Quality System Assessment (QSA) Checklist

I. COMPANY INFORMATION

☐ Name of Company & Est. No (if known): Date:

☐ Company Address (Street, City, State, Zip): Audit Identifier:

☐ Contact Name: Title:

☐ Phone #: Email:

☐ Location(s) of Audit:

☐ Type of Audit
- ☐ Desk Audit
- ☐ Initial Onsite Audit
- ☐ Onsite Surveillance Audit – at least two per fiscal year (October 1 – September 30) unless more are warranted by findings.
- ☐ Onsite Corrective Actions Audit

☐ Audit Team:
- ☐ Team Leader
- ☐ Second Auditor
- ☐ Other (identify role)

II. PRE-AUDIT ACTIVITIES

☐ Obtain & review most recent copy of program documentation from the company.

- ☐ Title of Documentation?

  _____

- ☐ Date or revision number of Documentation?

  _____

☐ Review previous PEV Grading Branch Audit Report for company (or desk audit documentation if this is the initial onsite audit).

☐ Review previous PEV Grading Branch Corrective Actions Report for company as applicable.

☐ QSVP Grading Branch Audit Plan (See Audit Plan & Form)
- ☐ Complete audit plan.
- ☐ Verify that audit plan reflects the correct information.

☐ QSVP Grading Branch Cost Estimate (See Cost Estimate & Form)
- ☐ Complete audit estimate.
- ☐ Obtain client's approval.

III. ON-SITE AUDIT ACTIVITIES

☐ **Conduct an opening meeting (ISO 19011), including as appropriate:**

- ☐ Introduction of participants & their roles;
- ☐ Confirmation of audit objectives, scope, and criteria;
- ☐ Confirmation of audit timetable and other relevant arrangement;
- ☐ Methods and Procedure to be used to conduct the audit;
- ☐ Confirmation of formal communication channels;
- ☐ Confirmation that auditee will be kept informed of audit process during the audit;
- ☐ Confirmation that the resources and facilities needed by the audit team are available;
- ☐ Confirmation of confidentiality matters;
- ☐ Confirmation of relevant work safety, emergency, and security procedure for the audit team;
- ☐ Confirmation of the availability, roles, and identities of guides;
- ☐ The method of reporting, including types of non-conformances; and
- ☐ Information about conditions under which the audit may be terminated.

☐ **Complete the following Attendance List:**

Name	Title or Position	Opening	Closing
	PY QSVP Auditor		

☐ Review audit plan. Have there been any changes since approved?
No Yes - What are the changes?

☐ Review program documentation. Have there been any changes since the last audit?
No Yes - What are the changes?

☐ Review & verify the information that the company would like to list on the Official Listing (if different).
☐ Company name, address, & contact information:

☐ Have findings from previous audits been addressed? (if applicable) Yes No

IV. CHECKLIST

[Insert Applicant Name] **USDA Quality Management System Program** (ISO 9001:2000)	**Applicant Reference Document**	**Objective Evidence**	**Conform (Y/N)**	**Findings/Remarks**
5 Applicant Responsibilities				
The applicant shall develop and implement a documented program that addresses all requirements of the Specific USDA QMS Program.				
6 Frequency of Audits				
The AMS Branch shall conduct the audit in accordance with a specified time frame stated in a Specific USDA QMS Program. However, the program audit shall be performed two times per year at a minimum.				
7 Program Requirements (Sections 7 - 12)				
7.1 General Requirements				

[Insert Applicant Name] **USDA Quality Management System Program** (ISO 9001:2000)	**Applicant Reference Document**	**Objective Evidence**	**Conform (Y/N)**	**Findings/Remarks**
The applicant shall establish, document, implement, and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this Program.				
Where an applicant chooses to outsource any process that affects product conformity with requirements, the applicant shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.				
Note: Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization, and measurement.				
7.2 Documentation Requirements				
7.2.1 General				
The quality management system documentation shall include:				
a. A quality manual;				
b. Documented specified product requirements;				
c. Documented procedures required by this Program;				
d. Documents needed by the applicant to ensure the effective planning, operation, and control of its processes; and				
e. Records required by this Program				
NOTE 1: Where the term "documented procedure" appears within this document, this means that the procedure is established, documented, implemented, and maintained.				

