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Inspection Branch Internal Quality Management System Quality System Service Standards

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**Inspection Branch Internal Quality Management System
Quality System Service Standards**

Table of Contents

Quality System Service Standards	1
1 Cooperator Management Responsibilities	2
2 The Quality System	4
3 Contract Review	6
4 Document and Record Control.....	6
5 Purchasing Inspection Equipment and Printed Materials.	7
6 Inspection Equipment Supplied by Applicants.....	8
7 Control of Inspection, Measuring and Test Equipment.....	8
8 Positive Lot Identification and Traceability.....	9
9 Process Control	9
10 Verification and Evaluation	10
11 Control of Unsatisfactory Inspection Services.....	11
12 Corrective and Preventative Actions	11
13 Handling, Storage, Packaging, Preservation.....	12
14 Training.....	13

QUALITY SYSTEM SERVICE STANDARDS

Preface

The objective of this document is to outline expectations of Fruit and Vegetable Inspection programs that deliver quality assurance, inspection and auditing services with USDA oversight. This document contains the requirements for the operation of cooperating bodies. This document is designed to provide a basis for quality systems so that they may conform to USDA AMS FV Specialty Crops Inspection (SCI) Division policies and procedures and for conformity assessment of the bodies providing service.

Introduction and Scope

State cooperating inspection bodies perform quality assessments and auditing services of fresh and/or processed fruits and vegetables on behalf of the SCI Division. These activities involve professional judgment to determine if general requirements are being met. For this reason, the inspection body needs the necessary competence to perform the task. These standards specify the quality system requirements for use where a contract (cooperative agreement) between two parties requires the demonstration of a cooperator's capability to control the processes that determine the acceptability of quality assurance, inspection, and auditing services supplied on behalf of USDA.

This standard is applicable in contractual situations when:

- A. The specified requirements for services to be performed are stated in terms of established requirements and policies; and
- B. Confidence that the services are being performed correctly can be attained by adequate demonstration of the cooperator's capabilities in the performance of the services.

In this standard the following shall apply to verbs:

Shall	-	indicates a requirement
Should	-	indicates a recommendation
May	-	indicates a permission
Can	-	indicates a possibility or a capability

Other definitions are adopted by reference.

References

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 17020:2012 (E) Conformity assessment – Requirements for the operation of various types of bodies performing inspection.

Code of Federal Regulations – 7 CFR parts 51 and Part 52

USDA referenced documents include Shipping Point and SCI Auditing instructions, Federal and Federal-State Shipping Point Supervisors Instructions and other applicable inspection and/or auditing instructions and policies.

USDA may perform work under agreement with other government agencies (Department of Defense, Department of Health and Human Services, FDA, etc.) in which case referenced instructions are included.

Quality System Requirements

1 Cooperator Management Responsibilities

Current representatives of the cooperators top management and the USDA AMS SCI Division Inspection Branch Chief shall have signed a commitment for implementing and maintaining these Quality System Requirements.

1.1 Quality Policy

The Federal-State Inspection Program's cooperating Agency (State Agency) shall define the policies of the inspection body and its commitment to performing quality inspection services and auditing services on behalf of USDA. The State Agency shall ensure that this policy is understood, implemented, and maintained at all levels in the organization. The quality policy shall be signed by the top management of the State Agency. All documentation, processes, systems, records, etc., related to the fulfillment of this standard shall be included, referenced, or linked to the documentation of the management system.

1.2 Organization

The State Agency has the overall responsibility of fulfilling the terms of the quality system operating under terms of a Cooperative agreement with the USDA. The inspection body may be the State Agency and/or another body, including individuals, contracted to perform the assigned work. Relationships between the State Agency and inspection bodies shall be defined.

Note: An organizational chart shall be incorporated with this document or referenced to it.

1.2.1 Management Representative

The State Agency top management shall designate in this policy the title of a member of management who, irrespective of other responsibilities, shall have the responsibility to ensure that the processes and procedures needed to implement the management system are established, and who shall report to top management on the performance of the management system and any need for improvements.

1.2.2 Resources and Personnel

The State Agency shall identify and provide adequate resources, including the assignment of trained personnel, for management and for performance of inspection work and verification activities.

