Partners In Quality

Audit Procedure Guidelines

Partners In Quality Audit Procedure Guidelines

These guidelines are specifically developed by the Fresh Products Branch to inform and assist individuals involved in the audit-based Partners In Quality (PIQ) alternative inspection program.

This publication supercedes the previously issued guidelines referred to in the Partners In Quality Audit Procedures Guidelines, May 1997, (and all earlier editions) as Chapters 4 through 7.

The Partners In Quality Program Development Guidelines, dated March 1997, and August 1998, are still usable.

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INTRODUCTION

The Department of Agriculture (USDA), Agricultural Marketing Service (AMS), Fruit and Vegetable Programs (FVP), Fresh Products Branch (FPB) and their respective cooperators, the Federal-State Inspection Service (FSIS) have approved the auditing standard and these procedures that guide the examination of quality systems. "Audit Management" as referenced in this handbook may include any or all of the above mentioned entities.

An audit is an examination of the records, procedures, and product of a participants quality system performed by auditors who are uninvolved with the preparation of these records, procedures or products. On the basis of this examination, auditors provide an objective report of whether the auditee's records are accurate; the appropriate controls are maintained and effective; the procedures have been followed; the product meets the various requirements; and if other criteria have been satisfied as outlined in the quality manual.

This audit procedures guide has been developed for use by individuals who have had formal, classroom auditor training and have participated in quality systems audits as on-the-job training. This handbook is to assist auditors in performing validation, verification and close-out audits and includes information to ensure that quality systems audits are as objective as possible. It should be used in conjunction with the audit plan, audit checklists (reports) and definitions of non-conformities. An example of each of these is included in this handbook. All audit procedures should be coordinated with the participants management for their concurrence and support. This will provide reliable management information while identifying opportunities to improve their quality system.

Definitions

The following table includes some commonly used definitions in quality systems audits.

Assessment	An estimate or determination of the significance, importance or value of something.
Audit	An objective evaluation of a quality system based on known criteria. It encompasses product, processes and paperwork.
Audit Program	The organizational structure, commitment, and documented methods used to plan and perform audits.
Audit Standard	The authentic description of essential characteristics of audits that reflects current thought and practice.

Audit Team	The group of individuals conducting an audit under the direction of a team leader.
Auditee	The organization to be audited.
Auditing Organization	A unit or function that carries out audits through its employees. This organization may be a department of the auditee, a client, or an independent third party.
Auditor	A person who is trained and designated to perform audits of documented quality assurance systems.
Certification	The procedure and action, by a duly authorized body, of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with applicable requirements.
Characteristic	A property that helps to identify or to differentiate between entities and that can be described or measured to determine conformance or non-conformance to requirements.
Client	The person or organization requesting the audit. Depending on the circumstances, the client may be the auditing organization, the auditee, or a third party.
Compliance	An affirmative indication or judgement that the supplier of a product or service has met the requirements of the relevant specifications, contract, or regulation.
Conformance/ Conformity	An affirmative indication or judgement that a product or service has met the requirements of the relevant specifications, contract, or regulation.
Contractor	Any organization under contract to furnish items or services; a vendor, supplier, subcontractor, fabricator, and sub-tier levels of these, where appropriate.
Convention	A customary practice, rule or method.
Corrective Action	Action taken to eliminate the root cause(s) and symptom(s) of an existing undesirable deviation or non-conformity to prevent recurrence.
Critical Control Point	A point or operation, beyond which if not controlled, non-conforming product will be produced.
Deviation	The departure from a specified requirement.
Documents	Information and its supporting medium, including manuals, written procedures, organizational charts, work instructions, plans, designs, drawings, specifications, test methods, job descriptions, pre-printed forms, tags, labels, and all manner of records related to the quality system.
Evaluator	A person knowledgeable of the policies and procedures applicable to the specific audit program for which the audit is conducted. An evaluator may be a supervisor, trainer, program manager or team leader.

Finding	A conclusion of importance based on observation(s).
Follow-up Audit	An audit where the purpose and scope are limited to verifying that corrective action has been accomplished as scheduled and to determine that the action prevented recurrence effectively.
Guidelines	Documented instructions that are considered good practice but are not mandatory.
Independence	Freedom from bias and external influence.
Inspection	Activities such as measuring, examining, testing, and gauging one or more characteristics of a product or service and comparing these to specified requirements to determine conformity.
Internal Audit	A formal evaluation of the status and adequacy of the quality system by top management, in relation to the quality policy and new objectives resulting from changing circumstances. Also known as a "quality system review;" can be applied to a participant or the inspection service.
Non-conformity	The non-fulfillment of a specified requirement and categorized as minor, major or critical.
NUOCA	Notice of Unusual Occurrence and Correction Action form. The form used by the participant to document unusual occurrences.
Objective Evidence	Verifiable qualitative or quantitative observations, information, records, or statements of fact pertaining to the quality of an item or service; or to the existence and implementation of a quality system element.
Observation	An item of objective evidence found during an audit.
Procedure	A document that specifies the way to perform an activity.
Qualification	The status given to a person or entity when the fulfillment of specified requirements has been demonstrated; the process of obtaining the status.
Quality	All the features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs.
Quality Assurance	The planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy specified requirements for quality.
Quality Control	The operational techniques and activities that are used to fulfill requirements for quality.
Quality Management	The aspect of the overall management function that determines and implements the quality policy.
Quality Manual	A document produced by a participant operating under a PIQ contract to describe the quality system in operation at the facility and to satisfy all of the specifications of the quality assurance system.

Quality Plan	A document that describes the specific quality practices, resources and activities relevant to a particular product, process, service, contract or project.
Quality Policy	The overall quality intentions and direction of a participant regarding quality, as formally expressed by top management.
Quality System	The organizational responsibilities, procedures, processes and resources for implementing quality management.
Quality System Audit	A systematic and independent examination to determine whether quality activities and results comply with planned procedures and whether these procedures are implemented effectively and are suitable to achieve objectives.
Record	Any written or printed findings or results pertaining to design, inspection, testing, auditing, surveying, reviewing or other observations related to the quality system.
Root Cause	A fundamental deficiency that results in a non-conformity which must be corrected to prevent recurrence of the same or similar non-conformity.
Specification	The document that prescribes the requirements to which the product or service must conform.
Traceability	The ability to trace the history, application, or location of an item or activity and like items or activities by means of recorded identification.
Verification	The act of reviewing, inspecting, testing, checking, auditing, or otherwise establishing and documenting whether items, processes, or documents conform to specified requirements.

AUDITS

The purpose of an audit is to determine whether a participants quality system is effective in maintaining control of the various requirements under which they are governed or regulated. These requirements may include program specifications or standards, minimum quality levels, pack or marking regulations, marketing order requirements, etc.

A clearly defined policy from the participants senior management outlining the reasons for participation in the program is critical to its success, not only to assure senior management involvement, but to ensure management support if an impasse with the FSIS is reached. Senior management involvement is key to successful participation in the PIQ program.

Authority to Conduct Audits

Quality systems audits should encompass all aspects of the quality system. With this in mind, the authority for conducting audits must come from, and be supported by, the chief executive of the participating company. Without this authority, program cooperation and value of the quality audit is limited. USDA policy advises participants of any audit program to plan and maintain quality systems. The assessment of their program effectiveness will be through internal audits as well as external quality audits performed by the FSIS. This authority usually resides within program specifications or standards and in the participants quality manual.