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NOTE 2: The extent of the quality management system documentation can differ from one applicant to another due to a) the size of the applicant and type of activities; b) the complexity of processes and their interactions; and c) the competence of personnel.				
NOTE 3: The documentation can be in any form or type of medium.				
7.2.2 Quality Manual				
The applicant shall establish and maintain a quality manual that includes				
a. The scope of the quality management system, including details of and justification for any exclusions (see 1.2);				
b. The specified product requirements;				
c. The documented procedures established for the quality management system, or reference to them;				
d. Other documents as required by the quality management system.				
7.2.3 Control of Documents				
Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 7.2.4.				
A master document list shall be established that shows the most current issue of the quality management system procedures, work instructions, forms, tags, and labels used to track or demonstrate conformance.				
A documented procedure shall be established to define the controls needed to:				

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a. Approve documents for adequacy prior to issue;				
b. Review and update as necessary and re-approve documents;				
c. Ensure that changes and the current revision status of documents are identified on all pages;				
d. Ensure that relevant versions of applicable documents are available at points of use;				
e. Ensure that documents remain legible and readily identifiable;				
f. Ensure that documents of external origin are identified and their distribution controlled;				
g. Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose; and				
h. Retain all documents for the timeframe necessary to provide evidence of conformance.				
Changes significantly affecting the approved program, such as intended modification to the program, manufacturing process, or if relevant, its quality management system, which affects the conformity of the program including product produced under the program, shall be submitted to the AMS Branch for approval prior to implementation.				
7.2.4 Control of Records				

[Insert Applicant Name] **USDA Quality Management System Program** (ISO 9001:2000)	**Applicant Reference Document**	**Objective Evidence**	**Conform (Y/N)**	**Findings/Remarks**
Records shall be established and maintained to provide evidence of conformity to requirements, including the QMS points, and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time, and disposition of records.				
Records shall be retained for the timeframe necessary to provide evidence of conformance.				
8 Management Responsibility				
8.1 Management Commitment				
Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:				
a. Communicating to the organization the importance of meeting customers as well as statutory and regulatory requirements;				
b. Ensuring that specified product requirements are established; and				
c. Ensuring the availability of resources.				
8.2 Responsibility, Authority, and Communication				
8.2.1 Responsibility and Authority				
Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.				

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An organization chart or similar document listing all personnel, and their responsibilities and authorities, assigned to managerial positions within the program shall be included in the quality manual.				
8.2.2 Management Representative				
Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that processes needed for the quality management system are established, implemented, and maintained.				
9 Resource Management				
9.1 Human Resources				
9.1.1 General				
Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills, and/or experience, as applicable.				
9.1.2 Competence, Awareness, and Training				
The applicant shall determine the necessary competence for personnel performing work affecting product quality.				
The applicant shall determine the criteria for training and shall provide training to all personnel performing work affecting product quality.				
The applicant shall have a documented procedure to ensure all personnel performing work affecting product quality are properly trained in relevant aspects of the quality management system.				
The documented procedure shall include:				
a. Providing training or take other actions to satisfy these needs;				

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b. Evaluating the effectiveness of the actions taken; and				
c. Ensuring that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.				
The applicant shall maintain appropriate records of education, training, skills, and experience. Training records shall include the scope of the training received.				
The applicant shall determine and manage the work environment needed to achieve conformity to product requirements.				
10 Product Realization				
10.1 Purchasing				
10.1.1 Purchasing Process				
The applicant shall ensure that product purchased and/or received from outside establishments and used in the program conforms to specified purchase requirements. The type and extent of controls applied to the supplier and the purchased and/or received product shall be dependent upon the effect of the purchased and/or received product on subsequent product realization or the final product.				
The applicant shall evaluate and select suppliers based on their ability to supply product in accordance with the applicant's requirements. Criteria for selection, evaluation, and re-evaluation shall be established and documented. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.				
10.1.2 Purchasing Information				

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The applicant shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.				
10.1.3 Verification of Purchased Product				
The applicant shall establish, document, and implement the inspection or other activities necessary for ensuring that purchased and /or received product meets specified purchase requirements.				
Where the applicant or its customer intends to perform verification at the supplier's premises, the applicant shall state in the purchasing information the intended verification arrangements and method of product release in the purchasing information.				
The applicant shall maintain records to provide evidence of conformity of the purchased product to the specified purchase requirements.				
10.1.4 Identification and Traceability				
The applicant shall have a documented procedure to identify the product (raw materials and finished product) by suitable means throughout product realization, where appropriate.				
The documented procedure shall describe the method for				
a. Identifying product by suitable means throughout product realization, where appropriate;				
b. Identifying the product status with respect to monitoring and measurement requirements;				
c. Controlling and recording the unique identification of the product, when traceability is a requirement; and				

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The unique identification of the product shall be such that the identification will transfer through all phases of product realization, from receipt into the program through production to delivery.				
The applicant shall maintain records of all products as identified and records of all changes of identities.				
10.1.5 Preservation of Product				
The applicant shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage, and protection. Preservation shall also apply to the constituent parts of a product.				
10.2 Control of Monitoring and Measuring Devices				
The applicant shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 10.2.1).				
The applicant shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.				
Where necessary to ensure valid results, measuring equipment shall:				

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a. Be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;				
b. Be adjusted or re-adjusted as necessary;				
c. Be identified to enable the calibration status to be determined;				
d. Be safeguarded from adjustments that would invalidate the measurement result;				
e. Be protected from damage and deterioration during handling, maintenance, and storage.				
In addition, the applicant shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The applicant shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained.				
When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.				
10.3 Customer Communication				
The applicant shall determine and implement effective arrangements for communicating with customers in relation to:				
a. Product information;				

