, swales, diversions, etc. Back flow devices are generally required. Auditors should check for backflow prevention devices when required by code or evaluation..

Testing the water until it is known to be adequate, treatment of the water with filtration and/or chemical means or protection of the source from animals or other pollutant sources by fencing or other means may provide sufficient steps to maintain a quality source.

Auditors must secure additional information in the form of documentation of testing or observation of premises in order to answer this question correctly. This statement can only be answered N/A when there is no need to further protect the water supply or no water is being used to irrigate, fertigate or spray the product.

Sewage Treatment

Treatment methods may be municipal treatment or septic systems. Municipal or commercial treatment systems are designed for treatment of large volumes of sewage, such as that generated by small towns to large cities. Septic systems are designed to treat small volumes of sewage, such as that amount coming from a single farm house or facility.

Treating any farm sewage through a municipal system reduces the possibility of contaminating water from wells or other sources. Municipal systems also have regular testing and treatment procedures in place. If the septic system is near the water source, there is a contamination potential, especially if the water source is not sealed.

	Questions	Points	YES	NO	N/A	Doc
1-6	The farm sewage treatment system/septic system function properly and there is no evidence of leakage or runoff.	15				

Most treatment systems consist of a simple septic tank system consisting of a holding tank for solids and leach lines for liquids. If it appears that the system is sealed and there are no leaks near the tank or within the leach field, then it will be considered as functioning properly. If a public sewage line is present, and the line shows no evidence of leakage, the points can be awarded for this question.

This statement may be answered N/A with a proper explanation in the COMMENTS section if there is no sewage treatment system on the facility operation or sewage treatment is not required. An example of this would be a field or location that is "just a field" with no standing buildings or sewage treatment connections on site. If there is no sewage to treat, this question may be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
1-7	There is no municipal/commercial sewage treatment facility or waste material landfill adjacent to the farm.	10				

This statement shall be answered YES if no municipal or commercial sewage treatment facility is adjacent to the farm. Adjacent means approximately 1/4 mile or closer.

Animals/Wildlife/Livestock

While it is not possible to completely exclude animal life from all fresh produce production areas, many field programs include elements to protect crops from animal damage. Growers should review existing practices and conditions to assess the potential for significant amounts of uncontrolled deposits of animal feces coming into contact with crops. Good agricultural practices for minimizing hazards from livestock include but are not limited to:

- Exclusion of domestic animals from fresh produce fields, vineyards and orchards during the growing season. This would include pet dogs, goats, sheep, cows, horses, fowl, etc.
- Depending on the operation, good management practices may include keeping livestock confined (e.g., in pens or yards) or preventing their entry into fields by using physical barriers such as fences.
- Ensure that animal waste from adjacent fields or waste storage facilities does not contaminate the production area.

Growers should determine whether surrounding fields and farms are used for animal production.

They may need to consider measures to ensure that animal waste from adjacent fields or waste storage facilities does not contaminate the produce production areas during heavy rains, especially if fresh produce is grown in low-lying fields or orchards. Measures might include physical barriers, such as ditches, mounds, grass/sod waterways, diversion berms, and vegetative buffer areas that prevent flowing or splashing water from contaminating crops.

High concentrations of wildlife (such as deer or waterfowl in a field) or domestic animals (cows, sheep, horses, fowl) may increase the potential for microbial contamination by significant or uncontrollable amounts of fecal material.

Control of wild animal populations in the field may be difficult, especially where crop production areas are adjacent to wooded areas, open meadows, and waterways.

It is important for the auditor to be aware that fencing, vegetation removal, and destruction of habitat may result in adverse impact to the environment. As always, auditors are not to make any recommendations or suggestions. They should refer the auditee to check for local, state and federal laws that protect riparian habitat, restrict removal of vegetation or habitat, or restrict construction of wildlife deterrent fences in riparian areas or wildlife corridors.

	Questions	Points	YES	NO	N/A	Doc
1-8	Crop production areas are not located near or adjacent to dairy, livestock, or fowl production facilities unless adequate barriers exist.	15				

Currently, there is not any conclusive science to validate the exact distance needed between crop production areas and sources of potential contamination. Auditors need to use their best judgment and be observant to the presence of dairy or livestock production facilities, including feedlots (beef, swine, chickens, etc.). Concentrated feeding operations are defined by EPA and will have bare ground not covered by vegetation. When these types of facilities are within approximately one to two miles of the crop production area, factors such as topography, wooded areas or other natural barriers shall be taken into consideration when answering this question. For example, if the farm being audited sits on top of a hill and a dairy operation is downwind at the bottom of the hill, the distance between the two operations can be closer than if the farm locations were reversed. As a guide, if crop production areas are closer than 1 mile to an animal production area and no natural barriers exist, this question shall be answered NO.

For enclosed greenhouses the auditor should consider the type of barriers in place (grass, slope, trees, etc.).

	Questions	Points	YES	NO	N/A	Doc
1-9	Manure lagoons located near or adjacent to crop production areas are maintained to prevent leaking/overflowing, or measures have been taken to stop runoff from contaminating the crop production areas.	10				

Where it is possible that manure lagoons from adjacent or close dairy or livestock facilities can be a possible source of contamination, operations must take some measures to prevent the contamination.

Lagoons must be of sufficient construction to prevent leaking or overflowing or operations must protect the crop growing area. Measures might include physical barriers, such as ditches, mounds, grass/sod waterways or diversion berms. In locations where the farming operation is on higher elevation ground than the lagoon, there will be little need for such barriers, as the elevation is a barrier itself.

This statement shall be answered N/A, when there are no near or adjacent manure lagoons.

	Questions	Points	YES	NO	N/A	Doc
1-10	Manure stored near or adjacent to crop production areas is contained to prevent contamination of crops.	10				

Manure is a major source of potential contamination. Manure storage areas should be constructed to contain any potential leaching and runoff from entering the crop production areas.

	Questions	Points	YES	NO	N/A	Doc
1-11	Measures are taken to restrict access of livestock to the source or delivery system of crop irrigation water.	10				

In certain cases, it is possible that livestock may have access to the source of the water supply (wellhead area or pond/stream) or to the delivery system (canal/ditch). Where this is the case, operators should take measures to keep such livestock away. Where there are only a few head of livestock and access is random, they should not come within approximately 200 feet of the water source.

This statement shall be answered N/A, when there are no livestock present or dairy/livestock production facilities are not adjacent or nearby.

	Questions	Points	YES	NO	N/A	Doc
1-12	Crop production areas are monitored for the presence or signs of wild or domestic animals entering the land.	5				R

Regularly completed “notes,” “scouting lists,” or “crop maintenance reports” may include this information. This task does not need to be completed on a daily basis, but a regular schedule that shows the producer has an awareness of the animal populations in the production areas. This question may only be answered N/A for fully enclosed greenhouses.

	Questions	Points	YES	NO	N/A	Doc
1-13	Measures are taken to reduce the opportunity for wild and/or domestic animals from entering the crop production areas.	5				R

Farming operations are never going to be able to completely exclude wild and/or domestic animals from entering crop production areas. However, every effort should be made to limit the access to the production areas. Ideally, when there are only a few animals on adjacent land, there is a low risk of contamination. Occasional entry by normally seldom seen animals is tolerable.

When needed, measures should be taken to reduce the entry into crop production areas by wild and domestic animals, including poultry and pets. This can be accomplished many ways, which can include such items as noise cannons or scare balloons to scare away birds and migratory water fowl, or fencing or other barriers to limit wildlife access. Auditors should understand that federal, state, or local environmental laws or policies may regulate certain species of animals, and that producers may have limited options for their control.

Where there is open entry on a frequent basis or an operation has allowed frequent visits by wild or domestic animals without a positive attempt of deterrence, there is a greater likelihood of fecal contamination and this question must be answered NO.

This statement may be answered N/A only when monitoring verifies there is very infrequent or no animal entry and it is not necessary to take proactive measures to deter or stop access. If question 1-12 is answered N/A then this question shall also be answered N/A.

When farm service animals (horses, oxen, and mules) are used, an operation shall address possible sources of contamination caused by these animals and remediation that will be taken if they cause any contamination through a risk assessment and documented SOP's to control those risks.

Manure and Municipal Biosolids

Animal manure and human fecal matter represent a significant source of potential contamination. Properly treated manure or biosolids can be an effective and safe fertilizer. Untreated, improperly treated, or recontaminated manure or biosolids used as a fertilizer, used to improve soil structure, or that enters surface or ground waters through runoff, may contain pathogens of public health significance that can contaminate produce. Crops in or near the soil are most vulnerable to pathogens which may survive in the soil. Low growing crops that may be splashed with soil during irrigation or heavy rainfall are also at risk if pathogens in manure persist in the soil. Produce where the edible portion of the crop generally does not contact soil is less at risk of contamination provided that produce that does contact the ground (e.g., windfalls) is not harvested. As with agricultural water, physical characteristics of produce that foster entrapment or attachment also affect risk.

Growers using manure or biosolids need to follow good agricultural practices to minimize microbial hazards. Growers also need to examine their specific growing environment to identify obvious sources of fecal matter that could be a source of contamination.

When answering the section on manure/biosolids, please follow the instructions as outlined below and on the checklist.

Manure and Municipal Biosolids

Please choose **one** of the following options as it relates to the farm operation:

_____ **Option A.** Raw manure or a combination of raw and composted manure is used as a soil amendment.

_____ **Option B.** Only composted manure/treated municipal biosolids are used as a soil amendment.

_____ **Option C.** No manure or municipal biosolids of any kind are used as a soil amendment.

Only answer the following manure questions (questions 1-14 to 1-22) that are assigned to the Option chosen above. DO NOT answer the questions from the other two options. The points from the manure and municipal biosolids are worth 35 of a total 190 points, and answering questions from the other two options will cause the points to not calculate correctly.

Option A: Raw Manure

	Questions	Points	YES	NO	N/A	Doc
1-14	When raw manure is applied, it is incorporated at least 2 weeks prior to planting and a minimum of 120 days prior to harvest.	10				R
1-15	Raw manure is not used on commodities that are harvested within 120 days of planting.	10				R

DO NOT harvest vegetables or fruits until 120 days after raw manure application. Remember to document rates, dates, and locations of manure applications.

If it is necessary to apply manure or slurry to vegetable or fruit soil, incorporate it at least two weeks prior to planting and observe the 120-day pre-harvest interval. If the 120-day waiting period is not feasible, such as for short season crops like lettuce or leafy greens, apply only properly composted manure.

Auditors must assess whether or not raw manure is properly used, according to the recommendations. They must review manure application records in order to adequately answer this question.

	Questions	Points	YES	NO	N/A	Doc
1-16	If both raw and treated manure are used, the treated manure is properly treated, composted	10				R

	or exposed to reduce the expected levels of pathogens.					
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In a farming operation that uses both raw and composted manure, it will be necessary to review documentation to verify that the manure has been properly treated to kill pathogens. See question 1-18 for specific composting information. This question may be answered N/A if no composted/treated manure is used.

	Questions	Points	YES	NO	N/A	Doc
1-17	Manure is properly stored prior to use.	5				

Any untreated manure that is stored at the facility must be stored in a way that ensures that it does not leach or runoff into adjacent crop production areas. The auditor should investigate to verify that raw manure cannot contaminate treated manure.

Option B: Composted Manure

	Questions	Points	YES	NO	N/A	Doc
1-18	Only composted manure and/or treated biosolids are used as a soil amendment.	10				R

Records shall be reviewed to verify that only composted manure or biosolids are used. If any raw manure is used, the auditor shall not use this option and use the questions for option A.

	Questions	Points	YES	NO	N/A	Doc
1-19	Composted manure and/or treated biosolids are properly treated, composted, or exposed to environmental conditions that would lower the expected level of pathogens.	10				D

There are various methods used to treat manure so that it is safer as a fertilizer than raw manure. The following discussion is from “The Guide.”

2.1.1 Passive treatments

Passive treatments rely primarily on the passage of time, in conjunction with environmental factors, such as natural temperature and moisture fluctuations and ultraviolet (UV) irradiation, to reduce pathogens.

To minimize microbial hazards, growers relying on passive treatments should ensure manure is well aged and decomposed before applying to fields. Holding time for passive treatments will vary depending on regional and seasonal climatic factors and on the type and source of manure. Passive treatments such as aging should not be confused with actively managed treatments such as composting.

2.1.2 Active treatments

Active treatments generally involve a greater level of intentional management and a greater input of resources compared with passive treatments. Active treatments include pasteurization, heat drying, anaerobic digestion, alkali stabilization, aerobic digestion, or combinations of these. Composting is an active treatment commonly used to reduce the microbial hazards of raw manure. It is a controlled and managed process in which organic materials are digested, aerobically or anaerobically, by microbial action. When composting is carefully controlled and managed, and the appropriate conditions are achieved, the high temperature generated can kill most pathogens in a number of days. Thus, the risk of microbial contamination from composted manure is reduced compared to untreated manure.

Composting should not be confused with simpler passive treatments such as aging. In general, passive treatments, such as aging, will require a significantly longer period of time to reduce microbial hazards compared to active treatments which expose pathogens to lethal conditions, such as high temperature or high pH. In addition, much of the research on the composting of manure and application of manure to field crops has focused on the effects of different practices on soil fertility and crop quality.

Research on pathogen survival in untreated manure, treatments to reduce pathogen levels in manure, and assessing the risk of cross-contamination of food crops from manure under varying conditions is largely just beginning. Some pathogens tolerate higher temperatures than others. In addition, management practices required to achieve the time and temperature necessary to eliminate or reduce microbial hazards in manure or other organic materials may vary depending on seasonal and regional climatic factors (such as ambient temperature and rainfall) and on the specific management practices of an individual operation.

Auditors must review any documentation that indicates the product has been sufficiently treated to reduce the pathogens. This would include time charts for passive type treatment or time and temperature charts, process explanations and microbial testing reports for active treatment methods.

	Questions	Points	YES	NO	N/A	Doc
1-20	Composted manure and/or treated biosolids are properly stored and are protected to minimize recontamination.	10				

Products used to fertilize fruit or vegetable crops may or may not be stored at the production/application site prior to use. In some cases, they may be brought directly from the treatment site and applied from the same conveyance at the time of delivery.

When they are delivered to the production site and stored for future application, they must be properly stored to reduce recontamination and the likelihood of contaminating the production area or adjacent fields. Growers may use the following methods to reduce potential contamination.

Consider barriers or physical containment to secure manure storage or treatment areas where contamination from runoff, leaching, or wind spread is a concern. Physical containment may include concrete block or soil berms, pits, or lagoons. Practices such as storage on concrete slabs or in clay lined lagoons may reduce the potential of leachate entering groundwater. Such storage must be away from irrigation, spray dilution or processing water sources.

Consider good agricultural practices to minimize leachate from manure storage or treatment areas contaminating produce. Rainfall onto a manure pile can result in leachate, potentially containing pathogens. Growers may want to consider covering manure piles, such as storing manure under a roof or covering piles with an appropriate covering.

Alternatively, growers may consider collecting water that leaches through manure that is being stored or treated. Collecting leachate allows the grower to control its disposal (e.g., on a vegetative grassway) or use (e.g., to control moisture during composting). Leachate may pose a microbial hazard similar to the manure from which it originates. Growers using manure leachate or manure tea in fresh produce production areas should follow good agricultural practices, such as maximizing time between application and harvest, to minimize microbial hazards.

Auditors must complete a site review when manure or biosolid materials are stored on site prior to application.

	Questions	Points	YES	NO	N/A	Doc
1-21	Analysis reports are available for composted manure/treated biosolids.	5				R

Natural fertilizers, such as composted manure, and fertilizers containing natural components, should be processed and handled in a manner to reduce the likelihood of introducing pathogens into produce production areas. Growers and manure suppliers should apply good agricultural practices that ensure that all materials receive an adequate treatment, such as thorough mixing and turning outside edges into the center of a compost pile. Cold spots or other pockets that do not receive an adequate treatment can cause recontamination of the rest of the batch. Growers treating or composting their own manure should have some type of procedure to follow. Growers purchasing manure should obtain a specification sheet from the manure supplier for each shipment of manure containing information about the method of treatment. Auditors shall review specification sheets from sourced manure in order to answer this question. This question cannot be answered N/A.

Option C: No Manure/Biosolids Used

	Questions	Points	YES	NO	N/A	Doc
1-22	No animal manure or municipal biosolids are used.	35				P

This option shall only be used if no manure (raw or treated) or biosolids are used on the farm.

Soils

	Questions	Points	YES	NO	N/A	Doc
1-23	A previous land use risk assessment has been performed.	5				R

Auditors should review the previous land use history with the operator.

	Questions	Points	YES	NO	N/A	Doc
1-24	When previous land use history indicates a possibility of contamination, preventative measures have been taken to mitigate the known risks and soils have been tested for contaminants and the land use is commensurate with test results.	10				R

In most cases the land will have been used as crop land or fallow land for many previous years. There is a minimum risk of contamination if there is no recent dumping, use as a dairy, livestock, or poultry feedlot or no evidence of improper use of animal

wastes. Auditor should visually look for evidence of old building sites or other risk factors when on site. Recent land use history may indicate that the land was used as a dairy, feedlot or other waste site. Operators should have the soil tested for microbial contaminants and adjust their use of the land for crops that will have minimal contact with the soil.

If the land use history assessment does not indicate a possibility of contamination, this question shall be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
1-25	Crop production areas that have been subjected to flooding are tested for potential microbial hazards.	5				R

Flood waters can carry potential contamination from areas outside the crop production areas and spread it over a wide area. Fields that have been flooded should be tested for harmful pathogens prior to use to determine the suitability of its use. In answering this question, auditors should consider whether the crop is an annual that will be planted and harvested in the same season, or a perennial that will be planted but not harvested for several seasons, as the annual crops are at greater risk than perennial crops. Auditors should observe site for signs of flooding or locations where flooding could easily occur such as along stream beds, swamps, etc., and ask if/when flooding last occurred. This question may be answered N/A if no flooding has occurred on the farm.

	Questions	Points	YES	NO	N/A	Doc
1-26	Each production area is identified or coded to enable traceability in the event of a recall.	10				R

A map or record that shows the crops grown in each field or production area should be available. The record should allow traceability of the product forward or back to the next step in the marketing chain.

Auditors must explain all questions for which a NO or N/A answer was noted.

Any additional comments pertaining to interviewed persons or to observations made during the audit should be made here. Auditors must be specific when making comments about YES answers to questions, as an additional statement here may indicate that the question might be better answered NO instead.

COMMENTS:

Part 2

FIELD HARVEST AND FIELD PACKING ACTIVITIES

This part relates to harvesting commodities and packing them in the location where they were harvested (field or greenhouse). Many commodities are packed at the same time they are harvested. This reduces the need for a packing building and the equipment that is required to pack at a stationary facility. The emphasis in this part is on worker sanitation and harvesting activities. The auditor must observe the harvest crew(s) of the crops listed. If the same crew(s) is used in harvesting similar crops the observation must be done in at least one of the crop production areas.

Harvesting equipment should be cleaned regularly. Packing equipment that comes into contact with the product should be as clean as possible, depending on the commodity. Auditors must remember that a lettuce field packing operation will be much cleaner than an onion packing operation, because of the nature of the commodity. However, this does not free the onion operation from keeping the equipment as clean as practicable.

	Questions	Points	YES	NO	N/A	Doc
2-1	A documented pre-harvest assessment is made on the crop production areas. Risks and possible sources of crop contamination are noted and assessed.	15				D

The farm operation must have completed a pre-harvest assessment on each production area prior to harvesting any crop being certified by the audit. **The auditor shall take care not to interpret the assessment but rather to verify the fact that an assessment has been made.** The assessment may include statements which address the following items that are applicable;

- Are toilet and wash facilities properly located?
- Is potable water available for workers?
- Are harvest containers available, clean, well located and protected?
- Is harvest equipment available and in good condition?
- Is there evidence of unauthorized entry in the crop area and if so, has it been investigated?
- Is there evidence of domestic or wild animal crop damage?
- Is there evidence of physical contamination in the crop area?
- Are fuel and chemicals which might contaminate crop areas isolated?

- If areas are contaminated are they isolated for “no-harvest”?
- Are there any other notable sources of biological or physical contamination such as dump sites, manure, burning debris, water that may affect food safety?
- Is transportation equipment clean and available?
- The assessment may include other information such as condition of the weather and or crops.

The date of the assessment and the projected date of harvest along with a signature or initials, must be included. The assessment may be documented in various forms such as a self completed audit checklist or a separate pre-harvest checklist. This question cannot be answered NA.

Worker Sanitation and Hygiene

Operations with poor management of human wastes in the field or packing facility can significantly increase the risk of contaminating produce. Good field sanitation helps reduce the potential for contaminating produce and may reduce the chance of food borne diseases.

Field sanitation laws are prescribed under the Occupational Safety and Health Act, 29CFR, Part 1928.110. This describes the appropriate ratio of toilet facilities to the number of workers, proper hand washing facilities, and maximum worker to toilet facility distance. All facilities should be clean, accessible to the workers, properly located in relation to irrigation or other water sources and well supplied with paper, soap and waste disposal devices. Sewage from portable toilet facilities should be properly disposed of and facilities should be serviced regularly.