The responsibility, authority and the interrelationship of all State Agency personnel who manage, perform, and verify the quality of inspection and auditing services shall be defined particularly for personnel responsible for:

- Initiating action to prevent the occurrence of nonconformance with policies;
- Identifying and recording any problems with the performance of inspection services;
- Initiating, recommending, or providing solutions through designated channels; and
- Controlling further performance of inspection services until the deficiency or unsatisfactory condition has been corrected.

1.3 Management Review

To ensure continued suitability, adequacy, and effectiveness, the quality system adopted to satisfy the requirements of these standards shall be reviewed at planned intervals by the State Agency's management according to a schedule stated in this section of the policy. Records of such reviews shall be maintained.

1.3.1 Scheduling the Management Review

Management review shall include, at a minimum, an annual meeting of top management, the Management Representative, and lower level managers/supervisors as appropriate. A complete management review may consist of several parts occurring at various times throughout the 12-month period.

1.3.2 Review Inputs

The management review shall include discussion and assessment of:

- Results of internal and external reviews (performance reviews) (See sec.1.3.4);
- The status and effectiveness of preventive and corrective actions;
- Follow-up activities from previous management reviews;
- The fulfillment of objectives;

- Personnel, servicing, and financial planning for the coming period;
- Changes that could affect the management system;
- Feedback from clients and interested parties related to the services provided; and
- Complaints and appeals.

1.3.3 Review Outputs

The outputs from the management review shall include decisions and actions related to:

- Improvement of the effectiveness of the management system;
- Improvement of the cooperating State Agency; and
- Resource needs.

1.3.4 Internal reviews (performance reviews)

The State Agency shall establish procedures for internal reviews to verify that it fulfills the requirements of this standard and that the management system is effectively implemented. Internal reviews shall be documented and:

- At a minimum, shall be completed once every 12-month period;
- Shall be conducted by qualified personnel knowledgeable in the inspection and verification services provided by the State Agency;
- Personnel who perform internal reviews should not review their own work;
- Persons responsible for the area reviewed shall be informed of the results of the review;
- Shall identify any nonconformities, observations that could lead to nonconformities, and opportunities for improvement;
- Steps shall be taken to correct any nonconformities; and
- Actions taken to correct nonconformities or to take preventive actions shall be recorded.

2 The Quality System

2.1 System Documentation

The State Agency shall define, document, and maintain a management system. Documented procedures shall be consistent with the USDA Quality System Service Standards. Documented procedures may be incorporated into the Quality Manual or kept as separate instructions and referenced in the manual (e.g. commodity inspection manuals and instructions; contract specifications for inspection/auditing services; other USDA or State Agency procedures). New, revised or amended quality system policies shall be submitted to appropriate State Agency officials and to USDA for approval.

2.2 Quality Manual

The State Agency shall establish, document, and maintain a Quality Manual addressing each of the requirements of these Service Standards as a means of ensuring that the inspection and auditing services provided on behalf of USDA conform to USDA specified requirements. The Quality Manual shall allow for the effective implementation of the quality system and its documented procedures.

2.3 Impartiality and Independence

Services provided on behalf of USDA under the quality system of the State Agency shall be undertaken with impartiality. The State Agency shall be responsible for the impartial and ethical delivery of services on an ongoing basis and shall not allow commercial, financial or other pressures to compromise impartiality.

The State Agency shall:

- Have top management commitment to impartiality;
- Identify risks to its impartiality on an ongoing basis; and
- Be able to demonstrate how risks to impartiality are eliminated or minimized.

Note: A relationship that threatens the impartiality of the inspection body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing, etc.

2.4 Quality Planning

The State Agency shall define and document how the requirements for delivery of inspection and auditing services delivered on behalf of USDA will be met. As appropriate, the State Agency shall give timely consideration to the following:

- The preparation of Quality Plans;
- The identification and acquisition of any necessary supervisory, inspector or auditor training, office or site checklists, inspection equipment, facilities, and any other resources or skills necessary to ensure the quality of inspection and auditing services;
- The updating, as necessary, of supervisory oversight practices and on-site supervisory checklists, including the development of new oversight procedures;
- The clarification to all inspectors and supervisors of the standards of acceptability for all phases of work performance including those which contain a subjective element;
- The identification of suitable verification procedures and audit frequencies at appropriate stages in the development and/or delivery of services; and
- The identification and preparation of quality records (those records which demonstrate achievement or non-achievement of the required quality of services and the effective operation of the quality system).