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b. Enquires, contracts or order handling, including amendments; and				
c. Customer feedback, including customer complaints.				
11 Measurement, Analysis, and Improvement				
11.1 General				
The applicant shall plan and implement the monitoring, measurement, analysis, and improvement processes needed:				
a. To demonstrate conformance of the product;				
b. To ensure conformity of the quality management system; and				
c. To continually improve the effectiveness of the quality management.				
This shall include determination of applicable methods, including statistical techniques, and the extent of their use.				
11.2 Monitoring and Measurement				
11.2.1 Customer Perception				
As one of the measurements of the performance of the quality management system, the applicant shall monitor information relating to customer perception as to whether the applicant has met customer requirements. The methods for obtaining and using this information shall be determined by the applicant.				
The applicant shall maintain records relating to customer perception relating to conformance of the program or products produced under the program.				

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The applicant shall take appropriate action addressing customer complaints and any deficiencies found in the program, or product, if applicable, that affect conformance. The applicant shall maintain records of such actions taken.				
11.2.2 Monitoring and Measurement of Processes				
The applicant shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.				
11.2.3 Monitoring and Measurement of Product				
The applicant shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process.				
Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product.				
Product release and service delivery shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.				
11.3 Control of Non-conforming Product				
The applicant shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.				

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The identification of non-conforming product; the controls used to prevent the unintended use or delivery of non-conforming product; and the related responsibilities and authorities for dealing with non-conforming product shall be defined in a documented procedure.				
The applicant shall deal with non-conforming product by one or more of the following ways:				
a. By taking action to eliminate the detected non-conformity				
b. By authorizing its use, release, or acceptance under concession by a relevant authority and, where applicable, by the customer; or				
c. By taking action to preclude its original intended use or application.				
Records of the nature of non-conformances and any subsequent actions taken, including concessions obtained, shall be maintained.				
When non-conforming product is corrected, it shall be subject to re-verification to demonstrate conformance to the requirements.				
When non-conforming product is detected after delivery or use has started, the applicant shall take action appropriate to the effects, or potential effects, of the non-conformance.				
11.4 Improvement				
11.4.1 Continual Improvement				

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The applicant shall continually improve the effectiveness of the quality management system through the use of customer satisfaction records, conformity to planned results, monitoring and measurement of product and processes, audit results, and corrective and preventative actions.				
The applicant must ensure that the integrity of the quality management system is maintained when changes to it are planned and implemented.				
11.4.2 Corrective Action				
The applicant shall take action to eliminate the cause of non-conformances in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the non-conformances encountered.				
The applicant shall maintain records of the results of any actions taken.				
11.4.3 Preventative Action				
The applicant shall determine action to eliminate the causes of potential non-conformances in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.				
The applicant shall maintain records of the results of any actions taken.				

V. POST - AUDIT ACTIVITIES

☐ ***Conduct closing meeting (ISO 19011), as applicable:***

☐ Sign out on attendance list;

- ☐ Present audit findings and conclusions;
- ☐ Discuss next steps in report distribution process:
  (1) report sent to Audit Section representatives for review and approval,
  (2) Audit Section decides on approval/denial/suspension and finalizes report,
  (3) report includes request for corrective and/or preventative actions, if necessary, and is distributed to auditor for distribution to the applicant.
- ☐ Information about any appeal system on the conduct or conclusion of the audit; and
- ☐ Ask for any questions.

NON-CONFORMANCES

(Note: A non-conformance should be value-adding and must be against a specific requirement of the audit criteria. List 1) the requirement, 2)statement of non-conformity, and 3) objective evidence for each NC.

- ☐ NC1 - Major or Minor –
- ☐ NC2 - Major or Minor -
- ☐ NC3 - Major or Minor -
- ☐ NC4 - Major or Minor -
- ☐ NC5 - Major or Minor -

☐ NC6 - Major or Minor -

CONTINUOUS IMPROVEMENT POINTS

(Note: A CIP is an observation or area identified as opportunities for improvement. Although not identified as non-conformances, CIPs have the potential to become non-conformances if not corrected or addressed. For example: 2 of the 10 necessary training records were not available.)

☐ CIP1 -

☐ CIP2 -

☐ CIP3 -

☐ CIP4 -

RECOMMENDATION:

☐ Program Approval (Initial audit)
- ☐ 6 month approval
- ☐ Other (specify):

☐ Program Approval with Conditions (Initial audit)

- ☐ 6 month approval
- ☐ Other (specify):
  - State the conditions that should apply

☐ Continued Program Approval
- ☐ 6 month approval
- ☐ Other (specify):

☐ Continued Program Approval with Conditions
- ☐ 6 month approval
- ☐ Other (specify):
  - State the conditions that should apply

☐ Program Denial

☐ Program Suspension