



United States
Department of
Agriculture

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Fruit and
Vegetable
Program

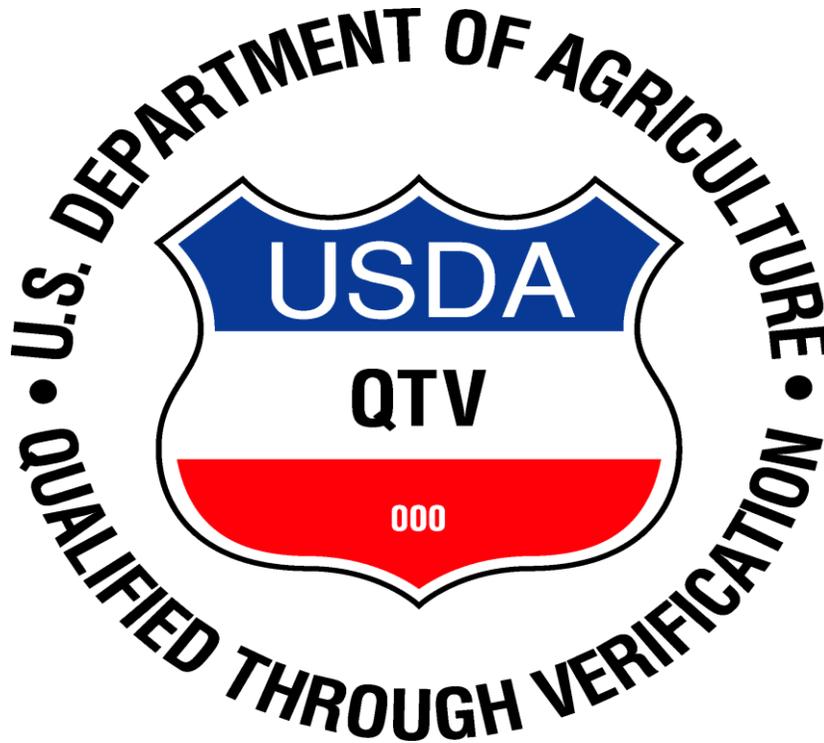
Processed
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Division

AIM
Instructional
System

Inspection
Series

July 2012

“Qualified Through Verification”(QTV) Program for the Fresh-Cut Produce Industry



AGRICULTURAL MARKETING SERVICE QUALIFIED THROUGH VERIFICATION (QTV) PROGRAM MANUAL

EXECUTIVE SUMMARY

The Agricultural Marketing Service (AMS), Fruit and Vegetable Program (FV) Qualified Through Verification (QTV) program is a voluntary, user-fee, audit-based inspection service for producers of fresh-cut fruits and vegetables. The program is designed to verify the suitability of a firm's Hazard Analysis Critical Control Point (HACCP) food safety system. QTV is a voluntary program. QTV empowers firms to apply science-based HACCP principles to identify food safety hazards in their food manufacturing processes and take steps to prevent, eliminate, or reduce the occurrence of the hazard to an acceptable level.

Under QTV, AMS reviews and assesses a firm's documented HACCP-based food safety QTV plan. After a plan is found to meet QTV program requirements, AMS uses on-site audits to determine the suitability of a firm's implementation of its plan. AMS auditors, review records, observe and interview employees, conduct pre-operation sanitation inspections, and follow a specialized Audit Checklist to verify that the company is following its QTV plan. Only companies that are able to meet existing good manufacturing and sanitation practices, source raw product from suppliers that comply with Good Agricultural Practices and Good Handling Practices, and demonstrate that they are following their QTV plan, including adherence to the required HACCP based techniques, are qualified to be in the program. QTV provides for reduced audit frequency when a facility has established and maintained a documented and verified food safety history. Firms under QTV meeting all program requirements may use the USDA QTV shield on packaging for products covered by the program.

This manual provides a description of the QTV program for current and potential applicants. AMS's program for the fresh-cut produce industry offers its clients value-added incentives. The requirements for participation in the QTV program include:

1. Orientation and Hazard Analysis Critical Control Point (HACCP) Training;
2. Successful Completion of an AMS Plant Survey;
3. Successful Completion of an AMS Plant Survey;
4. Comprehensive Hazard Analysis;
5. Microbiological Testing Program;
6. Raw Produce Specifications with Suppliers' Successful Completion of Quarterly "Good Agricultural Practices" and/or "Good Handling Practices" (GAP/GHP) Audits;
7. Implementation of a HACCP Program with Suitable Critical Control Points;
8. AMS Review of Company Plan and Prerequisite Programs;
9. Validation Audit;
10. Contract Agreement with AMS; and
11. Audits for Verification by AMS

AMS can provide companies producing products that contain fresh-cut, minimally processed fruit or vegetable ingredients with the "Qualified through Verification" inspection service to help them distribute safe, wholesome food products. Although the service focuses on continuous improvement in producing safe, wholesome food, this voluntary service can lead to substantial efficiencies in cost and personnel resources to the applicant.

Advertising and promotions must not misrepresent any USDA, AMS shield or suggest that only products bearing the shield are safe.

In addition to the criteria mentioned above, companies (herein referred to as applicants) interested in enrolling in this program must meet the following:

Demonstrate a commitment by top management to QTV concepts and the scope of the program;

Send personnel to approved HACCP training;

Be "in production or service" at least four months of each year; and

Following the guidelines in this manual does not mitigate or affect in any way a food producer's responsibility to comply with the Federal Food, Drug, and Cosmetic Act or any other applicable Federal, State, or Local laws or regulations.

Address inquiries to:

Director, Processed Products Division
Fruit and Vegetable Program, AMS
U.S. Department of Agriculture
1400 Independence Ave, SW
Room 0728 South Building
Washington, DC 20250-0001
Phone: (202) 720-4693
Fax: (202) 690-1527
or e-mailed to randle.macon@ams.usda.gov.

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INTRODUCTION

This manual is provided to Processed Products Division (PPD) inspection personnel to promote uniformity in the performance of QTV procedures. If needed, contact your immediate supervisor for any situation not addressed in this manual.

This manual contains links to various internal and external sources of information. For inspection personnel without internet or intranet access, please contact your immediate supervisor to obtain hard copies of documents as needed.

GUIDE FOR ELECTRONIC USAGE

The Administrative, Inspection, and Management (AIM) System of instructional manuals is available electronically in Adobe Acrobat Portable Document Format (PDF) at the following intranet address: <http://agnis/sites/FV/PPB/AIM/default.aspx>.

When accessed electronically, AIM materials have hyperlinks and hypertext (visible as underlined [blue text](#)) available to the PDF user. Clicking on a hyperlink takes the reader to a web site with information relating to the subject. Hypertext will link the reader to a different page within the current manual - or even a different manual - with information relating to the subject. For example, the hypertext in the Table of Contents allows a reader to go directly to the section of interest in the manual by clicking on the section title within the Table of Contents.

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PROGRAM SCOPE

QTV is a food safety management system based on Hazard Analysis Critical Control Point (HACCP) principles, Good Manufacturing Practices (GMP's), "Good Agricultural Practices" and "Good Handling Practices" (GAP and GHP) Verification, effective sanitation programs, product recall planning, and microbiological testing. The Agency has found that QTV fosters a proactive approach by the production facilities management for identifying process deficiencies during production rather than after production is completed.

The QTV program is funded through user fees. Authority to charge fees for service is provided for under Title 7, Code of Federal Regulations (CFR) §52.5 1 (a). The QTV fee is charged for the time required by AMS personnel to review company QTV plans, travel to and from an audit site, perform the audit and associated administrative and management activities. All work conducted by AMS is charged on an hourly basis.

DEFINITIONS: Most of the following definitions¹ are the same as those established by the National Advisory Committee on Microbiological Criteria for Foods publication, "Hazard Analysis and Critical Control Point Principles and Application Guidelines," adopted August 14, 1997.

Audit Rating: The level achieved by an applicant based on their performance during a validation or Audit. The audit rating is used to determine the facility rating.

Control Point: Any step in a process whereby biological, chemical, or physical hazards can be controlled.

Corrective Action: Procedures followed when a deviation occurs.

Critical Control Point (CCP): A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical Deficiency: A deviation from the QTV Plan requirements or other condition(s) that has lead to an unsafe product or that brings the underlying commitment of the firm to the QTV program (e.g., falsified documents or interference with the audit) into question.

Deviation: Failure to meet a critical limit.

Facility Rating: The level a facility achieves based on the results, or audit rating of a validation or Audit. The facility rating is used to determine the frequency of the audits.

¹ Exceptions to this are definitions specific to the QTV Program.

Good Agricultural Practices and Good Handling Practices (GAP and GHP)

Verification: An audit verification program that helps the produce industry verify voluntary adherence to the Food and Drug Administration's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." To inquire about GAP/GHP audits please contact USDA, AMS, Fruit and Vegetable Program, Fresh Products Division; 1400 Independence Avenue, SW; Room 1661, Stop 0240; Washington, D.C. 20250-0240; Phone: (202) 720-5870 or (202) 720-2482.

Good Manufacturing Practices: Food and Drug Administration regulations that describe the methods, equipment, facilities, and controls required for producing processed food (21 CFR 110).

Hazard: A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

Hazard Analysis: The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan.

Hazard Analysis Critical Control Point (HACCP): A systematic approach to the identification, evaluation, and control of food safety hazards.

Hazard Analysis Critical Control Point (HACCP) Plan: The written document which is based upon the principles of HACCP and which delineates the procedures to be followed.

HACCP-Certified Training: Training for HACCP certification shall include a minimum of 12 hours of instruction with a certificate issued upon completion. The agenda shall include: an overview of HACCP, hazard analysis, preventive measures, critical control point determination, sanitation Standard Operating Procedures (SOPs), critical limits, monitoring procedures, corrective actions, record keeping, and how to develop a HACCP team and HACCP plan.

Major Deficiency: A deviation from QTV plan requirements which may inhibit the maintenance of safety but does not result in an unsafe product.

Minor Deficiency: A deviation in part of the QTV-based system relative to facility sanitation which is not likely to materially reduce the facility's ability to meet acceptable sanitation requirements.

Notice of Unusual Occurrence and Corrective Action (NUOCA): Procedures that are followed by the applicant when an unusual occurrence not anticipated by the applicant's plan occurs. Examples of unusual occurrences include, but are not limited to: floods, hurricanes, tornados, earthquake, and rolling black outs.

Prerequisite Programs: Procedures, including Good Manufacturing Practices and Standard Operating Procedures (SOPs) that address operational conditions providing the foundation for the HACCP system. (These programs also include raw product supplier verification programs, microbiological testing programs (product, environmental, and equipment), SSOP, pest control, and employee training)

Preventive or Control Measure(s): Any action or activity that can be used to prevent, eliminate or reduce a significant hazard.

Process: One or more actions or operations to harvest, produce, manufacture, store, handle, distribute, or sell a product or a group of similar products.

QTV Plan: A description of a company's processes and procedures to assure the production of safe, wholesome product in accordance with HACCP, USDA and FDA criteria.

Sanitation Standard Operating Procedures (SSOPs): Written procedures that describe how a plant conducts sanitary operations before, during, and after production to prevent direct product contamination or adulteration.

Serious Deficiency: A deviation from the QTV plan that has the potential to lead to an unsafe product and is highly objectionable (e.g., modification of critical limits without approval, records not available for inspection).

Systems Audit: Unannounced on-site AMS audit of the company's effectiveness in following the QTV plan after the company has been validated.

Validation: The element of verification focused on collecting and evaluating scientific and technical information to determine if the QTV plan at a facility, when properly implemented, will effectively control the hazards.

Validation Audit: Prearranged on-site AMS audit of the completeness and performance of a company's QTV plan, and the company's effectiveness in following the QTV plan.

Verification: Those activities, other than monitoring, that determine the validity of the HACCP plan and whether the system is operating according to the plan.

FEES

The Agricultural Marketing Act of 1946, as amended, provides AMS general authority for fee-for-service programs. The fee an applicant is charged is based on the time required by AMS personnel to review company QTV plans for AMS acceptance, travel to and from an audit site to conduct the Audits, audit time, and associated administrative activities. Currently, the total time for a typical QTV Audit and associated travel, based on recently completed QTV Audits by two auditors, averages about 25 hours. Costs for analytical work regularly performed by a firm or an outside provider to support a firm's QTV program are the firm's responsibility. AMS will make any necessary fee rate adjustments to ensure that fees are adequate to cover the costs of providing the service and are not excessive. The overall cost of the QTV program for a participating firm is based on the frequency of the QTV audits. This frequency is based, in turn, on a firm's level of performance as determined by the periodic QTV audits. After validation, all firms begin at a "level four" rating which requires an unannounced QTV audit every two weeks. Under current QTV program requirements, a firm which demonstrates exemplary performance during all audits could advance from level four to level one in approximately seven months, or six audits, significantly reducing their costs. Level one currently requires an unannounced audit every three months. Alternatively, a firm that only did well enough to stay at level four would be audited by AMS every two weeks. This would significantly increase the cost to remain in the program compared to a firm at level one.