	Questions	Points	YES	NO	N/A	Doc
2-2	The number, condition, and placement of field sanitation units comply with applicable state and/or federal regulations.	10				

Operators should manage their facilities or farms in accordance with the laws and regulations that describe field and facility sanitation practices. The field sanitation laws prescribed under the Federal Occupational Safety and Health Act (OSHA) part 29 CFR 1928.110 describe such regulations and practices. The following is quoted, in part, from the Act:

(a) Scope. This section shall apply to any agricultural establishment where eleven (11) or more employees are engaged on any given day in hand-labor operations in the field.

(2) Toilet and hand washing facilities.

(i) One toilet facility and one hand washing facility shall be provided for each twenty (20) employees or fraction thereof, except as stated in paragraph (c)(2)(v) of this section.

(ii) Toilet facilities shall be adequately ventilated, appropriately screened, have self-closing doors that can be closed and latched from the inside and shall be constructed to insure privacy.

(iii) Toilet and hand washing facilities shall be accessibly located and in close proximity to each other. The facilities shall be located within a one-quarter-mile walk of each hand laborer's place of work in the field.

(iv) Where due to terrain it is not feasible to locate facilities as required above, the facilities shall be located at the point of closest vehicular access.

(3) Maintenance. Potable drinking water and toilet and hand washing facilities shall be maintained in accordance with appropriate public health sanitation practices, including the following:

(ii) Toilet facilities shall be operational and maintained in clean and sanitary condition.

Paragraph (c)(2)(v), referenced in the Act, exempts the operation from providing field sanitation units if the employees work three hours or less during the day, including travel time.

This question can only be indicated as N/A when field sanitation units are not required.

	Questions	Points	YES	NO	N/A	Doc
2-3	When question 2-2 is answered "NA," (sanitation units are not required), a toilet facility is readily available for all workers.	10				

For small farm operations that are not required by applicable local, state, or federal regulations to have field sanitation units on site, a toilet facility and hand washing station is readily available for any workers. Home toilet facilities may need to be observed. When sanitation units are not required, but are provided, this question may be answered yes. This question can only be answered N/A if question 2-2 is answered YES.

	Questions	Points	YES	NO	N/A	Doc
2-4	Field sanitation units are located in a location that minimizes the potential risk for product contamination and are directly accessible for servicing.	10				

The field sanitation units or toilet facilities should not be so located in the field as to contaminate product that will be harvested or product that already is harvested and/or packed. Units should not be located close to where product is harvested or stored, or where there is a possibility of spilled sewage running down hill into the production area or into a packed product storage area.

The OSHA language (29 CFR, 1928.110), in part, is:

(3) Maintenance. Potable drinking water and toilet and hand washing facilities shall be maintained in accordance with appropriate public health sanitation practices, including the following:

(ii) Toilet facilities shall be operational and maintained in clean and sanitary condition.

(iii) Hand washing facilities shall be refilled with potable water as necessary to ensure an adequate supply and shall be maintained in a clean and sanitary condition; and

(iv) Disposal of wastes from facilities shall not cause unsanitary conditions. The location of the field sanitation units shall not be in a location where any “grey water” can potentially contaminate the crop.

In general, contracted or leased field sanitation units are serviced at a designated servicing facility not located in the production area. In many cases, the farming operation may own the units and will also service them away from the production area.

Auditors should review the accessibility of the location. Locations that are inaccessible would result in a NO answer. Inaccessible locations may include a narrow roadway with no easy access. This question may be answered as N/A when field sanitation units or toilet facilities are not present.

	Questions	Points	YES	NO	N/A	Doc
2-5	A response plan is in place for the event of a major spill or leak of field sanitation units or toilet facilities.	10				P

The operator should have a documented emergency clean-up procedure to follow in case contamination occurs. The procedure should include what will be done to contain the spill and to prevent additional contamination, what will be done to clean it up and what will be done with contaminated product. This question may be answered as N/A when field sanitation units or toilet facilities are not present.

Field Harvesting and Transportation

Microbial contamination or cross-contamination of fresh produce during pre-harvest and harvest activities may result from contact with soils, fertilizers, water, workers and harvesting equipment. Any and all of these may be a means where food contamination may occur.

	Questions	Points	YES	NO	N/A	Doc
2-6	All harvesting containers and bulk hauling vehicles that come in direct contact with product are cleaned and/or sanitized on a scheduled basis and kept as clean as practicable.	10				D

Keep harvest containers as clean as practicable to prevent cross-contamination of fresh produce. Harvest containers used repeatedly during a harvest should be cleaned after each load is delivered and prior to reuse. If the containers are stored outside, they should be cleaned and sanitized before being used to haul fresh produce. Workers should not stand inside bins. Bulk hauling vehicles carrying unwashed crops should be swept out on a regular basis.

Assign responsibility for equipment to the person in charge of the harvesting crews or designated person. The person with assigned responsibility needs to know how equipment is being used during the day, ensure that it is functioning properly, and take steps to ensure proper cleaning and sanitizing of equipment when needed.

Under no conditions should buckets, bags, or other containers that have held hazardous chemicals be used for food contact. Any reused containers should be clean and free from debris. Dirty packing containers that cannot be cleaned should not be used.

Containers, such as picking bins, used as refuse receptacles must be prominently marked for this use and workers must not use these for picking and transporting produce.

For some commodities, containers are not used repeatedly because they are the final shipping containers. Where applicable, the containers should be clean at time of harvest and steps should indicate an attempt to protect final product contact surfaces. This does not require that new containers be intentionally cleaned and sanitized before use. They should be considered clean as arrived from the supplier. This question applies to both final and interim harvest containers and cannot be answered as N/A.

	Questions	Points	YES	NO	N/A	Doc
2-7	All hand harvesting equipment and implements (knives, pruners, machetes, etc.) are kept as clean as practical and are disinfected on a	10				D

	scheduled basis.					
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Any hand harvesting implements should be kept as clean as possible, and cleaned on a scheduled basis. The auditee’s food safety manual should show what the schedule for cleaning and disinfecting harvesting implements is. It is understandable that these implements are going to get dirty from constant, repeated use during the course of a harvesting day and auditors should not answer NO in this section just because a harvester is using a dirty knife. However, the points should not be given if there is no documented procedure for a scheduled cleaning of the implements.

Auditors should determine if the facility has a policy for cleaning equipment and harvesting aids. This may be verified through questioning of the workers, through a written policy or records of the cleaning process. This question may only be answered as N/A if there is no hand harvesting implements used during harvesting.

	Questions	Points	YES	NO	N/A	Doc
2-8	Damaged containers are properly repaired or disposed of.	5				

Repair or discard damaged containers. Inspect containers for damage on a regular basis. Because damaged container surfaces may harbor pathogenic microorganisms and cause damage to the surface of fresh produce, they should not be used.

New, unused containers are the lowest risk; however, if containers are reused, they shall be clean and or sanitized, and air-dried before use. Buckets, bags, or other containers that have held hazardous chemicals should not be used for food contact. Any reused containers should be clean and free from debris. Dirty packing containers that cannot be cleaned should not be used.

This question applies both to harvesting containers such as bins, packing containers and the bulk container part of vehicles when the product is placed directly into them during harvest. Auditors should determine what the company does to repair or dispose of damaged containers. Damaged harvesting containers should not be used.

	Questions	Points	YES	NO	N/A	Doc
2-9	Harvesting equipment and/or machinery which comes into contact with product is in good repair.	10				

Field equipment and/or machinery shall be kept in good repair. Field equipment/machinery that is leaking fluids or has loose or damaged parts can be a source of physical contamination. If this question is answered NO, auditors should pay special attention to questions 2-10, 2-11, and 2-12. This question may be answered “NA” if no equipment or machinery comes into contact with the product during harvest.

	Questions	Points	YES	NO	N/A	Doc
2-10	Light bulbs and glass on harvesting equipment are protected so as not to contaminate produce or fields in the case of breakage.	10				

Any exposed glass fixtures (including flood lights or brake/driving lights) on harvesting equipment should be protected to reduce the potential for contamination of the crop. This question is meant to cover mechanical harvesters for root crops, or machinery that sits directly over the un-harvested crop. Protection can include such practices as using plastic or wire covers, or enclosed fixtures. This question may be answered N/A if no glass is on harvesting equipment.

	Questions	Points	YES	NO	N/A	Doc
2-11	There is a standard operating procedure or instructions on what measures should be taken in the case of glass/plastic breakage and possible contamination during harvesting operations.	5				P

The auditee food safety plan should outline an SOP or instructions documenting the procedures that will take place in the case of glass/plastic breakage contaminating the crop. This question is most relevant for crops that are mechanically harvested, although it can apply to any commodity.

	Questions	Points	YES	NO	N/A	Doc
2-12	There is a standard operating procedure or instructions on what measures should be taken in the case of product contamination by chemicals, petroleum, pesticides or other contaminating factors.	5				P

The auditee's food safety plan should outline an SOP or instructions documenting the procedures that will take place in the case of contamination by chemicals, petroleum, or pesticides on the crop.

	Questions	Points	YES	NO	N/A	Doc
2-13	For mechanically harvested product, measures are taken during harvest to inspect for and remove foreign objects such as glass, metal,	5				

	rocks, or other dangerous/toxic items.					
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For products that are mechanically harvested, measures should be taken to inspect for non produce ending up in the product. Auditors should either observe the harvesting process or interview harvesters to determine if these inspections are taking place.

	Questions	Points	YES	NO	N/A	Doc
2-14	Harvesting containers, totes, etc. are not used for carrying or storing non-produce items during the harvest season; farm workers are instructed in this policy.	5				P

Workers shall not carry personal food items or other non-produce items in their harvesting containers. Auditors should verify this through observation and questioning. The question would be answered NO if it is determined that any equipment used to haul garbage, manure, or other potentially contaminating items is used to hold fresh produce. This statement cannot be answered as N/A.

	Questions	Points	YES	NO	N/A	Doc
2-15	Water applied to harvested product is microbially safe.	15				R

Washing fresh produce (also known as surface treatment) can reduce the overall potential for microbial food safety hazards. This is an important step since most microbial contamination is on the surface of fruits and vegetables. If pathogens are not removed, inactivated, or otherwise controlled, they can spread to surrounding produce, potentially contaminating a greater proportion of the produce.

Water quality needs may vary depending on where the water use falls within the series of processes and whether a particular process is followed by additional cleaning processes. For example, water quality needs may be greater for water used for a final rinse before packaging compared with water in a dump tank where field soil from arriving produce quickly mixes with the water. The Environmental Protection Agency (EPA) established a standard for reclaimed water (treated effluent) used on non-processed fresh produce of less than 2.2 fecal coliforms per 100 milliliters (mls) of water. This is considered free of pathogens for nonpotable agricultural purposes.” (*Food Safety Begins on the Farm*” Cornell University.) Water used in the final rinse or overhead irrigation shortly before packaging shall be microbially safe. If the water is reused, its quality and/or content of antimicrobial agents should be monitored.

Water quality consistent with U.S. EPA requirements for drinking water, or similar standards, is recommended by the *FDA Guide*. While water quality management may vary throughout all operations, packers should follow good manufacturing practices to

minimize the potential for the introduction or spread of pathogens via processing water. Water that meets the microbial standards for drinking water is considered "safe and sanitary."

Municipal water supplies are regulated by law and are required to be potable. Well water may or may not be potable but should be microbially safe. Surface water is subject to various uncontrollable influences and should be considered unsafe without further testing. Surface water should not be applied to the finished product. Auditors must review water tests in order to determine that the water is microbially safe. This question may be answered as N/A when water is not applied to field harvested product.

	Questions	Points	YES	NO	N/A	Doc
2-16	Efforts have been made to remove excessive dirt and mud from product and/or containers during harvest.	5				

Every effort should be made to keep the crop and containers as clean as possible. In the event that the crop or containers are covered with excessive dirt and/or mud, efforts are taken to remove the excess dirt/mud from the products and containers to prevent the spread of potential contamination to other areas of the farming operation.

	Questions	Points	YES	NO	N/A	Doc
2-17	Transportation equipment used to move product from field to storage areas or storage areas to processing plant which comes into contact with product is clean and in good repair.	10				

It is wise to prevent unnecessary contamination. If using an open truck bed to haul unprotected produce, line it and cover the food with clean washable covers. Truck beds should be washed or otherwise cleaned whenever they become dirty.

Ensure that transportation vehicles are clean. Dirty vehicles can contaminate produce with harmful microbes. Auditors should review equipment in order to verify this factor. Some operations may establish standard procedures and logs in order to ensure clean equipment. Auditors should review records and documentation to verify that a schedule is being followed. This question may be answered as N/A.

	Questions	Points	YES	NO	N/A	Doc
2-18	There is a policy in place and has been implemented that harvested product being moved from field to storage areas or processing plants are covered during transportation.	5				P

Products that are transported in bulk from the field or from storage for further packing may be contaminated during this time. Steps should be taken to reduce the possible contamination by other vehicles on the roads, overhead contamination from overpasses, from birds or other means. Using tarps, enclosed trailers or other means to cover loads are examples of good practices. Products being moved in enclosed containers (boxes, cartons, etc.) would not be considered covered. This question cannot be answered N/A.

Auditors must question company personnel to determine if loads are covered as they are transported from the field to the packing operation. Auditors should also observe loads being delivered to confirm the answers to their questions.

	Questions	Points	YES	NO	N/A	Doc
2-19	In ranch or field pack operations, only new or sanitized containers are used for packing the product.	10				D

Packers that use new containers to package products are taking the highest possible means to reduce microbial contamination provided they are stored properly. The use of new containers eliminates the possibility of cross contamination of produce from used containers. Some operations are packing directly into reusable plastic containers (RPC) to meet buyer specifications. These containers are meant to be reused. In the case of RPCs, they should be sanitized prior to each reuse in the field. A cleaning log or record from either the producer or RPC management company shall be reviewed to verify they have been sanitized. This question shall be answered N/A if no field packing occurs.

	Questions	Points	YES	NO	N/A	Doc
2-20	Packaging materials used in ranch or field pack operations are properly stored and protected from contamination.	10				

Packing containers and other packing materials that are not used right away should be stored in a way that protects them from contamination by pests (such as rodents), dirt and water. Packing containers stored outside should be covered in some manner to protect against rain, bird droppings, etc. if necessary. Using the top container in a pile for a cover is not sufficient.

Auditors should observe where and how packing containers are stored. This question must be answered NO when containers which are stored in a manner that may lead to contamination.

Total points earned for PART 2 = _____.

Total Possible = 185 *The total number of points possible for this section.*

Subtract "N/A" - _____ *Enter the additive number of N/A points (+ points) here.*

Adjusted Total = _____ *Subtract the N/A points from the Total possible points.*

X .8 (80%) *Multiply the Adjusted Total by .8 and show it as the Passing Score.*

Passing Score _____

(please circle one) Pass / Fail

Part 3

HOUSE PACKING FACILITY

Part 3 of the Good Agricultural Practices and Good Handling Practices Audit is applicable to packing houses where the fresh product is first packed after harvesting. Generally this will be near the crop production area but in some cases where the product is transported in bulk it may be some distance away. This part of the audit should not be used in areas where the product is removed from a retail/wholesale package and replaced into a retail/wholesale package.

Receiving

	Questions	Points	YES	NO	N/A	Doc
3-1	Product delivered from the field which is held in a staging area prior to packing or processing is protected from possible contamination.	5				

Product which is delivered to the house packing facility may or may not be immediately processed depending on the operational capacity to process the product. In many cases, incoming product is kept in a staging area until it is ready to be sent through the packing house. This staging area may be a permanent structure such as a pole barn, or a designated area where the full bins of product are placed, usually in an area not directly in the sun so the product isn't damaged by sunburn or will build up field heat.

Auditors shall observe the staging area to determine if the product is being protected from sources of possible contamination and not placed under trees or other sources of potential contamination. Some acceptable scenarios may be pulling wagons under a pole barn, tarping the bulk bins, or keeping the product in an enclosed trailer.

	Questions	Points	YES	NO	N/A	Doc
3-2	Prior to packing, product is properly stored and/or handled in order to reduce possible contamination.	5				

Harvested product should be properly stored after delivery to the packing house. Product that will be packed in a short amount of time should be located or covered so as to prevent contamination from birds or other pests. Mesh type coverings discussed under question 3-1 are not considered adequate cover.

In addition, smaller operations have been observed to store bucket - harvested produce in the shade under trees. This is a prime source for contamination from roosting birds and is not acceptable unless the buckets or the trailer are covered.

Product that will be packed several hours to a day or more after harvest should be properly stored appropriate to the commodity to protect from contamination.

Auditors must review the storage of harvested and unloaded product while it is set aside or being stored before it is packed for market. This question cannot be answered as N/A.

Washing/Packing Line

	Questions	Points	YES	NO	N/A	Doc
3-3	Source water used in the packing operation is potable.	15				R

**** Source water used in the packing of fresh fruits and vegetables should be potable. Municipal water supplies are regulated by law and are required to be potable. Well water may or may not be potable. Surface water is subject to various uncontrollable influences and is generally considered non-potable for use in a repacking operation.

Auditors must review documentation that indicates source water meets the microbial requirements of the EPA Drinking Water Standard in order for an auditee to show they are meeting the requirements for water used in the postharvest process. The EPA "Total Coliform Rule" has a zero tolerance for coliforms including E. coli. If the source water used in the operation does not meet the microbial requirements but is then treated, see question 3-5. (To evaluate water quality, refer to the Water Quality Risk Sources and Testing Treatment in Part 1.) This question may be answered N/A when products are not washed.

	Questions	Points	YES	NO	N/A	Doc
3-4	If applicable, the temperature of processing water used in dump tanks, flumes, etc., is monitored and is kept at temperatures appropriate for the commodity.	10				D

For commodities which are susceptible to water infiltration, special attention to the water temperature in the dump tank and flumes and the temperature of the product is required. Water temperature should be maintained within 10 degrees F of incoming product pulp temperature to minimize water infiltration. If contaminated water infiltrates the product, it is very difficult if not impossible to remove the contamination. The water may need to be heated or cooled and/or the product heated or cooled to equalize the temperature. This question may be answered N/A when no water is used or the commodity being repacked is not susceptible to water infiltration. Examples of

commodities which are susceptible to water infiltration are Tomatoes, Cantaloups, Peppers, Apples, Potatoes and Pears.

	Questions	Points	YES	NO	N/A	Doc
3-5	Processing water is sufficiently treated to reduce microbial contamination.	10				D

Water used during the post-harvest handling of fruits and vegetables often involves a high degree of water-to-produce contact. Although water is a useful tool for reducing potential contamination, it may also serve as a source of contamination or cross-contamination. Re-using processing water may result in the build-up of microbial loads, including undesirable pathogens.

Consider practices that will ensure and maintain water quality. Such practices may include:

- Perform periodic water sampling and microbial testing.
- Change water as necessary to maintain sanitary conditions.
- Consider developing SOPs (standard operating procedures or sanitary operating plans), including water change schedules.
- For all processes that use water; clean and sanitize water contact surfaces, such as dump tanks, flumes, wash tanks, and hydro coolers, as often as necessary to ensure the safety of produce.
- Install backflow devices and legal air gaps, as needed, to prevent contamination of clean water with potentially contaminated water (such as between potable water fill lines and dump tank drain lines).
- Routinely inspect and maintain equipment designed to assist in maintaining water quality, such as chlorine injectors, filtration systems, and backflow devices, to ensure efficient operation.

Auditors must review documentation that shows water is treated to reduce microbial populations that could be present. When water is re-used in the repacking process this question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
3-6	Water-contact surfaces, such as dump tanks, flumes, wash tanks and hydro coolers, are cleaned and/or sanitized on a scheduled basis.	10				D

Operations with poor sanitation in the packing environment can significantly increase the risk of contaminating fresh produce and water used on produce. Pathogenic microorganisms may be found on the floors and in the drains in the packing facility and

on the surfaces of sorting, grading, and packing equipment. Without good sanitary practices, any of these surfaces that come in contact with fresh produce could be a potential source of microbial contamination.

Packers should employ good sanitation practices as a standard operating procedure to maintain control throughout the packing operation. Clean packing areas at end of each day. As necessary, clean and sanitize the washing, grading, sorting, and the packing lines to reduce the potential for microbial contamination of fresh produce.

Auditors must review operator procedures, procedural documents and records in order to determine if there is a program and that it is being followed. This question may only be answered N/A when water is not used in the packing process.

	Questions	Points	YES	NO	N/A	Doc
3-7	Water treatment (strength levels and pH) and exposure time is monitored and the facility has demonstrated it is appropriate for product.	10				D

Prevention of contamination is preferred over corrective action(s) once contamination has occurred. However, antimicrobial chemicals in processing water are useful in reducing microbial build-up in water and may reduce microbial load on the surface of produce. Thus, antimicrobial chemicals may provide some assurance in minimizing the potential for microbial contamination.

The effectiveness of an antimicrobial agent depends on its chemical and physical state, treatment conditions (such as water temperature, acidity [pH], and contact time), resistance of pathogens, and the nature of the fruit or vegetable surface. Chlorine is commonly added to water for post-harvest treatment of fresh produce at 50 to 200 parts per million total chlorine, at a pH of 6.0 to 7.5, with a contact time of 1 or 2 minutes.