A declaration of commitment to the participant's written policy or contractual agreement with USDA are the most common places to find authority and support for conducting quality audits. Support from the highest level of the participants management personnel is essential for quality audits to achieve maximum benefits. The fact that audits are required by contract or specification means little if the requirement is not supported by company management.

Auditing

The audit program should identify non-conformities as early as possible. This early detection allows participant management to implement corrective actions before the non-conformity affects delivery of services (quality of product, meeting program requirements, etc.). It should also prevent recurrence of the non-conformities. ***The purpose of an audit is not to find fault, but to focus management attention on areas where the system can be improved.***

Audit Frequency

Audit frequency may be based on regulation, audit program, standards, or contract requirements. Frequency varies relative to confidence in the quality system, and quality of the operations, management, or specific objectives of the audit. A participant striving to reach the optimum frequency (Level 1) contributes to the effectiveness and economy of audits. The audit frequency established for the PIQ program define three levels: Level 3 - one audit in a two day period; Level 2 - one audit in a seven day period; and, Level 1 - one audit in a 14 day period. This audit frequency is based on a 9 - 10 month commodity season. The frequency can be modified for shorter season commodities or as agreed to by the FSIS and industry.

Opportunities for Improvement

An audit generally examines every aspect of the quality system and, regardless of the result, is an opportunity for improvement. An audit of a specific operation within the system is a prime example of an evaluation that exposes opportunities for improvement.

Many audits reveal that procedural processes need to be evaluated. Sometimes an inspection process cannot be understood due to lack of instructions. Other times, too many procedures address the same subject and confuse the issue. Participants understand the economics of their operation, so when a more economical way can be suggested through an audit report, its value to the participant will be recognized and management support will continue.

THE AUDITOR

The auditor must be perceived as competent and qualified. Confidence in audit results is directly related to auditor proficiency, independence of judgment, and professional conduct. The auditor must possess technical expertise needed for evaluating technical activities, and must meet the qualifications established by USDA.

Auditor Criteria

USDA, AMS, FPB auditor criteria are based on 5 core requirements: personal attributes, education, work experience, auditor training, and audit experience.

FPB quality systems auditors, including auditors-in-training shall meet all of the following Fundamental Requirements:

(a) Possess personal attributes important in the performance of auditing activities.

(b) Have a high school diploma or equivalent.

(c) Have completed a minimum of 36 months experience post-high school which shall be in an agricultural related field, such as: (1) an Agricultural Commodity Grader (ACG), (2) an Agricultural Marketing Specialist, (3) quality assurance (4) food processing, (5) applicable farm experience, (6) auditing, (7) process control application, (8) or ISO application.

- Education may be substituted for experience: a 4 year course of study leading to a bachelor's degree in a related field (agriculture, statistics, science or business will meet the experience requirement).
- A combination of education and experience may be substituted for the 36 months of experience: Combinations of successfully completed post-high school education and experience may be used to meet total qualification requirements for the 36 months experience. Combinations may be computed by (1) determining the total qualifying experience as a percentage of the 36 months experience required; (2) determining the education as a percentage of the education required for the position; and (3) adding the two percentages. The total percentage must equal at least 100 percent to qualify.

(d) Demonstrate the ability to effectively communicate orally and in writing.

(e) Have successfully completed an FPB approved course for ISO 19011:2002 Section 4 - Principles of Auditing and Section 6 - Audit Activities.

(f) H ave successfully completed specific audit program training as defined by FPB.

An individual who meets the Fundamental Requirements may participate as an FPB auditor-in-training. An individual who does not meet the Fundamental Requirements may participate only as an observer.

Standard Training and Audit Experience Requirements

An FPB auditor who meets all of the Fundamental Requirements shall also meet the following Standard Training and Audit Requirements:

(a) Demonstrate the ability to manage and coordinate audits.

(b) Have successfully completed an FPB approved course for process-based auditing.

(c) Meet the training requirements based on the type of audit program:

- USDA Quality Management System (QMS) Program - successfully completed ISO 9001:2000 Lead Auditor training course.
- USDA Process Verified Program - ISO 9001:2000 Lead Auditor training course.

(d) Participated in a minimum of 3 complete audits. (A complete audit is one which evaluates the entire program or system.)

- 2 of the 3 complete audits shall be for the specific audit program acting in the capacity of a team leader under the supervision of an evaluator. An FPB Auditor-in-Training Evaluation Worksheet must be completed for each training audit.
- The result of the 2nd evaluation must be a Fully Successful rating for the FPB Auditor-in-Training to be considered an FPB Auditor qualified to perform the audit for the Specific Audit Program. An example of the evaluation worksheet can be found in Appendix I.

(e) Must be licensed by the Federal Program Manager or FPB Field Operations Section in quality systems auditing.

(f) Must attend FPB approved auditor refresher training, currently a minimum four (4) hours per year.

An FPB Auditor who meets all of the Fundamental Requirements and Standard Training and Audit Experience Requirements for a specific audit program is considered "qualified" for the specific program and may act in the capacity of a team leader without the supervision of a qualified FPB auditor.

The following are requirements for an **Audit Team:**

(a) Shall be made up of at least two (2) quality systems auditors.

(b) Shall have at least one (1) auditor licensed as an inspector on the commodity being audited.
(c) Shall include a "lead" auditor who is in charge of the specific audit and audit team.

The following are requirements for each **individual audit:**

(a) A individual quality systems auditor shall not audit the same facility on more than two (2) consecutive audits of that facility.

Desirable Auditor Traits

Auditor demeanor and conduct is directly related to the audit success. Auditor, USDA and FSIS credibility can be severely damaged if the auditor is not professional. Auditor candidate selection should be made with the following attributes in mind:

- Ability to communicate: choice and flow of words; clarity of thought; listening, understanding, and responding; writing skills.
- Ability to plan and control: organize, initiate, observe, and analyze.
- Ability to lead: supervise, delegate, gain acceptance, and accomplish objectives.
- Ability to gain cooperation with other auditors, supervisors, FSIS, and USDA.
- Ability to reach decisions: separate facts from opinions; compile information and evidence, and compare evidence with standard.
- Ability to administer: recordkeeping and reporting.
- Ability to work independently, systematically, and energetically.
- Ability to acquire and use special knowledge and skills.
- Ability to adapt to changing work assignments and conditions.
- Professional appearance and conduct.
- Intelligent, alert, comprehending, and reasoning.
- Emotionally stable, calm, self-confident, persistent, insistent, and task-oriented.
- Good character: honest, reliable, constructive, helpful, and diplomatic.
- Professional attitude, values, interest, work habits: initiative, careful, curious, and open-minded.

Knowledge

Auditors must complement each other with their knowledge to provide necessary technical and managerial expertise. Audit criteria are only guides and auditors should understand the subject well enough to not be misled by the auditee.

An auditor must know the standards, regulations, regulatory guides, and other documents that serve as references in the specific area being audited. Prior knowledge of the number and nature of different processes or products, number of employees, and physical size of the participants system is always important. This general information can usually be found in the participants quality manual.

Experience

Knowledge of the participants organization simplifies the audit planning process. This knowledge exposes auditors to the participants program activities, and they can participate in discussions of quality specifications, standards, and procedures. Auditor study of discrepancies provides an understanding of non-conformities which have a bearing on quality systems.

Independence & Objectivity

Auditor independence rests on the absence of conflict of interest in organizational relationships and in their attitude regarding the audit and associated judgment. Lead auditors or supervisors with the overall authority for audit planning should consider this since confidence in audit results depends on the known and/or perceived independence of the auditor.

Lead Auditor

The lead auditor controls the audit. This person has additional qualifications and duties compared to the journeyman auditor. The lead auditor guides the audit team in planning and preparation, opening and exit meetings, and in making assignments of audit team members.