APPLICATION PROCESS

- A. **Initial contact:** Companies that wish to participate in this program may apply in writing to AMS at Processed Products Division, Fruit and Vegetable Program, AMS, U.S. Department of Agriculture, STOP 0247, 1400 Independence Ave, SW, Room 0728 South Building, Washington, DC 20250-0247, or telephone (202) 720-4693 to schedule a formal presentation of the program. During the presentation, AMS will provide detailed information about the service to the company's senior management.
- B. **AMS Plant Survey:** Each company must satisfy and meet criteria described in an **AMS Plant Survey**, [AIM Inspection Series, Sanitation and Safety Manual](#).
- C. **Employee training:** Applicants are required to employ at least one HACCP-certified person knowledgeable in the QTV program's principles to be present **during all processing periods**. Training for HACCP certification shall include a minimum of 12 hours of instruction with a certificate issued upon completion. The agenda must include the following topic areas:
an overview of HACCP, hazard analysis, preventive measures, critical control point determination, sanitation SOPs, critical limits, monitoring procedures, corrective actions, record keeping, and how to develop a HACCP team and HACCP plan. The HACCP certification must be kept on file and available to AMS at all times. More than one HACCP-certified person will be needed to cover multiple shifts, vacations and periodic travel.
- D. **Required Raw Produce Supplier Verification:** The QTV Program requires that the facility's raw produce suppliers must participate in and pass an AMS Good Agricultural Practices and/or Good Handling Practices (GAP and GHP) Verification Audit. Whether one or both are required of a particular supplier depends on the role the supplier has in the supply chain. In order to fulfill this requirement, QTV applicants must supply AMS with a list of their raw produce suppliers, the suppliers' addresses and growing locations, a list of commodities, and tentative harvesting dates. Applicants must also include a listing of their supplier specifications for the raw produce used in their production processes.
- E. **QTV plan:** Each applicant develops its QTV plan (which includes prerequisites and HACCP plan) and submits it for review according to the QTV Review Procedures below.

The applicant's QTV plan may be drafted by its own staff or with assistance from outside experts. The plan must include the following elements:

1. Organizational Chart and Organizational Chart Narrative;
2. Description of Product and Labels;
3. Process Flow Chart and Process Chart Narrative;
4. Hazard Analysis;
5. Raw Produce Specifications with Required GAP and GHP Verification; Critical Control Points Summary Table and Critical Control Point Narrative;
6. Record Keeping Methods and CCP Logs and Forms;
7. Sanitation Standard Operating Procedures and Good Manufacturing Practices (GMPs);
8. Microbiological Testing Program;
9. Pest Control Program;
10. Standard Operating Procedures (Optional);
11. Standard Testing Procedures (Optional);
12. Coding System and Recall Procedures;
13. Customer Complaint Procedures;
14. Employee Training Program for GMPs, HACCP and Sanitation; and
15. Verification Procedures.

F. QTV Plan Review for Suitability: Submission and review of QTV plans will be handled using the following procedures:

1. Applicant submits QTV Plans and procedures to AMS for review.
2. AMS reviews the submitted plan and requests any necessary changes.

G. Pre-Validation Audit Period: before AMS will conduct a [Validation Audit](#) of a company's [QTV plan](#), the firm must operate using its approved plan, once it has been determined that it is suitable, for a minimum of 30 days unless otherwise specified. This allows the firm time to evaluate the effectiveness of its QTV plan and generate a record of processing history. This will also provide the AMS Validation team with necessary information regarding the company's ability to

follow their own written procedures. During the period prior to a validation audit by AMS, a company must perform the following:

1. Follow their QTV plan;
2. Adhere to the plan's provisions and keep all records associated with the approved QTV plan for at least 30 consecutive production days unless otherwise noted; and
3. Contact AMS as soon as they believe their plan is functioning successfully and when they have records covering at least thirty (30) consecutive production days.

AMS will contact the company to schedule a date and time for the Validation Audit

H. Modifications to the QTV plan: After the QTV plan **has been reviewed** by AMS, modifications may be made under the following conditions:

1. The company **must notify AMS**, in writing (faxes and e-mails are acceptable), of any modifications in their QTV plan **before implementing** the changes. AMS acknowledgment and response to the modification will be faxed or e-mailed promptly to the applicant.
2. Any changes made to the plan due to unusual circumstances, such as to address a health or safety issue, must also be documented in a corrective action plan. AMS will assess the modifications for acceptability as appropriate and AMS will fax or e-mail a confirmation of approval or recommended changes will be to the applicant.

VALIDATION AUDIT

The [validation audit](#) will determine if all of the [critical control points](#) have been identified, whether the plan is being followed and monitored by the company, and whether it is effectively controlling the identified [hazards](#). **Verification that the company's [hazard analysis](#) is complete and that CCPs have been properly identified, is the first step toward AMS' Validation Audit.** This audit follows the 30-day pre-validation period when the firm operated under its approved plan. Typically, it takes three QTV auditors two or three days to conduct the validation audit. This is a complete review by AMS QTV auditors of the company's QTV plan in operation. The auditors will follow the [Audit Checklist](#), which is found in this manual. Procedures for validation are as follows:

1. The number of auditors and structure of the AMS audit team will be determined by the size and complexity of the company's process.

2. The AMS audit team leader will have final authority in determining the facility's rating based on the team's findings. A consensus from all auditors is required for the classification of deficiencies.
3. Validation includes, but is not limited to, interviewing company employees, conducting paperwork reviews of [prerequisite programs](#) and the HACCP plan, recording sanitation and process observations, and determining the disposition of finished product.
4. Companies will be rated using the Audit Checklist. If a company receives a Level IV or higher audit rating (see "[Audits](#)" on page 10), it will qualify as a participant in the program and contractual arrangements with AMS may be finalized.
5. A company passing its validation audit enters into a contractual agreement with AMS, with duties and responsibilities as identified in Appendix C. Packages of all designated products under review during the validation are eligible to bear the appropriate official mark(s) or otherwise note participation in the QTV program.
6. Companies not currently participating in the QTV program will enter the program at a facility rating of Level IV after successful validation. The results of subsequent Audit ratings may allow changes in the facility rating and audit frequency.

AUDIT

The QTV Audit Team will complete the [Audit Checklist](#) in accordance with the instructions in [Appendix A](#) and [Appendix B](#). The information recorded on the checklist is an indication of the company's performance in meeting its QTV plan, including its prerequisites.

Once a company has entered a contractual agreement, AMS will conduct unannounced Audits at the frequency identified below to determine the company's continued adherence to its plan.

The result of each Audit is based upon the findings as recorded on the appropriate Audit Checklist and will be used with the following criteria to determine the facility's next rating.

Audit Frequency Schedule					
Facility Rating	Audit Frequency Schedule	Maximum Number of Deficiencies Allowed			
		Minor	Major	Serious	Critical
Level IV	1 visit/2 weeks	NA**	≥11	4-5	0
Level III	1 visit/1 month	≥8	7-10	2-3	0
Level II	1 visit/2 mos.	7	6	1	0
Level I	1 visit/3 mos.	0-6	0-5	0	0

For Facilities That Fall Below Level IV Facility Rating

Level V	Daily or weekly as necessary	NA**	NA**	≥ 6	1
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** NA = Not Applicable

- A. Level IV** - All applicants not currently participating in the QTV program will enter the program at Level IV facility rating, regardless of the audit rating. The deficiency level found by the audit will determine the facility rating level. A company will remain at a Level IV facility rating as long as they can maintain this level of performance, as defined in the table above, on each audit. After performing at a higher facility rating for two consecutive audits, at a bi-weekly frequency, the facility can achieve a Level III facility rating.
- B. Level III** - A company will remain at a Level III facility rating as long as it can maintain this level of performance, as defined in the table above, on each audit. The deficiency level found by the audit will determine the facility rating level. After performing at a higher facility rating for two consecutive audits at a monthly frequency, the facility can achieve a Level II facility rating.
- C. Level II** - A company will remain at a Level II facility rating as long as it can maintain this level of performance, as defined in the table above, on each audit. The deficiency level found by the audit will determine the facility rating level. After performing at a higher facility rating for two consecutive audits at a bi-monthly frequency, the facility can achieve a Level I facility rating.

- D. Level I** - A company will remain at this facility rating as long as they can maintain this level of performance, as defined in the table above, on each quarterly audit. The deficiency level found by the audit will determine the facility rating level.

E. Procedures for Facilities That Fall Below Level IV Facility Rating

There are many potential conditions that could warrant withdrawal of service from a facility. Conditions such as the willful shipment of products that could be harmful if consumed would be cause for terminating service. In other cases, where several critical deficiencies were found and the facility undertook vigorous corrective measures, and there was no actual or imminent public harm, withdrawal of service may be warranted. An applicant receiving a Level V facility rating has demonstrated difficulties in administering their QTV Plan.

If an Audit team determines that a facility has fallen to Level V, the team leader and/or the Officer-in-Charge (OIC) of the PPD area field office will contact the National office immediately with their findings and recommendations.

A **final** decision will be made by the PPD National office and given to the Audit team, which will report the decision orally and in writing to the company. The **final** decision will be made within one working day.

Facilities which fall to Level V or receive a critical deficiency at any time will be subject to an accelerated audit schedule (daily or weekly) or the withdrawal of QTV status.

If a facility does not reach Level IV rating within the next audit, which may be as soon as the next day or week, depending on the severity, AMS may withdraw its service and approval to use the QTV mark. In deciding to withdraw service, AMS will treat each occurrence, the severity of the deficiency, the surrounding circumstances, and the facility's response, on a case-by-case basis.

The following criteria will be used to determine if an **increased** frequency of audits, in lieu of withdrawal of service, will be acceptable to AMS.

1. The applicant's senior management must submit in writing a Corrective Action Plan to AMS when an accelerated audit schedule is recommended. The Plan must detail how the facility will correct the problem and obtain a Level IV facility rating and include, at a minimum, detailed descriptions of the following:
 - a. A statement of the problem(s) including the root cause of the problem;

- b. Identification of the person or persons responsible for correcting the situation;
 - c. The methods to be used to correct the problem(s); and
 - d. A schedule which details the time frame for correcting the problem.
2. AMS will review the corrective action plan submitted by the company.
3. The Plan will be accepted or rejected, and AMS will notify the company. If accepted, AMS will tell the company how long they must remain on an increased auditing schedule.
4. At the auditor's discretion, product compliance will be verified by end-item inspection.

A company dropped from the QTV program can reapply for the service. An audit will be required which includes a determination by AMS that all deficiencies have been corrected and that changes have been implemented to prevent recurrence. A fee for the audit and all related expenses will be charged to the applicant.

MICROBIOLOGICAL TESTING IN THE FACILITY

A microbiological testing program is an important tool to monitor the microbiological conditions of the facility and product throughout the entire production process. **Applicants in the QTV program are required to design and implement a microbiological testing program based on the complexity of their processes and types of commodities to be processed.** For example, the company must decide if testing will be in-house or performed by an outside laboratory, which types of testing methods to employ, which microorganisms to test for, what criteria and levels to set, etc. Testing can be accomplished by outside laboratories or in-house if there are suitable facilities and appropriate qualified staff.

The protocol for microbiological testing of the incoming product, equipment, environment, etc., is the responsibility of the plant management and shall be designed for the specific facility. It is also the responsibility of the company to comply with all applicable state and federal regulations. A microbiological testing program shall, at least, address the following areas:

Incoming product, equipment and environment, and corrective actions when microbiological testing for targeted microorganisms identifies the presence of possible contamination.

Incoming product testing can be used as a tool to verify the condition of the raw product received and can contribute to a history of the supplier's ability to deliver a sound product that meets the applicant's purchase specification. One of the first steps in minimizing the microbial load is to receive and use products of the best quality and condition. Equipment and environmental testing can be used to monitor the overall performance of the company's sanitation procedures and processes. It can also be used as a gauge of the changes that can occur in a facility during processing especially when different types of products are produced.