Ozone has been used to sanitize wash and flume water in packing house operations. Ultraviolet radiation may also be used to disinfect processing water. Chlorine dioxide, trisodium phosphate, and organic acids (such as lactic and acetic acids) have been studied for use as antimicrobial agents in produce wash water, although more research needs to be done. Operators should consider options for water sanitation most appropriate for their individual operations.

The strength and acidity of the treated water must be appropriate for the commodity. If these are not, the process may not be effective in reducing the microbe population or may create problems for the produce, such as burning. Although there has been a lot of research on this aspect of packing, not all commodities have established and recommended levels. The following chart is reprinted from academic literature and is a guide for most commodities when the treatment is with chlorine.

Crop	Chlorine Strength (Total Titratable Chlorine)
General	50-500 Parts Per Million

Apples	100-150 Parts Per Million
Asparagus	125-250 Parts Per Million
Cantaloup, Honey Dew Melons	100-150 Parts Per Million
Lettuce, Cabbage, Leafy Greens	100-150 Parts Per Million
Tomatoes, Potatoes, Peppers	200-350 Parts Per Million

Auditors must review all appropriate documents and records in order to determine if the operator is effectively monitoring and maintaining the water quality. Auditors must also observe and question operators who are responsible to complete the monitoring and adjusting functions.

In some cases, the job of maintaining processing water quality will be contracted to an outside water quality management firm. In this case, auditors must review documentation showing the frequency of monitoring in order to determine that this is completed. Documentation may include an on-site log, monthly bills/invoices or other documents that show the process is being completed. If a water quality technician is present at the time of the audit, the technician should be interviewed to determine if the water treatment meets company specifications.

Use of water and water treatments are not required of packing operations, but are used voluntarily. Some commodities are not normally washed at all before packing (berries). This question shall be answered N/A when water is not used in the packing process, or when operation does not reuse the water (i.e. single use).

	Questions	Points	YES	NO	N/A	Doc
3-8	Food contact surfaces are in good condition; cleaned and/or sanitized prior to use and cleaning logs are maintained.	15				D

Many operations have located stainless steel tables or benches upon which packing processes are completed. Other operations may have established a mechanized system.

Brushes may be a part of the packing system to clean the product. Conveyors, such as belts, are very commonly used to move product through the packing system. These parts of the system can be easily contaminated from produce, workers or from other equipment in the packing system. Brushes or conveyors that physically touch the produce should be regularly cleaned, as needed. Conveyors that transport containers of packed product should be reasonably clean, but there is less possibility of contamination from this source.

Auditors should observe the operation and food contact surfaces to determine the condition and cleanliness of the surfaces. Operations must have a regular cleaning schedule. It is important for the auditor to recognize that different commodities may

require different cleaning and/or sanitizing schedules (daily, weekly, etc.) than others due to the conditions in which the product is harvested and the nature of the product.

Auditors should review documentation and/or records showing that an established schedule is being followed. This question may be answered N/A when the product is packed directly from one container to another and the product does not come into contact with any surface other than the container.

	Questions	Points	YES	NO	N/A	Doc
3-9	Product flow zones are protected from sources of contamination.	10				

The flow zone is that area through which the product moves from unloading to the storage and from storage to that point where it is loaded again for further shipment. As product moves through flow zone areas, it can become contaminated by substances not intended to be put on the product. Areas of possible contamination would include open mesh steel cat-walks, motors without shields, overhead dripping/leaking pipes or ceilings from condensation, box conveyors to second floor storages/palletizing areas, etc. Product in flow zones running under these mentioned areas could be subject to contamination from dirty shoes (catwalks), dripping lubricants (non-food grade in motors), cobwebs or dust hanging from ceilings or on light fixtures, etc.

**** Possible contamination by glass should be addressed in question 3-24. ****

Auditors must observe the flow of the product through the system and look up (or down) to determine if there is a possibility of contamination of product from overhead sources. Where possible and practical, operators should shield the flow zone or keep the area free of contaminants. This question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
3-10	The water used for cooling and/or making ice is potable.	15				R

Ice or cold water (hydro-cooling) is often used by some commodity packers to reduce product temperature. Source water for this procedure should be potable to reduce the risk of food contamination.

**** Auditors must investigate the source of the **water/ice** and review records to **verify** that there is no indication of microbial contamination of the water source. In some cases, ice may be manufactured on-site. In other cases, it may be provided by another entity. In either case, the water must meet the microbial requirements of the EPA Drinking Water Standard. The EPA "Total Coliform Rule" has a zero tolerance for coliforms including E. coli. If water is not potable this question must be answered NO. If ice or cooling water is not used, this question may be answered N/A. ****

	Questions	Points	YES	NO	N/A	Doc
3-11	Any ice used for cooling produce is manufactured, transported and stored under sanitary conditions.	10				R

Ice making facilities may be located on the site of the operation or may be contracted out and supplied by another operation. In either case, the facility must provide records that indicate there is a regular schedule to sanitize the ice production and storage facility and any means of transportation to reduce the microbial population. This would include augurs, conveyors and shovels used to transport the ice from one part of the facility to another.

Worker Health and Personal Hygiene

	Questions	Points	YES	NO	N/A	Doc
3-12	Employee facilities (locker rooms, lunch and break areas, etc.) are clean and located away from packing area.	10				

Facilities used by employees to take breaks, prepare to go to work, eat lunches, etc. must be clean and separate from the packing area. Some operators will have a separate room designed and identified for eating, others will identify an area in a corner of the packing house building or somewhere outside of the immediate packing area and supply it with tables. All of these are acceptable. The intent is that workers do not eat or take breaks within the packing area.

Applicable portions of 29 CFR, Part 1910.141 state:

(3) Housekeeping. (i) All places of employment shall be kept clean to the extent that the nature of the work allows.

(ii) The floor of every workroom shall be maintained, so far as practicable, in a dry condition. Where wet processes are used, drainage shall be maintained and false floors, platforms, mats, or other dry standing places shall be provided, where practicable, or appropriate waterproof footgear shall be provided.

(iii) To facilitate cleaning, every floor, working place, and passageway shall be kept free from protruding nails, splinters, loose boards, and unnecessary holes and openings.

This question cannot be answered as N/A.

	Questions	Points	YES	NO	N/A	Doc
3-13	When there is a written policy regarding the use of hair nets/beard nets in the production area, it is being followed by all employees and visitors.	5				P

Hair nets and beard nets are worn in order to keep stray hair from entering the food and food containers being packed. In addition, wearing of hairnets when the hair is very long reduces the risk of catching hair in machinery.

Operations that have a written policy must follow the policy. Auditors must review the policy and observe to determine if it is being followed. This question may be answered N/A when there is no written policy.

	Questions	Points	YES	NO	N/A	Doc
3-14	When there is a written policy regarding the wearing of jewelry in the production area, it is being followed by all employees and visitors.	5				P

Jewelry can be both a safety and a food safety hazard. It can become dislodged from the person wearing it and fall into the food item or the container. It can get caught on machinery and injure the worker.

Operations that have a written policy must follow the policy. Auditors must review the policy and observe to determine if it is being followed. This question may be answered N/A when there is no written policy.

Packing House General Housekeeping

Operations with poor sanitation in the packing environment can significantly increase the risk of contaminating fresh produce and water used on produce. Pathogenic microorganisms may be found on the floors and in the drains in the packing facility and on the surfaces of sorting, grading, and packing equipment. Without good sanitary practices, any of these surfaces that come in contact with fresh produce could be a potential source of microbial contamination. Packers should employ good sanitation practices as a standard operating procedure to maintain control throughout the packing operation.

	Questions	Points	YES	NO	N/A	Doc
3-15	Only food grade approved and labeled lubricants are used in the packing equipment/machinery.	10				R

Food grade approved lubricants should be used in areas where lubricating agents may come into contact with produce. Containers are normally marked. Auditors should ask to see containers of the food grade lubricants that are being used. If the lubricant is indeed food grade, the label is normally so marked. The container may also include a reference to meeting the applicable standards for FDA or other government agencies, regarding food grade lubricants.

If the auditor is not shown either the containers of food grade lubricants being used, or recent receipts for the food grade lubricants, this question must be answered NO. In some cases, operators will use food grade lubricants for equipment that is located over the flow zone and non-food grade lubricants in other areas. This practice will be cause for answering this question NO. In addition, if the auditor sees any evidence that non-food grade lubricants are being used in the packing area (for example: WD-40, Liquid Wrench, etc.) then the question must be answered NO. In facilities that have no mechanized equipment used for packing this question may be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
3-16	Chemicals not approved for use on product are stored and segregated away from packing area.	10				

Non-food grade chemicals may be used in the packing operation. Non-food grade approved chemicals must be stored outside the packing area or be physically separated by storage in a room or behind a physical barrier. This is to reduce the possibility of chemical contamination of the produce.

Food grade and non-food grade lubricants/chemicals should be stored separately from each other, either in separate rooms or separated and segregated within the same room. The intent is that the two are sufficiently separated and prominently marked in order to prevent cross-contamination or misuse of non-food grade for food grade.

This question must be answered NO if the auditor feels that there is not sufficient segregation to prevent cross-contamination or non-food grade approved chemicals are not properly stored in the packing area. This question may be answered as N/A when no chemicals are in use.

	Questions	Points	YES	NO	N/A	Doc
3-17	The plant grounds are reasonably free of litter and debris.	5				

Grounds in the immediate vicinity of all packing areas should be kept clear of waste, litter and improperly stored garbage. Keep all grasses cut to discourage the breeding, harboring and feeding of pests, such as rodents and reptiles.

It would be impractical for auditors to expect to see absolutely no debris at all. If the auditor feels that the amount or type of debris represents a possible risk of microbial contamination or is sufficient to attract pests to the area, this question should be answered NO.

Piles of wood, such as pieces of broken pallets, garbage or waste collected or scattered along the grounds, food products, food wrappers, cigarette butts or soda or drink containers scattered across the grounds, are all examples of possible reasons to answer this question NO. This question cannot be answered as N/A.

	Questions	Points	YES	NO	N/A	Doc
3-18	The plant grounds are reasonably free of standing water.	5				

Maintain adequate surface drainage to reduce breeding places for pests. Auditors should consider weather conditions (rain vs. dry) and standing water incident to receiving or storage operations when answering this question. These conditions would not be considered as detrimental unless there is indication that the water will not properly drain.

Auditors must judge such things as recent rain fall in the area which may have left a puddle or water which dripped from a recently used hose which was not completely shut off as excusable examples of standing water and answer this question YES. If the standing water does not look relatively fresh, such as being greenish from algae growth; or the operator has not taken any proactive action to drain or dry up the source, this question must be answered NO. This question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
3-19	Outside garbage receptacles/dumpsters are closed or are located away from packing facility entrances and the area around such sites is reasonably clean.	5				

Open garbage receptacles/dumpsters attract pests such as birds, vermin, flies and wildlife because of odors and discarded food products. All containers with lids should be kept closed whenever they are not in use or should be so located that they are a reasonable distance from the storage facility entrances in order that pests will not be drawn to the facility. They should be emptied regularly. This question must be answered NO when open or un-lidded receptacles or dumpsters are close to the facility entrances and it is likely pests will enter the facility.

The area surrounding the dumpsters or garbage receptacles needs to be maintained in a clean and orderly manner. Auditors must keep in mind that there may be a small amount of garbage spilled on the outside area surrounding the garbage receptacle or

dumpster because of how it may be dumped. This is normal. When the garbage is allowed to sit or accumulate or there is no action being taken to clean the spillage, this question must be answered NO. This question can only be answered N/A when no outside receptacles or dumpsters are present.

	Questions	Points	YES	NO	N/A	Doc
3-20	Packing facilities are enclosed.	5				

Not all facilities will be fully enclosed to keep out pests. Some facilities are open pole barns with no walls; others may be closed on three sides, but have an open side or have four perimeter walls, but the bottom portion of several walls is open to facilitate cleaning and washing the floors.

Buildings that are fully enclosed can easily exclude or reduce the possibility of contamination by most pests. Enclosed means that all doorways are capable of being closed or shut and will effectively exclude pests, especially during non-work hours. Any doors that are open during packing operations for passage of fork lift traffic, employee entrance, etc., should be considered as a part of the packing operation and the question will be answered YES. In some operations that are fully enclosed, there may be doors that are always left open, regardless of usage or there are doorways that have had the door removed. None of these would meet the test of being enclosed and the question must be answered NO. This question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
3-21	The packing facility interior is clean and maintained in an orderly manner.	5				

Remove as much as practicable all visible debris, soil, dirt and unnecessary items from product storage areas on an ongoing basis. These areas must be cleaned on a regularly scheduled and "as needed" basis and steps taken to minimize free-floating dust and other airborne contaminants.

For some commodities such as onions, it may not be possible to maintain the area at the same level of cleanliness as it would be for a fruit or a leafy vegetable commodity. Auditors must consider the product when assessing this question.

When it appears that there is no proactive effort to keep the storage area reasonably clean and orderly, this question must be answered NO. This question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
3-22	Floor drains appear to be free of obstructions.	5				

Operators should maintain adequate surface drainage to reduce breeding places for pests and to reduce product contamination. Auditors must look into the drain (or lift a drain cover if applicable) to see if there is any debris or are obstacles impeding the flow through the drain. A build-up of fruits or vegetables, sludge or dirt or anything else that may be considered as an obstruction will cause this question to be answered NO. This question can only be answered N/A when no floor drains are present.

	Questions	Points	YES	NO	N/A	Doc
3-23	Pipes, ducts, fans and ceilings which are over food handling operations are clean.	5				

Pipes, ducts, fans, and ceilings over the food handling or storage operation need to be clean. In addition, paint chips, loose screws, exposed insulation, or anything that stands out as a possible contamination factor must also be considered. Operations are not intended or expected to be meticulously clean. However, any readily noticeable build up of dust, dirt, debris, cobwebs or other contaminants that could fall onto product being packed is sufficient to answer this question NO. This question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
3-24	Glass materials above product flow zones are contained in case of breakage.	10				

This question pertains to glass light-bulbs and any other glass-made products that may be located above the product flow zone. Overhead lighting, regardless of height above the product, that may be susceptible to breakage should be protected from falling onto conveyor lines or into product containers such as bins or final packages. Other glass items, either in whole or broken form, must be contained or prevented from falling into product.

In the case of lighting equipment (fluorescent, incandescent, krypton vapor, etc.), there are many commercially available products and lighting equipment/types that may be used. In some cases, lighting fixtures may cover or enclose the bulb; in other cases, the bulbs may be coated with some medium that retards breakage and shattering; in other cases shields to cover the fixture are available.

Operators must take preventive measures to effectively prevent glass, broken or whole, from falling into the flow of product. Auditors must observe the lighting or other glass being used in the operation and determine whether or not it is possible that falling pieces may contaminate the produce. This question can only be answered as N/A when there is no glass located over all flow zones.

	Questions	Points	YES	NO	N/A	Doc
3-25	Possible wastewater spillage is prevented from contaminating any food handling area by barriers, drains or a sufficient distance.	10				

Waste water from toilets and hand washing sinks or other sources not intended to be used to wash or rinse product must not be permitted to run into the packing or storage area if a spill occurs. Waste water spillage sources that are a reasonable distance from the packing area and product flow zone are acceptable. Drains which are in place must drain away from the packing and storage area. Sanitary sewer lines and drains should not leak.

This question must be answered NO when it is observed that potential spillage of non-processing water is likely to run into and contaminate the production or storage area or the product. This question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
3-26	There is a policy describing procedures which specify handling/disposition of finished product which is opened, spilled or comes into contact with the floor.	15				P

Auditors should review the SOPs for the facility to identify if there is a procedure in place which identifies how product that spilled or comes in contact with the floor is handled. Spilled product that comes in contact with the floor can become contaminated and should not be used without some sort of corrective action such as washing or disposing of the product. This question cannot be answered as N/A.

	Questions	Points	YES	NO	N/A	Doc
3-27	Only new or sanitized containers are used for packing the product.	10				D

Packers that use new containers to package products are taking the highest possible means to reduce microbial contamination. The use of new containers eliminates the possibility of cross contamination of produce from used containers. Some operations are packing directly into reusable plastic containers (RPC) to meet buyer specifications. These containers are meant to be reused. In the case of RPCs, they should be sanitized prior to each reuse in the field. A cleaning log or record from either the producer or RPC management company shall be reviewed to verify they have been sanitized. This question cannot be answered as N/A.

	Questions	Points	YES	NO	N/A	Doc
3-28	Pallets and containers are clean and in good condition.	5				

Auditors must review the condition of pallets and containers being used and those stored for future use. Auditors must question the operator to determine what is done with broken or dirty pallets or containers. When operators use dirty or broken pallets and containers or do not clean and/or repair pallets and containers the answer to this question is NO.

	Questions	Points	YES	NO	N/A	Doc
3-29	Packing containers are properly stored and protected from contamination (birds, rodents, and other pests).	10				

Packing containers and other packing materials that are not ready for immediate use should be stored in a way that protects them from contamination by any source (pests, rodents, dirt, and water condensation, etc.) Packing containers stored outside should be covered in some manner to protect against contamination. Using the top container in a pile is not sufficient.

Auditors should observe where and how packing containers are stored. Containers which are stored in a manner that may lead to contamination by any reasonable means will result in a NO answer for this question.

Pest Control

	Questions	Points	YES	NO	N/A	Doc
3-30	Measures are taken to exclude animals or pests from packing and storage facilities.	10				D

All packing and storage facilities should establish a pest control program to reduce the risk of contamination by rodents and other animals, including pets. This program should include regular and frequent monitoring of affected and treated areas to accurately assess the program's effectiveness.

The auditee should consider the use of screens, wind curtains, bird deterrent tape and traps to minimize risk of product contamination. Pet dogs, cats or other animals should not be allowed in the packing and storage facilities.

Auditors must review the facilities' SOPs to determine if there is a proactive effort to exclude animals and pests from the facility. When guide dogs or similar animals are

present, SOP's must include corrective measures. This question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
3-31	There is an established pest control program for the facility.	10				D

A pest control log must be maintained that includes inspection dates, inspection reports, and procedures implemented to eliminate any problems. Frequent monitoring of affected and treated areas must take place to determine the effectiveness of the treatment applied. Generally, all traps and bait stations will be marked and flagged by numbers or some type of coding system. It is likely that there will also be a map of the premises that shows the location of such bait stations and traps.

All bait stations containing poison attractants must be located outside the facility. Traps or other non-poison methods should be the only control program located within a structure.

Auditors should be aware of and look for an organized method of pest detection and elimination. This question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
3-32	Service reports for the pest control program are available for review.	5				R

Generally, traps and bait stations will be regularly checked and have documentation showing when this was completed. This documentation may consist of a report or inspection log for all stations or may be a sticker or other marking on individual stations throughout the facility.

Auditors must review documentation and records that pertain to the pest control program. In some cases, it may be necessary to obtain this information from an independent pest control company contracted to provide these services. This question can only be answered as N/A when the answer to Question 3-31 is NO.

	Questions	Points	YES	NO	N/A	Doc
3-33	Interior walls, floors and ceilings are well maintained and are free of major cracks and crevices.	5				

Potential entryways for pests into the facility must be eliminated by blocking/repairing areas such as holes in walls, doors, flooring, vents, etc. To assess this question,

auditors must look closely at the inside walls, doors, floors and ceilings of an operation. Small cracks or crevices incident to structure age should be disregarded, unless it is obvious that pests are in the area. Cracks and crevices do not necessarily need to lead to the outdoors for infestation to occur. Certain pests can easily use areas inside walls as a living space and the food products within the facility provide a food source.

The facility should be well maintained to repair or eliminate problem areas. There should be no loose insulation materials protruding from the walls or hanging from the ceiling. This question must be answered NO when the facility is not well maintained and cracks or crevices may harbor pests or provide access. This question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
3-34	Records are kept recording the source of incoming product and the destination of outgoing product which is uniquely identified to enable traceability.	10				D

The Bioterrorism Act of 2002 requires certain handlers of foods to keep records that allow the handler to keep trace of produce “one step forward” and “one step back” within the food chain. For packing facilities, storage and transportation facilities and wholesale distribution/terminal warehouses, record keeping that keeps trace of the source of incoming produce and the destination of outgoing produce is a critical component of a documented traceability program. Traceability markings shall be at the container/master container level, and shall include other identifying marks as outlined in the company’s traceability program.

Auditors must explain all questions for which a NO or N/A answer was noted.

Any additional comments pertaining to individuals or to observations made during the audit should be made here. Auditors must be specific when making comments about YES answers to questions, as an additional statement here may indicate that the question might be better answered NO instead.

COMMENTS:

Total points earned for Part 3 = _____.

Total Possible = 290 *The total number of points possible for this section.*

Subtract "N/A" - _____ *Enter the additive number of N/A points (+ points) here.*

Adjusted Total = _____ *Subtract the N/A points from the Total possible points.*

X .8 (80%) *Multiply the Adjusted Total by .8 and show it as the Passing Score.*

Passing Score _____

(please circle one) Pass / Fail

Part 4

STORAGE AND TRANSPORTATION

Produce in the production area is generally stored at the packing facility or at a commercial cold storage. Many operations have both a packing operation and cold storage under the same roof. Auditors would normally assess both operations during the same audit. In some cases, the product may be held in storage for some time before being packed.