The lead auditor has responsibility for all assignments, tie breaking decisions, leads discussion during conference, writes the report (or delegates this task) and presents the audit report, findings and rating to management. Other team members may be assigned some of these responsibilities, but only at the direction of the lead auditor. At the direction of the lead auditor, audit team members shall answer specific questions or make specific reports to management during the exit meeting.

PERFORMING QUALITY SYSTEMS AUDITS

Definition of the Audit

The audit must be clearly defined and understood by both the participant and auditor. A significant number of audits are performed during the training and early development of the participant's audit program. Both parties must know and understand what the audit process involves. In all cases, however, the auditor must ensure that the participant knows the following:

- The audit objective.
- Who will conduct the audit.
- What is expected of the participant before, during, and after the audit.
- Standards that the participant will be audited against (PIQ specifications, municipal or State regulations, contract specifications, company quality manual, etc.).
- How the audit results will be used.

The planning phase should include preparation of an agenda and notifying the participant of the above considerations.

Audit Phases

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

Planning and Preparation

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

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

The audit plan must be based on the quality system developed and implemented by the participant to supply the service as well as a knowledge of previous (past audits) or current problems and corrective actions. This knowledge is vital for identifying the expertise needed by the auditor(s) and for preparing the audit criteria.

Applicable requirements in the participants quality manual, procedural manuals, work instructions, and any participant generated-specification should be identified. This information should be compared to ensure that there are no obvious conflicts.

It is critical to review the contract or other requirement(s) that identify operational needs outside the participants normal operation. A search of this information should identify applicable requirements which then need to be related to special procedures. The task of formulating audit questions can then begin.

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

After the scope of the audit has been established to encompass specific areas, development of an organized audit checklist should proceed. Organization of the specific audit plan should follow a systematic audit path.

It is advisable to identify the source (procedures, regulations, contract requirements, quality objectives, etc.) from which a checklist point is derived. This will add credibility to the checklist.

A predetermined plan related to the checklist should be established and used to formulate the auditor's opinions and judgments. An audit should start with planned objective requirements following a thorough review of applicable procedures, specifications, contract requirements, and regulations. This is accomplished in the planning and preparation phase for each audit.

Opening Meeting

Upon entering the facility, the audit team should make their presence known to the appropriate staff person. The identity of this individual will be apparent through quality manual review and will likely be the quality assurance manager or packing house manager.

The lead auditor will conduct the opening meeting, which typically takes only a few minutes. The lead auditor will reiterate the audit purpose, inform the participants management of the audit scope, introduce audit team members, request pertinent records/documentation, and inquire about the availability of a participant-provided escort. It is also at this time that the lead auditor will request a private meeting area for the audit team and access to telephone and copier services at the facility.

Audit Implementation

The actual audit may take several hours or longer, depending on the complexity of the audit and the facility. Auditors need to know their particular assignment and

perform their assigned duties; keep notes, make observations, examine product, etc. Each auditor should have note paper and a copy of an audit checklist for reference. The team should also have access to a controlled copy of the auditee's quality manual. Details of an observation or finding should always be documented at the time of discovery. Before leaving the area, auditors should ask the person(s) responsible in the area of concern to confirm the finding whenever a non-conformity is suspected.

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

Where continuous monitoring or inspection by facility personnel is not performed, records of previous inspections must be examined to determine that both the quality and quantity of the service are within the specified requirements or regulations.

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

The product of an audit is the written report. If any non-conformities are found during the audit, the audit team also fills out a non-conformity report, which is given to the auditee. This multi-part form provides documentation that highlights the non-conformity and affords the auditee an opportunity to address the non-conformity in writing, at the exit meeting. The auditee's response to the non-conformity must provide an immediate quick fix (when possible) and long term corrective action(s) to prevent re-occurrence. The value of such an approach is to provide participant management the opportunity to formulate corrective and preventive actions to their system. Samples of all auditor reports are shown in Appendix II.

Exit Meeting

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

aspect of the audit. Information discussed during this meeting may also have a bearing on the auditee's response to the non-conformity report.

A responsible person at the facility is provided a copy of the audit report and all associated paperwork. Entries on the non-conformity report are required by both the lead auditor and auditee management. The lead auditor reviews the proposed corrective action plan and associated time-frame for overall effectiveness. It is entirely the responsibility of the auditee to formulate and implement a corrective action plan.

An appropriate auditee corrective action plan will correct the specific non-conformity, identify the root cause of the non-conformity, and schedule the actions to preclude a recurrence. A topical fix to a non-conformity may be easy; identifying the root cause and addressing it is often difficult.

Follow-up

A follow-up audit is performed to confirm that the proposed corrective actions were put in place during the agreed-upon time-frame; that they were effective in correcting the problem, and prevent it from happening again. The resources necessary to perform the follow-up include a copy of the audit report, the corrective action report, and a copy of the quality manual.

When the participant has implemented corrective actions resulting from audit findings, the adequacy of those actions must be evaluated. All non-conformities will require some type of follow-up to verify the timeliness and effectiveness of the corrective action. The scheduling of a follow-up is a decision of PIQ audit management and based on the severity and complexity of the non-conformity, the auditee's proposed time-frame and the current audit frequency of the auditee. When practical, a follow-up should be completed as soon as possible after the corrective action implementation time-frame.

There is a tendency to consider the audit complete or "closed," when the audit report is issued. However, the audit is technically not completed until the auditor is confident that the auditees' actions to correct non-conformities have been implemented and are effective.

TYPES OF AUDITS

Internal audits, performed by the participant, are planned and accomplished at regular intervals. USDA-performed external audits are unannounced and scheduled according to the current audit frequency of the participant.

Internal Audit

An internal audit should be performed by the participant on a regular basis and as required to assure continued quality. This is especially important to assure that the services or products are maintained within limits. In addition to assuring continued quality, these audits are performed when specific needs are identified. These audits are management's verification that the program is performing as required. Identifying problems on a timely basis allows management to make adjustments within the program with minimum effort.

Some quality systems will specifically define the internal review period. This information can be audited as a benefit to the participant. USDA recognizes that internal audits, which provide documented records of their quality system, provide an increased assurance of an effective quality program producing consistent quality.

The dynamics of industry change is inevitable; therefore, participants need to protect themselves from any adverse effects. Changes in personnel, technology, and customer expectations provide a portion of the management data base from which decisions are made. A regularly scheduled quality system audit keeps management informed of the following possible circumstances:

- Employees becoming lax in procedural rules and regulations.
- Employee transfer, termination or quitting; putting less experienced people into postions with inadequate training.
- Employees developing more efficient methods and training without documentation.
- Changes in specifications not always communicated effectively.
- Shortcuts taken by personnel.
- Not producing product the customer requires.

A participants quality system should identify a policy for conducting regularly scheduled internal audits. These internal audits should demonstrate that each segment is in compliance with the specifications and the participants quality manual. This auditing policy is necessary to focus program support and to give the participant assurances that the services performed are maintained at an acceptable level.

A quality system also requires internal audits when services or customer problems are encountered. Often, these concerns will be brought to light by a well planned audit. Problem areas may be detected from records control, excessive rejections in receiving inspections, productivity reduction, personnel problems, or industry concerns. These audits normally receive maximum visibility and are directed by upper management.

The audit plan should include a complete review of recent non-conformity reports and corrective actions, as well as facility, equipment, and personnel training. Even though a previous audit indicated an acceptable or unacceptable quality program, no aspect of an audit should be disregarded due to the very nature of quality assurance systems.