A company must have corrective actions in place when test results are positive for the existence of a possible problem. It is the responsibility of the company to develop appropriate actions and be ready and able to initiate them when necessary. AMS auditors will review and evaluate these corrective actions as part of the Audit.

REPORTING AND DOCUMENTATION CONTROL

A. QTV Plan and prerequisite programs:

All company QTV plans and company-generated QTV related materials are the property of the applicant and AMS will treat them accordingly. Applicant QTV records and plans are to be protected to the extent possible with respect to the Freedom of Information Act (FOIA).

1. All company-related QTV materials in AMS possession will be marked "**CONFIDENTIAL**" and stored in a secured area by AMS.

2. Copies of the QTV Plan may be made only under the following conditions:
 - a. Each page must be stamped "**CONFIDENTIAL**" in red ink.
 - b. All copies must be numbered.
 - c. The QTV Plan will include the statement, "This document is the property of (Place applicant name here)." for each QTV applicant.
3. Only authorized personnel may receive a copy of the QTV plan.
4. Approved QTV plans of applicants no longer in the QTV program and unapproved QTV submissions will be returned to the applicant.

B. Audit Reporting and Distribution:

Auditors are encouraged to use a laptop with Lotus Notes installed for the audit in order to save time entering information and to facilitate distribution of audit information.

1. The audit team will send the completed **original** [Audit Checklist](#) to the Officer-in-Charge of the area field office in which the facility is located. A copy shall also be promptly mailed or faxed to the QTV Program Coordinator in the National office by the Audit Team Leader. A copy of the completed Audit Checklist may be distributed to each auditor, if needed.
2. The team leader or their delegate will be responsible for promptly replicating information into the Lotus Notes database upon return to the office.
3. The audit team will give at least one signed copy of the completed Audit Checklist and report of the observations from the checklist will be given to the facility during the exit briefing.

Distribution of Audit Report

- **Original** to Area Officer-in-Charge
- One or more copies to:
 - QTV facility
 - QTV Coordinator (National office)
 - Each attending Auditor (optional)

AMS QTV PROGRAM SUBMISSION GUIDE

This guide is designed to provide the potential applicant with an outline for developing a QTV plan. It provides the format that must be followed as well as brief discussions on each important point in the QTV plan. Every page of the QTV plan shall be stamped "**Confidential**" and **numbered**. QTV plans in AMS's possession remain the property of the company and are privileged and confidential.

The **plan must** be submitted in the following format. Also, potential applicants shall use **Figure 1** as a table of contents for their plan.

1. Organizational Chart and Organizational Chart Narrative;
2. Description of Product(s) and Labels;
3. Process Flow Chart and Process Chart Narrative (See Figures 4 and 6);
4. Hazard Analysis;
5. Raw Produce Specifications with Required AMS GAP and GHP Verification;
6. Critical Control Points Summary Table and Critical Control Point Narrative;
7. Record Keeping Methods and CCP Logs and Forms;
8. Sanitation Standard Operating Procedures and GMPs;
9. Microbiological Testing Program;
10. Pest Control Program;
11. Standard Operating Procedures (Optional);
12. Standard Testing Procedures (Optional);
13. Coding System and Recall Procedures;
14. Customer Complaint Procedures;
15. Employee Training Program for GMPs, HACCP and Sanitation; and
16. Verification.

Figure 1

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1.	Organizational Chart and Organizational Chart Narrative
2.	Description of Product(s) and Labels
3.	Process Flow Chart and Process Chart Narrative
4.	Hazard Analysis
5.	Raw Produce Specifications with Required AMS GAP and GHP Verification
6.	Critical Control Points Summary Table and Critical Control Point Narrative
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14.	Customer Complaint Procedures
15.	Employee Training Program for GMPs, HACCP and Sanitation
16.	Verification

1. **Organizational Charts and Narrative**

The facility must prepare an organizational chart demonstrating the managerial responsibility of personnel in the company. This chart must show a chain of command within the management of the facility. The organizational chart must identify the organization of facility management to illustrate how the QTV program fits into the company's organization. The relationship between the position(s) responsible for the QTV program and the production manager(s) must be indicated. The chart must also indicate all person(s) who are HACCP certified. Copies of the certificates for each HACCP certified person shall also be included in this part of the plan.

The organizational narrative shall explain how each position relates to the QTV program, day-to-day QTV operations, and the relationship of the position on the chart.

2. **Description of Product(s) and Labels**

Description of the Product(s): A description of the finished product (e.g., product form) must be developed in order to prepare a systematic evaluation of the hazards and associated risks in a specific food and its ingredients or components. The applicant shall also describe the product distribution, the intended use and the users of the product. Applicants shall also applicant to verify the process flow diagram. The description shall include the product specification, as it could affect the hazard analysis and any repacking processes that may be required. For example:

Product Description: Shredded lettuce packed in food grade plastic bags, 6 oz. to 1 lb. units; with an optimum shelf life of 9 days if refrigerated at 35°F- 37°F; throughout entire distribution chain. Product distributed to food service and retail markets and is intended for consumption by the general public and to be consumed directly from the container without washing or other preparation. Cases and plastic bags contain "use by" date.

Originals or copies of all product labels, including front and back panels, shall be made available for auditors upon request. Proofs of all labels and advertising containing the QTV shield shall be provided to USDA for review and approval before use. Applicants shall not make false or misleading claims.

Label Specifications: Use of Department of Agriculture (USDA) "approved identification" with the QTV program is only allowed after a firm enters into a contract with AMS upon successful completion of the validation audit. The QTV mark may only be used on approved products included in the QTV plan.

The QTV mark, used by an applicant operating under the QTV program, shall be a shield using at least two contrasting colors, similar in form and design to the examples below in Figures 2 and 3 or as approved by the AMS Administrator.



Figure 2

←Blue →
←White→
←Red →



QTV No. 000
Figure 3

Prior to use, approved firms must submit to AMS for review examples of all labels, packaging, and advertising materials that use the QTV mark or refer to QTV.

3. Process Flow Chart and Process Chart Narrative

To assist the plant in developing a QTV Plan, a process flow chart and description depicting the operational steps of how the processed product is handled throughout the plant must be made. The chart must show the steps in numerical order from when the firm takes control of the raw ingredients until the firm releases control of the finished product. For example, the process flow chart and process chart narrative will provide answers to the following types of questions:

How are raw ingredients handled from receipt into the plant (e.g., is it stored in a refrigerator or is it in frozen condition)

How is the product handled prior to processing (e.g., is the product thawed, fresh, chilled, etc.)?

How is the product handled on the processing line(s) (e.g., is it put on a conveyor belt, washed, peeled, sorted, sized, chilled, etc.)?

How is the product stored?

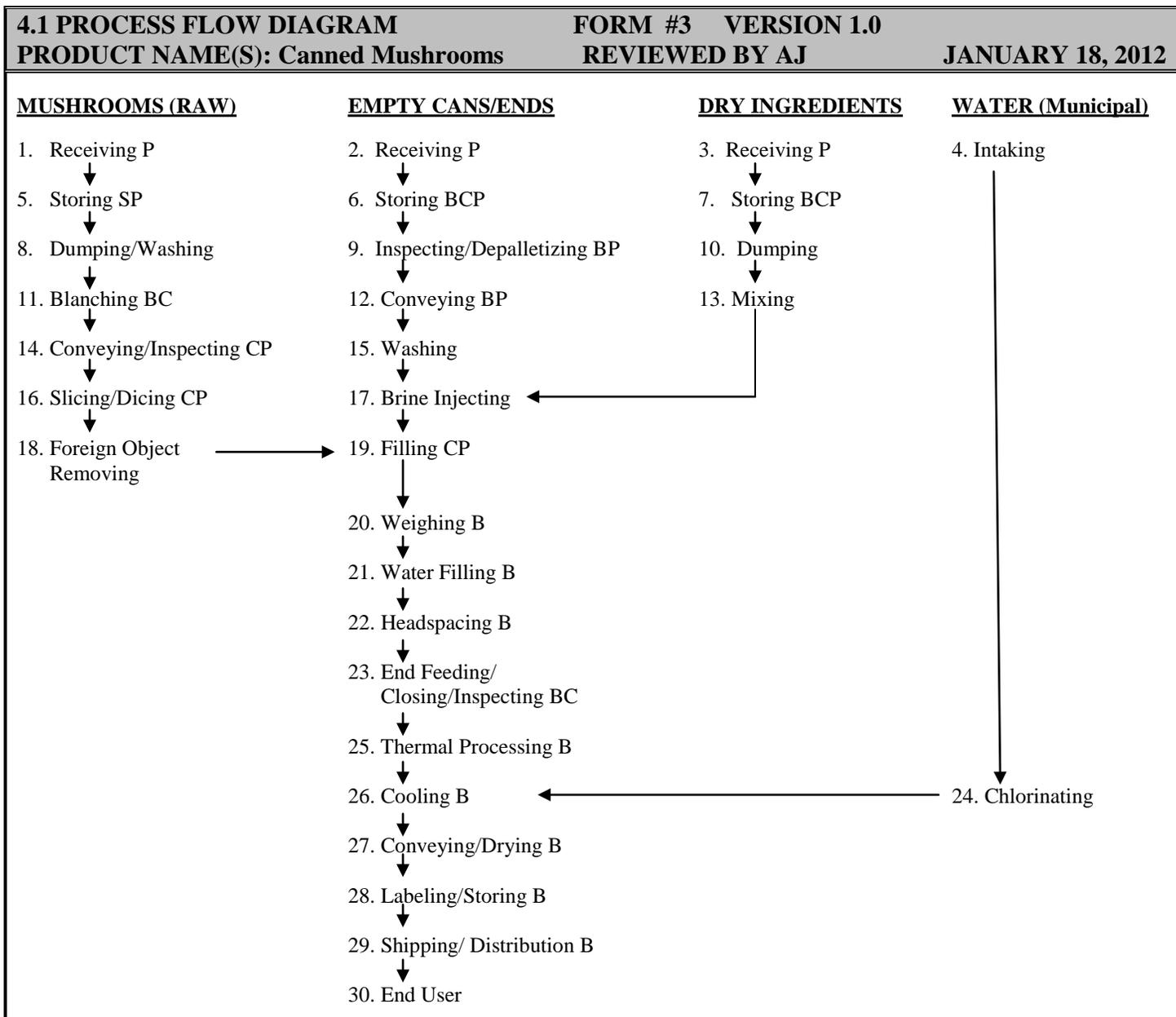
How is it packaged?

How is it shipped?

The process chart narrative describes each operational step involved with a product or similar products with designations of critical control points. A process is defined as "one or more actions or operations to harvest, produce, store, handle, distribute, or sell a product or group of similar products." The process flow description shall address all actions involved in the process. The company may design any type flow chart for their process. An example is shown in **Figure 4**. Other examples of flow charts for various product forms may be obtained from AMS.

Applicants shall verify process flow charts and process flow chart narratives annually, or more frequently as required by any changes to raw products, finished products, process chemistry, equipment, intended end use, or changes in warehouse or distribution.

Figure 4 - Example of Process Flow Chart



4. Hazard Analysis

a. Identification of Hazards:

A thorough [hazard analysis](#) is one of the most important elements in developing a [HACCP plan](#), and the QTV program requires firms to demonstrate that they have performed this step. A full discussion of the hazard analysis performed by a firm shall be included as part of the firm's [QTV plan](#), or alternatively, a firm shall include a summary of the results of their hazard analysis in their QTV plan with a reference in the plan to the location of the full documentation of the hazard analysis performed.

There are numerous references in the literature which describe the hazard analysis process in varying levels of detail. Among these references are the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) "Hazard Analysis and Critical Control Point Principles and Application Guidelines" adopted August 14, 1997, the International Fresh-cut Produce Association's "Guidelines for Fresh-cut Produce Food Safety" and the most recent edition, currently 2005, of the Food and Drug Administration's Food Code (the food code is revised every two years). These and other references are important sources of information and guidance for performing a thorough hazard analysis. Firms shall devote adequate resources and expertise to the hazard analysis process to ensure that it is comprehensive and exhaustive.

Whether temperature is a control factor at a critical control point is an issue being debated within the food safety community. Certainly, appropriate temperature control is a good manufacturing practice for refrigerated foods. AMS recognizes the merits of both sides in the debate, and QTV requirements allow a participating company to choose to control temperature of fresh-cut produce either as a CCP and part of the HACCP plan or as a regulatory control point and part of the GMPs and Standard Operating Procedures. Either way, AMS will require that temperature control be addressed by the company in their comprehensive hazard analysis and AMS will expect a QTV facility to monitor temperature as a significant factor in the safety of fresh-cut produce.