In some cases, a commercial operation provides cooling facilities and loading for finished products ready to be shipped to the terminal warehouse or wholesale distribution center. Part 4 applies to both the storage associated with a packing operation and the cold storage facility used in the production area, or in an interim area between the production area and the terminal market.

Storage Areas, Product, Containers, and Pallets

	Questions	Points	YES	NO	N/A	Doc
4-1	The storage facility is cleaned and maintained in an orderly manner.	5				

Remove as much as practicable all visible debris, soil, dirt and unnecessary items from product storage areas on an ongoing basis. These areas must be cleaned on a regularly scheduled and "as needed" basis.

For some commodities such as onions, it may not be possible to maintain the area at the same level of cleanliness as it would be for a fruit or a leafy vegetable commodity. Auditors must consider the product when assessing this question.

When it appears that there is no proactive effort to keep the storage area clean and orderly, this question must be answered NO. This question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
4-2	Bulk storage facilities are inspected for foreign material prior to use and records are maintained.	5				R

This question is specifically intended for bulk storage areas used for products such as potatoes or onions. It may include warehouses, cellars or areas where piles of product are to be stored and does not apply to product in containers. Auditors should observe or review documentation to verify that bulk storage areas are inspected and cleaned

prior to use. For products stored in totes, bins or other packages this question may be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
4-3	Storage rooms, buildings, and/or facilities are maintained and sufficiently sealed or isolated to be protected from external contamination.	10				

Storage areas shall be sufficiently sealed or isolated to protect stored product from windblown contaminants, rodents, rainwater, etc. This question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
4-4	Storage grounds are reasonably free of litter and debris.	5				

Grounds in the immediate vicinity of all storage areas should be kept clear of waste, litter and improperly stored garbage. The area around the facility should be maintained in a way to discourage the breeding, harboring and feeding of pests, such as rodents and reptiles.

It would be impractical for auditors to expect to see absolutely no debris at all. If the auditor feels that the amount or type of debris represents a possible risk of microbial contamination or is sufficient to attract pests to the area, this question should be answered NO.

Piles of wood, such as pieces of broken pallets, garbage or waste collected or scattered along the storage grounds, food products, food wrappers, cigarette butts or soda or drink containers scattered across the storage grounds, are all examples of possible reasons to answer this question NO. This question cannot be answered as N/A.

	Questions	Points	YES	NO	N/A	Doc
4-5	Floors in storage areas are reasonably free of standing water.	5				

Maintain adequate surface drainage to reduce breeding places for pests. Auditors should consider weather conditions (rain vs. dry) and standing water incident to receiving or storage operations when answering this question. These conditions would not be considered as detrimental unless there is indication that the water will not properly drain.

Auditors must judge such things as recent rain fall in the area which may have left a puddle or water which dripped from a recently used hose which was not completely shut off as excusable examples of standing water and answer this question YES. If the standing water does not look relatively fresh, such as being greenish from algae growth; or the operator has not taken any proactive action to drain or dry up the source, this question must be answered NO. This question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
4-6	Possible wastewater spillage is prevented from contaminating any food handling area by barriers, drains or a sufficient distance.	10				

Wastewater from toilets and hand washing sinks or other sources not intended to be used to wash or rinse product must not be permitted to run into the storage or transportation area if a spill occurs. Distance or other barriers should protect the storage areas and flow zones. Drains which are in place must drain away from the storage and transportation area. Sanitary sewer pipes and drains should not leak.

This question must be answered NO when it is observed that possible spillage of wastewater is likely to run into and contaminate the storage and transportation area, the flow zone or the product. This question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
4-7	There is a policy describing procedures which specify handling/disposition of finished product which is opened, spilled or comes into contact with the floor.	15				P

Auditors should review the SOPs for the facility to identify if there is a procedure in place which identifies how product that spilled or comes in contact with the floor is handled. Spilled product that comes in contact with the floor can become contaminated and should not be used without a corrective action such as washing or disposing of the product. This question cannot be answered as N/A, except in the case of bulk storage (onion, potatoes, etc.,) when no finished (packed) products are present.

	Questions	Points	YES	NO	N/A	Doc
4-8	Packing containers are properly stored and sufficiently sealed to be protected from contamination (birds, rodents, pests and other contaminants).	10				

Packing containers and other packing materials which are not ready for immediate use should be stored in a way that protects them from contamination by any source (pests, dirt and water condensation, etc.). Packing containers stored outside should also be covered in some manner to protect against contamination.

Auditors should observe where and how packing containers are stored. Containers which are stored in a manner that may lead to contamination by any reasonable means will result in a NO answer for this question.

If there are no packing containers in the storage area this question may be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
****	4-9 Pallets, pallet boxes, tote bags and portable bins, etc. are clean, in good condition and do not contribute foreign material to the product.	5				

It is not uncommon to see an area in the receiving yard specifically designated for cleaning containers and pallets. Containers used for ready-to-eat fresh produce should be cleaned and/or sanitized. If produce is field packed, care must be taken to prevent contamination of containers or bins by exposure to soil and manure.

Auditors must observe the condition of pallets and containers being used and also those being stored for future use. The auditee must be questioned to determine the disposition of broken or dirty pallets/containers. The answer to this question should be NO if auditors observe the use of dirty or broken pallets/containers, or if an effort is not being made to clean or stop using such items. This question cannot be answered N/A, except in the case of bulk handling (onions, potatoes, etc.,) when no product in containers are present. Bulk storage rooms and cellars are addressed in 4-1 to 4-3.

	Questions	Points	YES	NO	N/A	Doc
	4-10 Product stored outside in totes, trucks, bins, other containers or on the ground in bulk is covered and protected from contamination.	10				

Storage and transportation facilities may either be integrated into the packing operation or a standalone facility that accepts raw or finished product (i.e. an apple shed cold storage room vs. a potato bulk storage facility). It is important that product that is being temporarily stored or held outside of a storage facility be protected from possible sources of contamination.

Steps shall be taken to reduce possible contamination by other vehicles, contamination from birds, rodents or other means. Covering loads, temporarily storing loads under roofs or using enclosed trailers are examples of good practices. Auditors may see operations that store product under mesh covers/awnings. Mesh coverings over these

types of staging areas do not provide adequate protection against contamination and do not meet the requirements of this question.

Auditors shall observe loads being delivered to the packing or storage facility to adequately answer this question.

	Questions	Points	YES	NO	N/A	Doc
4-11	Non-food grade substances such as paints, lubricants, pesticides, etc., are not stored in close proximity to the product.	10				

Non-food grade chemicals shall not be stored in close proximity to stored product. Close proximity in this instance means close enough to the product that the chemicals, if leaked or spilled, would reach the product. Ideally, these types of chemicals shall be stored in a separate secured area or storage cabinet which would prevent any possible spillage from entering the product storage area.

	Questions	Points	YES	NO	N/A	Doc
4-12	Mechanical equipment used during the storage process is clean and maintained to prevent contamination of the product.	5				D

Any equipment used in the storage facility shall be clean and properly maintained. If equipment becomes soiled due to normal use during the production day, the auditor should not consider this as failing to meet the cleanliness requirement. Equipment shall be maintained to prevent leaking fluids that could potentially contaminate the product, and loose or broken parts must be repaired to prevent foreign objects from contaminating the product. Any equipment or portions of equipment that directly touches raw product must be maintained in a higher degree of cleanliness.

Pest Control

	Questions	Points	YES	NO	N/A	Doc
4-13	Measures are taken to exclude animals or pests from storage facilities.	10				D

All packing and storage facilities should establish a pest control program to reduce the risk of contamination by rodents and other animals, including pets. This program should

include regular and frequent monitoring of affected and treated areas to accurately assess the program's effectiveness.

The auditee should consider the use of screens, wind curtains, bird deterrent tape and traps to minimize risk of product contamination. Pet dogs, cats or other animals should not have free run of the facility.

Auditors must review the facilities' SOPs to determine if there is a proactive effort to exclude animals and pests from the facility. This question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
4-14	There is an established pest control program for the facility.	10				D

A pest control log must be maintained that includes inspection dates, inspection reports, and procedures implemented to eliminate any problems. Frequent monitoring of affected and treated areas must take place to determine the effectiveness of the treatment applied. Generally, all traps and bait stations will be marked and flagged by numbers or some type of coding system. It is likely that there will also be a map of the premises that shows the location of such bait stations and traps.

All bait stations containing poison attractants must be located outside the facility. Traps or other non-poison methods should be the only control program located within a structure.

Auditors should be aware of and look for an organized method of pest detection and elimination. This question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
4-15	Service reports for the pest control program are available for review.	5				R

Generally, traps and bait stations will be regularly checked and have documentation showing when this was completed. This documentation may consist of a report or inspection log for all stations or may be a sticker or other marking on individual stations throughout the facility.

Auditors must review documentation and records that pertain to the pest control program. In some cases, it may be necessary to obtain this information from an independent pest control company contracted to provide these services. This question can only be answered N/A when Question 4-14 is answered NO.

	Questions	Points	YES	NO	N/A	Doc
4-16	Interior walls, floors and ceilings are well maintained and are free of major cracks and crevices.	5				

Potential entryways for pests into the facility must be eliminated by blocking/repairing areas such as holes in walls, doors, flooring, vents, etc. To assess this question, auditors must look closely at the inside walls, doors, floors and ceilings of an operation. Small cracks or crevices incident to structure age should be disregarded, unless it is obvious that pests are in the area. Cracks and crevices do not necessarily need to lead to the outdoors for infestation to occur. Certain pests can easily use areas inside walls as a living space and the food products within the facility provide a food source.

The facility should be well maintained to repair or eliminate problem areas. There should be no loose insulation materials protruding from the walls or ceiling. This question must be answered NO when the facility is not well maintained or there is easy access or harborage by pests through large or numerous cracks. This question cannot be answered N/A.

Ice and Refrigeration

	Questions	Points	YES	NO	N/A	Doc
4-17	The water used for cooling and/or making ice is potable.	15				R

Ice or cold water (hydro-cooling) is often used by some commodity packers to reduce product temperature. Source water for this procedure should be potable to reduce the risk of food contamination.

Auditors must investigate the source of the water/ice and review records to verify that there is no indication of microbial contamination of the water source. In some cases, ice may be manufactured on-site. In other cases, it may be provided by another entity. In either case, the water must be potable. Water tests should show that the microbial contents are within the EPA, State, or local guidelines. The EPA "Total Coliform Rule" has a zero tolerance for coliforms, including E. coli. If water is not potable this question must be answered NO. If ice or chilled water is not used, this question may be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
4-18	Manufacturing, storage and transportation facilities used in making and delivering ice used for cooling the product have been sanitized.	10				R

Ice making facilities may be located on site or contracted out and supplied by an outside source. To reduce microbial risks in either case, the auditee must provide records indicating there is a sanitizing schedule for the ice production and storage facilities including any means of

necessary transportation. This should also include equipment (conveyors, belts, augers, etc.) used to move ice within the facility or into trucks.

	Questions	Points	YES	NO	N/A	Doc
4-19	Climate controlled rooms are monitored for temperature and logs are maintained.	5				D

Climate control systems must be working properly to minimize the survival and replication of food borne microbes. Although there are some microbes that will live and reproduce under cold or freezing temperatures, the majority do not.

Auditors must assess the operation by noting the room temperature as it relates to the product being stored. Some products are stored at 32° F, while others require higher temperatures due to cold sensitivity. Auditors should check available temperature logs. These should cover all storages at the audit site. These will lend credibility to the proper temperature operation of the facility. When stored product requires a certain temperature range and the system does not maintain those temperatures, this question must be answered NO.

Auditors should keep in mind that some products are frequently stored at temperatures higher than typically refrigerated products. In these cases, there are no temperature requirements and refrigeration systems may not be present. This question may be answered N/A as appropriate.

	Questions	Points	YES	NO	N/A	Doc
4-20	Thermometer(s) are checked for accuracy and records are available for review.	5				D

Thermometers used in cold storage areas and for determining product temperatures should be regularly checked for accuracy and operators must maintain records to validate this procedure. In some cases, thermometers are computerized with operation checked from a computer terminal. In other cases, a computer automatically verifies the temperature of the room on an ongoing basis.

This question must be answered NO when there are no verification checks or no records are being maintained. This question can only be answered N/A when product is not stored in coolers/refrigerated units.

	Questions	Points	YES	NO	N/A	Doc
4-21	Refrigeration system condensation does not come in contact with produce.	10				

The majority of refrigeration equipment is located inside the storage rooms. It is not uncommon for the equipment to drip liquid, usually water and whatever other substances that might be on the equipment. This condensation is a result of the combination of temperature and humidity within the room.

In some cases, it is possible for product to be stored underneath the refrigeration equipment. Whenever it is likely that produce would come into contact with the dripping condensation, the produce must be protected from the likelihood of contamination.

Auditors should review the storage of produce and note whether or not any condensation would come into contact with the product. The question would be answered NO when condensation will come into contact with the produce.

	Questions	Points	YES	NO	N/A	Doc
4-22	Refrigeration equipment (condensers, fans, etc.) is cleaned on a scheduled basis.	10				D

Refrigerated storages should be cleaned on a regular basis. This will reduce the amount of dust and dirt build-up and further reduce the possibility of contamination. Auditors should review the cleaning schedule documentation. This question can only be answered N/A when there is no refrigeration equipment.

	Questions	Points	YES	NO	N/A	Doc
4-23	Iced product does not drip on pallets of produce stored below.	10				

Many vegetable products are frequently packed with ice or crushed ice put on the tops of the cartons or pallets to keep them cold. This would include broccoli, sweet corn and cantaloups. In storages where pallets are stacked more than one high or when there are racks to stack pallets one above the other, the iced product should be stored on the bottom. If a product is stored beneath an iced product, it must be protected from the dripping of melting ice.

Auditors must review the storage, ask appropriate questions about storage of products packed with ice and assess the results.

Transportation and Loading

	Questions	Points	YES	NO	N/A	Doc
4-24	Prior to the loading process, conveyances are required to be clean, in good physical condition, free from disagreeable odors, and from obvious dirt/debris.	10				P

	Dirt/debris					
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All parties involved in the transport of fresh produce should help ensure that sanitation requirements for conveyances are maintained throughout the transportation chain. Trucks and transport containers must be inspected for cleanliness, odors, and debris before the loading process begins.

Drivers and operators should be aware of the contents of previously carried loads and consider this information when determining current usage. For example, trucks recently used to transport animals or animal products would increase the risk of contaminating fresh produce if not properly cleaned prior to produce loading. Auditors should not expect to see conveyances in like-new or sterilized condition. Conveyances should be acceptably clean.

Auditors should review auditee documentation to verify that there is an active policy in place addressing carrier condition. The Auditee must maintain records verifying that the overall physical condition of conveyances is being checked. If the auditee cannot provide records verifying that these procedures are being performed, this question must be answered NO. This question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
4-25	Produce items are not loaded with potentially contaminating products.	10				P

The Guide recommends that produce items should only be shipped with other produce items. They should definitely not be shipped with fertilizers, meats, poultry, or fish products. There may be times when produce must be shipped with non-produce items other than those mentioned. Shippers should adequately protect produce items from cross contamination by segregating and separating these items in the conveyance by a physical barrier. This question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
4-26	Company has a written policy for transporters and conveyances to maintain a specified temperature(s) during transit.	10				P

The auditee must work with transporters to ensure adequate control of transport temperatures from loading to receiving. Transporters should be aware of the temperature requirements for produce being hauled and avoid delivery of mixed loads with incompatible refrigeration requirements.

Auditors should recognize that not all products require refrigeration during transport. In certain cases, shippers may require or specify a higher temperature for transportation than that recommended for storage conditions. Shippers should recommend

temperatures according to the product and conditions for transport. In general, manifests should be marked with the temperature range that the shipper requires the carrier to maintain.

If there are no transportation temperatures required by the auditee, or there is no indication of required temperatures on the manifest, this question must be answered NO. This question may be answered N/A when specific shipping temperatures are not suggested for the product (nuts, for example).

	Questions	Points	YES	NO	N/A	Doc
4-27	Conveyances are loaded to minimize damage to product.	5				P

All fresh produce should be carefully packed and loaded to minimize physical damage and to reduce the potential for contamination during transport. A shipper should have an SOP describing the use of acceptable safe loading practices.

Produce which is damaged during harvesting, packing or transportation is more susceptible to microbial contamination than undamaged product. Precautions should be taken to minimize or prevent shifting of the load during transit. Load bracing, straps/belts and pallet wrapping are examples designed to keep containers in place. Shippers should strive to organize each load with a realistic attempt at securing packages and preventing spillage during transit. This question cannot be answered N/A.

Worker Health and Personal Hygiene

	Questions	Points	YES	NO	N/A	Doc
4-28	Employee facilities (locker rooms, lunch and break areas, etc.) are clean and located away from storage, shipping and receiving areas.	10				

Facilities used by employees to take breaks, prepare to go to work, eat lunches, etc. must be clean and separate from the storage, shipping and receiving areas. Some operators will have a separate room designed and identified for eating, others will identify an area in a corner of the packing house building or somewhere outside of the immediate packing area and supply it with tables. All of these are acceptable. The intent is that workers do not eat or take breaks within the packing area.

Applicable portions of 29 CFR, Part 1910.141 state:

(3) Housekeeping. (i) All places of employment shall be kept clean to the extent that the nature of the work allows.

(ii) The floor of every workroom shall be maintained, so far as practicable, in a dry condition. Where wet processes are used, drainage shall be maintained and false floors, platforms, mats, or other dry standing places shall be provided, where practicable, or appropriate waterproof footwear shall be provided.

(iii) To facilitate cleaning, every floor, working place, and passageway shall be kept free from protruding nails, splinters, loose boards, and unnecessary holes and openings.

This question cannot be answered as N/A.

	Questions	Points	YES	NO	N/A	Doc
4-29	When there is a written policy requiring the use of hair/beard nets in the storage and transportation areas, it is being followed by all affected employees and visitors.	5				P

Hair nets and beard nets are worn in order to keep stray hair from entering the food and food containers. In addition, wearing of these when the hair is very long reduces the risk of catching hair in machinery.

Operations that have a written policy must follow the policy. Auditors must review the policy and observe to determine if it is being followed. This question may be answered N/A when there is no written policy.

	Questions	Points	YES	NO	N/A	Doc
4-30	When there is a written policy restricting the wearing of jewelry in the storage and transportation areas, it is being followed by all affected employees and visitors.	5				P

Jewelry can be both a safety and a food safety hazard. It can become dislodged from the person wearing it and fall into the food item or the container. It can get caught on machinery and injure the worker. Jewelry, especially watchbands if not cleaned properly, can harbor microorganisms.

Operations that have a written policy must follow the policy. Auditors must review the policy and observe to determine if it is being followed. This question may be answered N/A when there is no written policy.

Total points earned for PART 4 = _____.

Total Possible = 250 *The total number of points possible for this section.*

Subtract "N/A" - _____ *Enter the additive number of N/A points (+ points) here.*

Adjusted Total = _____ *Subtract the N/A points from the Total possible points.*

X .8 (80%) *Multiply the Adjusted Total by .8 and show it as the Passing Score.*

Passing Score _____

(please circle one) Pass / Fail

Part 5

TRACEBACK

The checklist questions and explanatory narrative previously addressing Traceback have been removed from this chapter and incorporated into Parts 1, 2, 3 and 6 of the checklist, as appropriate. Please refer to those sections of this handbook for specific information applicable to this topic.

Part 6

WHOLESALE DISTRIBUTION CENTER/ TERMINAL WAREHOUSE

Although “*The Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*” is specific to growing, harvesting, packing, and storage in the shipping area, Good Handling and Sanitary Practices are applicable throughout the marketing chain.

Organizations and personnel at wholesale distribution warehouses in the produce industry are just as responsible for minimizing microbial food safety hazards as are organizations and personnel at the production and shipping levels.

Part 6 of the Good Agriculture Practices and Good Handling Practices, Audit Verification Program checklist is applicable to wholesale distribution warehouses commonly known in the inspection service as “Terminal Markets.” The checklist questions were developed for auditing steps taken by receivers and wholesalers in a Wholesale Distribution Center or Terminal Warehouse to minimize microbial food safety hazards.

Receiving

	Questions	Points	YES	NO	N/A	Doc
6-1	All companies that supply fresh produce are required to have passed a third party audit verification of GAP and/or GHP.	15				D

It is intended that any operation supplying produce items to a terminal market operation will be required to have passed some type of third party verification of good agricultural and/or good handling practices.

Auditors must review the terminal market operation documents for a policy and the documents that verify the supplier’s passing audit. Both must be available in order to answer the question YES. This question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
6-2	Upon receiving, conveyances are required to be clean, in good physical condition and free from obvious objectionable odors, dirt and/or debris at time of unloading.	10				P

Growers, packers, shippers, brokers, exporters, importers, retailers, wholesalers and others involved in the transport of fresh produce should ensure that sanitation requirements for trucks or other carriers are met at the different steps within the transportation chain. Receivers should inspect trucks or transport containers for cleanliness, odors, obvious dirt or debris before beginning the unloading process.

Conveyances are not always in 'brand new condition' or appear to be sterilized. However, it is expected that the unit would be at an acceptably clean level. The company being audited must maintain documentation (logs) that the conveyances are being checked for cleanliness, good physical condition, that they are free from odors, from dirt, mud, or debris.

