USDA Quality System Assessment Program

1 Purpose

This Procedure provides the requirements of a USDA Quality System Assessment (QSA) Program. It also provides the criteria used in the objective evaluation of USDA QSA Programs that are submitted for approval. Evaluations are conducted by the Agricultural Marketing Service (AMS), Poultry Programs.

2 Scope

This Procedure applies to marketing programs for agricultural products, including services, that are submitted to Poultry Programs for verification and monitoring. It is limited to programs or portions of programs where specified product requirements are supported by a documented quality management system. The extent of controls included in these programs may include all phases of production and marketing and through retail distribution, or any portion as described in the scope of the submitted program.

If any program requirements cannot be applied due to the nature of a company and its product, then these requirements may be considered for exclusion. Exclusions are limited to program requirements within *Clause 4 Product Realization* and must not affect the company's ability to provide a conforming product. Additionally, exclusions do not affect the company's responsibility to provide a conforming product.

3 References

Quality Systems Verification Programs General Policies and Procedures and Applicable Grading Branch Program Procedure.

4 Responsibilities

Companies must meet all applicable policies and procedures outlined in this Procedure, the applicable Program Procedure, and *Quality Systems Verification Program General Policies and Procedures*.

Poultry Programs must meet all applicable policies and procedures outlined in this Procedure, the applicable Program Procedure, and *Quality Systems Verification Program General Policies and Procedures*.

5 Audit Frequency

All approved programs will be audited at least twice per calendar year (October 1 to September 30). However, more frequent audits may be conducted (1) if numerous major or minor non-conformances are identified during an audit; (2) if customer complaints indicate an ongoing problem; (3) to satisfy specific requests as declared by customers, trading partners or other financially interested parties; or (4) as directed by Poultry Grading Branch Chief.

6 Listing of Approved Programs

Approved programs will be listed on the applicable Program website or on the USDA QSA Program website at http://www.ams.usda.gov/PYGrading which is currently under development. Information about the approved program will be in accordance with the applicable Program Procedure. The approved program listing on the USDA QSA Program website will include the following information:

a) Company name;
b) Company contact information;
c) Program requirements;
d) Report reference number (approval number); and
e) Renewal date.

7 Program Requirements (Sections 7 to 11)

7.1 General Requirements

The applicant shall establish, document, implement, and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this document.

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.

NOTE 2: The extent of the quality management system documentation can differ from one applicant to another due to a) The size of 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; and
d) Other documents as required by the quality management system.

7.2.3 Control of Documents

Documents required by this 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:

a) To approve documents for adequacy prior to issue;
b) To review and update as necessary and re-approve documents;
c) To ensure that changes and the current revision status of documents are identified on all pages;
d) To ensure that relevant versions of applicable documents are available to points of use;
e) To ensure that documents remain legible and readily identifiable;
f) To ensure that documents of external origin are identified and their distribution controlled;
g) To 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

Records shall be established and maintained to provide evidence of conformity to requirements 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 applicant the importance of meeting customer 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.

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 to ensure 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 must 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;
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.

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

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 must have a documented procedure to identify the product (raw materials and finished product) by suitable means throughout product realization, where appropriate.

The documented procedure must describe the method for

a) Identifying the product throughout product realization, where appropriate;
b) Identifying the product status with respect to monitoring and measurement requirements; and
c) Controlling and recording the unique identification of the product when traceability is a requirement.

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 specified product requirements.

The applicant shall establish processes to ensure that monitoring and measurement can be and are carried out in a manner that is consistent with monitoring and measurement requirements.

When necessary to ensure valid results, measuring equipment shall

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 product 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;
b) Enquiries, 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 system.

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 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.

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 planned results have been met. This shall be carried out at appropriate stages of the product realization process.

Evidence of conformity with the planned results shall be maintained. Records shall indicate the person(s) authorizing release of the product.

Product release and service delivery shall not proceed until the planned results have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

11.3 Control of Nonconforming 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.

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 nonconforming product shall be defined in a documented procedure.

The applicant shall deal with non-conforming product in one or more of the following ways:

a) By taking action to eliminate the detected nonconformity;
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

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-conformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities 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 nonconformities in order to prevent their occurrence. Preventative actions shall be appropriate to the effects of the potential problems.

The applicant shall maintain records of the results of any actions taken.

Appendix A - Definitions

1. Conforming Product – product within the QMS that meets, and can be verified as meeting, the specified product requirements. Such product must be identified as meeting the specified product requirements in accordance with the QMS and the applicable Program Procedure.

2. Corrective Action – action to eliminate the cause of a detected non-conformance.

3. Correction – action to eliminate a detected non-conformance.

4. Customer Satisfaction – customer's perception of the degree to which the customer's requirements have been fulfilled.

5. Non-conforming Product – product within the QMS that does not meet, or can not be verified as meeting, the specified product requirements. This includes raw materials and finished products. Non-conforming raw materials must be excluded from use within the program; and non-conforming finished products must be excluded from delivery.

6. Preventative Action – action to eliminate the cause of a potential non-conformance.

7. Process – a set of interrelated or interacting activities which transforms inputs into outputs.

8. Product – a raw material or a finished good. The type of product depends upon where it is within product realization.

9. Product Realization – the process of developing a product from initial acceptance of the raw materials through production to delivery.

10. Product Requirements – includes, but is not limited to, the requirements of this Procedure, the requirements outlined in the QMS, the customer requirements, and the specified product requirements.

11. Specified Product Requirements – the requirements listed within the applicable Program Procedure or as stated by the company.

Appendix B – Documentation Requirements

1. Clause 7.2.2 - Quality Manual

2. Documented Procedures:
   1) Clause 9.1.2 – training of personnel
   2) Clause 10.1.3 – receiving of product from outside sources
   3) Clause 10.1.4 – identification and traceability
   4) Clause 11.3 – control of non-conforming product

3. Records:
   1) Clause 9.1.2 – training, education, skills and/or experience
   2) Clause 10.1.1 – results of supplier evaluations and any necessary actions
   3) Clause 10.1.3 – evidence of conformity to the receiving process and it's effective operation
   4) Clause 10.1.4 – product identification and changes of identities
   5) Clause 10.2 – results of calibration and verification
   6) Clause 11.2.1 – customer perception
   7) Clause 11.2.3 – evidence of conformity to specified product requirements
   8) Clause 11.3 – non-conforming product and subsequent actions taken
   9) Clause 11.4.2 – corrective actions
   10) Clause 11.4.3 – preventative actions

4. Any other documents necessary to ensure the effective operation and control of the QMS.