A typical hazard analysis includes:

Identifying factors which can contribute to food safety hazards for a product. These factors include, but are not limited to, the nature

of the product; the raw materials and ingredients from which it is produced; each step in the process from planting through to consumption by the consumer; equipment involved at each step; environmental conditions; and product packaging; etc.

Identifying all potential biological, chemical or physical hazards which could affect the food safety of each product or group of similar products.

Evaluating each potential hazard to determine if it shall be addressed in the HACCP plan. The severity of a potential hazard and the likelihood of its occurrence are factors which shall be considered in determining whether a particular hazard should be addressed in the HACCP plan.

A hazard analysis shall consider potential hazards at all stages of the product's development, starting from planting, growing, harvesting, transporting, and storing raw ingredients, to processing, packing, storing, and shipping finished products. The hazard analysis process identifies hazards that must be eliminated, reduced to a safe level, or prevented in order to produce a safe product. Listed below are some examples of types of hazards that could affect the product.

Biological - Harmful bacteria and viruses

Chemical - Pesticide residues, acid, cleaners, sanitizers, food grade oil, allergens, etc.

Physical - Box staples, wood, glass, rocks, insects, metal, etc.

When identifying hazards, it may be helpful to ask some basic questions.

Regarding the Receiving Department; for example:

Question: What is the product coming into the facility?

Answer: Fresh lettuce grown locally from a known supplier.

Question: What undesirable physical hazards and factors can be encountered?

Answer: Foreign material and toxic plants, etc.

Question: What undesirable chemical hazards and factors can be encountered?

Answer: Pesticide residues, toxic cleaning solutions, allergens, poisons, etc.

Steps in hazard analysis include identifying biological, chemical, and physical hazards that can be associated with products described in the product description.

Additional steps are to identify the points in the process flow where the hazards can occur. These processing steps or control points are located in the facility where biological, chemical, or physical hazards may be controlled. These locations include, but are not limited to:

Raw material receiving;
Chilling room;
Inspection table;
Processing room chiller;
Metal detector;
Filler/packaging;
Storing;
Shipping/loading dock, and
Transport to end user.

Note: Any thermal process, used in the facility, must have been established by a qualified person(s) having expert knowledge acquired by appropriate training and experience in the processing of the product. If included in the company QTV Plan, any critical limits designed by the person(s) will be in writing and will be used in the monitoring of the processing step.

b. Critical Control Point Determination

Critical Control Points (CCPs) are determined once the potential hazards and preventive measures are identified. CCPs are those points in a facility's process where identified hazards can be prevented, eliminated, or reduced to acceptable levels. The determination of CCPs typically includes:

Listing of hazards to be addressed in the HACCP plan;

Identifying control measures (including preventive measures) for each hazard which can prevent, eliminate, or reduce the hazard to an acceptable level; and

Identifying those points in the process where control measures can be applied to prevent, eliminate, or reduce the hazard to an acceptable level.

5. **Raw Produce Specifications with Required [GAP and GHP](#) Verification**

This section includes a listing of the facility's supplier specifications for the raw produce used in its production process. The first step in determining supplier performance is to have established objective specifications that are communicated to the supplier.

The QTV Program requires that the facility's raw produce suppliers must participate in and pass Good Agricultural Practices and Good Handling Practices ([GAP and GHP](#)) Verification Audit. In order to fulfill this requirement, QTV applicants shall supply AMS with a list of their raw produce suppliers, the suppliers' addresses and growing locations, list of commodities, and tentative harvesting dates.

[GAP and GHP](#) is an audit verification program that helps the produce industry verify voluntary adherence to the Food and Drug Administration's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." This program is an audit based service. It assesses a supplier'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 at the supplier on a **quarterly basis** depending on harvesting dates and locations. The responsibility for continuing product safety and the continued observance of practices leading to a minimized possibility of microbial contamination rests with the supplier.

To inquire about GAP and GHP audits please contact USDA, AMS, Fruit and Vegetable Programs, Fresh Products Division; 1400 Independence Avenue, SW; Room 1661, Stop 0240; Washington, D.C. 20250-0240; Phone: (202) 720-5870 or (202) 720-2482.

6. **Critical Control Points (CCP) Summary Table and Critical Control Point Narrative**

[Figures 5 and 6](#) show examples of a CCP summary table and narrative for listing the elements of a CCP in the HACCP plan and shall be used for QTV plan submission.

[Figure 5](#) is an example of a summary table used as a quick reference listing all numbered CCPs and the information pertaining to each. The table provides information in summary form for the following required steps: CCP (location), Hazard, Preventive Measure(s), Critical Limit, Monitoring Procedures, Corrective Action, Records, and Verification. The CCP narrative is an extension of the summary table with each CCP having its own page. Each narrative is titled by its CCP number and area

of concern. The narrative shall cover everything found in the summary table and allow for a more in-depth explanation of the processes in each of the steps.

Figure 6 is an example of the narrative description for each CCP. The narrative shall completely explain the following:

a. Preventive (Control) Measures

Identification and description of the preventive measures determined for each of the identified significant hazards. Preventive measures prevent, reduce, or eliminate a significant hazard. These measures can include, but are not limited to:

Vendor certification of pesticide residue-free raw product;

Visits to suppliers' growing fields and harvesting operations;

Pesticide residue testing;

Purchasing specifications;

Maintenance of proper temperature;

Refrigeration maintenance;

Training programs for employees;

Calibration of equipment (scales, thermometers, metal detector);

Proper time and temperature control;

Production scheduling;

Adherence to current Good Manufacturing Practices;

Physical inspection;

Certificate of water potability;

Proper packaging;

Supervisory checks; and

Inventory control.

Employee training is a preventive measure that is paramount in launching and maintaining a HACCP plan. HACCP is built on the premise of having a proactive or preventive system which identifies and corrects problems before the product is released from the facility. In order to accomplish this, a facility must have trained employees able to recognize and prevent problems as they arise.

b. Critical Limits

A critical limit as defined in the Food Code means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a CCP to minimize the risk that the identified food safety hazard may occur.

Under critical limits, show the "operating range" that is to be met (see [Figure 6](#)). There may be more than one critical limit for a CCP. If during production, value(s) are outside of the critical limit(s), the process will be out of control and a potential hazard can exist.

The critical limit is used as a marker, which if exceeded, alerts the firm that a potential hazard/problem exists at a particular CCP. If a critical limit is exceeded, the firm will weigh the possible solutions and decide what to do to correct the problem.

Criteria most frequently utilized for limits include temperature, time, available chlorine, pH, titratable acidity, preservatives, salt concentration, water activity (A_w), and other criteria. Critical limits can be quantitative (i.e., a numerical value) or qualitative (e.g., evidence of decomposition as determined by an organoleptic evaluation). They can be a maximum, minimum, or range value. Many different types of critical limit information may be needed for control of a CCP.

It is important to establish reasonable critical limits that will ensure control of the potential hazard. The firm may want to set limits that are more stringent than regulatory limits or product purchasing specifications to ensure that the product will be acceptable.

c. Monitoring Procedures

Monitoring procedures are the scheduled evaluation and/or observations recorded by the firm to report the results at each CCP. Monitoring results must be documented. Failure to exercise

control of a CCP, which includes proper monitoring and documentation of the CCP, is a critical deficiency in the Program.

A critical deficiency is a serious deviation from Plan requirements that compromises the safety of the product. Because of the potentially serious consequences of a critical deficiency, monitoring procedures at each CCP must be effective. Continuous monitoring is possible with some types of physical and chemical methods and shall be applied. However, when this is not possible, it is necessary to establish monitoring intervals that will reliably indicate that the critical limit(s) are being met and the hazard is under control.

For each CCP, list the procedures to be used to monitor the control of that specific CCP. Be specific. List:

What is the monitoring procedure?

Who will perform the procedure?

What is the frequency at which the procedure will be followed; and

Any associated criteria for the procedure. For example; sampling plans used, definitions of samples and/or lots, etc.

d. Corrective Actions

Corrective Actions are defined as procedures to be followed when a deviation occurs. When critical limits are exceeded at a CCP, corrective actions must be taken to eliminate the hazard created by the deviation. These actions must also ensure proper disposition of the product involved. Due to variations in product and the diversity of associated deviations, corrective action for each critical limit of a critical control point must be developed.

Note: After a facility executes a [Notice of Unusual Occurrence and Corrective Action](#) (NUOCA), it must follow up by calling the PPD National office within a reasonable amount of time (next business day) to report the corrective action taken. (See definitions)

Corrective Actions will involve:

A statement of the anticipated problem (usually in an "If...then" format);

Procedures for handling of the product;

Identifying the person responsible for the corrective action;

Testing to establish the acceptability of affected product (if applicable);

Final disposition of the product; and

Documentation and signatures.

e. Records

For each CCP, records are created demonstrating that monitoring procedures and corrective actions are being followed.

The types of records that would demonstrate adequate documentation that CCPs are being controlled are:

Records showing that CCPs are being monitored. **The critical limit** shall be incorporated on the monitoring record as a constant reminder to the examiner or observer.

Records documenting deviations from the HACCP plan and the corrective actions taken when critical limits are exceeded. These records shall include disposition of the product(s) involved. If the decision is made to use the product, indicate under what conditions it was maintained pending evaluation. **All reports of corrective actions must be kept in a separate file or log with copies attached to the monitoring record where the problem occurred.**

Note: Records showing that instrumentation or other equipment essential to the monitoring process have been properly checked for accuracy and reliability, and are being properly maintained shall also be included with each corrective action report.

f. Verification Procedures

Verification consists of periodic review by the company to determine the overall effectiveness of its QTV plan.

Verification helps confirm that all hazards were identified, that the appropriate CCPs were selected, and that the QTV plan is functioning properly.

Figure 6

**Example of Critical Control Point Narrative
Critical Control Point 4 - Metal Detector**

Hazard(s):

Preventive Measures:

Critical Limit:

EXAMPLE

Monitoring Procedures:

Corrective Actions:

Records:

Verification:

7. Record Keeping Methods and CCP Log and Forms

Maintenance of all logs and forms is an essential part of the QTV program. Documentation provides a history and establishes that processes are in control. For auditing purposes it is crucial that documents be readily available for review. A detailed description of where documents are located and filed is required.

Example: Documents for CCP5 are located in the QC manager's office, brown metal filing cabinet #3, drawer 3b.

All documents related to CCPs shall be identified by their corresponding CCP number and document creation date. The CCP number identifies that the document is used for a particular area. The date acts as an identifier for document revisions. Copies of all forms and documents that are used in the QTV program shall be maintained in the QTV plan. A listing of all CCP logs and forms used in the program will aid the auditor when reviewing documentation. Developing an accurate record keeping system that demonstrates control over critical control points will:

- a. Advise facility management and AMS of the performance of an applicant's QTV plan on a day-to-day basis;
- b. Provide evidence of proper and safe operation; and
- c. Serve as a mechanism for indicating potentially serious problems, and assisting the responsible individuals in determining the proper corrective action.

An efficient filing system must be set up for all QTV-related records and forms. **CCP monitoring records and CCP deviation and corrective action records shall be maintained for a period of one year after the shelf-life of the product; and records for prerequisite programs are maintained for a period of one year.** Annual verification audits (in-depth evaluations of the HACCP system to ensure that the prerequisite programs and HACCP plan are being implemented as designed) shall be taken into account when considering record retention time periods. All of the records and forms in this filing system shall be accessible to AMS at all times.

8. Sanitation Standard Operating Procedures

Equally important but distinct from the CCPs are the [Sanitation Standard Operating Procedures](#) (SSOPs). Applicants must develop standard operating procedures for daily, weekly, and other periodic sanitation practices and procedures at their facility. Standard operating procedures shall be specific with regard to how sanitation practices are performed. The QTV plan shall list who will perform these procedures, the frequency of the procedures, and any associated information. Standard operating procedures shall be written with the following assessment areas, and others as appropriate, in mind:

Structure and Layout;

Maintenance;

Cleaning and Sanitizing;

Personnel;

Restrooms;

Water Supply;

Ice;

Chemicals;

Ventilation; and

Waste Disposal.

Monitoring procedures for the SSOP's shall be established. These shall include who will perform the monitoring, the frequency of monitoring, and any forms or records used to document this monitoring.

All the above areas will be evaluated by AMS using the appropriate form(s) for the applicant's type of operation.

These sanitation assessment areas are cross-cutting throughout the facility. This is why the QTV-based Submission Guide discusses items relating to "process" factors separately from "sanitation."

