

USDA PROCESS VERIFIED PROGRAM		AMS - POULTRY PROGRAMS GRADING BRANCH AUDIT SECTION POULTRY AUDIT MANAGEMENT PROGRAM
<u>AUTHORITY:</u> AUDIT SECTION SUPERVISOR	<u>EFFECTIVE DATE:</u> March 14, 2011	<u>DOCUMENT TYPE AND NUMBER:</u> Procedure PAMP 100.1

1 Scope

This document specifies the requirements for the USDA Process Verified Program, based on ISO 9001. It also provides the requirements used for the objective evaluation of USDA Process Verified Programs that are submitted for approval and are monitored by the Agricultural Marketing Service (AMS). This Program is offered by the Poultry (PY) Programs, Grading Branch.

The provisions of this procedure apply to marketing programs for poultry, shell eggs, and agricultural products that are submitted to the applicable PY Program for verification and monitoring. It is limited to programs or portions of programs where specified process verified points are supported by a documented quality management system. The extent of controls included in these programs may include all phases of production and marketing from genetic development through retail distribution, or any portion as described in the scope of the submitted program.

The Program is based on ISO 9001, where a client:

- a) Needs to demonstrate the ability to consistently provide product(s) that meets customer and applicable statutory and regulatory requirements; and
- b) Aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

All requirements of this Program are generic and are intended to be applicable to all clients, regardless of type, size, and product provided.

Where any requirement(s) of this Program cannot be applied due to the nature of the client and its product, this can be considered for exclusion.

Where exclusions are made, claims of conformity to this Program are not acceptable unless these exclusions are limited to requirements within Clause 4 of the Program Requirements, and such exclusions do not affect the client's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.

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2 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.

- 2.1.1 PAMP 100.1A Checklist, *USDA Process Verified Program for Auditors*
- 2.1.2 PAMP 100.1B Certificate, *USDA Process Verified Program Certificate*
- 2.1.3 USDA Process Verified Program Web site:
<http://www.ams.usda.gov/PYProcessVerifiedProgams>
- 2.1.4 PAMP 100.0 Procedures, *QSVP General Policies and Procedures*
- 2.1.5 PAMP 111.5 Procedure, *Program Review Committee Procedures*
- 2.1.6 PAMP 110.2 Procedure, *Selection of Audit Team Members for the QSVP Programs*

3 Responsibilities

- 3.1 Clients must meet all applicable policies, procedures, and requirements outlined in this document and the Branch's *QSVP General Policies and Procedures*.
- 3.2 Clients must provide access to all processes and areas, records, and personnel for the purposes of initial approval, surveillance, re-approval, and the resolution of complaints.
- 3.3 The Branch must meet all applicable policies, procedures, and requirements outlined in this document and the Branch's *QSVP General Policies and Procedures*, and referenced documents as applicable.
- 3.4 The Branch must select an auditor in accordance with the Branch's *Selection of Audit Team Members* procedure.

4 Desk Audit

- 4.1 The client may not request to forego a desk audit. A desk audit is conducted prior to each audit. The scope of the desk audit is based on the scope of the audit.

5 Preliminary Visit

- 5.1 Prior to the initial approval audit, a preliminary visit may be conducted with the agreement of the client. This visit may result in the identification of deficiencies in the system of the applicant client or its competencies. The Branch does not consult and exercises due care to avoid consultancy during such a visit.

6 Initial Approval Audit

- 6.1 Initial approval audits are conducted on-site for new programs. Initial approval audits include the witnessing of activities at one or more suppliers of the client, when applicable. A representative sample of suppliers is selected to ensure proper evaluation of the client's competence.

7 Surveillance Audit

7.1 Surveillance audits are conducted on-site and are less comprehensive than the initial approval audit and the re-approval audit. All locations from which one or more key activities are performed are assessed during the 2-year period prior to the re-approval audit. Surveillance audits may include the witnessing of activities at one or more suppliers of the client to ensure proper evaluation of the client's competence.

7.2 Surveillance audits are conducted twice per year after approval. However, more frequent surveillance audits may be conducted (1) if either numerous minor non-conformances or a major non-conformance are identified during the audit; (2) if customer complaints indicate an ongoing problem; or (3) as directed by the Branch Chief.