Verification of Program Integrity

Service integrity should be reviewed and areas that could have an impact on industry acceptance of the programs' services should be specifically added to the audit. This function is generally performed by and for the upper management of the governing or regulatory authorities (those conducting the audits and for whom requirements are being met). This includes verification of corrective action effectiveness, industry satisfaction, re-inspections, statistics, etc. Depending on the service, any or all of these may apply.

After validation of a quality system, verification audits, performed by auditor supervisors or personnel with higher authority in the program, are performed to verify the adequacy of its intended purpose. This may lead to improvements, in order to meet employee and industry expectations. An audit may be performed when specific areas of concern are identified or when reliability is in question. All levels of management should cooperate to avoid unnecessary conflicts. This cooperative support is a positive step in any audit, and success will depend on how these managers view the audit function.

Quality System Verification

The FSIS provides the majority of inspection services within growing and shipping areas of their respective States. Knowing that a participants reputation relies heavily on the quality of services makes this type of audit necessary.

Participant Contract Requirements and Review

A function of a successful quality system is contract review, which can include requirements from clients and customers as well as local, State and Federal agencies. When contracts specify certain requirements, the quality system must address them. The quality system and quality manual should address the contract requirements and demonstrate control and compliance. The auditor must recognize the requirements of the contract. A non-conformity found in contract services should be corrected with a great sense of urgency, otherwise the potential for loss may be considerable.

Pre-Validation Audit

The pre-validation audit (or informational assessment) is a trial or practice validation audit. The purpose of this audit type is to inform the participant if their quality system is ready for validation.

At the participant's request, a pre-validation audit is performed before full scale PIQ services begin. A narrower scope audit may be performed prior to product being packed. Requirements for the specific product should be reviewed for final acceptance. A thorough review of contract requirements, if appropriate, should be made to ensure that all aspects of the program have been considered. Verification of general operations and a review of any changes in the quality system is accomplished during the pre-validation audit.

Benefits of a pre-validation audit include the following: provide an opportunity to review the quality manual and system, calibration of measuring and testing equipment, personnel needs, certificate supplies, and the tools and supplies needed to deliver the required services. Although the pre-validation audit may prove the system, equipment and personnel to be adequate, they must be evaluated periodically (through internal and FSIS verification audits) to assure that quality service is continually provided. Auditors-in-training also benefit in a pre-validation setting by having the audit process demonstrated by experienced USDA audit personnel.

Validation Audit

The validation audit is the initial audit performed to determine whether the quality system being implemented is effective in demonstrating control. It is scheduled with the full knowledge of the participant and includes representation from all appropriate Federal and State agencies. All records generated during the entire validation period are reviewed. Audit review also includes packed product on-line and in storage, in addition to the personnel and procedures by which it is processed. It is not uncommon for a validation audit to last a full day or longer, depending on the complexity of the operation.

The validation audit affords the opportunity to identify strengths and weaknesses of a system, process, or product. This audit is then used to initiate improvements aimed at assuring the future integrity of the program. It also establishes a baseline that may be used to evaluate and measure future progress. Planning for the validation audit, by both the audit team and auditee, should be extremely thorough and encompass all functions and elements of the quality system.

For regulated commodities and non-regulated commodities using voluntary inspection, traditional inspection will continue until a participant is validated. For non-regulated commodities without voluntary inspection, there may be a need for inspection during the validation period in order to verify results.

The validation audit should be scheduled at the mutual convenience of the auditor and the participant. Production schedules, vacations, unusually heavy work loads, etc., should be considered by both parties.

Verification Audit

The verification audit is to confirm the participants continued control of the system. In almost every instance, an experienced auditor will find non-conformities if they exist. However, the objective is to verify control of the system, not nit-pick the system.

Verification audits are scheduled by audit management but not announced to the participant prior to arrival. All unannounced audits require tact and diplomacy on the part of the audit team. Arrival times should vary from one audit to the next, to avoid a predictable pattern. The participant should be contacted to obtain information pertaining to hours of operation, including break and lunch times, etc. If the system is not operating when the audit team arrives, the audit can be modified to a limited scope basis such as records review, for example, instead of canceling the entire audit. This is an option that should be used sparingly.

A thorough review of previous audit non-conformities and corrective actions should be planned. The non-conformity report from the previous audit will indicate a time-frame for corrective action implementation. If the time-frame has not expired, no additional non-conformities may be assessed for that specific point.

The audit is of the quality system in place, the quality manual as written and approved by the USDA and FSIS, and the PIQ program specifications. The audit team should have reviewed a copy of the quality manual prior to the audit. Return the controlled copy of the participant's quality manual to the appropriate office at the conclusion of the audit. Copies of quality manuals are not for public distribution; the contents are CONFIDENTIAL.

The audit team shall provide a copy of the audit report and all supporting documents to the participant. A copy of the audit report and supporting documents should also be provided to the appropriate audit management as soon as practicable.

Close-Out Audit

For seasonal commodities (any commodity that is not packed year round), a close-out audit should be performed to "finalize" the season. Due to the seasonality of the product, the quality system may not be operating for a number of weeks, possibly months. The close-out audit accounts for all inspection related equipment, certificates and PLI or other stamps.

AUDIT PLANNING

The audit planning process starts when assigned by audit management. Planning is a group effort with authority for final decisions given to the lead auditor. Audit team members are assigned tasks by the lead auditor during the planning phase.

Each packing house is unique, with proprietary quality systems developed for their specific facility. As a result, each audit should be separately planned and prepared for.

The audit plan should address all parts of the audit, including the opening meeting, the audit itself and the exit meeting. At audit management's discretion, paperwork generated by the audit, including all planning documentation, may need to be provided for review.

The following page is a guide that illustrates the types of activities and questions that should be addressed during the audit process.

PLANNING & PREPARATION

Attendees: ..... Date: .....
..... Start time:.....
..... End time:.....
.....
.....

Opening Meeting - AGENDA

Introduce the audit team. State objective & scope of the audit. Request records for a specific number of days or lots. Inform participant that samples will be examined on line and in storage for quality and other appropriate factors. Inquire about escort, (insert name); request permission to interview staff.

Request an area with desk and phone to review and discuss findings, finalize audit report, and call audit management if necessary. Ask for access to photocopy services in the facility. Inform participant that the audit report and supporting documentation will be provided to USDA audit management for review and filing.

Audit - AGENDA

Lead auditor will make assignments.

Run samples for grade on line, at packed product, and in storage (for quality and condition), maintain notesheet. Review active records at control points and all recordkeeping stations. Interview QA staff at stations. Observe procedures being run by QA staff as documented in Quality Manual. Observe procedures/actions that should be done during operations - PLI requirements, special testing procedures, etc.

Bring non-conformities to attention of escort or other responsible packing house staff when found. If necessary ask for clarification, explanation or verification. Document who was informed of what and when. Reconvene & confer with audit team for decision making and writing audit report. Make copies of documentation with non-conformities highlighted, copy audit report.

Exit Meeting - AGENDA

Present audit findings and formal report, present audit rating, include notesheets and non-conformity reports. Request corrective action plan and corrective action reports (based on non-conformity reports).

Allow time for participant representative to discuss findings. Explain appeal procedures if requested.

General Comments: .....
.....
.....

AUDIT REPORTS AND DOCUMENTATION

The various audit reports and documentation used in the PIQ program are explained below. These include: Validation Audit Report, Verification Audit Report, Non-Conformity Report; Closeout Audit Report and the NUOCA form.