9. Microbiological Testing Program

This section describes the applicant's microbiological testing procedures used to monitor their process, product, and sanitation techniques to determine if they are effective in controlling food safety hazards, and in compliance with the applicable regulatory guidelines. **Applicants in the QTV program shall design and implement a microbiological testing program based on the complexity of their processes and types of commodities to be processed.**

The microbiological testing procedures include, as applicable:

The organisms to test for;

The types of tests used and how to count the organisms;

In-house testing and outside laboratory testing;

Incoming raw product testing;

Environmental and equipment testing;

Finished product testing;

Sampling conventions that will be used; and

The baseline standards employed.

The facility shall identify corrective actions it will take if or when microbiological testing finds contamination of product, equipment, and/or facility, or that an established microbial threshold was exceeded. Such corrective steps shall include, but are not limited to:

Sanitizing affected areas and equipment;

Reviewing processing and/or sanitation procedures;

Reviewing supplier records and area; and

Holding or destroying contaminated product.

AMS recognizes the use of outside analytical laboratories for microbial testing and food safety training.

Note: Microbiological testing alone may be an inadequate means to monitor a CCP. The product may be out of the facility's control before results are available.

However, testing can be used to verify that processes and sanitation techniques are effective.

10. Pest Control Program

The Pest Control program shall identify how a company is effectively managing pest control in their plant. It is important to identify who has the responsibility and the authority to implement, evaluate and make decisions regarding the pest control program. If an outside contractor for pest control is being used, the name of the company, their procedures and methods, how often they return to check traps, and a map of where all the traps have been placed shall be documented.

A pest control program shall include, but is not limited to, the following:

Sanitation, housekeeping and good manufacturing practices;

Facility and grounds inspection and surveillance;

Proper facility design, maintenance, and physical pest exclusion;

Proper stock handling and warehousing techniques;

Appropriate use of mechanical pest control techniques and trapping strategies;
and

Proper selection and application of pesticides.

Documentation shall be maintained to provide evidence that a pest control program is in operation, surveillance is on-going, and verification is taking place.

11. Standard Operating Procedures

This section includes the procedures for monitoring critical control points and other processes in the QTV program if more detail is needed, and it is referenced in the QTV plan. The purpose of this section is to give applicants the option of cataloging their procedures. The Standard Operating Procedures (SOP's) shall include, but are not limited to: details on the procedures for monitoring temperature, pH, chlorine, etc. Each SOP must identify the procedure, its location, equipment, method, documentation, and accountable personnel, including who will verify the SOP.

12. Standard Testing Procedures

This section includes the methodology of the tests used to implement the SOP's. The purpose of this section is to describe test procedures and equipment. Standard Testing Procedures (STP's) include, but are not limited to: details of the

type of chlorine test(s) used, type(s) of thermometer(s) used, etc. Each STP shall identify the procedure or equipment and corresponding SOP with which it is associated.

13. Coding System and Recall Procedures

A detailed explanation of the plant's product coding system and an example of each type of code used shall be included. Recall procedures for identifying, locating, and retrieving products are an important tool used by industry to protect their customers. The Food and Drug Administration (FDA) has provided guidelines which direct how recalls are initiated and carried out. A copy of the facility's recall program shall be submitted along with the QTV plan.

Each recall program shall contain a current written contingency plan for use in initiating and implementing a recall, coding strategy that makes positive lot identification possible, and a listing of product distribution records necessary to facilitate the location of a recalled product. See 21 Code of Federal Regulations (CFR) Part 7 for more information and requirements.

14. Consumer Complaint Procedure

This section includes a consumer complaint file and a standard operating procedure for handling consumer complaints. A company must establish a procedure to deal with customer complaints. AMS will not routinely review specific complaints; however, it may do so as a result of a food safety complaint or incident.

15. Employee Training Program

An overview of the organization's training program shall be provided in the QTV plan. This shall include the type of training provided, its frequency, and how the training is documented. A comprehensive training program includes, but is not necessarily limited to, training in the areas of:

Current Good Manufacturing Practices (GMPs);
Sanitation;
Hazard Analysis Critical Control Point (HACCP); and
Qualified Through Verification (QTV).

The program shall also emphasize each employee's role and responsibilities in these areas. In addition, retraining of employees shall be addressed. The training program description shall address:

What determines the need for an employee's retraining?

How is retraining accomplished?

Is there documentation supporting the need for retraining?

When did retraining occur, and is it documented?

16. Verification

There are three levels of verification with corresponding frequencies that will strengthen a firm's reliability in the QTV program. These three types of verifications are categorized by their frequencies: daily, monthly or quarterly, and annual.

Daily: A supervisor not involved in documenting plant performance under the QTV plan shall verify all QTV-related records each day to ensure that the operating decisions made by plant personnel are consistent with QTV plan requirements. The supervisor shall follow-up when inconsistencies occur. That supervisor shall also review any reports of critical limit deviations and follow-up corrective action reports, and ensure that the QTV plan is followed. The review shall be documented by the supervisor's signature on reports and forms completed by plant personnel.

**Monthly/
Quarterly:** This periodic review verifies the HACCP plan and other intermittent records. This particular type of verification is designed to verify the proper implementation of QTV controls, and identify trends that might indicate problems.

Annual: The annual verification shall review the QTV plan and verify that any changes to the plan have been identified and evaluated for effectiveness. The review shall include, but is not limited to, the following records: prerequisite programs, SOPs, lists of product ingredients and suppliers, process flow charts, QTV record forms, and filing procedures and the QTV plan.

The annual verification is also an evaluation of the overall HACCP program. The hazard analysis shall be reevaluated thoroughly to determine:

Whether there are any new scientific data that impact upon the operation;

Whether all processes, product, or other changes are adequately considered and addressed in the current hazard analysis;

What progress has been made to provide data where questions are raised about potential hazards and the likelihood of their occurrence; and

Whether the best control methods are being applied in the proper context (prerequisite programs versus **CCP**).

The HACCP plan shall be evaluated to verify that the appropriate critical limits are being applied. A report shall be generated documenting that:

QTV controls including HACCP, CCPs have been verified;

Changes have been made to improve implementation as applicable; and

The QTV plan and related documents are up-to-date.

It is also recommended that re-signing and re-dating of the SOPs, hazard analysis, and the QTV plan be done to document that this annual verification activity has been performed.

Note: A firm must have an adequate quality assurance program which can provide the infrastructure to support all the elements in the QTV program. Appropriate quality assurance operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.

Appendix A

Audit Checklist

This appendix provides instructions for completing the Audit Checklist. The Audit Checklist will be used by AMS auditors during Validations and Audits. When using the Lotus Notes database, AMS auditors should see “Help” and “Using this Database” for instructions.

AMS auditors will perform a Validation or Audit and note any deficiencies. Deficiency areas include a company's adherence to their QTV plan, completeness of records, and sanitation.

Complete the Audit Checklist as follows:

1. Enter the complete name and address of the firm in the **Name and Address of Facility Inspected** area.
2. Enter all of the owners (company or individuals) in the **Facility Owner** area.
3. Enter the associated products which are being Validated or Audited in the **Products Concerned** area. The associated products can be taken from the products list in the submitted plan.
4. Enter the names of all auditors that are taking part in the Validation or Audit in the **Name(s) of Auditors** area.
5. If representative(s) from the firm or other individuals accompany the AMS audit team during the validation or audit, enter the individuals' names and titles in the **Name and Title of Accompanying Individual** area.
6. Enter the Processed Products Division (PPD) office where the facility is located in the **PPD Office** area.
7. Enter the State where the facility is located in the **State** area.
8. Enter the QTV facility number, if applicable, assigned to the facility in the **Facility Number** area.
9. Enter the month, day(s), and year the Validation or Audit has taken place in the **Date (mm/dd/yyyy)** area. If the validation or audit takes more than one day, include **all** of the dates in the appropriate area.

10. Enter the phone number of the facility in the **Phone Number** area.
11. Each deficiency found during the validation or audit will be checked in the appropriate box on the Audit Checklist. The weight of the deficiency (Minor, Major, Serious, Critical) **cannot** be changed. There are 31 areas on the Checklist that have two or more boxes. If a deficiency is found in that area, the auditors must agree on the severity of the deficiency and select the appropriate box. For all items of Section A, Records, except section A.4., "Falsification of records," use the following guidance for determining the weight of the deficiency, based on the percentage of records that were found to be inaccurate:

SERIOUS: Equal to or greater than eight (8), but less than 10 percent of records; and

CRITICAL: Equal to or greater than 10 percent of records.

Note: A record is a document which records the results of monitoring procedures or corrective actions. To determine the percentage of records, divide the total number of daily records or forms for that procedure by the number of inaccurate records. Example: You are reviewing records for the month of May. CCP 1- Receiving Form is missing information for two checks on Monday, May 22. Tuesday through Friday make up the rest of the work week, two shifts each day. There are a total of 22 records for the month of May for CCP-1, where one record covers two shifts. Therefore, one divided by 22 equals 4.5 percent.

12. An explanation for each box checked on the Audit Checklist will be recorded under the **Audit Listing of Observations** section, **except** when entering the information into Lotus Notes. In Lotus Notes, record the explanation in the area where the deficiency is scored. This explanation will list out each deficiency and include the specifics of each deficiency and how it relates to the QTV plan. In this case, observations and follow-up comments **not** associated with a deficiency are listed under the "Listing of Observations" section. For example, if monitoring procedures are not being followed at several critical control points, the box under B., PROCEDURES, "Monitoring Procedures not followed" would be checked. "The Audit Listing of Observations" would then have each instance of this deficiency noted in detail unless you are using Lotus Notes, then the deficiency would be noted in the area within B.1.

This detail would include specifics such as the critical control point, person(s) not following the monitoring procedures, and references to the monitoring procedures in the plan.

Note: Be sure to follow up on previous audit deficiencies. Include a summary of discussions with management and suggested timetables. Also note any changes and improvements to the facilities.

13. Total the Minor, Major, Serious, and Critical boxes that have been checked in the **SUMMARY: Total Deficiencies** area.
14. Check the applicable symbol { and () } in the "**Beginning Facility Rating Level**" area. Use the totals of the present audit to arrive at the "**Audit Rating Level**" and check the applicable symbol { and () } for the facility. Enter the new facility rating in the "**Final Facility Rating**" area and check the applicable symbol { and () }. The facility will be placed on a Audit frequency as they correspond to the table on the checklist. Lotus Notes will automatically compute the final level.
15. All AMS auditors will sign their names and enter the date in the **Auditor(s) Signature and Date(s)** area. In Lotus Notes, type the name of each auditor in the signature area and sign above the typed name.

AUDIT CHECKLIST		
Name and Address of Facility Audited	PPD Office:	
	State:	
	Facility Number:	
Facility Owner (Company or Individual):	Start Date (mm/dd/yyyy):	
	End Date (mm/dd/yyyy):	
Products Concerned:	Phone Number:	
Names of Auditors:	Check one: Validation Audit: <input type="checkbox"/>	
Name and Title of Accompanying Individual:	Audit: <input type="checkbox"/>	

Minor Deficiency (MIN): A deviation in part of the QTV-based system relative to facility sanitation which is not likely to materially reduce the facility's ability to meet acceptable sanitation requirements.

Major Deficiency (MAJ): A deviation from QTV plan requirements which may inhibit the maintenance of safety but does not result in an unsafe product.

Serious Deficiency (SER): A deviation from the QTV plan that has the potential to lead to an unsafe product and is highly objectionable (e.g., modification to critical limits without approval, or certified trained personnel not available).

Critical Deficiency (CR): A deviation from the QTV plan requirements or other conditions that have lead to an unsafe product or that brings into question the underlying commitment of the firm to the QTV program (e.g., falsified documents, or interference with the audit).