Auditors should review receiver documents (policy and logs) to verify that there is a policy to verify the condition of the carrier. The policy should also state what will be done if a conveyance is found to be dirty beyond a reasonable amount. If the company representative cannot provide documentation, the question should be answered NO. This question cannot be answered as N/A.

	Questions	Points	YES	NO	N/A	Doc
6-3	Company does not accept produce items that are loaded with or not protected from potentially contaminating products.	10				P

The Guide recommends that produce items should only be shipped with other produce items. They should definitely not be shipped with fertilizers, meats, and poultry or fish products. There may be times when produce has to be shipped with non-produce items other than those mentioned. Terminal Warehouse Receivers must have a policy that prohibits the acceptance of produce items that are loaded with potentially contaminating products.

	Questions	Points	YES	NO	N/A	Doc
6-4	Refrigerated commodities are monitored for temperatures at time of receiving.	5				R

Generally all perishable produce items have recommended shipping temperatures. Shippers normally require delivery companies to maintain the recommended temperatures during the transit time from the shipping area to the Terminal Warehouse. Such recommended temperatures are frequently printed on the shipping manifest. It is also common for shippers to insert temperature recording devices in the refrigerated area of the conveyance in order to provide a record of temperatures during the transit time.

Terminal Warehouse Receivers must monitor the temperatures of produce at the time of receiving/unloading to verify that proper temperatures were maintained. Auditors should review records of one or both of the following.

- Documentation showing the temperatures of the produce at time of arrival.
- Originals or copies of the temperature recording device documents.

This question may be answered as N/A if no refrigerated product is received.

	Questions	Points	YES	NO	N/A	Doc
6-5	The company has a written policy regarding the disposition of product when temperatures are not within the company's guidelines at time of receiving.	5				P

Auditors should review the company policy regarding temperatures of received product. If there is a policy or operating procedure for disposition of product that is not within the company's guidelines upon arrival, this question should be answered yes. If no refrigerated product is received and/or there are no temperature guidelines, this question may be answered N/A.

Storage Facility/Ice/Temperature Control

	Questions	Points	YES	NO	N/A	Doc
6-6	The facility is clean and maintained in an orderly manner.	5				

Remove as much as practicable, all visible debris, soil, dirt, and unnecessary items from product storage areas on an ongoing basis. Clean these areas on a regularly scheduled and "as needed" basis and take steps to minimize free-floating dust and other airborne contaminants.

For some commodities, such as onions, it may not be possible to have the area at the same level of cleanliness and orderliness as it would be for a fruit or a leafy vegetable commodity. Auditors must consider the product. It is also recognized that some Terminal Warehouse Receivers market products that have different storage requirements. These are usually stored in appropriate places in the warehouse. With this in mind, it is recognized that an area where vegetables, such as lettuce is stored or displayed, may be cleaner than an area where onions or potatoes are stored or displayed. Auditors must keep these characteristics in mind when assessing the overall appearance and orderliness of the operation.

When it appears that there is no proactive effort to keep the storage in a reasonably clean and orderly manner according to the items being marketed, this question must be answered NO. This question cannot be answered N/A.

Excerpts from 29 CFR, Part 1910.141:

(3) Housekeeping. (i) All places of employment shall be kept clean to the extent that the nature of the work allows.

(ii) The floor of every workroom shall be maintained, so far as practicable, in a dry condition. Where wet processes are used, drainage shall be maintained and false floors, platforms, mats, or other dry standing places shall be provided, where practicable, or appropriate waterproof footwear shall be provided.

(iii) To facilitate cleaning, every floor, working place, and passageway shall be kept free from protruding nails, splinters, loose boards, and unnecessary holes and openings.

	Questions	Points	YES	NO	N/A	Doc
6-7	Refrigerated rooms are monitored for temperature and logs are maintained.	5				D

Refrigeration systems which are working properly will reduce food borne microbial activity and reproduction. Although there are a few microbes that continue to reproduce the majority of microbes do not thrive at cold or freezing temperatures.

Auditors must assess the system operation by observing the temperature in the room (including walk in storage trailers and other types of storage areas) as it relates to the product being stored. Some products are stored at 32°F, others require higher temperatures because they are cold sensitive.

In all cases, the operation must have temperature recording logs available for review. These will lend credibility to the proper operation of the facility. When it is found that the system is not working properly or no logs are available, this question must be answered NO.

Auditors should keep in mind that products such as onions or nuts are frequently stored at room temperature. In these cases, there are no temperature requirements and there are not likely to be refrigeration systems present. No documentation will be available. If this is the case, this question may be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
6-8	Thermometer(s) are checked for accuracy and records are available for review.	5				D

Thermometers used in cold storage areas and for determining product temperatures should be regularly checked for accuracy and operators must maintain records to validate this procedure. In some cases, thermometers are computerized with operation checked from a computer terminal. In other cases, a computer automatically verifies the temperature of the room on an ongoing basis.

This question must be answered NO when there are no verification checks or no records are being maintained. This question can only be answered N/A when product is not stored in coolers/refrigerated units.

	Questions	Points	YES	NO	N/A	Doc
6-9	Refrigeration system condensation does not come in contact with produce.	10				

The majority of refrigeration equipment is located inside the storage rooms. It is not uncommon for the equipment to drip liquid, usually water and whatever other substances that might be on the equipment. This condensation is a result of the combination of temperature and humidity within the room.

In some cases, it is possible for product to be stored underneath the refrigeration equipment. Whenever it is likely that produce would come into contact with the dripping condensation, the produce must be protected from the likelihood of contamination.

Auditors should review the storage of produce and note whether or not any condensation would come into contact with the product. The question would be answered NO when condensation will come into contact with the produce. This question can only be answered N/A when product is not stored in a cooler/refrigerated unit.

	Questions	Points	YES	NO	N/A	Doc
6-10	Refrigeration equipment (condensers, fans, etc.) is cleaned on a scheduled basis.	10				D

Refrigerated storages should be cleaned on a scheduled basis. This will reduce the amount of dust and dirt build-up and further reduce the possibility of contamination. Auditors should review the cleaning schedule documentation. This question can only be answered N/A when there is no refrigeration equipment.

	Questions	Points	YES	NO	N/A	Doc
6-11	Iced product does not drip on pallets of produce stored below.	10				

Many vegetable products are frequently packed with ice or crushed ice is put on the tops of the cartons or pallets to keep them cold. This would include broccoli, sweet corn and cantaloupes. In storages where pallets are stacked more than one high or when there are racks to stack pallets one above the other, the iced product should be stored on the bottom. If a product is stored beneath an iced product, it must be protected from the dripping of melting ice.

Auditors must review the storage, ask appropriate questions about storage of products packed with ice and assess the results.

	Questions	Points	YES	NO	N/A	Doc
6-12	The water used for cooling/ice is potable.	10				R

Ice or cold water (hydro-cooling) is often used by some commodity industries to reduce the temperature of the product. Such water used for this should be potable in order to reduce the risk of food contamination.

Auditors must investigate the source of the water or ice and review records indicating that there is no indication of microbial contamination of the water source. In some cases, ice may be manufactured on-site. In other cases, it may be provided by another entity. In either case, the water tests should show that the microbial contents are within the EPA, State, or local guidelines. The EPA "Total Coliform Rule" has a zero tolerance for coliforms, including E. coli. If not, the question must be answered NO. If ice or chilled water is not used, then this question may be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
6-13	Manufacturing, storage and transportation facilities used in making and delivering ice used for cooling the product are sanitized on a scheduled basis.	10				D

Ice making facilities may be located on the site of the operation or may be contracted out and supplied by another operation. In either case, the facility must provide records that indicate there is a regular schedule to sanitize the production facility, the storage facility and any means of necessary transportation to reduce the microbial population. This would include conveyors and augurs used to transport the ice from one part of the facility to another.

	Questions	Points	YES	NO	N/A	Doc
6-14	There is a policy describing procedures which specify handling/disposition of finished product which is opened, spilled or comes into contact with the floor.	15				P

Auditors should review the SOPs for the facility to identify if there is a procedure in place which identifies how product that spilled or comes in contact with the floor is handled. Spilled product that comes in contact with the floor can become contaminated and should not be used without some sort of corrective action such as washing or disposing of the product. This question cannot be answered as N/A.

	Questions	Points	YES	NO	N/A	Doc
6-15	Product flow zones are protected from sources of contamination.	10				

The flow zone is that area through which the product moves from unloading to the storage and from storage to that point where it is loaded again for further shipment. As product moves through flow zone areas, it can become contaminated by substances not intended to be put on the product. Areas of possible contamination would include open mesh steel cat-walks, motors without shields, overhead dripping/leaking pipes or ceilings from condensation, box conveyors to second floor storages/palletizing areas, etc. Product in flow zones running under these mentioned areas could be subject to contamination from dirty shoes (catwalks), dripping lubricants (non-food grade in motors), cobwebs or dust hanging from ceilings or on light fixtures, etc. Possible contamination by glass should be addressed in question 6-16.

Auditors must observe the flow of the product through the system and look up (or down) to determine if there is a possibility of contamination of product from overhead sources. Where possible and practical, operators should shield the flow zone or keep the area free of contaminants. This question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
6-16	Glass materials above product flow zones are contained in case of breakage.	10				

This question pertains to glass light-bulbs and any other glass products that may be located above the product flow zone. Overhead lighting, regardless of height above the product that may be susceptible to breakage should be protected from falling onto conveyor lines or into product containers such as bins or final packages.

Other glass items, either in whole or broken form, must be contained or prevented from falling into product.

In the case of lighting equipment (fluorescent, incandescent, krypton vapor, etc.), there are many commercially available products and lighting equipment/types that may be used. In some cases, lighting fixtures may cover or enclose the bulb; in other cases, the bulbs may be coated with some medium that retards breakage and shattering; in other cases shields to cover the fixture are available.

Operators must take preventive measures to effectively prevent glass, broken or whole, from falling into the flow of product. Auditors must observe the lighting or other glass

being used in the operation and determine whether or not it is possible that falling pieces may contaminate the produce. This question can only be answered N/A when there is no glass over any of the product flow zones.

	Questions	Points	YES	NO	N/A	Doc
6-17	The grounds are reasonably free of litter and debris.	5				

Grounds in the immediate vicinity of all storage areas should be kept clear of waste, litter, and improperly stored garbage. Keep all grasses cut to discourage the breeding, harboring, and feeding of pests, such as rodents and reptiles.

It would be impractical for auditors to expect to see absolutely no debris at all. If the auditor feels that the amount or type of debris represents a possible risk of microbial contamination or is sufficient to attract pests to the area, this question should be answered NO. Piles of wood, such as pieces of broken pallets, garbage or waste collected or scattered along the grounds, food products, food wrappers, or soda or drink containers scattered across the grounds, are all examples of possible reasons to answer this question NO. This question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
6-18	The grounds are reasonably free of standing water.	5				

Maintain adequate surface drainage to reduce breeding places for pests. Auditors should consider weather conditions (rain vs. dry) and standing water incident to receiving or storage operations when answering this question. These conditions would not be considered as detrimental unless there is indication that the water will not properly drain.

Auditors must judge such things as recent rain fall in the area which may have left a puddle or water which dripped from a recently used hose which was not completely shut off as excusable examples of standing water and answer this question YES. If the standing water does not look relatively fresh, such as being greenish from algae growth; or the operator has not taken any proactive action to drain or dry up the source, this question must be answered NO. This question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
6-19	Outside garbage receptacles/dumpsters are closed or are located away from facility entrances and the area around such sites is reasonably clean.	5				

Open garbage receptacles/dumpsters attract pests such as birds, vermin, flies and wildlife because of odors and discarded food products. All containers with lids should be kept closed whenever they are not in use or should be so located that they are a reasonable distance from the storage facility entrances in order that pests will not be drawn to the facility. They should be emptied regularly. This question must be answered NO when open or un-lidded receptacles or dumpsters are close to the facility entrances and it is likely pests will enter the facility.

The area surrounding the dumpsters or garbage receptacles needs to be maintained in a clean and orderly manner. Auditors must keep in mind that there may be a small amount of garbage spilled on the outside area surrounding the garbage receptacle or dumpster because of how it may be dumped. This is normal. When the garbage is allowed to sit or accumulate or there is no action being taken to clean the spillage, this question must be answered NO. This question can only be answered N/A when no outside receptacles or dumpsters are present.

	Questions	Points	YES	NO	N/A	Doc
6-20	The facility is enclosed.	5				

Not all facilities will be fully enclosed to keep out pests. Some facilities are open loading docks with no walls; others may be closed on three sides, but have an open side or have four perimeter walls, but the bottom portion of several walls is open to facilitate cleaning and washing the floors. In some operations that are fully enclosed, there may be doors that are always left open, regardless of usage or there are doorways that have had the door removed. None of these would meet the test of being enclosed and the question must be answered NO.

Buildings that are fully enclosed can easily exclude or reduce the possibility of contamination by most pests. Enclosed means that all doorways are capable of being closed or shut and will effectively exclude pests, especially during non-work hours. Any doors that are open during packing operations for passage of fork lift traffic, employee entrance, etc., should be considered as a part of the packing operation and the question will be answered YES. In some operations that are fully enclosed, there may be doors that are always left open, regardless of usage or there are doorways that have had the door removed. None of these would meet the test of being enclosed and the question must be answered NO. This question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
6-21	Floor drains appear to be free of obstructions.	5				

Operators should maintain adequate surface drainage to reduce breeding places for pests and to reduce product contamination. Auditors must look into the drain (or lift a drain cover if applicable) to see if there is any debris or are obstacles impeding the flow

through the drain. A build-up of fruits or vegetables, sludge or dirt or anything else that may be considered as an obstruction will cause this question to be answered NO. This question can only be answered N/A when no floor drains are present.

	Questions	Points	YES	NO	N/A	Doc
6-22	Pipes, ducts, fans and ceilings in the facility are reasonably clean.	5				

Pipes, ducts, fans, and ceilings over the food handling or storage operation need to be clean. In addition, paint chips, loose screws, exposed insulation, or anything that stands out as a possible contamination factor must also be considered. Operations are not intended or expected to be meticulously clean. However, any readily noticeable build up of dust, dirt, debris, cobwebs or other contaminants that could fall onto product being packed is sufficient to answer this question NO.

	Questions	Points	YES	NO	N/A	Doc
6-23	Possible wastewater spillage is prevented from contaminating any food storage or handling area by barriers, drains or a sufficient distance.	10				

Waste water from toilets and hand washing sinks or other sources not intended to be used to wash or rinse product must not be permitted to run into the packing or storage area if a spill occurs. Waste water spillage sources that are a reasonable distance from the packing area and product flow zone are acceptable. Drains which are in place must drain away from the packing and storage area.

This question must be answered NO when it is observed that potential spillage of non-processing water is likely to run into and contaminate the production or storage area or the product. This question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
6-24	Non-food grade substances such as paints, lubricants, pesticides, etc., are not stored in close proximity to the product.	10				

Facilities may apply food grade approved products such as waxes to the product. In addition, there may be non-food grade approved chemicals used in the operation for other purposes. Non-food grade approved chemicals must be stored outside the repacking area or physically separated by storage in a room or behind a physical barrier. This is to reduce the possibility of chemical contamination of the produce.

Food grade and non-food grade lubricants/chemicals should be stored separately from each other, either in separate rooms or separated and segregated within the same room. The intent is that the two are sufficiently separated and prominently marked in order to prevent cross-contamination or misuse of non-food grade for food grade.

If the auditor feels that there is insufficient segregation to prevent cross-contamination or non-food grade approved chemicals are stored in the repacking area, but not properly stored, this question should be answered NO.

Pest Control

	Questions	Points	YES	NO	N/A	Doc
6-25	Measures are taken to exclude animals or pests from the facility.	10				D

The facility should consider the use of screens, wind curtains, bird deterrent tape and traps to minimize risk of product contamination. Pet dogs, cats or other animals should not be allowed in the packing and storage facilities.

Auditors must review the facilities' SOPs to determine if there is a proactive effort to exclude animals and pests from the facility. When guide dogs or similar animals are present, SOP's must include corrective measures. This question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
6-26	There is an established pest control program for the facility.	10				D

All packing and storage facilities should establish a pest control program to reduce the risk of contamination by rodents and other animals, including pets. This program should include regular and frequent monitoring of affected and treated areas to accurately assess the program's effectiveness. A pest control log must be maintained that includes inspection dates, inspection reports, and procedures implemented to eliminate any problems.

Generally, all traps and bait stations will be marked and flagged by numbers or some type of coding system. It is likely that there will also be a map of the premises that shows the location of such bait stations and traps. All bait stations containing poison attractants must be located outside the facility. Traps or other non-poison methods should be the only control program located within a structure.

Auditors should be aware of and look for an organized method of pest detection and elimination. This question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
6-27	Service reports for the pest control program are available for review.	5				R

Generally, traps and bait stations will be regularly checked and have documentation showing when this was completed. This documentation may consist of a report or inspection log for all stations or may be a sticker or other marking on individual stations throughout the facility.

Auditors must review documentation and records that pertain to the pest control program. In some cases, it may be necessary to obtain this information from an independent pest control company contracted to provide these services. This question can only be answered as N/A when the answer to Question 6-26 is NO.

	Questions	Points	YES	NO	N/A	Doc
6-28	Interior walls, floors and ceilings are well maintained and free of major cracks and crevices.	5				

Potential entryways for pests into the facility must be eliminated by blocking/repairing areas such as holes in walls, doors, flooring, vents, etc. To assess this question, auditors must look closely at the inside walls, doors, floors and ceilings of an operation. Small cracks or crevices incident to structure age should be disregarded, unless it is obvious that pests are in the area. Cracks and crevices do not necessarily need to lead to the outdoors for infestation to occur. Certain pests can easily use areas inside walls as a living space and the food products within the facility provide a food source.

The facility should be well maintained to repair or eliminate problem areas. There should be no loose insulation materials protruding from the walls or hanging from the ceiling. This question must be answered NO when the facility is not well maintained and cracks or crevices may harbor pests or provide access. This question cannot be answered N/A.

Repacking/Reconditioning

(6-29) Does the facility repack and/or recondition product?

YES / NO /

If the answer to question 6-29 is YES, then questions 6-30 through 6-41 must be answered. The auditor should be able to observe the repacking and/or reconditioning process.

If the answer is NO, then questions 6-30 through 6-41 are N/A.

	Questions	Points	YES	NO	N/A	Doc
6-30	Repacking/reconditioning processes are confined to an established location in the facility.	5				P

Repacking or reconditioning of products in the facility should be completed in an area established and maintained for such practices. This provides a location that can be regularly cleaned and maintained in a manner that promotes safe food handling practices.

Auditors should check the operation for the established location(s) where repacking and reconditioning takes place. If the facility repacks or reconditions products whenever and wherever, without regard to safe handling practices this question must be answered NO. This question cannot be answered as N/A.

	Questions	Points	YES	NO	N/A	Doc
6-31	Food contact surfaces are in good condition; cleaned and/or sanitized prior to use and cleaning logs are maintained.	15				D

Many operations have located stainless steel tables or benches upon which packing processes are completed. Other operations may have established a mechanized system.

Brushes may be a part of the packing system to clean the product. Conveyors, such as belts, are very commonly used to move product through the packing system. These parts of the system can be easily contaminated from produce, workers or from other equipment in the packing system. Brushes or conveyors that physically touch the produce should be regularly cleaned, as needed. Conveyors that transport containers of packed product should be reasonably clean, but there is less possibility of contamination from this source.

Auditors should observe the operation and food contact surfaces to determine the condition and cleanliness of the surfaces. Operations must have a regular cleaning schedule. Auditors should review documentation and/or records showing that an established schedule is being followed. This question may be answered N/A when the product is repacked directly from one container to another and the product does not come into contact with any surface other than the container.

	Questions	Points	YES	NO	N/A	Doc
6-32	Source water used in the repacking operation is potable.	15				R

Source water used in the repacking of fresh fruits and vegetables must be potable. Municipal water supplies are regulated by law and are required to be potable. Well water may or may not be potable. Surface water is subject to various uncontrollable influences and is generally considered non-potable for use in a repacking operation.

Auditors must review documentation (including water test results) that indicates source water meets the microbial requirements of the EPA Drinking Water Standard in order for an auditee to show they are meeting the requirements for water used in the postharvest process and no microbial contamination hazards are present. If the source water used in the operation does not meet the microbial requirements but is then treated, see question 6-33. (To evaluate water quality, refer to the Water Quality Risk Sources and Testing Treatment in Part 1) This question may be answered N/A when products are not washed.

	Questions	Points	YES	NO	N/A	Doc
6-33	Processing water is sufficiently treated to reduce microbial contamination.	10				D

Water used during the post-harvest handling of fruits and vegetables often involves a high degree of water-to-produce contact. Although water is a useful tool for reducing potential contamination, it may also serve as a source of contamination or cross-contamination. Re-using processing water may result in the build-up of microbial loads, including undesirable pathogens.