The **Validation Audit Report** is used during the pre-validation audit and the validation audit. Non-conformities are written in the body of the report. Additional pages can be added if necessary. Commodity notesheets (for examination of product by the auditors) will be included with this report.

The **Verification Audit Report** is used during verification audits that are ongoing throughout the verification period. These audits are unannounced and performed on a frequency schedule based on participant performance within the PIQ program. Each major or critical non-conformity is written on a separate Non-Conformity Report form. Minor non-conformities are written in the "general comments" section. Commodity notesheets (for examination of product by the auditors) are to be included with this report.

The **Closeout Audit Report** is used at the season's final audit (for non-year round commodities). Its primary purpose is to account for inspection equipment, certificates, and stamping devices prior to the facility closing for the season. It may also be used if a participant continues to pack product but is no longer using the PIQ program.

The **NUOCA Form** (Notice of Unusual Occurrence and Corrective Action) is used by the participant to document when an unusual occurrence takes place in the facility. "Unusual occurrence" is defined as something taking place unexpectedly or without design. It happens outside of normal activity or operations, is totally unplanned or unforeseen, and is not already controlled or accounted for in the quality system. Examples of an unusual occurrence could include: a power failure; a structural failure within the building; and, acts of nature (tornado, flood, etc.) resulting in a shut down or serious disruption of the process. This form should be used when necessary, but not over-used. If unusual occurrences happen repeatedly within a facility, it may be an indication that the quality system needs modification to permanently address the situation.

NON-CONFORMITIES IN QUALITY SYSTEMS AUDITS

Programs with specific requirements that are not addressed in the audit reports described on the following pages may add sections or factors as appropriate. Please contact the applicable Federal Program Managers and the Field Operations Section for

approval to any additions. Examples of current audit reports are included in Appendix II.

Minor Non-Conformity:

A failure of the documented quality assurance system which is not likely to materially reduce the participants ability to meet acceptable rules and regulations pertaining to product requirements. It does not meet the PIQ specifications and does not significantly impact the overall performance of the quality system or the ability for the audit to continue.

Major Non-Conformity:

A significant deviation from the documented quality assurance system requirements such that program integrity or compliance with acceptable rules and regulations is inhibited. If allowed to continue, it may result in the product or process not meeting requirements. Affects the auditors ability to audit the quality system. May affect quality of the product. The same repeated minor non-conformity in successive audits.

Critical Non-Conformity:

A critical deviation from the documented quality assurance system requirements such that program integrity or compliance with acceptable rules and regulations is absent. It has resulted in the product, the process, or the quality system not meeting requirements. The same repeated major non-conformity in successive audits.

General Comments Section of the Validation Audit Report:

Observations that are not non-conformities should always be noted. Indicate the potential of observations becoming a detriment to the system if allowed to continue. If still present on the next audit, those observations may be elevated to non-conformity status when appropriate. All meaningful auditor observations should be discussed with the participant's management. Observations may include a potential hazard to the product, the quality system or personnel.

DEFINITIONS OF NON-CONFORMITIES

This section contains definitions and explanations of non-conformities that may be encountered while auditing. The scenarios and examples contained are not meant to be inclusive. Auditors should make a determination on the severity of each non-conformity by careful examination of the audit findings.

SECTION A - RECORDS & DOCUMENTATION

"Records" are any written/printed findings or results pertaining to inspection, testing, auditing, surveying, reviewing or other observations related to the quality system. It is a document(s) stating results that are achieved or providing evidence of activities being performed. Records are heavily used to validate the success of a documented quality assurance system.

"Documentation" describes tasks or written procedures (paper or electronic), such as the PIQ specifications. It is a description of who-what-when-where-why-how. Documentation can include manuals, written procedures, organizational charts, work instructions, plans, designs, drawings, pictures, videos, specifications, test methods, job descriptions, pre-printed forms, tags and labels. Any non-compliance found in an audit pertaining to records or documentation can raise serious questions as to control of the process or system.

1. Quality Manual not available for review. During an audit, a controlled copy of the participant's quality manual must be available for review. The auditor must request to see a controlled copy from company personnel responsible for the quality system (usually a quality assurance staff member). If the company's copy is not made available for review within a reasonable amount of time (15 minutes), the company is in non-compliance; **CRITICAL**.

2. Quality Manual not up-to-date. All controlled copies of the quality manual must be up-to-date. The auditor should compare their controlled copy to the other controlled copies that the company holds. This also includes documentation that is referenced in the quality manual, such as work procedures, grade standards, etc. Obsolete copies of such materials should have been discarded or otherwise controlled. Materials referenced in the quality manual that are not up-to-date; **MAJOR**. Pages in the quality manual that are not up-to-date; **CRITICAL**.

3. Records not up-to-date. All records must be kept in accordance with time/frequency schedules outlined in the quality manual. Record entries must be made as tasks are performed. Measurements observed but not recorded (more than 2 measurements taken but not recorded); partial entry of information from monitoring procedures; initials for records verification not recorded in a timely manner (before the end of the next business day); **MAJOR**. Corrective Action report not documented, no records verification for more than 2 days; **CRITICAL**.

4. Records inaccurate. All entries must be accurate or the record is meaningless. Calculations and figures must be correct. Packed product examination and testing must reflect records kept on associated product. Figures kept by quality assurance personnel on examined samples should be relatively close to those found by the auditors when examining the same product. Auditor samples of packed product that exceed critical limits but within lot tolerance not shown on packing house records; **MINOR**. Auditor

samples of packed product that exceed critical limits but within container tolerance not shown on packing house records; **MAJOR**. Container tolerance exceeded not shown on packing house records; **CRITICAL**.

The same example would apply for compliance of product designated for shipment. If auditor sampling shows a lot previously determined acceptable by packing house records as *not* acceptable, the packing house must take corrective action so the non-conforming product is not shipped. Follow-up action may be necessary to verify product is not shipped in its present condition.

5. Records not available for review. If the packing house does not provide the applicable records for auditor review within a reasonable time (15 minutes); **CRITICAL**. If portions of a record are not available; **CRITICAL**. The auditor must verify that the packing house operated on specific days to determine if records should have been generated on those days.

6. Records falsified. Any item on a record that was altered by any means must be unequivocally proven by the auditor. It must also show that someone with full knowledge of the situation changed the entry to reflect a value that was not measured or observed. Intent to falsify on behalf of the packing house must be shown. Otherwise, it shall be considered an inaccurate entry (see 4, previous). Changing records to reflect compliance; **CRITICAL**.

7. Records not complete. Records must contain all required information. Depending on what is missing, this non-conformity could be assessed **Minor** to **Critical**.

8. Records not maintained. The auditor must determine what records are being maintained throughout the participant's quality system. This information should be contained in the quality manual. Examples of non-conformity include missing records from a days information, records not kept during operation, supporting records and documents not being available. If records are not maintained at critical control points in the quality system; **CRITICAL**. Examples include preliminary and finished product notesheets, any supplemental notesheets, manifests, phytosanitary declarations, and certificates, etc. Records not maintained at other locations throughout the packing house (not critical control points); **MAJOR**. Examples include stored product notesheets, equipment maintenance and calibration logs, DOC container permits, etc.

An exception will be considered when a NUOCA form is filed for the missing record prior to the audit. The NUOCA form becomes part of the permanent records for that day. Repeated NUOCA filing may indicate abuse and would be assessed a non-conformity; **CRITICAL**.

9. Record entries made by unauthorized personnel. Only authorized personnel designated in the quality manual shall enter record information. A signature or initials of the person responsible shall appear somewhere on the record. The auditor shall

determine who has authority to record information at the critical control points throughout the system. Entries by unauthorized personnel; **CRITICAL**.