3 Contract Review

The State Agency shall maintain and establish documented procedures for review of all applications, requests, or contracts for inspection and auditing services to ensure that:

- The requirements of the customer are adequately defined and documented;
- The cooperator has the capability and legal authority to meet the requirements of the customer, applying the USDA service standards and ensuring that the assignment of inspectors complies with USDA policies on conflict of interest and inspector rotation; and
- Any differences between the inspection services requested by the applicant and those delivered to the applicant are resolved.

4 Document and Record Control

The State Agency shall establish and maintain documented procedures to control all documents, records, and data related to the requirements of the USDA service standards or to the provision of inspection services on behalf of USDA.

4.1 Approval

A Master File of approved documents shall be established which identifies the current revisions and amendments. All documents originated by the State Agency shall have the signature of the approving official and date of approval. Documents and forms must be approved for adequacy prior to use. Only approved documents and forms may be used in the performance of inspection and audit services.

4.2 Document Control Procedures

The State Agency shall establish procedures to control documents. These may include not only documents of the quality system created by the State Agency, but also documents created by USDA and used by State Agency employees, including but not limited to inspection handbooks, product grade standards, etc. The procedures shall define the controls needed to:

- Review and update (as necessary) and re-approve documents;
- Ensure that changes and the current revision status of documents are identified;
- Prevent the unintended use of obsolete documents, and apply suitable identification to them if they are retained for any purpose;
- Ensure that relevant versions of applicable documents are available at points of use;
- Ensure that documents remain legible and readily identifiable; and
- Ensure that external-origin documents are identified and their distribution controlled.

Note: Documentation can be in any form or type of medium, and includes proprietary and in-house developed software.

4.3 Control of Records

The State Agency shall establish procedures to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of its records relating to the provision of inspection services or the quality system.

- Where applicable, retention times and control must conform to established USDA policies;
- Access to these records shall be consistent with the confidentiality arrangements; and
- Records shall be stored in such a way to prevent damage, deterioration or loss and be readily retrievable.

5 Purchasing Inspection Equipment and Printed Materials.

The State Agency shall ensure that purchased equipment and printed material conforms to USDA specified requirements.

5.1 Selection of Suppliers

Where applicable, the State Agency shall select suppliers of inspection equipment and printed materials on the basis of their ability to meet USDA specifications. Purchases from suppliers must have State Agency approvals.

5.2 Purchasing Data

The State Agency shall ensure that purchased inspection equipment and printed material conforms to USDA specified requirements. When equipment is purchased for special contract specifications, applicable specifications and technical data, including approval or qualification, shall be maintained. Where relevant for the outcome of inspection activities, the State Agency shall have procedures for the following:

- Verification of incoming goods for suitability or correctness including checking and calibrating purchases before they are issued for use;
- Notification to the supplier if goods are not suitable;
- Maintenance records of verification and purchase data; and
- Ensuring appropriate storage facilities.

When printed material or inspection equipment is purchased from USDA, the State Agency shall record the receipt of goods and respond to USDA that goods have been received. The response shall include any applicable serial numbers and specifications.

6 Inspection Equipment Supplied by Applicants

The State Agency need not be the owner of the facilities or equipment that it uses. Facilities and equipment can be borrowed, rented, hired, leased or provided by applicants. However, the State Agency shall establish and maintain procedures for the suitability and the calibration status of the equipment supplied by applicants when used in Federal-State inspection services.

7 Control of Inspection, Measuring and Test Equipment

The State Agency shall have available, suitable and adequate facilities and equipment to permit all activities associated with the inspection activities to be carried out in a competent and safe manner.

7.1 Control Procedure

The State Agency shall have rules for the access to, and the use of, specified facilities and equipment used to perform inspections. They shall ensure the continued suitability of the facilities and the equipment for their intended use. All equipment (including the concentration of any chemical solutions) having a significant influence on the results of the inspection shall be:

- Defined and uniquely identified; and
- Maintained and/or calibrated in accordance with documented procedures and instructions.