8 Re-approval Audit

8.1 Re-approval audits are similar to initial approval audits, except that experience gained during previous audits is taken into account. Re-approval audits include the witnessing of activities at one or more suppliers of the client, when applicable. A representative sample of suppliers is selected to ensure proper evaluation of the client's competence.

8.2 Re-approval audits are conducted every 3 years prior to the expiration date. Extensions may be granted.

9 Program Review Committee

9.1 Applications are reviewed by the Program Review Committee. The purpose of the review is to determine:

- a) the Branch's capabilities to conduct the audit by evaluating the Branch's own policies and the availability of suitable auditors and experts with the appropriate competence to perform the audit in a timely manner; and
- b) that client's proposed specified process verified points meet the requirements outlined in Clause 2.4.3 of the Program Requirements.

9.2 The Branch may also appoint a Program Review Committee to review the results of the audit and recommend the final decision.

9.3 Reviews are conducted in accordance with the Branch's *Program Review Committee Procedures*.

10 Listing of Approved Programs and Programs Under Review

10.1 The Branch provides public information about the current status of a client's program in the *Official Listing of Approved USDA Process Verified Programs*.

10.2 The *Official Listing* is maintained on the USDA Process Verified Program Web site and contains information including:

- a) Client's name or position title;
- b) Client's address or corporate address;

- c) Client's contact information including telephone number, fax number, and email address, when available;
- d) PVP certificate number;
- e) Effective date (date originally approved);
- f) Renewal date (date approval expires)
- g) Scope, including products, locations, and services; and
- h) Claims verified (specified process verified points).

10.3 In addition:

- a) If the client is undergoing an initial audit, the statement "Under Review" is included.
- b) If the client is under suspension, the scope of the suspension, the effective date of the suspension and the following statement are included: "Under Suspension – Agricultural products certified under the program prior to suspension remain certified. No additional products may be certified while the suspension is in effect."
- c) If the client is under withdrawal, the effective date of the withdrawal and the following statement are included: "Under Withdrawal – Agricultural products certified under the program prior to suspension are no longer certified. No additional products may be certified."
- d) If the client has requested to cancel service, the following statement is included: "Requested to Cancel Service – Agricultural products certified under the program are eligible until [date]." The date referenced is the date that cancellation is effective, normally the date that the surveillance or reassessment was to occur.

11 Certificate of Conformance

11.1 A *Certificate of Conformance* is issued to all approved programs (hard copy and/or in electronic form). The Certificate identifies the following:

- a) Client's name;
- b) Client's address;
- c) Claims verified (specified process verified points);
- d) Client's quality manual used for the audit;
- e) Premises from which one or more key activities are performed and which are covered by the approval;
- f) Certificate number;
- g) Issue date;
- h) Renewal date (date approval expires); and
- i) In the event of issuing a revised Certificate, a means to distinguish the revised Certificate from obsolete Certificates.

11.2 Certificates are valid for up to three years and may be renewed provided the client's quality management system is maintained as described in program documentation and subsequent audits provide objective evidence of ongoing conformance. Extensions may be granted on a case-by-case basis.

11.3 A client who is withdrawn from the USDA Process Verified Program or cancels service must discontinue using the *Certificate of Conformance*.

12 References to Approval and Use of the USDA Process Verified Shield and Term

12.1 A client with an approved USDA Process Verified Program may:

- a) make references to approval by the Branch;
- b) use the USDA Process Verified shield and term in communication media and promotional and advertising materials, which includes labels, packaging, Web sites, brochures, and other marketing materials; and
- c) apply the USDA Process Verified shield to conforming product to denote that the product has been produced under an approved program.

12.2 References to approval and use of the shield and term must be in accordance with Clause 6 of the Program Requirements.

12.3 Clients are responsible for correcting erroneous references to approval and/or erroneous use of the shield and term in a sufficient manner that is appropriate to the situation.

12.4 If a client continuously makes erroneous references to approval and/or erroneous use of the shield and/or term, then the Branch may not allow the client to make references or use the shield and/or term until such time that the Branch is assured that references and/or use will be accurate.

13 Program Requirements (Clauses 1-6)

The client must submit a documented program that addresses the USDA Process Verified Program requirements as outlined in the following clauses (Clauses 1-6).

1 Quality Management System

1.1 General Requirements

1.1.1 The client must establish, document, implement, and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this Program.