Consider practices that will ensure and maintain water quality. Such practices may include:

- Perform periodic water sampling and microbial testing.
- Change water as necessary to maintain sanitary conditions.
- Consider developing SOPs (standard operating procedures or sanitary operating plans), including water change schedules.
- For all processes that use water; clean and sanitize water contact surfaces, such as dump tanks, flumes, wash tanks, and hydro coolers, as often as necessary to ensure the safety of produce.
- Install backflow devices and legal air gaps, as needed, to prevent contamination of clean water with potentially contaminated water (such as between potable water fill lines and dump tank drain lines).
- Routinely inspect and maintain equipment designed to assist in maintaining water quality, such as chlorine injectors, filtration systems, and backflow devices, to ensure efficient operation.

Auditors must review documentation that shows water is treated to reduce microbial populations that could be present. When water is re-used in the repacking process this question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
6-34	Water treatment (strength levels and pH) and exposure time is monitored and is appropriate for product.	10				D

Prevention of contamination is preferred over corrective action(s) once contamination has occurred. However, antimicrobial chemicals in processing water are useful in reducing microbial build-up in water and may reduce microbial load on the surface of produce. Thus, antimicrobial chemicals may provide some assurance in minimizing the potential for microbial contamination.

The effectiveness of an antimicrobial agent depends on its chemical and physical state, treatment conditions (such as water temperature, acidity [pH], and contact time), resistance of pathogens, and the nature of the fruit or vegetable surface. Chlorine is commonly added to water for post-harvest treatment of fresh produce at 50 to 200 parts per million total chlorine, at a pH of 6.0 to 7.5, with a contact time of 1 or 2 minutes.

Ozone has been used to sanitize wash and flume water in packing house operations. Ultraviolet radiation may also be used to disinfect processing water. Chlorine dioxide, trisodium phosphate, and organic acids (such as lactic and acetic acids) have been studied for use as antimicrobial agents in produce wash water, although more research needs to be done. Operators should consider options for water sanitation most appropriate for their individual operations.

Use of water and water treatments are not required of packing operations, but are used voluntarily. Some commodities are not normally washed at all before packing (berries). This question should be answered N/A when water is not used in the repacking process.

The strength and acidity of the treated water must be appropriate for the commodity. If these are not, the process may not be effective in reducing the microbe population or may create problems for the produce, such as burning.

Although there has been a lot of research on this aspect of packing, not all commodities have established and recommended levels.

The following chart is reprinted from academic literature and is a guide for most commodities when the treatment is with Chlorine.

Crop	Chlorine Strength (Total Titratable Chlorine)
General	50-500 Parts Per Million
Apples	100-150 Parts Per Million
Asparagus	125-250 Parts Per Million
Cantaloup, Honey Dew Melons	100-150 Parts Per Million
Lettuce, Cabbage, Leafy Greens	100-150 Parts Per Million
Tomatoes, Potatoes, Peppers	200-350 Parts Per Million

Auditors must review all appropriate documents and records in order to determine if the operator is effectively monitoring and maintaining the water quality. Auditors must also observe and question operators who are responsible to complete the monitoring and adjusting functions.

In some cases, the job of maintaining processing water quality will be contracted to an outside water quality management firm. In this case, auditors must review documentation showing the frequency of monitoring in order to determine that this is completed. Documentation may include an on-site log, monthly bills/invoices or other documents that show the process is being completed. If a water quality technician is present at the time of the audit, he/she should be interviewed to determine if the water treatment meets company specifications.

	Questions	Points	YES	NO	N/A	Doc
6-35	If applicable, the temperature of processing water used in dump tanks, flumes, etc., is monitored and is kept at temperatures appropriate for the commodity.	10				D

For commodities which are susceptible to water infiltration, special attention to the water temperature in the dump tank and flumes and the temperature of the product is required. Water temperature should be maintained within 10 degrees F of incoming product pulp temperature to minimize water infiltration. If contaminated water infiltrates the product, it is very difficult if not impossible to remove the contamination. The water may need to be heated or cooled and/or the product heated or cooled to equalize the temperature. This question may be answered N/A when no water is used or the commodity being repacked is not susceptible to water infiltration. Examples of commodities which are susceptible to water infiltration are Tomatoes, Cantaloupes, Peppers, Apples, Potatoes and Pears.

	Questions	Points	YES	NO	N/A	Doc
6-36	Any ice used for cooling produce is manufactured, transported and stored under sanitary conditions.	10				R

Ice making facilities may be located on the site of the operation or may be contracted out and supplied by another operation. In either case, the facility must provide records that indicate there is a regular schedule to sanitize the ice production and storage facility and any means of transportation to reduce the microbial population. This would include augurs, conveyors and shovels used to transport the ice from one part of the facility to another.

	Questions	Points	YES	NO	N/A	Doc
6-37	Water used for chilling and/or to make ice is potable.	15				R

Ice or cold water (hydro-cooling) is often used by some commodity packers to reduce product temperature. Source water for this procedure should be potable to reduce the risk of food contamination.

Auditors must investigate the source of the **water/ice** and review records to **verify** that there is no indication of microbial contamination of the water source. In some cases, ice may be manufactured on-site. In other cases, it may be provided by another entity. In either case, the water must be potable. If water is not potable this question must be answered NO. If ice or cooling water is not used, this question may be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
6-38	Only food grade approved and labeled lubricants are used in the repacking equipment/machinery.	10				D

Food grade approved lubricants should be used in areas where lubricating agents may come into contact with produce. Containers are normally marked. Auditors should ask to see containers of the food grade lubricants that are being used. If the lubricant is indeed food grade, the label is normally so marked. The container may also include a reference to meeting the applicable standards for FDA or other government agencies, regarding food grade lubricants.

If the auditor is not shown either the containers of food grade lubricants being used, or recent receipts for the food grade lubricants, this question must be answered NO. In some cases, operators will use food grade lubricants for equipment that is located over the flow zone and non-food grade lubricants in other areas. This practice will be cause for answering this question NO. In addition, if the auditor sees any evidence that non-food grade lubricants are being used in the packing area (for example: WD-40, Liquid Wrench, etc.) then the question must be answered NO. In facilities that have no mechanized equipment used for repacking this question may be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
6-39	Only new or sanitized containers are used for product repacking.	10				P

Repackers that use new or sanitized containers to repackage products are taking the highest possible means to reduce microbial contamination. The use of new containers eliminates the possibility of cross contamination of produce from used containers. Some operations are packing directly into reusable plastic containers (RPC) to meet

buyer specifications. These containers are meant to be reused. In the case of RPCs, they should be sanitized prior to each reuse in the field. A cleaning log or record from either the producer or RPC management company shall be reviewed to verify they have been sanitized. This question cannot be answered as N/A.

	Questions	Points	YES	NO	N/A	Doc
6-40	Pallets and containers are clean and in good condition.	5				

Auditors must review the condition of pallets and containers being used and those stored for future use. Auditors must question the operator to determine what is done with broken or dirty pallets or containers. When operators use dirty or broken pallets and containers or do not clean and/or repair pallets and containers this question must be answered NO. This question cannot be answered as N/A.

	Questions	Points	YES	NO	N/A	Doc
6-41	Packing containers are properly stored and protected from contamination (birds, rodents, and other pests, etc.).	10				

Packing containers and other packing materials including pads, cartons, sacks, totes, bulk bins, etc. that are not ready for immediate use should be stored in a way that protects them from contamination by any source (pests, rodents, dirt, and water condensation, etc.). Packing containers stored outside should be covered in some manner to protect against contamination. Using the top container in a pile is not sufficient.

Auditors should observe where and how packing containers are stored. Containers which are stored in a manner that may lead to contamination by any reasonable means will result in a NO answer for this question.

Worker Health and Personal Hygiene

	Questions	Points	YES	NO	N/A	Doc
6-42	Employee facilities (locker rooms, lunch and break areas, etc.) are clean and located away from repack and storage area.	10				

Facilities used by employees to take breaks, prepare to go to work, eat lunches, etc. must be clean and separate from the packing area. Some operators will have a separate room designed and identified for eating, others will identify an area in a corner

of the packing house building or somewhere outside of the immediate storage and packing area and supply it with tables. All of these are acceptable. The intent is that workers do not eat or take breaks within the storage and packing area.

Applicable portions of 29 CFR, Part 1910.141 state:

(3) Housekeeping. (i) All places of employment shall be kept clean to the extent that the nature of the work allows.

(ii) The floor of every workroom shall be maintained, so far as practicable, in a dry condition. Where wet processes are used, drainage shall be maintained and false floors, platforms, mats, or other dry standing places shall be provided, where practicable, or appropriate waterproof footwear shall be provided.

(iii) To facilitate cleaning, every floor, working place, and passageway shall be kept free from protruding nails, splinters, loose boards, and unnecessary holes and openings.

This question cannot be answered as N/A.

	Questions	Points	YES	NO	N/A	Doc
6-43	When there is a written policy requiring the use of hair nets/beard nets in the facility, it is being followed by all affected employees and visitors.	5				P

Hair nets and beard nets are worn in order to keep stray hair from entering the food and food containers being stored or packed. Hair may be a place where microorganisms can be found. In addition, wearing of these when the hair is very long reduces the risk of catching hair in machinery.

Operations that have a written policy must follow the policy. Auditors must review the policy and observe to determine if it is being followed. This question may be answered N/A when there is no written policy.

	Questions	Points	YES	NO	N/A	Doc
6-44	When there is a written policy restricting the wearing of jewelry in the facility, it is being followed by all affected employees and visitors.	5				P

Jewelry can be both a safety and a food safety hazard. It can become dislodged from the person wearing it and fall into the food item or the container. It can get caught on machinery and injure the worker. The intricate places on some jewelry, such as watch bands, can be places where microorganisms can reside.

Operations that have a written policy must follow the policy. Auditors must review the policy and observe to determine if it is being followed. This question may be answered N/A when there is no written policy.

Shipping/Transportation

	Questions	Points	YES	NO	N/A	Doc
6-45	Prior to the loading process, conveyances are required to be clean, in good physical condition, free from disagreeable odors, and from obvious dirt/debris.	10				P

All parties involved in the transport of fresh produce should help ensure that sanitation requirements for conveyances are maintained throughout the transportation chain. Trucks and transport containers must be inspected for cleanliness, odors, and debris before the loading process begins.

Drivers and operators should be aware of the contents of previously carried loads and consider this information when determining current usage. For example, trucks recently used to transport animals or animal products would increase the risk of contaminating fresh produce if not properly cleaned prior to produce loading. Auditors should not expect to see conveyances in like-new or sterilized condition. Conveyances should be acceptably clean.

Auditors should review auditee documentation to verify that there is an active policy in place addressing carrier condition. The auditee must maintain records verifying that the overall physical condition of conveyances is being checked. If the auditee cannot provide records verifying that these procedures are being performed, this question must be answered NO. This question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
6-46	Produce items are not loaded with potentially contaminating products.	10				P

The Guide recommends that produce items should only be shipped with other produce items. They should definitely not be shipped with fertilizers, meats, poultry or fish products.

There may be times when produce has to be shipped with non-produce items other than those mentioned. Terminal Warehouse Receivers should adequately protect the produce items from cross contamination by segregating and separating the items in the conveyance by some type of physical barrier. This question cannot be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
6-47	Company has a written policy for transporters and conveyances to maintain a specified temperature(s) range during transit.	10				P

Terminal Market facilities must establish a written policy for transporters to maintain temperatures appropriate to the commodity during transit. Transporters should be aware of the temperature requirements for produce being hauled and avoid delivery of mixed loads with incompatible refrigeration requirements.

Auditors should recognize that not all products require refrigeration during transport. In certain cases, shippers may require or specify a higher temperature for transportation than recommended for storage conditions. Shippers should recommend temperatures according to the product and conditions for transport. In general, manifests should be marked with the temperature range that the shipper requires the carrier to maintain.

Auditors should review auditee documentation to verify that there is an active policy in place addressing the ability of conveyances to maintain specified transport temperatures. If there are no transportation temperatures required by the auditee, or there is no indication of required temperatures on the manifest, this question must be answered NO. This question may be answered N/A when specific shipping temperatures are not suggested for the product (nuts, for example).

	Questions	Points	YES	NO	N/A	Doc
6-48	Records are kept recording the source of incoming product and the destination of outgoing product which is uniquely identified to enable traceability.	10				D

The Bioterrorism Act of 2002 requires certain handlers of foods to keep records that allow the handler to keep trace of produce “one step forward” and “one step back” within the food chain. For packing facilities, storage and transportation facilities and wholesale distribution/terminal warehouses, record keeping that keeps trace of the source of incoming produce and the destination of outgoing produce is a critical component of a documented traceability program. Traceability markings shall be at the container/master container level, and shall include other identifying marks as outlined in the company’s traceability program.

Auditors must explain all questions for which a NO or N/A answer was noted.

Any additional comments pertaining to individuals or to observations made during the audit should be made here. Auditors must be specific when making comments about YES answers to questions, as an additional statement here may indicate that the question might be better answered NO instead.

Part 6A

TRACEBACK OF WHOLESALE DISTRIBUTION CENTER/TERMINAL MARKET

The checklist questions and explanatory narrative previously addressing Traceback have been removed from this chapter and incorporated into Parts 1, 2, 3 and 6 of the checklist, as appropriate. Please refer to those sections of this handbook for specific information applicable to this topic.

Part 7

PREVENTIVE FOOD DEFENSE PROCEDURES

After 9/11/01, protection of the nation's food supply from attacks became a national priority. The President has issued a series of directives—Homeland Security Presidential Directives (HSPD's) that cover outlining the security of the United States. HSPD 9 addresses the need to protect the nation's food supply. In response, both the FDA and the USDA issued voluntary food defense guidelines to help food processors identify measures to prevent or mitigate the risk of intentional food contamination. In 2003 the FDA published the Guidance Document *Food Producers, Processors, and Transporters, Food Security Preventative Measures Guidance*.

Food Defense vs. Food Safety

Food safety differs from food defense in the following way: Food safety is the protection of food products from unintentional contamination by pathogens or chemicals. A GAP & GHP program will address reducing the risk of unintentional contamination. Food Defense is the protection of the food supply from intentional contamination by chemical, biological, or radiological means by an aggressor.

Food Defense Audits

The purpose of the food defense audit is not to require that every farm in the United States build a fence around their property and hire security guards, but to take steps to protect their product from intentional contamination. A food defense plan should address four (4) main areas: (1) Management, (2) Human Element (staff), (3) Facility, and (4) Operations, as outlined in the FDA's *Food Producers, Processors, and Transporters, Food Security Preventative Measures Guidance* document.

Management

Management is responsible for the overall preparation for the possibility of tampering or other malicious, criminal, or terrorist actions.

- Assign responsibility for security.
- Conduct initial assessment of food security procedures and operations.
- Having a security management strategy.
- Planning for emergency evacuation.
- Becoming familiar with local emergency response system.
- Making staff aware of emergency contact information for local, State, and federal police/fire/rescue, health, homeland security agencies.

- Develop a system to communicate relevant food security issues.

Human Element - (Staff & Contractors)

- Management is required by law to verify the employment eligibility of all new hires in accordance with the Immigration and Nationality Act.
- Background screening as appropriate to the position being hired.
- Establishing a system of positive identification for all personnel.
- Limiting access of staff to areas of facility necessary for their job function.
- Restricting the type of personal items allowed in production areas.

Facility (Physical Security)

- Evaluate physical security.
- Restrict access to laboratory and chemical storage areas.
- Access to water supply is secure.

Operations (Processing and Production)

- Evaluate incoming materials and contract operations.
- Security of water and utilities.
- Security of mail and packages.
- Access to computer systems.
- Security of finished products.

Other Resources

- Food and Drug Administration – ALERT – Food Defense Awareness program.
www.cfsan.fda.gov/fooddefense
- Food Defense Awareness – An Awareness Program for AMS Livestock and Seed Employees July 2006.
- Food Defense Awareness CD Series. FDA and Centers for Disease Control.

FOOD DEFENSE AUDIT GUIDELINES

Because of the wide variety and complexity of operations that we can audit for Part 7 Food Defense, auditors should take into consideration the complexity, size, and scope of the facility. In general, farm operations will have different food defense requirements than an enclosed packing shed or wholesale distribution warehouse. For instance, it is not practical for a farm to enclose their entire operation in a fence, where in a packing facility or warehouse operation, it would make sense.

Additionally, a small operation with few employees may have different requirements than a large facility with many employees. For purposes of the Food Defense audit, a small farm or facility shall be defined as 15 or less employees. This is the number of employees that an owner/manager can reasonably be expected to identify on sight.

Because of the wide variations in food defense facilities and procedures, auditors should take the time to review the auditee's food defense plan prior to the audit to become familiar with it. This makes it easier to audit the farm/facility on the day of the audit.

Part 7 - Employee/Visitor Procedures

	Questions	Points	YES	NO	N/A	Doc
7-1	The company has a documented food defense plan and a person has been designated to oversee it. Name: _____	5				D

A documented food defense plan is critical to the implementation of a successful food defense plan. Documentation may include a Food Defense Manual, various published SOP's, and/or documentation that a program is implemented and being followed. If performed, it will also contain information or references pertaining to internal or self audits of the program. Other similar documentation may also be applicable and acceptable if it indicates that a formally established program is in place. It is recommended that the lead auditor inform the auditee that all applicable documentation be gathered prior to the audit. This not only ensures that the auditee verifies that all records are available, but also saves time on the day of the audit.

The Food Defense plan shall also indicate that there is a person in the operation that has implemented and will oversee the food defense program. Operations which are serious about following established food defense programs will have a designated person whom is responsible for ensuring that the program is being followed. This question cannot be indicated as an N/A.

	Questions	Points	YES	NO	N/A	Doc
7-2	Food defense training has been provided to all employees.	5				D

Food defense training should be given to all employees and should cover potential threats and vulnerabilities of the food supply and how they apply to the produce industry. Training should also include who employees should contact if they observe a potential food defense issue. Auditors should look for training instructions and training

documents that each employee has signed. This question cannot be indicated as an N/A.

	Questions	Points	YES	NO	N/A	Doc
7-3	<p>Employees are aware of whom in management they should contact about potential security problems/issues.</p> <p>Name of management representative: _____</p>	5				

As part of food security plan, each company should designate a contact person who is responsible for overseeing the plan. This person(s) should be the point of contact for employees to point out potential security problems or issues. This person can also designate another person, for example shift supervisors, who can be the contact person for employees.

	Questions	Points	YES	NO	N/A	Doc
7-4	Visitors are required to check in (showing proof of identity) and out, when entering/leaving the facility.	5				D
7-5	The purpose of visitation to site is verified before admittance to the facility.	5				D

A comprehensive food security plan should address access procedures to identify who has access to sensitive areas of the facility. This includes verifying the identity of visitors to the facility and the purpose for the visit. Check in procedures can vary from a formal sign in/sign out procedure in enclosed facilities to visitors checking in with the owner/manager (or designated person) of a small operation. The auditor shall look for the documented procedure and verify that the procedure is being followed.

If an auditor is able to gain access to an enclosed packing house or wholesale warehouse facility without showing ID and signing in or checking in with an owner/supervisor, this is a sign that their visitor check-in policy is not working.

	Questions	Points	YES	NO	N/A	Doc
7-6	Visitors are prohibited from the packing/storage areas unless accompanied by an employee.	5				D

Limiting access to packing/storage areas by unauthorized personnel is one of the foremost procedures that can be taken to reduce the risk of intentional contamination. Visitors should be accompanied by an employee. A facility can designate exceptions to this for frequent visitors to the facility such as USDA inspectors, health department inspectors, the pest control contractor, etc., as long as a documented list of exempted people is maintained.

	Questions	Points	YES	NO	N/A	Doc
7-7	Incoming and outgoing employee and visitor vehicles to and from the site are subject to inspection.	5				D

All vehicles should be subject to inspection to look for any obvious sources of contamination. Auditors shall look for documentation that vehicles are being searched and/or evidence that vehicles are subject to search.

	Questions	Points	YES	NO	N/A	Doc
7-8	Parked vehicles belonging to employees and visitors display a decal or placard issued by the facility.	5				

All vehicles on the facility should be able to be traced to the owner of the vehicle. This can be accomplished by a decal or placard that is clearly visible that allows auditee management to identify that a vehicle is allowed access to the facility and who it belongs to. If the operation is considered a small farm or facility and management/supervisors can readily identify each employees vehicle by sight, placards or decals shall not be required and this question shall be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
7-9	Staff is prohibited from bringing personal items into the handling or storage areas.	5				D

A policy should be in place that prohibits workers from bringing personal items into the production, handling, or storage areas. This reduces the possibility of an insider from contaminating product. Many packing facilities will allow workers to bring water to the packing line. This is an acceptable practice as long as the water is supplied by the facility and is not brought from outside sources.

Typically farm worker crews will bring their lunch bag/cooler with them out to the field. This is an acceptable practice only if there is a policy in place that excludes them from bringing their personal items into the actual field. The lunch bag/cooler must remain in

an area outside the perimeter of the field such as a lunch wagon or designated eating area (i.e. picnic benches, etc.). The only exception to the personal item rule would be water jugs that the workers use to drink from during the course of the day, as long as the water is supplied by the facility and not from outside sources.