The State Agency shall have documented procedures for dealing with defective equipment. Defective equipment shall be removed from service by segregation, prominent labeling or marking. The State Agency shall examine the effect of defective equipment on previous inspections and, when necessary, take appropriate corrective action. Relevant information on the equipment, including software, shall be recorded and records maintained. This shall include identification and, where appropriate, information on calibration and maintenance.

7.2 Calibrations

Inspection equipment shall be calibrated before being put into service, and thereafter, at prescribed intervals or prior to each use. These calibrations shall be documented. Equipment purchased from USDA will be presumed to be initially calibrated.

- A calibration program will be designed and operated so as to ensure that, wherever applicable, measurements made by the State Agency are traceable to USDA guidelines or, if not available, a national or international standard of measurement, where available. Where traceability to national or international standards of measurement is not applicable, the inspection body shall maintain evidence of correlation or accuracy of inspection results;

- Reference standards of measurement held by the State Agency shall be used for calibration only, and for no other purpose. Reference standards of measurement shall be calibrated providing traceability to a national or international standard of measurement; and
- Equipment shall be subjected to in-service checks between regular recalibrations.

7.3 Computers or Automated Equipment

If the State Agency uses computers or automated equipment in connection with inspections, it shall ensure that:

- Such equipment and generated reports/certificates are approved by USDA SCI Division for use prior to implementation;
- Computer software is adequate for use. This can be achieved by:
 - Validation of calculations before use;
 - Periodic (seasonal) revalidation of related hardware, software and calculations;
 - Revalidation whenever changes are made to related hardware or software; and
 - Software updates are implemented as required.
- Procedures are established and implemented for protecting the integrity and security of data; and
- Computer and automated equipment is maintained in order to ensure proper functioning.

8 Positive Lot Identification and Traceability

If the State Agency uses Positive Lot Identification (PLI), the State Agency shall establish procedures for:

- Maintaining control and accountability of all PLI devices during all stages of the inspection process; and
- Ensuring that any lot or package of product identified by PLI can be easily and quickly traced to a unique inspection certificate or serially numbered note sheet.

9 Process Control

For each type of inspection or auditing activity performed, the State Agency shall identify the essential functions and elements which directly affect the quality of the service and shall ensure that these functions and elements are carried out under controlled conditions. The State Agency shall have procedures to monitor and control the inspection or audit processes. Controlled conditions shall include the following:

- Methods and procedures for inspection and auditing which are defined in USDA or State Agency or Applicant instructions as applicable;

- All instructions, standards or written procedures, worksheets, check lists and reference data relevant to the work of the State Agency shall be maintained up-to-date and be readily available to appropriate personnel;
- The level of competence required for all personnel involved in inspection and auditing activities, including requirements for education, training, technical knowledge, skills and experience;
- The competence requirements can be part of the job description or other documentation.
- The approval process and the proper use of inspection equipment as appropriate; and
- Monitoring and control of inspection processes and results.

10 Verification and Evaluation

Designated personnel familiar with the inspection/auditing methods and procedures shall monitor all inspectors/auditors for satisfactory performance. Auditor monitoring shall be performed per current AMS Industry Services Audit and Accreditation Programs instructions. Inspection monitoring can include a combination of techniques, such as on-site observations, certificate and note reviews, interviews, simulated inspections and other techniques to assess performance, and will depend on the nature of the inspection activities involved.

10.1 Verification of Inspection Process

The State Agency shall:

- Perform supervisory checks during the inspection process at all inspection sites at a frequency defined in the quality manual;
- Determine conformance with applicable Federal inspection policies and procedures by use of inspection process monitoring and control methods; and
- Identify all areas of nonconformance with Federal policies and procedures and withhold/correct all incorrect certifications.

10.2 Verification of Inspection Results

During supervisory checks, qualified personnel shall select random samples of product recently inspected and perform a verification inspection. The supervisor will compare their inspection results to the inspector's, paying close attention to differences in results.