10. Associated records not available. An associated record is one that is not generated within the process control mechanism of the quality system. Records that are maintained during normal operations, such as trip tickets, protocol cards, caribfly trapping reports, field reports, etc., are considered associated records. Auditors should review the quality manual to determine what associated records are kept within the quality system. If one type of associated record is not being maintained; **MINOR**, two or more; **MAJOR**. Repeated instances could result in this being considered **CRITICAL**.

11. Corrective actions not documented. Corrective actions taken, but not documented is the same as no action being taken. The record, documenting any corrective action, demonstrates that while the quality system is not perfect, it is in control. Corrective actions that are not documented; **CRITICAL**.

12. Corrections not made properly. Corrections can be made by drawing a single line through the incorrect entry, initialing it, and writing the correct entry in available space as near the original location as possible. Some entries on the FV-185 certificate are never to be corrected (see the FV-185 certificate writing handbook for specific examples). If this is the case, the certificate shall be superseded or voided. Examples of corrections not made properly include cross-outs or write overs; **MINOR**. Repeated occurrences elevate the severity to **MAJOR** or **CRITICAL**. Corrections to reflect a value that was not measured or observed is falsification and shall be considered **CRITICAL** (see 6, previous).

13. General Records & Documentation Activities. This category is for records and documentation non-conformities that do not fit in any other specific category. A number of observations in recordkeeping and documentation that individually are not non-conformities but collectively are enough to have an impact on the quality system to the extent that up to 3 shall be considered **MINOR**, up to 6; **MAJOR**, and more than 6; **CRITICAL**. More than 3 Minor non-conformities in any single category elevates it to **MAJOR**. Repeated non-conformities in successive audits will be elevated to the next level of severity.

SECTION B - PROCEDURES

Procedures outlined in the participants quality manual must be followed as written. The quality manual was approved by the USDA, State and other involved agencies as a whole, not procedure by procedure. Not following a specific procedure could affect the entire quality system.

1. Monitoring Procedures not followed. Monitoring procedures at identified critical control points must be followed to maintain control of the process. If a monitoring

procedure has not been followed as outlined in the quality manual, there is no way to demonstrate control, and the packing house is in non-compliance.

The lead auditor will pre-determine what monitoring procedures to audit, based on the process as described in the quality manual. This will be specific for each packing house and each audit. If it is the intent to audit a monitoring procedure, but only a portion of it is complete, it shall be considered a non-conformity; **MAJOR**. Any monitoring procedure not performed; **CRITICAL**.

Repeated non-conformities in successive audits will be elevated to the next level of severity. More than one monitoring procedure non-conformity affecting the same factor in a single audit will be elevated to the next level of severity.

Monitoring procedures instituted by the packing house, but not part of the requirements of PIQ program specifications may also be audited. If a packing house feels strongly enough to include it in their quality manual, they should also want it audited. If non-conformities are found in these areas, they will be considered **MINOR**.

2. Monitoring procedures not effective. If procedures to monitor an area within the system are not timely in controlling the product, the system may be out of control. ***Example***: The quality manual states a specified monitoring procedure once every hour, when a 30 minute monitoring period would better control product in the system. This becomes apparent when a large amount of sub-standard product is routinely noticed downline. If the quality system contains an inadequate monitoring procedure(s); **MINOR** to **CRITICAL**.

3. Positive Lot Identification (PLI) procedures not followed. FPB PLI procedures must be followed in order to demonstrate proper use and control of PLI devices and markings. PLI devices must be controlled at all times. PLI markings must be legible and complete. There are various ways to accomplish PLI, including individual container marking and methods for palletized product. PLI devices not controlled; **CRITICAL**. Improper use of PLI devices or inadequate PLI markings; **CRITICAL**.

4. Corrective Actions not taken. A packing house using a quality system is provided a control mechanism by the availability of corrective actions. If an error or problem arises in the system, the packing house must take corrective action; then file a Corrective Action Report which documents the action taken. Any time a critical limit is exceeded, a corrective action must be taken. If, during the course of an audit, it is found that a critical limit is exceeded, a corrective action must be taken to bring that product or system back in control. Other non-conformities may possibly be avoided in this checklist if Corrective Action Reports are filed for each problem or situation. Failure to file a Corrective Action Report will be considered a failure to take Corrective Action; **CRITICAL**.

5. Corrective action taken, but not effective. It is recognized that no system is perfect and mistakes may be made. However, the foundation of a documented quality assurance system is the use of corrective actions when critical limits are exceeded or when the quality system is out of control. Corrective actions should prevent a re-occurrence of the problems root cause. It is also recognized that every corrective action may not be effective in controlling the problem and prevent it from reoccurring. ***Corrective actions must be effective and address product that is coming to the critical control point as well as product that got by the critical control point since the last sample demonstrated system control.*** This will include packed product. As important as the need for corrective actions to demonstrate control, it is even more important that those corrective actions ***be effective***. A number of corrective actions can conceivably be taken for a particular problem, but if they are not effective in controlling the root cause, time and effort will be wasted. Repeating the same corrective action should signal that it is not effective in controlling the problem, and that a different corrective action is necessary. If an effort is made to take a corrective action, but it is not effective in controlling the problem; **MAJOR**. A repeat of the same corrective action without modification, and without correcting the root cause; **CRITICAL**.

6. Modification to procedures without approval. The procedures as outlined in the quality manual or associated reference materials have been approved as written. Modification to these procedures is not allowed unless approval is granted by USDA audit management. This approval must be in writing, and must be reflected in an updated quality manual or updates page. Modifications to procedures without appropriate approval that do not impact on the specifications of the PIQ program; **MINOR**. Modifications to procedures at critical control points without appropriate approval; **MAJOR**.

7. Modification to critical limits without approval. The critical limits as outlined in the quality manual have been approved as written. Modifications to critical limits without written approval of USDA audit management; **MAJOR**.

8. Trained personnel not available. Only those packing house personnel that have been trained at particular critical control points shall work at those locations. During operation of the quality system, a responsible person (Quality Assurance Manager or their back-up) must be present in the facility. If trained personnel are not available it shall be considered a non-conformity; **MAJOR**. If a responsible person (Quality Assurance Manager or their back-up) not available; **CRITICAL**.

9. General procedural activities. This category is for procedural non-conformities that do not fit in any other specific category. ***Example:*** Samples examined throughout the system (ahead of the packing control point) vary between quality assurance personnel and auditor findings. Variance over what the quality assurance personnel found, if more than 5%; **MINOR**, more than 10%; **MAJOR**, more than 15%; **CRITICAL**. The auditor should make every attempt to choose samples as near to the quality

assurance personnel sample as possible. The same sampled product, if possible, should be used.

SECTION C - CONTAINER MARKINGS

This category may contain different elements and will be dependent upon the entities governing specific commodity packing requirements within each State or district. Markings may include PLI, protocol markings, variety, size, count, grade, brand and packing house. These markings must be complete, accurate and legible. Non-compliance in container markings makes it difficult to validate product identity.

1. Markings inaccurate. All marks and brands on product packaging must be accurate. Misrepresentation of product for any reason; **CRITICAL**. Containers with registered brand markings to indicating a certain grade containing out of grade product; **MAJOR**. Grade or protocol designations incorrect; **MAJOR** to **CRITICAL**. In this case, product must be designated as "hold, do not ship." An inspector may be assigned to the packing house until corrective actions have been instituted and prevention of re-occurrence is assured.