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Adherence to QTV Plan

A. RECORDS	MIN	MAJ	SER	CR
1. Records are not up-to-date.		<input type="checkbox"/>	<input type="checkbox"/>	
2. Records are inaccurate.			<input type="checkbox"/>	<input type="checkbox"/>
3. Records are not available for inspection.			<input type="checkbox"/>	<input type="checkbox"/>
4. Any documents or records are falsified.			<input type="checkbox"/>	<input type="checkbox"/>
B. PROCEDURES	MIN	MAJ	SER	CR
1. Preventive Measures not followed.			<input type="checkbox"/>	<input type="checkbox"/>
2. Monitoring Procedures not followed.			<input type="checkbox"/>	<input type="checkbox"/>
3. Corrective Action not taken.			<input type="checkbox"/>	<input type="checkbox"/>
C. OTHER	MIN	MAJ	SER	CR
1. Modification to QTV plan used without approval.		<input type="checkbox"/>		
2. Modification to critical limits without approval.			<input type="checkbox"/>	<input type="checkbox"/>
3. Certified trained personnel not available.			<input type="checkbox"/>	
4. QTV Plan Prerequisite Programs and/or Procedures not followed.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Facility Sanitation

1. PEST CONTROL	MIN	MAJ	SER	CR
1.1 Harborage and attractant areas present.		<input type="checkbox"/>		
1.2 Pest control measures not effective.		<input type="checkbox"/>		
1.2.1 Exclusion				
1.2.2 Extermination.			<input type="checkbox"/>	<input type="checkbox"/>
2. STRUCTURE AND LAYOUT	MIN	MAJ	SER	CR
2.1 Grounds condition can permit contamination to enter the facility.	<input type="checkbox"/>			
2.2 Facility.				
2.2.1 Design, layout, or materials used cannot be readily cleaned or sanitized; doesn't preclude contamination.		<input type="checkbox"/>	<input type="checkbox"/>	
2.2.2 Insufficient separation by space or other means allows product to be adulterated or contaminated			<input type="checkbox"/>	<input type="checkbox"/>
2.3 Equipment and utensil design, construction, location, or materials cannot be readily cleaned or sanitized; does not preclude product or primary packaging material.		<input type="checkbox"/>	<input type="checkbox"/>	
3. MAINTENANCE	MIN	MAJ	SER	CR
3.1 Condition of roof, ceiling, walls, floors or lighting not maintained; lights not protected.				
3.1.1 Area directly affecting product or primary packaging material.			<input type="checkbox"/>	<input type="checkbox"/>
3.1.2 Other.	<input type="checkbox"/>	<input type="checkbox"/>		
3.2 Insufficient Lighting	<input type="checkbox"/>			
3.3 Equipment, primary packaging material, and utensils not maintained in proper repair or removed when necessary.				
3.3.1 Product contact surfaces.		<input type="checkbox"/>	<input type="checkbox"/>	
3.3.2 Other.	<input type="checkbox"/>	<input type="checkbox"/>		
4. CLEANING AND SANITIZING	MIN	MAJ	SER	CR
4.1 Product contact surfaces not cleaned and sanitized before use.			<input type="checkbox"/>	<input type="checkbox"/>
4.2 Non-product contact surfaces not cleaned before use.		<input type="checkbox"/>	<input type="checkbox"/>	
4.3 Inadequate housekeeping.	<input type="checkbox"/>	<input type="checkbox"/>		
4.4 Cleaning methods permit adulteration or contamination.			<input type="checkbox"/>	<input type="checkbox"/>

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5. PERSONNEL	MIN	MAJ	SER	CR
5.1 Processing or food handling personnel do not maintain a high degree of personal cleanliness.		<input type="checkbox"/>	<input type="checkbox"/>	
5.2 Processing or food handling personnel do not take necessary precautions to prevent contamination of food.			<input type="checkbox"/>	<input type="checkbox"/>
5.3 Controls.				
5.3.1 Facility management does not have effect measures to restrict people with known disease from contaminating the product.			<input type="checkbox"/>	
5.3.2 Hand/foot washing and hand/foot sanitizing stations not present or conveniently located.			<input type="checkbox"/>	<input type="checkbox"/>
6. RESTROOMS	MIN	MAJ	SER	CR
6.1 Insufficient number of functional toilets.	<input type="checkbox"/>			
6.2 Inadequate supplies.			<input type="checkbox"/>	
6.3 Inadequate housekeeping.			<input type="checkbox"/>	<input type="checkbox"/>
7. WATER SUPPLY	MIN	MAJ	SER	CR
7.1 Unsafe water supply.				<input type="checkbox"/>
7.2 Inadequate protection against backflow, back-siphonage, or other sources of contamination.			<input type="checkbox"/>	
7.3 Inadequate supply of hot water.	<input type="checkbox"/>	<input type="checkbox"/>		
8. ICE	MIN	MAJ	SER	CR
8.1 Not manufactured, handled, or used in a sanitary manner.			<input type="checkbox"/>	<input type="checkbox"/>
9. CHEMICAL	MIN	MAJ	SER	CR
9.1 Chemical (s) improperly used or handled.			<input type="checkbox"/>	<input type="checkbox"/>
9.2 Chemical (s) improperly labeled.			<input type="checkbox"/>	<input type="checkbox"/>
9.3 Chemical (s) improperly stored.			<input type="checkbox"/>	
10. VENTILATION	MIN	MAJ	SER	CR
10.1 Condensation				
10.1.1 Areas directly affecting product and/or food contact surfaces and/or packaging material.			<input type="checkbox"/>	<input type="checkbox"/>
10.1.2 Nonfood contact areas		<input type="checkbox"/>		
10.2 Adequate air exchange does not exit.	<input type="checkbox"/>			
11. WASTE DISPOSAL	MIN	MAJ	SER	CR
11.1 Improper disposal of:				
11.1.1 Sewage.			<input type="checkbox"/>	<input type="checkbox"/>
11.1.2 Processing waste.			<input type="checkbox"/>	
Summary	MIN	MAJ	SER	CR
Total Deficiencies				
Beginning Facility Rating Level	Audit Rating Level		Final Facility Rating Level	
<input type="checkbox"/> Level IV () 0 audit above level <input type="checkbox"/> Level III () 1 st above level <input type="checkbox"/> Level II <input type="checkbox"/> Level I	<input type="checkbox"/> Level IV <input type="checkbox"/> Level III <input type="checkbox"/> Level II <input type="checkbox"/> Level I		<input type="checkbox"/> Level IV () 0 audit above level <input type="checkbox"/> Level III () 1 st above level <input type="checkbox"/> Level II <input type="checkbox"/> Level I	
Facilities That Fall Below Level IV Facility Rating			<input type="checkbox"/> Level V	
Auditor(s)' Signature(s) and Date(s)				
Reviewer's Signature and Date				

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Audit Frequency Schedule					
Facility Rating	Audit Frequency Schedule	Maximum Number of Deficiencies Allowed			
		Minor	Major	Serious	Critical
Level IV	1 visit/2 weeks	NA**	≥11	4 -5	0
Level III	1 visit/1 month	≥8	7-10	2 -3	0
Level II	1 visit/2 mos.	7	6	1	0
Level I	1 visit/3 mos.	0-6	0-5	0	0
For Facilities Below Level IV Facility Rating					
Level V	Daily or as necessary	NA**	NA**	≥ 6	≥ 1

Appendix B**Audit Checklist Reference****Adherence to QTV-based Plan****A. RECORDS****REASON:**

Records are used to record the success of the facility's QTV system. Non-compliance in record keeping can make it difficult to prove control of the process.

1. Records are not up to date.**COMPLIANCE:**

MAJOR: Entries must be made as they are measured. All time schedules outlined in the QTV plan must be maintained.

SERIOUS: All labels must be up-to-date. All labels must be kept on file by the firm.

2. Records are inaccurate.**COMPLIANCE:**

All entries must be accurate or they are meaningless. If calculations or the times measurements taken, etc., are not correct, or are illegible, check the box for this deficiency. If incorrect entries are made on a record, a line must be drawn through it, the correct entry shall be made, and the new entry shall be initialed by the person making the entry. White-out (correction fluid) and pencils must not be used. If an auditor finds records deemed to be acceptable by the company that are unacceptable, the deficiency will be checked at the following level (for more information on the percentage of records verified, see note on page 35.):

SERIOUS: Equal to or greater than 8 percent, but less than 10 percent of entries;

CRITICAL: Equal to or greater than 10 percent of entries.

3. Records are not available for inspection.**COMPLIANCE:**

Records are readily available to AMS auditors.

SERIOUS: If the firm does not promptly provide the applicable records for review, or records are misplaced, they are not in compliance with this item.

CRITICAL: If portions of records are not available, the company **is not** in compliance with this item.

4. Any documents or records are falsified.

COMPLIANCE:

Documents or records are executed truthfully and correctly.

SERIOUS: If an entry on a record was shown to be corrected with correction fluid or other means of obliteration, this will be considered an inaccurate entry

CRITICAL: If records have been falsified.

B. PROCEDURES

REASON:

The procedures outlined in a company's QTV plan must be followed as written. The plan was approved by AMS as a whole, not procedure-by-procedure. Not following a procedure could affect an entire critical control point.

1. Preventive measures not followed.

COMPLIANCE:

Although no documentation is required, preventive measures provide a buffer for the company in keeping control of a particular critical control point. Not following these measures affects other subsequent procedures at that critical control point. If any preventive measure outlined is not followed and if a corrective action report is not filed, the company is not in compliance for this item. Use for CCPs only.

SERIOUS: A measure that is not adhered to, that could potentially lead to an unsafe product.

CRITICAL: A measure that is not adhered to, that has led to an unsafe product.

2. Monitoring procedures not followed.**COMPLIANCE:**

Monitoring procedures must be followed to maintain control of the process. If any monitoring procedure has not been followed and a corrective action report is not filed, the company is not in compliance with this item.

SERIOUS: A procedure that is not adhered to, that could potentially lead to an unsafe product.

CRITICAL: a procedure that is not adhered to, that has led to an unsafe product.

3. Corrective action not taken.**COMPLIANCE:**

If deviations occur or when QTV plan procedures are not followed, the company must take corrective action and document it in a corrective action report or a Notice of Unusual Occurrence and Corrective Action.

SERIOUS: Corrective action procedures not followed or documented but product still in control of the facility.

CRITICAL: No corrective action taken and product not in the facility's control.

C. OTHER**1. Modification to QTV plan used without approval.****COMPLIANCE:**

Facilities are required to immediately advise AMS when implementing tests or new procedures. This includes all procedures at critical control points, sanitation procedures, verification procedures, plan modifications, adding new products or styles and consumer complaint procedures. Exceptions will be allowed for those procedures the company can justify as necessary to avert or control a public safety or health situation, provided a corrective action report is on file for the incident and a request for plan modification is filed with AMS within a 24-hour period.

MAJOR: Any change in procedures without AMS approval, whether they are written or not, will be considered non-compliance by the company for this item. (MAJOR)

2. Modification to critical limits without approval.

COMPLIANCE:

No modifications to critical limits will be accepted without prior approval from AMS. Any deviation noted for this item will be considered non-compliance.

SERIOUS: No record of prior approval and has the potential to lead to an unsafe product.

CRITICAL: No record of prior approval and unsafe product has been shipped to consumers.

3. Certified trained personnel not available.

COMPLIANCE:

Each company must employ a person whose HACCP certification AMS recognizes for this program. At least one HACCP-certified person is **required to be present** during production.

SERIOUS: HACCP-certified person not present during production and/or copies of all HACCP certificates not on file with the company and QTV plan.

4. QTV Plan Prerequisite Programs and/or Procedures not followed.

COMPLIANCE:

Prerequisite programs and/or procedures, such as Good Manufacturing Practices, Good Agricultural Practices and Handling Practices that address operational conditions specific to the QTV plan, provide the foundation for the HACCP system and the QTV plan. Not following the prerequisites stated in the plan means that the system may be compromised, and the company is not in compliance for this item.

MAJOR: Elements of prerequisite programs are not adhered to, and may indirectly affect the safety of the product.

SERIOUS: Criteria for compliance not adhered to with potential to impact QTV program.

CRITICAL: Criteria for compliance not adhered to, significantly impacting QTV program.

Facility Sanitation

1. PEST CONTROL

REASON:

The presence of rodents, insects, and other animals in the facility shall not be allowed. They are sources for the contamination of food with foreign material, filth, and bacteria, etc.

1.1 Harborage and attractant areas present.

COMPLIANCE:

The facility and grounds are to be free of harborage areas. Harborage areas include but are not limited to: uncut weeds, brush or tall grass; improper storage of unused equipment or materials; presence of litter, waste and refuse; or standing or stagnant water. All garbage and refuse containers are rodent/insect-resistant and outside storage areas are properly constructed. (MAJOR)

1.2 Pest control measures not effective.

1.2.1 Exclusion

COMPLIANCE:

Openings to the outside of or within the facility may allow vermin or other pests to enter. Openings and cracks shall be screened or otherwise sealed. Screens must be of a mesh not larger than 1/16th of an inch in order to exclude insects. Cracks or holes shall be sealed and doors and windows shall close tightly (no opening larger than 1/4") to exclude rodents or other animals. Air curtains and strip curtains must be effective. Air curtains shall comply with National Sanitation Standard Number 37 for air curtains for entrances in food establishments.