	Questions	Points	YES	NO	N/A	Doc
7-10	Staff access in facility is limited to the area of their job function and unrestricted areas.	5				D

Management should determine if any staff should have limited access to certain areas of the operation. The food security plan should address those jobs and the details of how staff will be limited to areas of the operation that are related to their job function, and to general access areas (break rooms, locker rooms, etc.). This type of scenario usually applies to larger packing house facilities or wholesale warehouses. In the case of small operations that only have a limited number of employees who perform all job functions, this question may be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
7-11	Management is aware of which employee should be on the premises, and the area they are assigned to.	5				D

Employees should not be allowed to loiter around the grounds and facility after their work hours, especially in sensitive areas of the operation. A work schedule outlining employee's hours and area the employee is assigned to work should be available to all management. Auditors should look for an employee work schedule that shows what employees are on duty at what time.

	Questions	Points	YES	NO	N/A	Doc
7-12	A system of positive identification of employees has been established and is enforced.	5				

A form of identification should be worn by employees while on duty. This system should be appropriate for the nature of the workforce (uniforms, name tags, photo ID, etc.). If the farm/facility meets the criteria for a small operation and the owner/manager can positively identify each employee by site this question can be answered as N/A.

Facility Procedure

	Questions	Points	YES	NO	N/A	Doc
7-13	Uniforms, name tags, or identification badges are collected from employees prior to the termination of employment.	5				D

All items that identify a person as an employee of the company shall be returned to the company upon completion of employment. If an employee does not turn over these items, there is a procedure in place for management/security to be notified that the employee is not allowed access to the facility. A sign in/sign out log of equipment should be kept as documentation. If the facility is considered a small farm/operation and does not have a requirement for name tags/badges, uniforms, etc. this question may be answered as N/A.

	Questions	Points	YES	NO	N/A	Doc
7-14	The mailroom is located away from the packing/storage facilities.	5				

Facility should implement procedures to ensure the security of incoming mail and packages. The mailroom should not be located in the food packing or food storage areas to prevent potential contamination from the mail or packages. For small farms/operations this question may be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
7-15	Computer access is restricted to specific personnel.	5				D

The company's computer network should be restricted so that sensitive information is only accessed by authorized personnel. This restricted access will help to assure that packing labels, invoices, and shipping records are not accessed by people that do not need that information. This question may be answered N/A if there is not a computer used in the farm/operation.

	Questions	Points	YES	NO	N/A	Doc
7-16	A system of traceability of computer transactions has been established.	5				

All electronic transactions (bills of lading, purchase orders, etc.) are traceable to the person who initiated them. For larger operations, there may be several people that are assigned the responsibility to generating transactions. In small operations only one

person may be responsible for generating transactions, in this case this question may be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
7-17	A minimum level of background checks has been established for all employees.	5				D

Management is required by law to verify the employment eligibility of all new hires in accordance with the Immigration and Nationality Act. In addition, management should outline in the food safety plan what level of background checks they will perform. This can be a procedure as simple as a reference check, or more detailed such as a credit check for financial personnel.

Farms that employ farm workers through an outside contractor should stipulate in their contract that the contractor perform a minimum level of background checks as well.

	Questions	Points	YES	NO	N/A	Doc
7-18	Routine security checks of the premises are performed for signs of tampering, criminal or terrorist action.	5				D

Scheduled checks of the operation should be performed and documented that they were performed. On a farm, critical areas such as the storage barns, pesticide storage areas, and any product storage areas should be checked routinely. For packing sheds and wholesale warehouses that have a more permanent structure, the entire facility should be routinely checked.

	Questions	Points	YES	NO	N/A	Doc
7-19	Perimeter of facility is secured by fencing or other deterrent.	5				

Obviously it is very difficult, if not impossible to fence an entire farm operation. This question specifically deals with packing facilities and other buildings on the operation. The buildings should have some sort of deterrent such as fencing, locked doors, or similar items that will deter potential intruders from entering the facility. In the case of a farm this question may be answered N/A.

	Questions	Points	YES	NO	N/A	Doc
7-20	Checklists are used to verify the security of doors, windows, and other points of entry.	5				D

In performing the routine security checks from question 7-18, a checklist should be used to verify the points of entry into buildings, either on the farm or packing house/wholesale warehouse.

	Questions	Points	YES	NO	N/A	Doc
7-21	All keys to the establishment are accounted for.	5				D

There shall be an accountability log showing who is in possession of any keys to enter the facility. Lost keys are documented on the accountability log, and steps are taken if keys to sensitive areas such as chemical storage areas are reported lost or stolen. These steps may include changing the lock or adding additional security measures.

	Questions	Points	YES	NO	N/A	Doc
7-22	The facility has an emergency lighting system.	5				

If necessary, the facility should be equipped with emergency lighting. This question may be answered N/A if the operation has no permanent buildings, or the packing facility is not enclosed.

	Questions	Points	YES	NO	N/A	Doc
7-23	The facility is enclosed.	5				

Not all packing facilities will be fully enclosed. Some facilities are open pole barns with no walls; others may be closed on three sides, but have an open side or have four perimeter walls, but the bottom portion of several walls is open to facilitate cleaning and washing the floors. In some operations that are fully enclosed, there may be doors that are always left open, regardless of usage or there are doorways that have had the door removed. None of these would meet the test of being enclosed and the question must be answered NO.

Those that are fully enclosed can easily exclude or reduce the possibility of unauthorized entry. Enclosed means that all doorways are capable of being closed or shut and will effectively exclude unauthorized entry. Any doors that are open during packing operations for passage of fork lift traffic, employee entrance, etc., should be considered as a part of the operation and the question will be answered YES.

	Questions	Points	YES	NO	N/A	Doc
7-24	Storage or vehicles/containers/ trailers/railcars that are not being used are kept locked.	5				

Any storage or transport vehicles used in the movement of product should be kept locked when not in use to prevent unauthorized access and potential contamination. If the only transportation used on the farm are tractors and flatbed wagons, this question can be answered as N/A.

	Questions	Points	YES	NO	N/A	Doc
7-25	Delivery schedules have been established.	5				

Any incoming products or supplies are known to the auditee, and should be accepted during designated times as outlined in the food safety plan. If a delivery is excessively late, there is a procedure to spot check the product for signs of obvious tampering or contamination.

	Questions	Points	YES	NO	N/A	Doc
7-26	The off-loading of incoming materials is supervised.	5				

Unless the incoming material is being delivered by an employee of the operation, or a designated person outlined in the food safety plan, all incoming product should be unloaded under the supervision of an auditee employee. Truck drivers and other delivery personnel should not have unrestricted access to the facility.

	Questions	Points	YES	NO	N/A	Doc
7-27	The organization has an established policy for rejecting deliveries.	5				D

The company should outline the policy for rejecting loads. The policy should include a list of criteria for why the product doesn't meet specified requirements as well as food safety requirements such as evidence of container tampering, evidence of suspicious foreign objects, etc.

	Questions	Points	YES	NO	N/A	Doc
7-28	Unauthorized deliveries are not accepted.	5				D

The receiving department/facility shall never accept incoming product that is from an unknown source. All deliveries should be listed on the delivery schedule, and only deliveries from that schedule should be accepted.

	Questions	Points	YES	NO	N/A	Doc
7-29	The company does not accept returned (empty) containers for packing of product unless they are sanitized containers that are intended for reuse.	5				D

Used containers shall not be accepted and reused to pack product. If cardboard, wood, styrofoam, or similar type of container is accepted and reused this question shall be answered "NO." However, the use of CHEP or other types of reusable plastic containers is becoming more prevalent in the produce industry. These types of containers are specifically meant to be returned and reused to pack product. It is acceptable to allow these containers as long as they are washed or sanitized prior to use, and stored in a manner that will reduce the chance of intentional contamination.

	Questions	Points	YES	NO	N/A	Doc
7-30	The facility has a program in place to inspect product returned to the facility for tampering.	5				D

Auditors should check to see if the food security plan and/or there is a procedure for inspection of any returned product. The returned product should be inspected for obvious signs of tampering or intentional contamination. Many operations will not reuse returned product.

	Questions	Points	YES	NO	N/A	Doc
7-31	The company has identified the individual(s), with at least one backup, who are responsible for recalling the product.	5				D
7-32	The company has performed a successful mock recall of product to the facility.	5				D

The Guide indicates that all facilities should work with their suppliers and customers to track the path the product takes from the farm to the consumer. This will provide a readily available trail in case there is a need to determine where product originated and to where it was shipped.

Operations must have some documented evidence of completing at least one practice recall within the 6 months previous to the audit and have assigned a person(s) to be responsible to implement any recalls. Documents must indicate the customers contacted, the amount of product remaining from the original shipment and the disposition of product which could not effectively be recalled. Such disposition may

include sales to customers, reshipment to a subsequent customer that could be contacted if a recall were necessary or destroyed product.

Auditor must review recall records and assess according to the above.

	Questions	Points	YES	NO	N/A	Doc
7-33	Product imported from outside the United States is segregated from domestic product.	5				D

USDA Commodity Procurement purchases require that all domestic products be segregated from any foreign product (Exhibit D). Additionally, because foreign product has the potential to be targeted for intentional contamination and shipped to the United States, it should be kept segregated from domestic product.

	Questions	Points	YES	NO	N/A	Doc
7-34	Allergens handled by the facility are segregated from products to avoid cross contamination.	5				D

Products that are known allergens, such as peanuts should be segregated for several reasons. First to avoid inadvertent cross contamination with other products, and secondly to minimize the potential for an insider to simply “reach across the aisle” and purposely contaminate other product stored in the same area.

	Questions	Points	YES	NO	N/A	Doc
7-35	Floor plans, product flow plans, and/or segregation charts are in a secure location.	5				D

A map of the facility showing the floor plans, flow plans, and segregation areas should not be left in an unsecured location. If an aggressor was able to get a copy of this information, it would serve as a “blueprint” to analyze weaknesses of the facility.

When U.S. military forces fought in Afghanistan and analyzed al Qaeda strongholds, they found hundreds of pages of documents on food production, processing and supply chains that outlined how to attack the US food sector, thus it is important to secure company information so it does not fall into the wrong hands.

	Questions	Points	YES	NO	N/A	Doc
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7-36	The organization has registered with the FDA and has been issued a registration number (do not record the number on checklist).	5				D
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Only Food Handlers need to register with the FDA, grower/packers are exempt from this provision.

Auditors must explain all questions for which a NO or N/A answer was noted.

Any additional comments pertaining to individuals or to observations made during the audit should be made here. Auditors must be specific when making comments about YES answers to questions, as an additional statement here may indicate that the question might be better answered NO instead.

COMMENTS:

Total points earned for PART 7 = _____.

Total Possible = 180 *The total number of points possible for this section.*

Subtract "N/A" - _____ *Enter the additive number of N/A points (+ points) here.*

Adjusted Total = _____ *Subtract the N/A points from the Total possible points.*

X .8 (80%) *Multiply the Adjusted Total by .8 and show it as the Passing Score.*

Passing Score _____

(please circle one) Pass / Fail

Appendix I – Government Citations

Food and Drug Administration



U.S. Food and Drug Administration



TITLE 21—FOOD & DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 110--CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD

- 110.3 Definitions
- 110.5 Current Good Manufacturing Practice
- 110.10 Personnel
- 110.19 Exclusions
- 110.20 Plant & Grounds
- 110.35 Sanitary Operations
- 110.37 Sanitary Facilities & Controls
- 110.40 Equipment & Utensils
- 110.80 Processes & Controls
- 110.93 Warehousing & Distribution
- 110.110 Natural or Unavoidable Defects in Food for Human Use that Present No Health Hazard

Subpart A--General Provisions

Sec. 110.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) are applicable to such terms when used in this part. The following definitions shall also apply:

- (a) Acid foods or acidified foods mean foods that have an equilibrium pH of 4.6 or below.

- (b) Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.
- (c) Batter means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.
- (d) Blanching, except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.
- (e) Critical control point means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.
- (f) Food means food as defined in section 201(f) of the act and includes raw materials and ingredients.
- (g) Food-contact surfaces are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment.
- (h) Lot means the food produced during a period of time indicated by a specific code.
- (i) Microorganisms mean yeasts, molds, bacteria, and viruses and include, but are not limited to, species having public health significance. The term "undesirable microorganisms" includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of the act. Occasionally in these regulations, FDA used the adjective "microbial" instead of using an adjectival phrase containing the word microorganism.
- (j) Pest refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.
- (k) Plant means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.
- (l) Quality control operation means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act.
- (m) Rework means clean, unadulterated food that has been removed from processing for reasons other than unsanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.
- (n) Safe-moisture level is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity (aw). An aw will be considered safe for a food if adequate

data are available that demonstrate that the food at or below the given aw will not support the growth of undesirable microorganisms.

(o) Sanitize means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

(p) Shall is used to state mandatory requirements.

(q) Should is used to state recommended or advisory procedures or identify recommended equipment.

(r) Water activity (aw) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

Subpart A--General Provisions

Sec. 110.5 Current good manufacturing practice.

(a) The criteria and definitions in this part shall apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

Subpart A--General Provisions

Sec. 110.10 Personnel.

The plant management shall take all reasonable measures and precautions to ensure the following:

(a) Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.

(b) Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the

extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:

- (1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.
 - (2) Maintaining adequate personal cleanliness.
 - (3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.
 - (4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.
 - (5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.
 - (6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.
 - (7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.
 - (8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.
 - (9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.
- (c) Education and training. Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.
- (d) Supervision. Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

Subpart A--General Provisions

Sec. 110.19 Exclusions.

(a) The following operations are not subject to this part: Establishments engaged solely in the harvesting, storage, or distribution of one or more “raw agricultural commodities,” as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.

(b) FDA, however, will issue special regulations if it is necessary to cover these excluded operations.

Subpart B--Buildings and Facilities

Sec. 110.20 Plant and grounds.

(a) Grounds. The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed. If the plant grounds are bordered by grounds not under the operator’s control and not maintained in the manner described in paragraph (a) (1) through (3) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(b) Plant construction and design. Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:

(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.

(2) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.

(3) Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:

- (i) Using protective coverings.
 - (ii) Controlling areas over and around the vessels to eliminate harborages for pests.
 - (iii) Checking on a regular basis for pests and pest infestation.
 - (iv) Skimming the fermentation vessels, as necessary.
- (4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.
- (5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.
- (6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.
- (7) Provide, where necessary, adequate screening or other protection against pests.

Subpart B--Buildings and Facilities

Sec. 110.35 Sanitary operations.

- (a) General maintenance. Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.
- (b) Substances used in cleaning and sanitizing; storage of toxic materials. (1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:
- (i) Those required to maintain clean and sanitary conditions;
 - (ii) Those necessary for use in laboratory testing procedures;
 - (iii) Those necessary for plant and equipment maintenance and operation; and
 - (iv) Those necessary for use in the plant's operations.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products should be followed.

(c) Pest control. No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(d) Sanitation of food-contact surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.

(1) Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.

(3) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.

(4) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.

(5) Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.

(e) Storage and handling of cleaned portable equipment and utensils. Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

Subpart B--Buildings and Facilities

Sec. 110.37 Sanitary facilities and controls.

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

(a) Water supply. The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(b) Plumbing. Plumbing shall be of adequate size and design and adequately installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

(4) Provide adequate floor 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.

(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

(c) Sewage disposal. Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.

(d) Toilet facilities. Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:

(1) Maintaining the facilities in a sanitary condition.

(2) Keeping the facilities in good repair at all times.

(3) Providing self-closing doors.

(4) Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive air-flow systems).

(e) Hand-washing facilities. Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:

(1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.

(2) Effective hand-cleaning and sanitizing preparations.

- (3) Sanitary towel service or suitable drying devices.
- (4) Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.
- (5) Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, or food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.
- (6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.
- (f) Rubbish and offal disposal. Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

Subpart C--Equipment

Sec. 110.40 Equipment and utensils.

- (a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.
- (b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.
- (c) Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.
- (d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.
- (e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer,

temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

Subpart D [Reserved]

Subpart E--Production and Process Controls

Sec. 110.80 Processes and controls.

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the act shall be rejected, or if permissible, treated or processed to eliminate the contamination.

(a) Raw materials and other ingredients.

(1) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

(2) Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the

meaning of the act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.

(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable Food and Drug Administration regulations and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food.

Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination.

(5) Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the act. Material scheduled for rework shall be identified as such.

(6) Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of the act.

(7) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.

(b) Manufacturing operations.

(1) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(2) All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, aw, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.

(3) Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act. Compliance with this requirement may be accomplished by any effective means, including:

(i) Maintaining refrigerated foods at 45 deg. F (7.2 deg. C) or below as appropriate for the particular food involved.

(ii) Maintaining frozen foods in a frozen state.

(iii) Maintaining hot foods at 140 deg. F (60 deg. C) or above.

(iv) Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

(4) Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling aw that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act.

(5) Work-in-process shall be handled in a manner that protects against contamination.

(6) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary.

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food shall be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination.

(8) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.

(9) Food, raw materials, and other ingredients that are adulterated within the meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food.

(10) Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of

all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.

(11) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.

(12) Batters, breading, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:

- (i) Using ingredients free of contamination.
- (ii) Employing adequate heat processes where applicable.
- (iii) Using adequate time and temperature controls.
- (iv) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.
- (v) Cooling to an adequate temperature during manufacturing.
- (vi) Disposing of batters at appropriate intervals to protect against the growth of microorganisms.

(13) Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including:

- (i) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.
- (ii) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.
- (iii) Using materials for food containers and food- packaging materials that are safe and suitable, as defined in Sec. 130.3(d) of this chapter.
- (iv) Providing physical protection from contamination, particularly airborne contamination.
- (v) Using sanitary handling procedures.

(14) Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of aw for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

- (i) Monitoring the aw of food.

(ii) Controlling the soluble solids-water ratio in finished food.

(iii) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the aw of the food does not increase to an unsafe level.

(15) Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the pH of raw materials, food in process, and finished food.

(ii) Controlling the amount of acid or acidified food added to low-acid food.

(16) When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

(17) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

[51 FR 24475, June 19, 1986, as amended at 65 FR 56479, Sept. 19, 2000]

Subpart E--Production and Process Controls

Sec. 110.93 Warehousing and distribution.

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

Subpart F [Reserved]

Subpart G--Defect Action Levels

Sec. 110.110 Natural or unavoidable defects in food for human use that present no health hazard.

(a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug Administration establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.

(b) Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.

(c) Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the act that food not be prepared, packed, or held under unsanitary conditions or the requirements in this part that food manufacturers, distributors, and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of the act, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated within the meaning of the act, regardless of the defect level of the final food.

(e) A compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from the Center for Food Safety and Applied Nutrition (HFS-565), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

[51 FR 24475, June 19, 1986, as amended at 61 FR 14480, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001]

FDA Defect Action Levels - Nuts

NUTS, TREE Multiple Defects (MPM-V81) Reject nuts (insect-infested, rancid, moldy, gummy, and shriveled or empty shells) as determined by macroscopic examination at or in excess of the following levels:

NUT TYPE	UNSHELLED %	SHELLED %
Almonds	5	5
Brazils	10	5
Cashew	--	5
Green Chestnuts	15	--
Baked Chestnuts	10	--
Dried Chestnuts	--	5
Filberts	10	5
Lichee Nuts	5	--
Pecans	10	5
Pili Nuts	15	10
Pistachios	10	5

Walnuts

10

5

DEFECT SOURCE: *Insect infested - preharvest and/or post harvest and/or processing, Mold - preharvest and/or post harvest and/or processing infection, Gummy & shriveled - preharvest physiological condition, Rancidity - post harvest*
SIGNIFICANCE: *Aesthetic, Potential health hazard - may contain mycotoxin producing fungi*

PEANUTS, SHELLED	Multiple defects (MPM-V89)	Average of 5% or more kernels by count are rejects (insect-infested, moldy, rancid, otherwise decomposed, and dirty)
	Insects (MPM-V89)	Average of 20 or more whole insects or equivalent in 100-pound bag siftings

DEFECT SOURCE: *Insect infested - post harvest and/or processing infestation, Moldy - preharvest and/or post harvest and/or processing infection, Rancid & decomposed - post harvest abuse, Dirty - harvest contamination.*
SIGNIFICANCE: *Aesthetic, Potential health hazard - may contain mycotoxin producing fungi*

PEANUTS, UNSHELLED	Multiple defects (MPM-V89)	Average of 10% or more peanuts by count are rejects (insect- infested, moldy, rancid, otherwise decomposed, and dirty)
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DEFECT SOURCE: *Insect infested - post harvest and/or processing infestation, Mold - preharvest and/or post harvest and/or processing infection, Rancid & decomposed - post harvest abuse*
SIGNIFICANCE: *Aesthetic, Potential health hazard - may contain mycotoxin producing fungi*

Occupational Safety and Health Administration



TITLE 29—OCCUPATIONAL SAFETY & HEALTH

TITLE 29--Labor

CHAPTER XVII--OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION,
DEPARTMENT OF LABOR

PART 1910--OCCUPATIONAL SAFETY AND HEALTH STANDARDS

1910.141 Sanitation

1910.151 Medical Services & First Aid

1928.110 Field Sanitation

Subpart J--General Environmental Controls

Sec. 1910.141 Sanitation.

(a) General

(1) Scope. This section applies to permanent places of employment.

(2) Definitions applicable to this section.

Nonwater carriage toilet facility, means a toilet facility not connected to a sewer.

Number of employees means, unless otherwise specified, the maximum number of employees present at any one time on a regular shift.

Personal service room, means a room used for activities not directly connected with the production or service function performed by the establishment. Such activities include, but are not limited to, first-aid, medical services, dressing, showering, toilet use, washing, and eating.