2. General container markings activities. This category is for container markings non-conformities that do not fit in any other specific category. A number of container markings non-conformities in a single audit will be elevated to the next level of severity. Repeated non-conformities in successive audits will be elevated to the next level of severity.

SECTION D - EQUIPMENT

Various equipment is used throughout the packing house in a quality system. All equipment must be used in the intended manner, and not misused. Some equipment may require calibration or independent certification prior to use.

1. Equipment not properly maintained. Equipment must be cleaned and maintained properly to ensure optimum results. Equipment that is damaged or excessively worn should not be used. The FSIS can instruct packing house personnel on the recommended condition of specific equipment. Equipment may include, but is not limited to; sizing rings, ridged jaw calipers, knives, area gauges, refractometer, penetrometer, and citrus maturity testing equipment. Miscellaneous equipment not properly maintained; **MINOR**. Pressure testing, maturity testing equipment and other equipment used at critical control points that is not properly maintained; **MAJOR**. Repeated examples (in the same audit) of equipment not properly maintained will be elevated to the next level of severity. Repeated non-conformities in successive audits will be elevated to the next level of severity.

2. Measuring / weighing equipment not calibrated. Measuring and weighing equipment must be periodically calibrated to ensure accurate measurement or product weight. Calibration should be done on a regular basis, or more frequently as specified. Calibration procedures may be done by the packing house personnel certified to perform calibration certification (State, municipal or county), or by certified private contractor. Use of measuring and weighing equipment that is not calibrated; **CRITICAL**.

3. General Equipment Activities. This category is for equipment non-conformities that are not appropriate in the previous categories.

SECTION E - OTHER

1. Product samples. This category refers to samples examined by the auditors and product examined and certified by the participant; **MINOR** to **CRITICAL**. Repeated examples (in the same audit) of significant discrepancies will be elevated to the next level of severity. Repeated non-conformities in successive audits will be elevated to the next level of severity.

SECTION F - SUPPLEMENTAL FACTORS

Nationwide participants of the PIQ program may have additional factors that are exclusive to their State, process, or commodity. This section should be used for the types of activities not covered in the previous categories. This could include items such as Florida Department of Citrus and Division of Plant Industry regulations and requirements, California Agriculture Code requirements, and Washington Agriculture Code, etc.

APPENDIX I Auditor-In-Training Evaluation Worksheet

USDA Agricultural Marketing Service
Fruit and Vegetable Programs
Fresh Products Branch

AMS Auditor-in-Training Evaluation Worksheet
- 1 -

Name of Auditor-in-Training: **Evaluation Date:**	
Indicate the capacity the Auditor-in-Training was acting during this audit or assessment:	☐ Lead Auditor ☐ Team Member
Type of Audit or Accreditation Program:	☐ USDA Quality Management System (QMS) Program ☐ USDA Process Audit Program ☐ Other, explain:
Scope of Audit: **(program elements audited)**	
Name of Evaluator:	

1 Steps for Completing the Evaluation:

1.1 Complete the AMS Auditor-in-Training Evaluation Elements table using the following scoring system:

3 = Exceeds (Surpasses expected knowledge and abilities)
2 = Fully Successful (Meets expected knowledge and abilities)
1 = Does Not Meet Fully Successful (Does not meet expected knowledge and abilities)
NA = Not applicable

1.2 Calculate the Percent Exceeds. (Step 1: Column 3 + Column 2 = Total Number of Ratings Step 2: Total Number in Column 3 divided by Total Number of Ratings times 100 = Percent Exceeds)

1.3 Provide comments for individual element ratings of Does Not Meet Fully Successful "1."

1.4 Complete the "Statement of AMS Auditor-in-Training's Overall Rating."

1.5 The evaluator may recommend additional training based on this evaluation. Ratings of Not Applicable "NA" are necessary to explain why only parts of the evaluation were performed. Comments for individual element ratings of Exceeds "3" are optional.

	AMS Auditor-in-Training Evaluation Elements	3	2	1	N A
1.	Knowledge of policies and procedures applicable to the audit or accreditation program noted	☐	☐	☐	☐
2.	Knowledge of the specific audit requirements for the applicable audit or accreditation program	☐	☐	☐	☐
3.	Ability to perform the desk audit	☐	☐	☐	☐
4.	Knowledge of and ability to perform pre-audit activities (identifying resources required for the audit; preparing the audit plan; assigning work to the audit team, as applicable)	☐	☐	☐	☐
5.	Knowledge of and ability to perform on-site audit activities				
a.	Ability to conduct or contribute to the opening meeting	☐	☐	☐	☐
b.	Ability to communicate effectively with the auditee and members of the audit team	☐	☐	☐	☐
c.	Ability to manage the audit team effectively *(Lead Auditor only)*	☐	☐	☐	☐
d.	Ability to control the audit effectively including leading the audit team in communications with the auditee, reaching audit conclusions, and preventing and resolving conflicts *(Lead Auditor only)*	☐	☐	☐	☐
e.	Ability to collect and verify information (or coordinate the collection and verification of information)	☐	☐	☐	☐
f.	Ability to interpret and apply the applicable audit or accreditation program as it relates to the auditee's business	☐	☐	☐	☐
g.	Ability to contribute to the audit findings	☐	☐	☐	☐
h.	Ability to conduct or contribute to the closing meeting	☐	☐	☐	☐
6.	Ability to contribute to the audit report	☐	☐	☐	☐
7.	Ability to prepare an audit report that is complete, technically accurate, and grammatically correct	☐	☐	☐	☐
8.	Ability to prepare audit documentation (checklists, notes, etc.) which is sufficient to write an accurate report documenting the audit results	☐	☐	☐	☐
9.	Ability to conduct follow-up audit activities (submits audit findings, follows-up on required corrective actions, etc)	☐	☐	☐	☐
10.	Personal attributes as defined in ISO 19011:2002				
a.	Ethical (fair, truthful, sincere, honest, and discreet, maintains confidentiality and security of information)	☐	☐	☐	☐
b.	Open minded (willing to consider alternative ideas or points of view)	☐	☐	☐	☐
c.	Diplomatic (tactful in dealing with people)	☐	☐	☐	☐
d.	Observant (actively aware of physical surroundings and activities)	☐	☐	☐	☐
e.	Perceptive (instinctively aware of and able to understand situation)	☐	☐	☐	☐
f.	Versatile (adjusts readily to varying situations)	☐	☐	☐	☐
g.	Tenacious (persistent, focused on achieving objectives)	☐	☐	☐	☐
h.	Decisive (timely conclusions based on logical reasoning and analysis	☐	☐	☐	☐

i.	Self-reliant (acts and functions independently while interacting effectively with others)	☐	☐	☐	☐
	Totals (Enter the Total Number for Each Column)				
	Percent Exceeds Step 1: Column 3 + Column 2 = Total Number of Ratings Step 2: Total Number in Column 3 divided by Total Number of Ratings times 100 = Percent Exceeds				

Statement of Auditor-in-Training's Overall Rating: *Evaluator must select appropriate statement*

☐	**Exceeds** expected knowledge and ability (80% of all elements rated "3;" and no individual element rated "1").
☐	**Fully Successful** - Meets expected knowledge and ability (Does not meet the Overall Rating of Exceeds; all individual elements rated either "3" or "2;" and no individual element rated "1").
☐	**Does Not Meet Fully Successful** - Does not meet expected knowledge and ability (rated "1" in any element). *Evaluator must provide comment for each individual element rating of "1" and recommended training or action. Indicate element number and explain below:*

Comments:
Evaluator shall explain ratings of "NA;" may provide comments for individual element ratings of "3; and may recommend additional training for a ratings of Fully Successful and above, if applicable. *Indicate element number and explain below:*

Auditor-in-Training Acknowledgment Signature: **Date:**

*If the Auditor-in-Training disagrees with the evaluation, a documented reason must be submitted.