MAJOR: Strip curtains must run the entire width of the opening with sufficient overlap between flaps (1/2 inch). In addition, effective efforts shall be made to keep birds from areas of the plant where food is transferred or processed, or packaging material is stored.

1.2.2 Extermination

COMPLIANCE:

Birds--Nesting areas which pose a hazard to food or packaging material must be eliminated.

Insects--There shall be not more than an insignificant number of insects present in the facility. Approved insecticides and/or devices shall be used whenever insect populations become noticeable.

Rodents--There shall not be evidence of rodent activity. Evidence of rodents includes, but is not limited to: fecal dropping present; urine stains on bags or walls; slide marks along rodent runways; or feeding areas around stored dry goods bags. The facility shall have appropriate rodent control measures in place. If not, the facility is not in compliance.
(SERIOUS)

CRITICAL: Any evidence of pest contamination or presence on food contact surfaces including packaging, ingredients, raw materials, or product.

2. STRUCTURE AND LAYOUT

REASON:

Care must be taken to not allow contamination of a food product through indirect means. Improperly maintained outside conditions can cause plant contamination through a variety of means, such as airborne, foot traffic, etc. In addition, an improper layout of operations within a facility can inadvertently result in adulteration or contamination of the food product through employee traffic, wind drafts, or other means.

2.1 Grounds condition can permit contamination to enter the facility.

COMPLIANCE:

MINOR: There shall be no condition on the grounds such as dusty roads or parking lots, mud puddles, chemical spills, etc., that can cause contamination to be carried into the plant through such means as wind drafts, personnel foot traffic, adherence to personnel clothing, flooding, etc. Design of the facility structure shall be such that access is easily obtained to all areas. This is necessary for proper cleaning and sanitizing of floors, walls, and ceilings, as well as for visual inspections.

2.2 Facility.**2.2.1 Design, layout, or materials used cannot be readily cleaned or sanitized.**

COMPLIANCE:

MAJOR: If the rooms (including restrooms and employee break rooms) in the facility are laid out or designed in such a way that they cannot be readily cleaned or sanitized, then the facility is not in compliance. This would include improper materials for walls, ceilings, etc., as well as hard-to-reach rooms or corners even when the equipment is removed from the room.

SERIOUS: If facility's design, construction, location, or materials could contribute to contamination of the product.

2.2.2 Insufficient separation by space or other means allows product to be adulterated or contaminated.

COMPLIANCE:

There must be sufficient separation between different activities in the storage, processing, packaging and handling of food products. This includes the complete separation of eating areas or heavy maintenance areas from food-handling areas. The food product shall flow easily from one stage to another and not be allowed to come into contact with non-food surfaces if exposed. In addition, the layout of the facility shall not be such that product contamination is likely due to heavy employee traffic through work areas.

SERIOUS: If insufficient separation between different activities in the storage, processing, packaging and handling of food products are found.

CRITICAL: If product contamination exists due to insufficient separation between different activities in the storage, processing, packaging and handling of food products.

2.3 Equipment and utensil design, construction, location, or materials cannot be readily cleaned sanitized; does not preclude product contamination or adulteration.

COMPLIANCE:

Any equipment used in the manufacturing or handling of the food product must be designed or constructed so that it does not contribute to the contamination of product and so that it can be easily taken apart for regular cleaning and inspection. Failure to do so will cause the facility to be out of compliance. In addition, if the materials used are not of a material suitable for the intended purpose or there is reuse of single-service items, then the facility is also out of compliance.

MAJOR: If equipment and utensil design, construction, location, or materials cannot be readily cleaned, and/or sanitized.

SERIOUS: If equipment and utensil design, construction, location, or materials could contribute to contamination of the product.

3. MAINTENANCE**REASON:**

The structural maintenance of food handling establishments must be maintained at a high level. Deterioration of the building such as a leaky roof, cracks or depressions in the floor, or unprotected glass lighting fixtures can be reservoirs for bacteria or can cause direct contamination of food products being manufactured in the facility. Equipment and utensils that are not well maintained also pose a risk of bacterial harborage or direct product contamination. Conditions such as rusted or pitted product-contact surfaces and frayed conveyor belts are examples of non-compliance.

3.1 Condition of roof, ceilings, walls, floors, or lighting not maintained; lights not protected.**3.1.1 Areas directly affecting products or packaging material.****COMPLIANCE:**

For those areas that will directly affect product or primary packaging materials, (i.e., packaging immediately surrounding product), the roof, ceilings, walls, floors, and lighting fixtures must be maintained as designed and lights must be protected. Failure to do so causes the facility to be out of compliance.

SERIOUS: Area is highly objectionable and could potentially lead to an unsafe product.

CRITICAL: Area that leads to an unsafe product or results in product contamination.

3.1.2 Other.

COMPLIANCE:

For areas in the facility other than in 3.1.1 above, the roof, ceilings, walls, floors, or lighting fixtures must also be maintained as designed. This does not include those areas designated as offices and in which food products or primary packaging materials in any stage of production will not be handled or stored.

MINOR: A deficiency that is not likely to reduce a facility's ability to meet acceptable sanitation requirements.

MAJOR: A deficiency that may inhibit the maintenance of food safety but does not result in unsafe product.

3.2 Insufficient lighting.

COMPLIANCE:

MINOR: Lighting in areas where food is handled, processed, stored, packaged, or displayed, and where sanitation is performed, must be adequate to allow the intended operation to be carried out in a sanitary manner. Lighting shall not be so excessive as to affect the temperature of the product.

3.3 Equipment, primary packaging materials, and utensils not maintained in proper repair or removed when necessary.

3.3.1 Product-contact surfaces.

COMPLIANCE:

All product-contact surfaces must be kept in good repair. If the contact surface cannot be repaired, then the piece of equipment or utensil shall be removed so as not to allow for its use. Primary packaging materials shall be adequately covered when stored or not in use. Failure to provide these conditions will result in non-compliance.

MAJOR: A deficiency that may inhibit the maintenance of food safety but does not result in unsafe product.

SERIOUS: A deficiency that has the potential to lead to unsafe product and is highly objectionable.

3.3.2 Other.

COMPLIANCE: All non-food contact surfaces shall also be maintained in good repair. The facility is in non-compliance when the maintenance of any additional equipment or areas of equipment and utensils not referred to in item 3.3.1 above is insufficient and may allow indirect product contamination or adulteration. This can include improper storage of tools or repair materials during maintenance or repair activities.

MINOR: A deficiency that is not likely to reduce a facility's ability to meet acceptable sanitation requirements.

MAJOR: A deficiency that may inhibit the maintenance of food safety but does not result in unsafe product.

4. CLEANING AND SANITIZING

REASON:

A sound cleaning and sanitizing operation is vital to facility's food hygiene program. Product contact surfaces are most important and the most obvious. However, improper cleaning of non-product contact surfaces can cause adulteration or contamination to occur indirectly. Good housekeeping in all areas is necessary, including employee locker rooms and break rooms. It also allows the auditor to effectively inspect rooms and areas to determine if they are, in fact, clean. In addition, the methods used for cleaning and sanitizing shall be such that the product will not be adulterated or contaminated.

4.1 Product contact surfaces not cleaned and sanitized before use.

COMPLIANCE:

Product contact surfaces must be cleaned using proper techniques to remove dirt and debris prior to start-up. Sanitizers must be used before any product contacts the surface. Sanitizing without cleaning is insufficient. Any violation will be considered as not being in compliance.

SERIOUS: If product contact surfaces are not cleaned and sanitized effectively.

CRITICAL: If product contact surfaces are not cleaned and sanitized before use.

4.2 Non-product contact surfaces not cleaned before use.

COMPLIANCE:

Non-product contact areas must also be cleaned prior to use. This includes walls, ceilings, floors, and other room areas as well as equipment.

MAJOR: If non-product contact surfaces not cleaned.

SERIOUS: If non-product contact surfaces not cleaned before start-up or use.

4.3 Inadequate housekeeping.

COMPLIANCE:

Any excess clutter in production areas, employee areas, or other areas of the facility will cause the facility to be in non-compliance. This does not include those areas designated as office areas.

MINOR: Excess clutter.

MAJOR: Excess clutter that is highly objectionable.

4.4 Cleaning methods permit adulteration or contamination.

COMPLIANCE:

Employees must take care to use methods that will not adulterate or contaminate the product. Any cleaning or sanitizing procedures or techniques that may cause the product to become adulterated or contaminated will cause the facility to be in non-compliance.

SERIOUS: A deficiency that is highly objectionable and could potentially lead to unsafe product.

CRITICAL: A deficiency that has led to unsafe product.

5. PERSONNEL

REASON:

A high degree of personnel compliance is necessary for a sanitation program to work properly. The best systems can easily be defeated if the

facility personnel do not maintain high standards throughout the production and handling of the food product.

5.1 Processing or food-handling personnel do not maintain a high degree of personal cleanliness.

COMPLIANCE:

All persons, while in food preparation or handling areas, shall wear clean outer garments, use clean cloths, and conform to hygienic practices while on duty, to the extent necessary to prevent contamination or adulteration of food. This includes occasional workers or visitors to the area.

MAJOR: A deficiency that may inhibit the maintenance of food safety.

SERIOUS: A deficiency that has the potential to lead to unsafe product.

5.2 Processing or food-handling personnel do not take necessary precautions to prevent contamination of food.

COMPLIANCE:

All persons, while in a food preparation or handling area, shall:

1. Wash their hands thoroughly to prevent contamination by undesirable microorganisms before starting work, after each absence from the work station, and at any other time when their hands may have become soiled or contaminated.
2. Remove all unsecured or loose jewelry, and when food is being manipulated by hand, remove from hands any jewelry that cannot be adequately sanitized.
3. If gloves, aprons or arm guards are used in food handling, maintain them in an intact, clean, and sanitary condition. Such items shall be of an impermeable material, except where their usage would be inappropriate or incompatible with the work involved. If these items are used, they will be washed and sanitized at the same frequency as employees' hands as described in number one of this list.
4. Wear hair nets, caps, masks, or other effective hair restraint. Other persons that may incidentally enter the processing areas shall also comply with this requirement.

5. Not expectorate, store clothing or other personal belongings, eat food, drink beverages, or use tobacco in any form, in areas where food or food ingredients are exposed, used for food processing or storage, or where washing of equipment and utensils is performed.
6. Take other necessary precautions to prevent (1) contamination of foods with microorganisms or foreign substances including, but not limited to: perspiration, hair, cosmetics, tobacco, chemicals, and medications; and (2) misuse of equipment or actions by workers that can cause cross-contamination to occur.

SERIOUS: An employee with potential to cause food contamination.

CRITICAL: An action that has definitely caused food contamination.

5.3 Controls.

5.3.1 Facility management does not have in effect measures to restrict people with known disease from contaminating the product.

COMPLIANCE:

No person affected by disease in a communicable form, or while a carrier of such disease, or while affected with boils, sores, infected wounds or other abnormal sources of microbiological contamination, shall work in a food plant in any capacity in which there is a reasonable possibility of food or food ingredients becoming contaminated by such person. Plant management will make effective effort to notice personnel that exhibit illness and shall require employees to report illness or injury to supervisors. (SERIOUS)

5.3.2 Hand/foot washing and hand/foot sanitizing stations not present or conveniently located.

COMPLIANCE: Hand/foot washing and hand/foot sanitizing stations must be present, functional with adequate supply and concentration of washing and sanitizing agent(s), located conveniently, and in sufficient numbers to provide employees with ease of use.

SERIOUS: If the deficiency has the potential to lead to unsafe product.

CRITICAL: If the deficiency has led to unsafe product.

6. RESTROOMS

REASON:

Sufficient restroom facilities and restroom supplies not only provide for the comfort of employees, but are necessary for good, healthy, and wholesome conditions for the production of food.

6.1 Insufficient number of functional toilets.

COMPLIANCE:

The facility must have one operable, conveniently accessible toilet in good repair, per fifteen (15) employees, per gender. For men, urinals may be substituted for toilet bowls, but only to the extent of one-third (1/3) of the total number of bowls required. (MINOR)

6.2 Inadequate supplies.

COMPLIANCE:

The restrooms must provide supplies such as toilet paper, soap, adequate water supply etc., to meet the employee's needs. (SERIOUS)

6.3 Inadequate Housekeeping.

COMPLIANCE:

The restroom facilities must be cleaned to provide for good, healthy, and wholesome conditions for the production of food.

SERIOUS: Restroom facilities not cleaned effectively.

CRITICAL: Restroom conditions exist that has lead to an unsafe product, etc., such as overflowing toilets, or human waste on floors.