1.1.2 The client must:

- a) Determine the processes needed for the quality management system and their application throughout the organization;
- b) Determine the sequence and interaction of these processes;
- c) Determine criteria and methods needed to ensure that both the operation and control of these processes are effective;

- d) Ensure the availability of resources and information necessary to support the operation and monitoring of these processes;
- e) Monitor, measure, where applicable, and analyze these processes; and
- f) Implement actions necessary to achieve planned results and continual improvement of these processes.

1.1.3 These processes must be managed by the client in accordance with the requirements of this Program.

1.1.4 Where a client chooses to outsource any process that affects product conformity to requirements, the client must ensure control over such processes. The type and extent of control to be applied to these outsourced processes must be defined within the quality management system.

NOTE 1: Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization, measurement, analysis, and improvement

NOTE 2: An “outsourced process” is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.

NOTE 3: Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as:

- a) The potential impact of the outsourced process on the organization’s capability to provide product that conforms to the requirements*
- b) The degree to which the control for the process is shared*
- c) The capability of achieving the necessary control through the application of Clause 4.5.*

1.2 Documentation Requirements

1.2.1 General

1.2.1.1 The client’s quality management system documentation must include:

- a) A quality manual;
- b) Documented specified process verified points;
- c) Documented statements of a quality policy and quality objectives;
- d) Documented procedures and records required by this Program; and
- e) Documents, including records, determined by the client to be necessary to ensure the effective planning, operation, and control of its processes.

NOTE 1: Where the term "documented procedure" appears within this document, this means that the procedure is established, documented, implemented, and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

NOTE 2: The extent of the quality management system documentation can differ from one client to another due to a) the size of organization 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.

1.2.2 Quality Manual

1.2.2.1 The client must establish and maintain a quality manual that meets the requirements of this Program and includes:

- a) The scope of the quality management system, including details of and justification for any exclusions;
- b) The specified process verified points;
- c) The documented procedures established for the quality management system, or reference to them;
- d) A description of the interaction between the processes of the quality management system; and
- e) Other documents as required by the quality management system.

1.2.3 Control of Documents

1.2.3.1 Documents required by the quality management system must be controlled. Records are a special type of document and must be controlled according to the requirements given in Clause 1.2.4.

1.2.3.2 A master document list must 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.

1.2.3.3 A documented procedure must be established to define the controls needed to:

- 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 determined by the client to be necessary for the planning and operation of the quality management system 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.

1.2.3.4 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, must be submitted to the AMS Branch for approval prior to implementation.

1.2.4 Control of Records

1.2.4.1 Records must be established to provide evidence of conformity to requirements, including the process verified points, and of the effective operation of the quality management system must be controlled. Records must remain legible, readily identifiable and retrievable.

1.2.4.2 A documented procedure must be established to define the controls needed for the identification, storage, protection, retrieval, retention time, and disposition of records.

1.2.4.3 Records must be retained for the timeframe necessary to provide evidence of conformance.

2 Management Responsibility

2.1 Management Commitment

2.1.1 Top management must 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) Establishing the quality policy;
- c) Ensuring that quality objectives are established;
- d) Conducting management reviews; and
- e) Ensuring the availability of resources.

2.2 Customer Focus

2.2.1 Top management must ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see Clauses 4.2.1 and 5.2.1).

2.3 Quality Policy

2.3.1 Top management must ensure that the quality policy:

- a) Is appropriate to the purpose of the organization in relation to its Process Verified Program;
- b) Includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system;
- c) Provides a framework for establishing and reviewing quality objectives;
- d) Is communicated and understood within the organization; and
- e) Is reviewed for continuing suitability.

2.4 Planning

2.4.1 Quality Objective

2.4.1.1 Top management must ensure that quality objectives, including those needed to meet requirements for product (see Clause 4.1a) are established at relevant functions and levels within the organization. The quality objectives must be measurable and consistent with the quality policy.

2.4.2 Quality Management System Planning

2.4.2.1 Top management must ensure that:

- a) The planning of the quality management system is carried out in order to meet the requirements given in Clause 4.1, as well as the quality objectives; and
- b) The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

2.4.3 Process Verified Points

2.4.3.1 Top management must ensure that the process verified points are:

- a) Established and stated in the quality manual; and
- b) Included as part of the overall quality management system.