Potable water means water which meets the quality standards prescribed in the U.S. Public Health Service Drinking Water Standards, published in 42 CFR part 72, or water which is approved for drinking purposes by the State or local authority having jurisdiction.

Toilet facility, means a fixture maintained within a toilet room for the purpose of defecation or urination, or both.

Toilet room, means a room maintained within or on the premises of any place of employment, containing toilet facilities for use by employees.

Toxic material means a material in concentration or amount which exceeds the applicable limit established by a standard, such as Secs. 1910.1000 and 1910.1001 or, in the absence of an applicable standard, which is of such toxicity so as to constitute a recognized hazard that is causing or is likely to cause death or serious physical harm.

Urinal means a toilet facility maintained within a toilet room for the sole purpose of urination.

Water closet means a toilet facility maintained within a toilet room for the purpose of both defecation and urination and which is flushed with water.

Wet process means any process or operation in a workroom which normally results in surfaces upon which employees may walk or stand becoming wet.

(3) Housekeeping.

(i) All places of employment shall be kept clean to the extent that the nature of the work allows.

(ii) The floor of every workroom shall be maintained, so far as practicable, in a dry condition. Where wet processes are used, drainage shall be maintained and false floors, platforms, mats, or other dry standing places shall be provided, where practicable, or appropriate waterproof footwear shall be provided.

(iii) To facilitate cleaning, every floor, working place, and passageway shall be kept free from protruding nails, splinters, loose boards, and unnecessary holes and openings.

(4) Waste disposal.

(i) Any receptacle used for putrescible solid or liquid waste or refuse shall be so constructed that it does not leak and may be thoroughly cleaned and maintained in a sanitary condition.

Such a receptacle shall be equipped with a solid tight-fitting cover, unless it can be maintained in a sanitary condition without a cover. This requirement does not prohibit the use of receptacles which are designed to permit the maintenance of a sanitary condition without regard to the aforementioned requirements.

(ii) All sweepings, solid or liquid wastes, refuse, and garbage shall be removed in such a manner as to avoid creating a menace to health and as often as necessary or appropriate to maintain the place of employment in a sanitary condition.

(5) Vermin control. Every enclosed workplace shall be so constructed, equipped, and maintained, so far as reasonably practicable, as to prevent the entrance or harborage of rodents, insects, and other vermin. A continuing and effective extermination program shall be instituted where their presence is detected.

(b) Water supply

(1) Potable water.

(i) Potable water shall be provided in all places of employment, for drinking, washing of the person, cooking, washing of foods, washing of cooking or eating utensils, washing of food preparation or processing premises, and personal service rooms.

(ii) [Reserved]

(iii) Portable drinking water dispensers shall be designed, constructed, and serviced so that sanitary conditions are maintained, shall be capable of being closed, and shall be equipped with a tap.

(iv) [Reserved]

(v) Open containers such as barrels, pails, or tanks for drinking water from which the water must be dipped or poured, whether or not they are fitted with a cover, are prohibited.

(vi) A common drinking cup and other common utensils are prohibited.

(2) Nonpotable water.

(i) Outlets for nonpotable water, such as water for industrial or firefighting purposes, shall be posted or otherwise marked in a manner that will indicate clearly that the water is unsafe and is not to be used for drinking, washing of the person, cooking, washing of food, washing of cooking or eating utensils, washing of food preparation or processing premises, or personal service rooms, or for washing clothes.

(ii) Construction of nonpotable water systems or systems carrying any other nonpotable substance shall be such as to prevent backflow or backsiphonage into a potable water system.

(iii) Nonpotable water shall not be used for washing any portion of the person, cooking or eating utensils, or clothing. Nonpotable water may be used for cleaning work premises, other than food processing and preparation premises and personal service rooms: Provided, That this nonpotable water does not contain concentrations of chemicals, fecal coliform, or other substances which could create insanitary conditions or be harmful to employees.

(c) Toilet facilities

(1) General.

(i) Except as otherwise indicated in this paragraph (c)(1)(i), toilet facilities, in toilet rooms separate for each sex, shall be provided in all places of employment in accordance with table J-1 of this section. The number of facilities to be provided for each sex shall be based on the number of employees of that sex for whom the facilities are furnished. Where toilet rooms will be occupied by no more than one person at a time, can be locked from the inside, and contain at least one water closet, separate toilet rooms for each sex need not be provided. Where such single-occupancy rooms have more than one toilet facility, only one such facility in each toilet room shall be counted for the purpose of table J-1.

Table J-1

Number of employees	Minimum number of water closets (1)
1 to 15	1
16 to 35	2
36 to 55	3
56 to 80	4
81 to 110	5
111 to 150	6
Over 150	(2)
(1) Where toilet facilities will not be used by women, urinals may be provided instead of water closets, except that the number of water closets in such cases shall not be reduced to less than 2/3 of the minimum specified.	
(2) 1 additional fixture for each additional 40 employees.	

(ii) The requirements of paragraph (c)(1)(i) of this section do not apply to mobile crews or to normally unattended work locations so long as employees working at these locations have transportation immediately available to nearby toilet facilities which meet the other requirements of this subparagraph.

(iii) The sewage disposal method shall not endanger the health of employees.

(2) Construction of toilet rooms.

(i) Each water closet shall occupy a separate compartment with a door and walls or partitions between fixtures sufficiently high to assure privacy.

(ii) [Reserved]

(d) Washing facilities

(1) General. Washing facilities shall be maintained in a sanitary condition.

(2) Lavatories.

(i) Lavatories shall be made available in all places of employment. The requirements of this subdivision do not apply to mobile crews or to normally unattended work locations if employees working at these locations have transportation readily available to nearby washing facilities which meet the other requirements of this paragraph.

(ii) Each lavatory shall be provided with hot and cold running water, or tepid running water.

(iii) Hand soap or similar cleansing agents shall be provided.

(iv) Individual hand towels or sections thereof, of cloth or paper, warm air blowers or clean individual sections of continuous cloth toweling, convenient to the lavatories, shall be provided.

(3) Showers.

(i) Whenever showers are required by a particular standard, the showers shall be provided in accordance with paragraphs (d)(3) (ii) through (v) of this section.

(ii) One shower shall be provided for each 10 employees of each sex, or numerical fraction thereof, who are required to shower during the same shift.

(iii) Body soap or other appropriate cleansing agents convenient to the showers shall be provided as specified in paragraph (d)(2)(iii) of this section.

(iv) Showers shall be provided with hot and cold water feeding a common discharge line.

(v) Employees who use showers shall be provided with individual clean towels.

(e) Change rooms. Whenever employees are required by a particular standard to wear protective clothing because of the possibility of contamination with toxic materials, change rooms equipped with storage facilities for street clothes and separate storage facilities for the protective clothing shall be provided.

(f) Clothes drying facilities. Where working clothes are provided by the employer and become wet or are washed between shifts, provision shall be made to insure that such clothing is dry before reuse.

(g) Consumption of food and beverages on the premises

(1) Application. This paragraph shall apply only where employees are permitted to consume food or beverages, or both, on the premises.

(2) Eating and drinking areas. No employee shall be allowed to consume food or beverages in a toilet room nor in any area exposed to a toxic material.

(3) Waste disposal containers. Receptacles constructed of smooth, corrosion resistant, easily cleanable, or disposable materials, shall be provided and used for the disposal of waste food. The number, size, and location of such receptacles shall encourage their use and not result in overfilling. They shall be emptied not less frequently than once each working day, unless unused, and shall be maintained in a clean and sanitary condition. Receptacles shall be provided with a solid tight-fitting cover unless sanitary conditions can be maintained without use of a cover.

(4) Sanitary storage. No food or beverages shall be stored in toilet rooms or in an area exposed to a toxic material.

(h) Food handling. All employee food service facilities and operations shall be carried out in accordance with sound hygienic principles. In all places of employment where all or part of the food service is provided, the food dispensed shall be wholesome, free from spoilage, and shall be processed, prepared, handled, and stored in such a manner as to be protected against contamination.

[39 FR 23502, June 27, 1974, as amended at 40 FR 18446, April 28, 1975; 40 FR 23073, May 28, 1975; 43 FR 49748, Oct. 24, 1978; 63 FR 33466, June 18, 1998]

Authority: Secs. 4, 6, and 8, Occupational Safety and Health Act of 1970, 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12-71 (36 FR 8754), 8-76 (41 FR 25059), 9-83 (48 FR 35736), 1-90 (55 FR 9033), or 6-96 (62 FR 111), as applicable.

Sections 1910.141, 1910.142, 1910.145, 1910.146, and 1910.147 also issued under 29 CFR, part 1911.

Subpart K--Medical and First Aid

Sec. 1910.151 Medical services and first aid.

(a) The employer shall ensure the ready availability of medical personnel for advice and consultation on matters of plant health.

(b) In the absence of an infirmary, clinic, or hospital in near proximity to the workplace which is used for the treatment of all injured employees, a person or persons shall be adequately trained to render first aid. Adequate first aid supplies shall be readily available.

(c) Where the eyes or body of any person may be exposed to injurious corrosive materials, suitable facilities for quick drenching or flushing of the eyes and body shall be provided within the work area for immediate emergency use.

Appendix A to Sec. 1910.151--First aid kits (Non-Mandatory)

First aid supplies are required to be readily available under paragraph Sec. 910.151(b). An example of the minimal contents of a generic first aid kit is described in American National Standard (ANSI) Z308.1-1978 "Minimum Requirements for Industrial Unit-Type First-aid Kits."

The contents of the kit listed in the ANSI standard should be adequate for small worksites. When larger operations or multiple operations are being conducted at the same location, employers should determine the need for additional first aid kits at the worksite, additional types of first aid equipment and supplies and additional quantities and types of supplies and equipment in the first aid kits. In a similar fashion, employers who have unique or changing first-aid needs in their workplace may need to enhance their first-aid kits.

The employer can use the OSHA 200 log, OSHA 101's or other reports to identify these unique problems. Consultation from the local fire/rescue department, appropriate medical professional, or local emergency room may be helpful to employers in these circumstances. By assessing the specific needs of their workplace, employers can ensure that reasonably anticipated supplies are available. Employers should assess the specific needs of their worksite periodically and augment the first aid kit appropriately.

If it is reasonably anticipated that employees will be exposed to blood or other potentially infectious materials while using first aid supplies, employers are required to provide appropriate personal protective equipment (PPE) in compliance with the

provisions of the Occupational Exposure to Blood borne Pathogens standard, Sec. 1910.1030(d)(3) (56 FR 64175). This standard lists appropriate PPE for this type of exposure, such as gloves, gowns, face shields, masks, and eye protection.

[39 FR 23502, June 27, 1974, as amended at 63 FR 33466, June 18, 1998]

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12-71 (36 FR 8754), 8-76 (41 FR 25059), 9-83 (48 FR 35736), or 6-96 (62 FR 111), as applicable, 29 CFR part 1911.

PART 1928--OCCUPATIONAL SAFETY AND HEALTH STANDARDS FOR AGRICULTURE

Subpart I--General Environmental Controls

Sec. 1928.110 Field sanitation.

(a) Scope. This section shall apply to any agricultural establishment where eleven (11) or more employees are engaged on any given day in hand-labor operations in the field.

(b) Definitions. Agricultural employer means any person, corporation, association, or other legal entity that:

(i) Owns or operates an agricultural establishment;

(ii) Contracts with the owner or operator of an agricultural establishment in advance of production for the purchase of a crop and exercises substantial control over production; or

(iii) Recruits and supervises employees or is responsible for the management and condition of an agricultural establishment.

Agricultural establishment is a business operation that uses paid employees in the production of food, fiber, or other materials such as seed, seedlings, plants, or parts of plants.

Hand-labor operations means agricultural activities or agricultural operations performed by hand or with hand tools. Except for purposes of paragraph (c)(2)(iii) of this section, hand-labor operations also include other activities or operations performed in conjunction with hand labor in the field. Some examples of hand-labor operations are the hand-cultivation, hand-weeding, hand-planting and hand-harvesting of vegetables, nuts, fruits, seedlings or other crops, including mushrooms, and the hand packing of produce into containers, whether done on the ground, on a moving machine or in a temporary packing shed located in the field. Hand-labor does not include such activities as logging operations, the care or feeding of livestock, or hand-labor operations in permanent structures (e.g., canning facilities or packing houses).

Handwashing facility means a facility providing either a basin, container, or outlet with an adequate supply of potable water, soap and single-use towels.

Potable water means water that meets the standards for drinking purposes of the state or local authority having jurisdiction or water that meets the quality standards prescribed

by the U.S. Environmental Protection Agency's National Interim Primary Drinking Water Regulations, published in 40 CFR part 141.

Toilet facility means a fixed or portable facility designed for the purpose of adequate collection and containment of the products of both defecation and urination which is supplied with toilet paper adequate to employee needs. Toilet facility includes biological, chemical, flush and combustion toilets and sanitary privies.

(c) Requirements. Agricultural employers shall provide the following for employees engaged in hand-labor operations in the field, without cost to the employee:

(1) Potable drinking water.

(i) Potable water shall be provided and placed in locations readily accessible to all employees.

(ii) The water shall be suitably cool and in sufficient amounts, taking into account the air temperature, humidity and the nature of the work performed, to meet the needs of all employees.

(iii) The water shall be dispensed in single-use drinking cups or by fountains. The use of common drinking cups or dippers is prohibited.

(2) Toilet and handwashing facilities.

(i) One toilet facility and one handwashing facility shall be provided for each twenty (20) employees or fraction thereof, except as stated in paragraph (c)(2)(v) of this section.

(ii) Toilet facilities shall be adequately ventilated, appropriately screened, have self-closing doors that can be closed and latched from the inside and shall be constructed to insure privacy.

(iii) Toilet and hand washing facilities shall be accessibly located and in close proximity to each other. The facilities shall be located within a one-quarter-mile walk of each hand laborer's place of work in the field.

(iv) Where due to terrain it is not feasible to locate facilities as required above, the facilities shall be located at the point of closest vehicular access.

(v) Toilet and hand washing facilities are not required for employees who perform field work for a period of three (3) hours or less (including transportation time to and from the field) during the day.

(3) Maintenance. Potable drinking water and toilet and hand washing facilities shall be maintained in accordance with appropriate public health sanitation practices, including the following:

(i) Drinking water containers shall be constructed of materials that maintain water quality, shall be refilled daily or more often as necessary, shall be kept covered and shall be regularly cleaned.

(ii) Toilet facilities shall be operational and maintained in clean and sanitary condition.

(iii) Hand washing facilities shall be refilled with potable water as necessary to ensure an adequate supply and shall be maintained in a clean and sanitary condition; and

(iv) Disposal of wastes from facilities shall not cause unsanitary conditions.

(4) Reasonable use. The employer shall notify each employee of the location of the sanitation facilities and water and shall allow each employee reasonable opportunities during the workday to use them. The employer also shall inform each employee of the importance of each of the following good hygiene practices to minimize exposure to the hazards in the field of heat, communicable diseases, retention of urine and agrichemical residues:

(i) Use the water and facilities provided for drinking, hand washing and elimination;

(ii) Drink water frequently and especially on hot days;

(iii) Urinate as frequently as necessary;

(iv) Wash hands both before and after using the toilet; and

(v) Wash hands before eating and smoking.

(d) Dates

(1) Effective date. This standard shall take effect on May 30, 1987.

(2) Startup dates. Employers must comply with the requirements of paragraphs:

(i) Paragraph (c)(1), to provide potable drinking water, by May 30, 1987;

(ii) Paragraph (c)(2), to provide hand washing and toilet facilities, by July 30, 1987;

(iii) Paragraph (c)(3), to provide maintenance for toilet and hand washing facilities, by July 30, 1987; and

(iv) Paragraph (c)(4), to assure reasonable use, by July 30, 1987.

[52 FR 16095, May 1, 1987]

Appendix II - Client Requested Audit Checklist and Scoresheet

Audits Requested by Sysco Corp. or Sodexho Corp.

All audits performed for either Sysco or Sodexho must be completed utilizing the Client Request Audit Checklist and Scoresheet. Once the audit is completed, it must be forwarded to the appropriate reviewing official (i.e. Federal Program Manager or Audit Program Coordinator) within 2 business days after the on-site completion of the audit. Both companies have established a time line when completed audits must be submitted to them, and there are several steps after the review process that need to take place in Headquarters.

Part 7- Food Defense is a mandatory part of all Sysco and Sodexho audits. It differs from the USDA Part 7 Preventative Food Defense Procedures, so auditors shall verify they are using the correct checklist before beginning the audit. Even if the auditee fails to meet the established minimum score for Part 7, Sysco and Sodexho may decide to accept the audit based on what questions were missed and the answers given by the auditor to any questions answered NO or NA. Thus it is extremely important to provide a clear, concise answer to these questions.

Once the reviewing official has signed off on the audit, the entire audit checklist and scoresheet is to be faxed to the Audit Program Coordinator, so that it may be converted into a pdf file and sent to the appropriate officials at Sysco or Sodexho.

Any questions regarding audit procedures for these two companies should be directed to your federal program manager or for federal audit staff, the audit program coordinator.

Appendix III – Assorted GAP&GHP Forms

USDA Audit Scoresheet

Please visit the USDA GAP&GHP website at www.ams.usda.gov/gapghp for the most current version of the scoresheet and checklist.

FPB 08-02 Corrective Action Form

USDA Fruit and Vegetable Programs Good Agricultural Practice & Good Handling Practices CORRECTIVE ACTION REPORT	Report #: 1 of 1
Company Name/Farm: QRS Produce Co Timbuktu, Some state USA	Date: November 21, 2007
Lead Auditor: Joe Q Auditor	Crop: Sweet Peppers
Description of Non-Conformity: <p>Observation - During review of the sorting and packing of sweet peppers on the packing line at approximately 10:45am, auditor observed several packers chewing tobacco and spitting tobacco juice onto the packing line in close proximity to unused packing cartons. The packers had just returned from a break and had not utilized this particular packing line today.</p> <p>Auditor reported issue to QC Manager who was acting as a guide to the audit team. QC Manager observed issue as well. Audit was terminated, as this observation is an automatic unsatisfactory under "Observation of employee practices that jeopardize or may jeopardize the safety of the produce."</p>	
Notified company staff at time of finding non-conformity: <input checked="" type="radio"/> YES or NO	
Checklist question and/or section of auditee food safety plan non-conformity is associated with: One of the 5 automatic unsatisfactory areas on audit	
Company Representative Signature: <i>IMA C Representative</i> <small>SIGNATURE AFFIRMS FACTS CONCERNING NON-CONFORMITY ARE CORRECT</small>	
Corrective Action Proposed and Time Frame for Implementation: (Attach separate sheet if necessary) <p>CORRECTIVE ACTIONS TAKEN: Graders were taken off the line and asked to remove chew. The packing line was shut down and the area cleaned and sanitized according to company's Food Safety Plan. Unused cartons that may have been contaminated were removed from area, and not used. Graders then returned to packing activities. All packers reminded that chewing or eating is not allowed on packing line. Upon review of personal hygiene training records by QC Manager, it was found that the graders that had the chew did not receive the required personal sanitation and hygiene training. QC Manager was instructed by senior management to verify that all current employees have received the proper training, and that all new employees must receive the proper training prior to working on the packing lines. Also each line supervisor must verify that any new employees are trained before allowing packer to work on the line.</p>	
Auditor Signature for Acceptance of Proposed Corrective Action and Timetable for Implementation: <i>Joseph Q Auditor 11/26/07</i>	

Top portion for AUDITOR USE ONLY; bottom portion for Company and Auditor use.

FPB 08-02 Example #2
 November 28, 2007

Appendix IV - Reference Materials

U.S. Department of Health and Human Services

<http://www.fda.gov>

Food and Drug Administration

Center for Food Safety and Applied Nutrition (CFSAN)

- Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (The Guide) October 1998
- Guidance for Industry Food Producers, Processors, and Transporters- Food Security Preventative Measures Guidance
- ALERT Food Defense Training Module

Food Safety Begins on the Farm

<http://www.gaps.cornell.edu>

Cornell Good Agricultural Practices Program

Cornell University, NY

607-254-5383

U.S. Department of Labor

Occupational Safety and Health Administration

Title 29, Code of Federal Regulations, Sections 1910 and 1928

U.S. Department of Health & Human Services

Food and Drug Administration

Title 21, Code of Federal Regulations, Sections 110 and 120

Kansas State University

<http://www.oznet.ksu.edu/library>

Agricultural Experiment Station and Cooperative Extension Service

Karen Penner, et al, Kansas Food *A* Syst

March 2001

U.S. Department of Agriculture

National Agricultural Library
Washington DC

<http://foodsafety.nal.usda.gov>

U.S. Department of Agriculture
Agricultural Research Service
Eastern Region Research Center
Food Safety Intervention
Wynmoor, PA

<http://www.ars.usda.gov>

University of California- Davis
<http://ucgaps.ucdavis.edu/>
University of California Food Safety Program
Davis, CA

Penn State University
<http://foodsafety.psu.edu/gaps/>
Food Science Department
State College, PA

For Further Information Regarding the USDA GAP&GHP Program

Please Contact:

Audit Programs Section
USDA, AMS, Fruit and Vegetable Program
Specialty Crops Inspection Division
202-720-5021
202-260-8927 (fax)
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