7. WATER SUPPLY

REASON:

Process water must be of very high quality as it directly interfaces or becomes part of the product being manufactured. As it will directly affect the safety of the product, no filth, deleterious chemicals, bacteria, or other contaminants may be present in solution. Water that is supplied to the plant must meet certain minimum standards. Available water must pass

potability standards established by federal, state, and local authorities. However, processing water must also be reasonably protected in the facility. Conditions that allow contamination to occur cannot be allowed. These may include cross-connection of plumbing, back siphonage, or backflow from a contaminated source to the supply system or open vessels of water.

7.1 Unsafe water supply.

COMPLIANCE:

The water supply, including well water, will be in compliance when, by certification or direct testing of the supply, it is found to meet the federal standards set forth by the Environmental Protection Agency. Certification of municipal or community systems shall be secured at a minimum of once per year. Private supply systems shall have testing performed a minimum of every six (6) months. (CRITICAL)

7.2 Inadequate protection against backflow, back-siphonage, or other sources of contamination.

COMPLIANCE:

A facility will be in compliance when all cross-connections are eliminated, and when backflow prevention devices are installed wherever backflow or siphonage may occur or where other possible forms of contamination may be present. (SERIOUS)

7.3 Inadequate supply of hot water.

COMPLIANCE:

Hot water is necessary for many cleaning techniques. In addition, a hot water supply is necessary to provide a comfortable means for employees to wash their hands. If the tap is on and a lukewarm supply of water is present in sufficient quantities to perform the necessary task, the plant is in compliance.

MINOR: Supply of hot water is not easily accessible for its proper use.

MAJOR: Inadequate supply of hot water in sufficient quantities to perform the necessary tasks.

8. ICE

REASON:

Ice shall be made from safe, potable water, and be handled in the same manner as a food product.

8.1 Not manufactured, handled, or used in a sanitary manner.

COMPLIANCE:

A facility will be in compliance when potable water is used for manufacturing ice, when the manufacturing equipment is clean, and the ice only touches impervious surfaces; when the ice holding containers are clean and made of appropriate impervious material; when handling equipment is clean and appropriate for food contact; and when ice is not reused on ready-to-eat product. For facilities receiving ice from an outside supply, a certificate of conformance will be necessary to ensure that the ice being received meets the standards set forth in this document. In addition, potability checks must be made at a minimum of every six (6) months on ice manufactured by outside suppliers.

SERIOUS: If the ice is not manufactured, handled, or used in a sanitary manner but doesn't come in contact with the product. Potability certificate not on file or over 6 months old for ice manufactured by an outside supplier.

CRITICAL: If the ice is not manufactured, handled, or used in a sanitary manner and comes in contact with the product.

9. CHEMICALS

REASON:

Plant chemicals include cleaners, sanitizers, rodenticides, insecticides, and machine lubricants, etc. They must be used according to manufacturers' instructions, have proper labeling, and be stored in a safe manner or they may pose a risk of contaminating the food product that the establishment is handling or manufacturing.

COMPLIANCE:

A facility will be in compliance when the chemicals are used according to manufacturers' instructions and recommendations, and stored in an area of limited access away from food handling or manufacturing. All chemicals must be labeled to show the name of the product, name of the

manufacturer, instructions for use, and the appropriate EPA or USDA approval.

9.1 Chemical(s) improperly used or handled.

SERIOUS: Chemicals improperly used or handled but will not result in an unsafe product.

CRITICAL: Chemicals improperly used or handled which lead to an unsafe product. Non-food grade chlorine used to correct free-chlorine levels.

9.2 Chemical(s) improperly labeled.

SERIOUS: Chemicals improperly labeled but will not result in an unsafe product.

CRITICAL: Chemicals improperly labeled which lead to an unsafe product.

9.3 Chemical(s) improperly stored.

Chemical(s) are not stored in designated area and/or the chemical storage area is not secured to prevent unauthorized access. (SERIOUS)

10. VENTILATION

REASON:

The lack of proper ventilation in a facility may cause condensation or foul odors to occur. Both are due to inadequate air exchange in the building. Condensation in a plant environment may cause filth, bacteria, or other contaminants to adulterate food products through drippage on exposed food, processing equipment, or packaging material. Foul odors normally reveal the presence of bacterial activity within the plant.

10.1 Condensation.

10.1.1 Areas directly affecting product and/or food contact surfaces and/or primary packaging material.

COMPLIANCE:

If any condensation is found in areas in the facility where the condensation has the potential to come in contact with product or primary packaging material or food contact surfaces, the facility is in non-compliance.

SERIOUS: Area is highly objectionable but does not lead to an unsafe product.

CRITICAL: Area has led to an unsafe product.

10.1.2 For nonfood contact areas. (MAJOR)

10.2 Adequate air exchange does not exist.

COMPLIANCE:

A facility is in compliance when adequate air exchange exists to preclude the development of foul odors. (MINOR)

11. WASTE DISPOSAL

REASON:

In a manufacturing environment raw material is either utilized in the product or discarded as waste which may be eliminated via the sewerage system or physically removed. Sewerage shall be regarded as anything that enters the sewage system including bodily wastes, process water, etc. Any failure to properly eliminate these wastes allows fecal and other human disease organisms to possibly contaminate the food product through splash, foot traffic, or other means. Processing waste is likely to carry filth, decompose quickly, and be an attractant to rodents, insects, and other vermin.

11.1 Improper disposal of:

11.1.1 Sewage.

COMPLIANCE:

A facility (including restrooms) is in compliance when sewerage systems drain properly, are vented to the outside, and are connected to an approved private septic system or a public septic and/or sewerage system.

SERIOUS: System is highly objectionable and has the potential to lead to an unsafe product. Example: System does not drain properly.

CRITICAL: Systems that lead to an unsafe product. Example: System overflows, is clogged or backs up into the facility, causing contamination of the product, or conditions where contamination is not precluded.

11.1.2 Processing waste.

COMPLIANCE:

A facility is in compliance with regard to processing wastes when personnel place the waste in proper containers, placed at appropriate locations throughout the plant, and the waste is removed frequently.
(SERIOUS)

UNITED STATES DEPARTMENT OF AGRICULTURE
Agricultural Marketing Service
Fruit and Vegetable Program
Processed Products Division

**AGREEMENT FOR QUALIFIED THROUGH VERIFICATION (QTV)
SYSTEMS AUDITS**

I (We) _____,
located at _____ hereinafter
referred to as the applicant, hereby make application for Systems Audits evaluation at the
plant(s) listed below to cover the following products:

EXAMPLE

I. The applicant agrees that with respect to:

- A. REGULATIONS** - In requesting this service the applicant agrees to conform to the Regulations Governing Inspection and Certification of Processed Fruits and Vegetables and Related Products (7CFR, Parts 52.1 through 52.83) and such instructions covering inspection and certification of the products listed as may be issued by the Administrator, Agricultural Marketing Service (AMS). And in addition:
1. Records - Maintain all records required by the QTV plan including, but not limited to, hazard analysis, preventive measures, critical control point and critical limit documentation; monitoring records of preventive measures associated with critical control points; corrective action reports; verification records including consumer complaints relevant to the QTV plan; making those records available at all reasonable times to QTV auditors; and
 2. Samples - Provide reasonable quantities of product samples during the QTV program at no cost to the Government.

- B. SURETY** - Furnish an acceptable surety, effective prior to the date of the first Systems Audit, guaranteeing payment for the services to be rendered in an amount sufficient to cover estimated billings for a period of 3 months in the form of a properly executed surety bond **or** advance payment.
- C. PAYMENT** - Pay by check, draft, or money order drawn to the order of "United States Department of Agriculture, USDA" for the service covered herein on or before the due date specified on the bill.
- D. PLANT APPROVAL** - The applicant is responsible for granting permission for AMS to enter plant premises to perform systems audits.

II. AMS agrees that with respect to:

- A. SYSTEMS AUDITS** - AMS agrees to provide objective third-party verification of the applicant's Qualified Through Verification (QTV) Plan. AMS agrees to:
 - 1. Verification - Review, evaluate, and verify the effectiveness of the processor's adherence to the QTV Plan. Methods used to accomplish this include, but are not limited to, performing on-site inspections, evaluation of production processes identified in the Plan, evaluation of product samples, audit of plant records and interviews with plant employees.
 - 2. Sanitation - Perform sanitation inspections. Record and report any sanitation deficiencies which may result in an unsatisfactory rating or cause product contamination.
 - 3. Sample - Randomly draw and evaluate official samples to verify the effectiveness of the applicant's QTV plan and determine if end items comply with applicable specifications.
 - 4. Formulation - Verify product formulation. Audit reports and records to determine if documentation of components and quantities used are accurate and complete.
 - 5. Calibration - Verify procedures used to calibrate scales and measuring devices and ensure that they are accurate.
 - 6. Packaging and Labeling - Verify that product packaging and labeling are in compliance with the applicable specifications in the QTV Plan.
 - 7. Recordkeeping - Review records associated with and identified in the QTV Plan to determine adherence to the Plan. No records will be duplicated or removed from the facility.

8. Exit Interview - Discuss and report the results and observations with the firm after each QTV Systems Audit, providing verification reports, sharing data and sample results as necessary, allowing for voluntary follow-up and corrective action, where appropriate. Provide written notification in the event any violative condition is found.
9. Report - Issue a report of audits and evaluations.
10. Confidentiality - Consider and treat any trade secrets or confidential information as proprietary and confidential. Consider any QTV records and related information provided to AMS because of the company's participation in the QTV program as information that is voluntarily submitted to the Agency.

B. CHARGES

1. Bill the applicant for Systems Audits on an hourly basis in accordance with the applicable sections of the Regulations.

III. It is mutually agreed that with respect to:

A. TERMINATION, SUSPENSION, OR WITHDRAWAL OF SERVICE

1. Systems Audits shall be continued until suspended, withdrawn, or the agreement is terminated by:
 - a. Mutual consent;
 - b. Either party giving the other party 30 days advance written notice specifying the date of suspension or termination;
 - c. A written notice by AMS if the applicant fails to honor any invoice within 60 days after date of receipt;
 - d. Bankruptcy of the applicant or closing out of business, or change in controlling ownership of the firm;
 - e. AMS at any time, acting pursuant to any applicable law, rule, or regulation, debarring the applicant from receiving any further benefits of the service; or
 - f. Non-performance by the applicant such that the applicant no longer satisfies the requirements for participation in the QTV program.

Approved by:
Randle A. Macon

Effective Date: July 2012

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IV. This application when approved shall constitute an agreement between the undersigned and AMS in accordance with the terms and conditions provided herein.

APPROVED:

APPROVED:

NAME OF APPLICANT

**U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
FRUIT AND VEGETABLE PROGRAM**

BY (signature)

BY (signature)

TITLE

TITLE

DATE

DATE

EXAMPLE

Surety - [Name of Company - \$ Amount]

Appendix D

References and Resources

Food and Drug Administration. Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food. Title 21, *Code of Federal Regulations*, Part 110 U.S. Government Printing Office, Washington, DC.

Food and Drug Administration. Fish and Fishery Products. Title 21, *Code of Federal Regulations*, Part 123. U.S. Government Printing Office, Washington, DC.

Food and Drug Administration. *Hazard Analysis Critical Control Point Pilot Program for Selected Food Manufacturers - Interim Report of Observations and Comments* U.S. Department of Health, Education and Welfare, Food and Drug Administration, Washington, DC.

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Food and Drug Administration *Guidance for Industry Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables October 1998*

Food and Drug Administration *Analysis and Evaluation of Preventive Control Measures for the Control and Reduction/Elimination of Microbial Hazards on Fresh and Fresh-Cut Produce September 2001*

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International Fresh-cut Produce Association, Produce Marketing Association, United Fresh Fruit and Vegetable Association, Western Growers *Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain April 25, 2006*.

Produce Marketing Association, United Fresh Fruit and Vegetable Association, *Commodity Specific Food Safety Guidelines for the Melon Supply Chain November 7, 2005*.

International Fresh-cut Produce Association, *Model Food Allergen Management for the Fresh-cut Produce Industry First Edition 2004*.

National Food Processors Association (NFPA). 1989. *Guidelines for the Development, Production, Distribution and Handling of Refrigerated Foods*. NFPA, Washington, DC.

Doyle, M. P., L. R. Beuchat, T. J. Montville. 1997. *Food Microbiology Fundamentals and Frontiers*. American Society for Microbiology Press, Washington, DC.

American Society for Quality. 1997. *The Quality Audit Handbook*. ASQ Quality Press, Milwaukee, Wisconsin.