2.4.3.2 Process verified points must:

- a) Add value to the product or service;
- b) Be substantive, verifiable, and repeatable; and
- c) Be within the scope of the Branch's authority.

NOTE: Process verified points must not be requirements of regulations, the USDA Process Verified Program requirements, or a standard under which clients in the same industry generally operate.

2.4.3.3 Allowable process verified points may include:

- a) Adherence to a recognized standard that is not otherwise required by industry or regulations;
- b) A unique production or handling practice;
- c) A service with a unique characteristic for that type of operation or outside normal business practices;
- d) A quantifiable characteristic such as size, weight, age, or grade;
- e) Documentation, monitoring, or auditing that is unique to the company and outside normal business practice; and
- f) A characteristic, practice, or requirement that is specifically requested by a customer or consumer.

2.4.3.4 Products or services produced under a USDA Quality System Assessment (QSA) Program may be incorporated into a USDA Process Verified Program provided that the products or services meet all applicable specified process verified points of the program.

2.5 Responsibility, Authority, and Communication

2.5.1 Responsibility and Authority

2.5.1.1 Top management must ensure that responsibilities and authorities are defined and communicated within the organization.

2.5.1.2 An organization chart or similar document listing all personnel, and their responsibilities and authorities, assigned to managerial positions within the program must be included in the quality manual.

2.5.2 Management Representative

2.5.2.1 Top management must appoint a member of the client's management who, irrespective of other responsibilities, must have responsibility and authority that includes:

- a) Ensuring that processes needed for the quality management system are established, implemented, and maintained;
- b) Reporting to top management on the performance of the quality management system and any need for improvement; and
- c) Ensuring the promotion of awareness of customer requirements throughout the organization.

NOTE: The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

2.5.3 Internal Communication

2.5.3.1 Top management must ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

2.6 Management Review

2.6.1 General

2.6.1.1 Top management must review the organization's quality management system at planned intervals to ensure its continuing suitability, adequacy, and effectiveness. This review must include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy, quality objectives, and process verified points.

2.6.1.2 Records from management reviews must be maintained.

2.6.2 Review Input

2.6.2.1 The input to management review must include information on:

- a) Results of audits;
- b) Customer feedback;
- c) Process performance and product conformity;
- d) Status of preventive and corrective actions;
- e) Follow-up actions from previous management reviews;

- f) Changes that could affect the quality management system; and
- g) Recommendations for improvement.

2.6.3 Review Output

2.6.3.1 The output from the management review must include any decisions and actions related to:

- a) Improvement of the effectiveness of the quality management system and its processes;
- b) Improvement of product related to customer requirements; and
- c) Resource needs.

3 Resource Management

3.1 Provision of Resources

3.1.1 The client must determine and provide the resources needed:

- a) To implement and maintain the quality management system and continually improve its effectiveness; and
- b) To enhance customer satisfaction by meeting customer requirements.

3.2 Human Resources

3.2.1 General

3.2.1.1 Personnel performing work affecting conformity to product requirements must be competent on the basis of appropriate education, training, skills, and/or experience, as applicable.

NOTE: Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.

3.2.2 Competence, Awareness, and Training

3.2.2.1 The client must determine the necessary competence for personnel performing work affecting conformity to product requirements.

3.2.2.2 The client must determine the criteria for training and must provide training to achieve the necessary competence for personnel performing work affecting conformity to product requirements.

3.2.2.3 The client must have a documented procedure to ensure all personnel performing work affecting product quality are properly trained in relevant aspects of the quality management system.

3.2.2.4 The documented procedure must 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.

3.2.2.5 The client must maintain appropriate records of education, training, skills, and experience. Training records must include the scope of the training received.

3.3 Infrastructure

3.3.1 The client must determine, provide, and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:

- a) Buildings, workspace, and associated utilities;
- b) Processing equipment (both hardware and software); and
- c) Supporting services (such as transport, communication, or information systems).

3.4 Work Environment

3.5 The client must determine and manage the work environment needed to achieve conformity to product requirements.

NOTE: The term “work environment” relates to those conditions under which work is performed including physical, environmental, and other factors (such as noise, temperature, humidity, lighting, or weather).