10.3 Records of Verification and Corrective Action

The State Agency shall establish and maintain records of:

- All supervisory checks which give evidence that inspections have been performed in accordance with Federal or established policies and procedures;

- All supervisory checks which give evidence that inspections have not been performed in accordance with Federal or established policies and procedures, including detailed descriptions of the areas of nonconformance; and
- All measures instituted to correct any nonconformance noted and to prevent future such nonconformance.

10.4 Evaluation

Inspector and auditor evaluations are required for continued licensing. The State Agency shall evaluate all USDA licensed inspectors and auditors at least annually. This may be done through a performance rating according to USDA policy, or other valid and approved method. Evaluations must be available to USDA management. The evaluation shall include the elements of the work and should include a statement regarding:

- Tact;
- Knowledge of product and/or service;
- Judgment;
- Attitude; and
- Cooperation

11 Control of Unsatisfactory Inspection Services

The State Agency shall have a documented process to receive, evaluate and make decisions on complaints and appeals. The process for handling complaints and appeals shall include at least the following elements and methods:

- A description of the process for receiving, validating, investigating the complaint or appeal, and deciding what actions are to be taken in response to it;
- Tracking and recording complaints and appeals, including actions undertaken to resolve them;
- Ensuring that any appropriate action is taken;
- Notification to the parties concerned, including USDA; and
- Timeframes for the above activities.

The State Agency shall also define the responsibility and authority for the review, evaluation, and correction of unsatisfactory or improper inspection procedures. USDA SCI Division policies regarding appeals and re-inspections shall be followed.

12 Corrective and Preventative Actions

12.1 Corrective Action

The State Agency shall establish and maintain documented procedures for identification and management of nonconformities in its operations. The State Agency shall also,

where necessary, take actions to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the impact of the problems encountered. The procedures shall define the following requirements for the effective handling of customer complaints and unsatisfactory inspection services:

- Identifying nonconformities, complaints or unsatisfactory service;
- Determining the causes of the nonconformity, complaint or unsatisfactory service;
- Investigation of the root cause of the problems;
- Determining the actions needed and implementing them in a timely manner;
- Evaluating the need for actions to ensure that nonconformities do not recur;
- Correcting nonconformities;
- Recording the results of actions taken; and
- Reviewing and evaluating the effectiveness of corrective actions.

12.2 Preventative Actions

The inspection body shall establish procedures for taking preventive actions to eliminate the causes of potential nonconformities. Preventive actions taken shall be appropriate to the probable impact of the potential problems. The procedures for preventive actions shall define requirements for the following:

- Identifying potential nonconformities and their causes;
- Evaluating the need for action to prevent the occurrence of nonconformities;
- Determining and implementing the action needed;
- Recording the results of actions taken; and
- Reviewing the effectiveness of the preventive actions taken.

Note: The procedures for corrective and preventive actions do not necessarily have to be separate.

13 Handling, Storage, Packaging, Preservation

To prevent damage, deterioration, or misidentification of any products, samples or equipment belonging to the customer that the inspection service uses or comes into contact with during provision of the service, the State Agency shall:

- Ensure items and samples to be inspected are identified as appropriate in order to avoid confusion regarding the identity of such items and samples;
- Establish whether the item to be inspected has been prepared;
- Ensure any apparent abnormalities notified to, or noticed by, the inspector shall be recorded. Where there is any doubt as to the item's suitability for the inspection to be carried out, or where the item does not conform to the description provided, the State Agency shall contact the client before proceeding; and
- Have documented procedures and/or appropriate facilities to avoid deterioration or damage to inspection items while under its responsibility.

14 Training

The State Agency shall have documented procedures for selecting, training, formally authorizing, and monitoring inspectors and other personnel involved in inspection and audit activities. The documented procedures for training shall address the following stages:

- An induction period;
- A mentored working period with experienced personnel (on the job training); and
- Continued training to maintain/enhance the skills and/or abilities needed.

The training required shall depend upon the ability, qualifications and experience of each person involved in inspection and auditing activities. Training will include monitoring and must conform to established AMS criteria for the training and licensing of inspectors/auditors. All licensed personnel shall receive annual refresher training.

The State Agency shall maintain records of monitoring, education, technical knowledge, skills, experience, training, and licensing of each member of its personnel involved in inspection and auditing activities and provide those records to USDA upon request.