APPENDIX II PIQ VALIDATION AUDIT REPORT

Company Name & Address: Packing House Registration Number (if applicable):	Validation Audit #: Date Start/End: Time Start/End:
Name & Title of Company Escort(s):	
Name of Auditors:	

Packing House Gained PIQ Program Status (check one and sign):

Yes	Signature of Lead Auditor:
No	

General Comments, Observations & Findings: (State non-conformity using a concise description, attach copies of documentation as necessary) .....

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Continue on additional pages as needed.

Validation Audit Notesheet For Auditors

Adherence to Quality Manual, Quality System, & PIQ Program Specifications

	A. Records & Documentation	Comments
	1. Quality Manual available for review	
	2. Quality Manual up-to-date	
	3. Records up-to-date	
	4. Records accurate	
	5. Records available for review	
	6. Records falsified	
	7. Records complete	
	8. Records maintained	
	9. Record entries made by authorized personnel	
	10. Associated records available	
	11. Corrective actions documented	
	12. Corrections made properly	
	13. General Records & Documentation Activities	

Continue as necessary

	B. Procedures	Comments
	1. Monitoring Procedures followed	
	2. Monitoring Procedures effective	
	3. PLI Procedures followed	
	4. Corrective Actions taken when necessary	
	5. Corrective Actions effective	
****	6. Modification to procedures without approval	
	7. Modification to critical limits without approval	
	8. Trained personnel available	****
	9. General Procedural Activities	

Continue as necessary

	C. Container Markings	Comments
	1. Markings accurate	
	2. General Container Markings Activities	

Continue as necessary

	D. Equipment	Comments
	1. Equipment properly maintained	
	2. Measuring / weighing equipment calibrated	
	3. General Equipment Activities	

Continue as necessary

	E. Other	Comments
	1. Product samples	
	2. Other	

Continue as necessary

	F. Supplemental Factor	Comments

Continue as necessary

PIQ VERIFICATION AUDIT REPORT

Company Name and Address: Packing House Registration Number (if applicable):	Verification Audit #: Date Start/End: Start time: End time: Break time if taken:
Name & Title of Company Escort (Note if **Declined)**	
Name of Auditors:	
Products / Processes Audited:	

Packing House Rating: Level (circle one each line)

This audit rating: 1 2 3 Non-PIQ

Next audit frequency: 1 2 3 Non-PIQ

Packing House Rating	**Audit Frequency**	**Number of Non-Conformities Allowed**			
		Minor	***Major***	***Critical***	
Level 1	1 audit per 14 days	4	2	0	
Level 2	1 audit per 7 days	4	3	0	
Level 3	1 audit per 2 days	4	4	1	

Verification Audit Checklist - Partners In Quality Program

	Adherence to Quality Manual - PIQ Program			
	A. Records & Documentation	**Minor**	**Major**	**Critical**
	1. Quality Manual not available for review			
	2. Quality Manual not up-to-date			
	3. Records not up-to-date			
	4. Records inaccurate			
	5. Records not available for review			
	6. Records falsified			
	7. Records not complete			
	8. Records not maintained			
	9. Record entries made by unauthorized personnel			
	10. Associated records not available			
	11. Corrective actions not documented			
	12. Corrections not made properly			
	13. General Records & Documentation Activities			

	B. Procedures	**Minor**	**Major**	**Critical**
	1. Monitoring Procedures not followed			
	2. Monitoring Procedures not effective			
	3. PLI Procedures not followed			
	4. Corrective actions not taken			
	5. Corrective action taken, but not effective			
	6. Modification to procedures without approval			
	7. Modification to critical limits without approval			
	8. Trained personnel not available			
	9. General Procedural Activities			

	C. Container Markings	Minor	Major	Critical
	1. Markings inaccurate			
	2. General Container Markings Activities			

	D. Equipment	Minor	Major	Critical
	1. Equipment not properly maintained			
	2. Measuring / weighing equipment not calibrated			
	3. General Equipment Activities			

	E. Other	Minor	Major	Critical
	1. Product samples			

	F. Supplemental Factor / Item	Minor	Major	Critical
	General Activities - EXPLAIN			

		Minor	Major	Critical
	Total Non-Conformities All Categories			

Audit findings discussed with: (Representative & Date):

Representative Signature & Date:

Auditor(s) Signature & Date:

General Comments:

- Observations and findings that could lead to non-conformities should be addressed below.
- Minor non-conformities must be addressed below.

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Minor Non-Conformity	Corrective Action

Corrective actions and time-frame for implementation must be offered by an auditee representative, and accepted by the lead auditor for all non-conformities noted in this report. The following non-conformity report pages and attached copies of documentation are part of this Verification Audit Report.

Reviewer's Signature & Date (if applicable):

Non-Conformity Report

Partners In Quality - Verification Audit **NON-CONFORMITY REPORT**	Audit #: Report #: _____ of _____
Company Name:	Date:
Lead Auditor:	Rating: MAJOR or CRITICAL

Description of Non-Conformity:

Location in quality system:

Notified company staff at time of finding non-conformity: YES or NO

____ Non-Conformity does not comply with PIQ Specifications ____ Non-Conformity does not comply with Quality Manual ____ Practice not effective in maintaining control of Quality Systems	Section Referenced in Audit Report

Company Representative Signature:

SIGNATURE AFFIRMS FACTS CONCERNING NON-CONFORMITY ARE CORRECT

Corrective Action Proposed and Time-Frame for Implementation:

Auditor Signature for Acceptance of Proposed Corrective Action and Timetable for Implementation:

Top portion for AUDITOR USE ONLY; bottom portion for Company and Auditor use.

PIQ CLOSEOUT AUDIT REPORT

Company Name, Address, Phone Number: Packing House Registration Number: #	**Close-Out** Audit # Date: Time Start/End:
Name & Title of Company Escort: (Circle if **Declined**)	Meal time, if taken:
Name of Auditor(s):	
Scope of Audit: Checklist of Equipment, Devices & Documents	
Last day of operation/process certification:	

Packing House Rating:
Audit frequency rating at end of season
(rating from previous **verification** audit):

Level (circle one)

1 2 3 Non-PIQ

Manifests on-hand: Starting number .....
to Ending number .....

Certificates (FV-185) on hand: Starting number .....
to Ending number .....

Seals on hand: Starting number .....
to Ending number .....

Hand Stamps on-hand (stamp each on back of this page, or attach separate page):

PLI number(s): .....

Other stamp number(s): .....
.....
.....

Location of hand stamps in packing house during off-season: .....
....

Testing Equipment (list below or attach separate page) collected by:

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Other Equipment (list below or attach separate page) collected by: .....

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General Comments (packing house representative or auditor): .....

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Packing House Representative Signature & Date:

Auditor(s) Signature & Date:

Reviewer's Signature & Date: (if applicable)

Note:

It is the responsibility of the packing house to notify FSIS of intended start-up date for next season and of intention to start season on PIQ or traditional inspection system.

Records generated by the PIQ documented quality assurance system must be retained for the minimum time required by USDA, FSIS, and other regulatory authorities.

NOTICE OF UNUSUAL OCCURRENCE AND CORRECTIVE ACTION (NUOCA)

Date:

Time:

Occurrence and location affected in packing house:

The following corrective action was taken:

_____

Signature & Date