4 Product Realization

4.1 Planning of Product Realization

4.1.1 The client must plan and develop the processes needed for product realization. Planning of product realization must be consistent with the requirements of the other processes of the quality management system (see Clause 1.1).

4.1.2 In planning product realization, the client must determine the following, as appropriate:

- a) Quality objectives and requirements for the product;
- b) The need to establish processes, documents, and provide resources specific to the product;
- c) Required verification, validation, monitoring, measurement, inspection, and test activities specific to the product and the criteria for product acceptance; and
- d) Records needed to provide evidence that the realization processes and resulting product meet requirements.

4.1.3 The output of this planning must be in a form suitable for the client's methods of operations.

NOTE 1: A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project, or contract, can be referred to as a quality plan.

NOTE 2: The client may also apply the requirements given in 10.4 to the development of product realization processes.

4.2 Customer-related Processes

4.2.1 Determination of Requirements Related to the Product

4.2.1.1 The client must determine:

- a) The specified process verified points;
- b) Requirements specified by the customer, including the requirements for delivery and post-delivery activities;
- c) Requirements not stated by the customer but necessary for specified or intended uses, where known;
- d) Statutory and regulatory requirements applicable to the product; and
- e) Any additional requirements considered necessary by the client.

NOTE: Post-delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services, such as recycling or final disposal.

4.2.2 Review of Requirements Related to the Product

4.2.2.1 The client must review the requirements related to the product. This review must be conducted prior to the client's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and must ensure that:

- a) Product requirements are defined;
- b) Contract or order requirements differing from those previously expressed are resolved; and
- c) The client has the ability to meet the defined requirements.

4.2.2.2 Records of the results of the review and actions arising from the review must be maintained.

4.2.2.3 Where the customer provides no documented statement of requirement, the customer requirements must be confirmed by the client before acceptance.

4.2.2.4 Where product requirements are changed, the client must ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE: In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.

4.3 Customer Communication

4.3.1 The client must 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.

4.4 Design and Development

4.4.1 Design and Development Planning

4.4.1.1 The client must plan and control the design and development of product.

4.4.1.2 During the design and development planning, the client must determine

- a) The design and development stages;
- b) The review, verification, and validation that are appropriate to each design and development stage; and
- c) The responsibilities and authorities for design and development.

4.4.1.3 The client must manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

4.4.1.4 Planning output must be updated, as appropriate, as the design and development progresses.

NOTE: Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the client.

4.4.2 Design and Development Inputs

4.4.2.1 Inputs relating to product requirements must be determined and records maintained. These inputs must include:

- a) Functional and performance requirements;
- b) Applicable statutory and regulatory requirements;
- c) Where applicable, information derived from previous similar designs; and
- d) Other requirements essential for design and development.

4.4.2.2 These inputs must be reviewed for adequacy. Requirements must be complete, unambiguous, and not in conflict with each other.

4.4.3 Design and Development Outputs

4.4.3.1 The outputs of design and development must be in the form suitable for verification against the design and development input and must be approved prior to release.

4.4.3.2 Design and development outputs must:

- a) Meet the input requirements for design and development;
- b) Provide appropriate information for purchasing, production, and service provision;
- c) Contain or reference product acceptance criteria; and
- d) Specify the characteristics of the product that are essential for its safe and proper use.

NOTE: Information for production and service provision can include details for the preservation of product.

4.4.4 Design and Development Review

4.4.4.1 At suitable stages, systematic reviews of design and development must be performed in accordance with planned arrangements (see Clause 4.4.1):

- a) To evaluate the ability of the results of design and development to meet requirements; and
- b) To identify any problems and propose necessary actions.

4.4.4.2 Participants in such reviews must include representatives of functions concerned with the design and development stage(s) being reviewed.

4.4.4.3 Records of the results of the reviews and any necessary actions must be maintained.

4.4.5 Design and Development Verification

4.4.5.1 Verification must be performed in accordance with planned arrangements (see Clause 4.4.1) to ensure that the design and development outputs have met the design and development input requirements.

4.4.5.2 Records of the results of the verification and any necessary actions must be maintained.

4.4.6 Design and Development Validation

4.4.6.1 Design and development validation must be performed in accordance with planned arrangements (see Clause 4.4.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation must be completed prior to the delivery or implementation of the product.

4.4.6.2 Records of the results of validation and any necessary actions must be maintained.

4.4.7 Control of Design and Development Changes

4.4.7.1 Design and development changes must be identified and records maintained. The changes must be reviewed, verified, and validated, as appropriate, and approved before implementation. The review of design and development changes must include evaluation of the effect of the changes on constituent parts and product already delivered.

4.4.7.2 Records of the results of the review of changes and any necessary actions must be maintained.

4.5 Purchasing

4.5.1 Purchasing Process

4.5.1.1 The client must 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 control applied to the supplier and the purchased and/or received product must be dependent upon the effect of the purchased and/or received product on subsequent product realization or the final product.

4.5.1.2 The client must evaluate and select suppliers based on their ability to supply product in accordance with the client's requirements. Criteria for selection, evaluation, and re-evaluation must be established and documented.

4.5.1.3 Records of the results of evaluations and any necessary actions arising from the evaluation must be maintained.

4.5.2 Purchasing Information

4.5.2.1 Documented purchasing information must describe the product to be purchased and/or received, including where appropriate:

- a) Requirements for approval of product, procedures, processes, and equipment;
- b) Requirements for qualification of personnel; and
- c) Quality management system requirements.

4.5.2.2 The client must ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

4.5.3 Verification of Purchased Product

4.5.3.1 The client must establish, document, and implement the inspection or other activities necessary for ensuring that purchased and/or received product meets specified purchase requirements.

4.5.3.2 Where the client or its customer intends to perform verification at the supplier's premises, the client must state the intended verification arrangements and method of product release in the purchasing information.

4.5.3.3 The client must maintain records to provide evidence of conformity to the purchasing process and of the effective operation of the purchasing process.

4.6 Production and Service Provision

4.6.1 Control of Production and Service Provision

4.6.1.1 The client must plan and carry out production and service provision under controlled conditions.

4.6.1.2 Controlled conditions must include, as applicable:

- a) The availability of information that describes the characteristics of the product;
- b) The availability of work instructions, as necessary;
- c) The use of suitable equipment;
- d) The availability and use of monitoring and measuring equipment;
- e) The implementation of monitoring and measurement; and
- f) The implementation of product release, delivery, and post-delivery activities.

4.6.2 Validation of Processes for Production and Service Provision

4.6.2.1 The client must validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

4.6.2.2 Validation must demonstrate the ability of these processes to achieve planned results.

4.6.2.3 The client must establish arrangements for these processes including, as applicable:

- a) Defined criteria for review and approval of the processes;
- b) Approval of equipment and qualification of the personnel;
- c) Use of specific methods and procedures;
- d) Requirements for records; and
- e) Re-validation.

4.6.3 Identification and Traceability

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

4.6.3.2 The documented procedure must 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 throughout product realization;
- c) Controlling and recording the unique identification of the product, when traceability is a requirement; and
- d) Controlling and recording the use of the "USDA Process Verified" shield or the term "USDA Process Verified", if applicable.

4.6.3.3 The unique identification of the product must be such that the identification will transfer through all phases of product realization, from receipt into the program through production to delivery.

4.6.3.4 The client must maintain records of all products as identified and records of all changes of identities.

4.6.4 Customer Property

4.6.4.1 The client must exercise care with customer property while it is under the client's control or being used by the client. The client must identify, verify, protect, and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged, or otherwise found to be unsuitable for use, the client must report this to the customer and maintain records.

NOTE: Customer property can include intellectual property and personal data.

4.6.5 Preservation of Product

4.6.5.1 The client must preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation must include identification, handling, packaging, storage, and protection. Preservation must also apply to the constituent parts of a product.

4.7 Control of Monitoring and Measuring Equipment

4.7.1 The client must determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements (see Clause 2.4.3).

4.7.2 The client must 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.

4.7.3 Where necessary, to ensure valid results, measuring equipment must:

- a) Be calibrated and/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 must be recorded;
- b) Be adjusted or re-adjusted as necessary;
- c) Have identification in order to determine its calibration status;
- d) Be safeguarded from adjustments that would invalidate the measurement result;
- e) Be protected from damage and deterioration during handling, maintenance, and storage.

4.7.4 In addition, the client must assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The client must take appropriate action on the equipment and any product affected.

4.7.5 Records of the results of calibration and verification must be maintained.

4.7.6 When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application must be confirmed. This must be undertaken prior to initial use and reconfirmed as necessary.

NOTE: Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.

5 Measurement, Analysis, and Improvement

5.1 General

5.1.1 The client must plan and implement the monitoring, measurement, analysis, and improvement processes needed:

- a) To demonstrate conformance to product requirements;
- b) To ensure conformity of the quality management system; and
- c) To continually improve the effectiveness of the quality management system.

5.1.2 This must include determination of applicable methods, including statistical techniques, and the extent of their use.

5.2 Monitoring and Measurement

5.2.1 Customer Perception

5.2.1.1 As one of the measurements of the performance of the quality management system, the client must monitor information relating to customer perception as to whether the client has met customer requirements. The methods for obtaining and using this information must be determined.

5.2.1.2 The client must maintain records relating to customer perception relating to conformance of the program or products produced under the program.

5.2.1.3 The client must take appropriate action addressing customer complaints and any deficiencies found in the program, or product, if applicable, that affect conformance. The client must maintain records of such actions taken.

NOTE: Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims, and dealer reports.

5.2.2 Internal Audit

5.2.2.1 The client must conduct internal audits at planned intervals to determine whether the quality management system:

- a) Conforms to the planned arrangements (see Clause 4.1), to the requirements of this document and to the quality management system requirements established by the client; and
- b) Is effectively implemented and maintained.

5.2.2.2 An audit program must be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, and methods must be defined. The selection of auditors and conduct of audits must ensure objectivity and impartiality of the audit process. Auditors must not audit their own work.

5.2.2.3 The responsibilities and requirements for planning and conducting audits, selecting auditors, reporting results, conducting follow-up activities, and maintaining records must be defined in a documented procedure.

5.2.2.4 Records of the audits and their results must be maintained.

5.2.2.5 The management responsible for the area being audited must ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected non-conformities and their causes. Follow-up activities must include the verification of the actions taken and the reporting of verification results (see Clause 5.5.2).

NOTE 1: See ISO 19011 for guidance.

NOTE 2: Prior to initial approval of a program, the client must conduct an internal audit and submit those results to the AMS Branch as part of the application for service.

5.2.3 Monitoring and Measurement of Processes

5.2.3.1 The client must apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods must demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action must be taken, as appropriate.

NOTE: When determining suitable methods, it is advisable that the client consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.

5.2.4 Monitoring and Measurement of Product

5.2.4.1 The client must monitor and measure the characteristics of the product to verify that product requirements have been met. This must be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see Clause 4.1).

5.2.4.2 Evidence of conformity with the acceptance criteria must be maintained. Records must indicate the person(s) authorizing release of product for delivery to the customer.

5.2.4.3 The release of product and delivery of service to the customer must not proceed until the planned arrangements (see Clause 4.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

5.3 Control of Non-conforming Product

5.3.1 The client must ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.

5.3.2 A documented procedure must be established to define 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.

5.3.3 The client must 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.

5.3.4 Records of the nature of non-conformances and any subsequent actions taken, including concessions obtained, must be maintained.

5.3.5 When non-conforming product is corrected, it must be subject to re-verification to demonstrate conformance to the requirements.

5.3.6 When non-conforming product is detected after delivery or use has started, the client must take action appropriate to the effects, or potential effects, of the non-conformance.

5.4 Analysis of Data

5.4.1 The client must determine, collect, and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This must include data generated as a result of monitoring and measurement and from other relevant sources.

5.4.2 The analysis of data must provide information relating to:

- a) Customer satisfaction (see Clause 5.2.1);
- b) Conformity to product requirements (see Clause 5.2.4);
- c) Characteristics and trends of processes and products including opportunities for preventive action (see Clauses 5.2.3 and 5.2.4); and
- d) Suppliers (see Clause 4.5).

5.5 Improvement

5.5.1 Continual Improvement

5.5.1.1 The client must continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management review.

5.5.2 Corrective Action

5.5.2.1 The client must take action to eliminate the cause(s) of non-conformances in order to prevent recurrence. Corrective actions must be appropriate to the effects of the non-conformances encountered.

5.5.2.2 A documented procedure must be established to define requirements for:

- a) Reviewing non-conformances (including customer complaints);
- b) Determining the causes of non-conformances;
- c) Evaluating the need for action to ensure that non-conformances do not recur;
- d) Determining and implementing action needed;
- e) Records of the results of action taken; and
- f) Reviewing the effectiveness of corrective action taken.

5.5.3 Preventative Action

5.5.3.1 The client must determine action to eliminate the causes of potential non-conformances in order to prevent their occurrence. Preventive actions must be appropriate to the effects of the potential problems.

5.5.3.2 A documented procedure must be established to define requirements for:

- a) Determining potential non-conformances and their causes;
- b) Evaluating the need for action to prevent occurrence of non-conformances;
- c) Determining and implementing action needed;
- d) Records of results of action taken; and
- e) Reviewing the effectiveness of preventive action taken.

6 Control of the "USDA Process Verified" Shield and Term

6.1 The client must request the use of the shield and/or term. To use the shield and/or term, the client must establish a documented procedure that:

- a) Identifies the person(s) with responsibility for the development, review, approval, and control of the materials;
- b) Addresses the development process of the materials;
- c) Ensures the specified process verified points are accurately represented in the materials;
- d) Ensures the use of the shield and/or term meet the requirements of Clauses 6.3, 6.4, 6.5, and 6.6, as applicable;
- e) Ensures that materials reference the USDA Process Verified Program website, when possible; and
- f) Provides for the proper control and use of the shield and/or term on materials by
 - 1) Ensuring that materials are supplied to and used only by approved entities;

- 2) Providing for a system of surveillance to prevent unauthorized use of the process verified points, the "USDA Process Verified" term, the "USDA Process Verified" shield, or promotional and advertising materials; and
 - 3) Ensuring that materials are submitted to the AMS Branch for review prior to use, as directed by the AMS Branch.
- g) Provides for correction and/or corrective action when the shield and/or term are misrepresented.

6.1.1 Records of the Branch's reviews and all approved materials must be maintained to show conformance to the documented procedure.

6.2 The client must ensure that the "USDA Process Verified" shield and/or term:

- a) Are not misrepresented; and
- b) Are not used in association with any company claims that are not part of the approved program.

6.3 The use of the "USDA Process Verified" shield must meet at least one of the following conditions:

- a) The specified process verified points are printed immediately adjacent to the "USDA Process Verified" shield; or
- b) An asterisk referring the consumer to the information panel for further information about the specified process verified points is printed with the "USDA Process Verified" shield; or
- c) An asterisk referring the consumer to point of sale information is printed with the "USDA Process Verified" shield. In this situation, the company must ensure that the point of sale information is readily available and within close proximity of the display counter containing the product; or
- d) A statement referring the consumer to the USDA Process Verified Program Web site to view the specified process verified points.

6.4 The client may make changes to the design of the USDA Process Verified shield as follows:

- a) The size and dimensions of the shield may be changed, but it must keep its approximate shape and proportions.
- b) Color schemes of both the background and lettering may be used as long as the shield presents the same basic image and meaning.

6.5 The client may create their own logo and use the term "USDA Process Verified" as long as it meets the following design requirements:

- a) All logos must include the words "USDA," "Process," and "Verified" in their logo.

- b) No emphasis is placed on any individual word or letter, except for the word "USDA."
- c) The font size must be approximately the same for all three words: "USDA," "Process," and "Verified." However, the word "USDA" may be a larger font size than the words "Process" and "Verified."
- d) The words "USDA," "Process," and "Verified" must be presented in order as "USDA Process Verified," when written horizontally, and that the end user understands the wording to effectively represent the USDA Process Verified Program.
- e) Any words, graphics, marketing terms, and/or label claims directly associated with the term must be part of the approved USDA Process Verified Program.
- f) The approved design must be used in conjunction with the USDA Process Verified shield.
- g) The approved design must be submitted electronically to the Branch to be posted on the *Official Listing*.

Appendix A - Definitions

1. **Conforming Product** – product within the QMS that meets, and can be verified as meeting, the product requirements. Such product may be identified and/or labeled as meeting the requirements of the USDA Process Verified Program.
2. **Corrective Action** – action to eliminate the cause of a detected non-conformance.
3. **Correction:** Action taken to eliminate a detected non-conformity. (rework, bringing product into conformance, diverting product, not using product, scrapping product, etc.)
4. **Customer Satisfaction** – customer's perception of the degree to which the customer's requirements have been fulfilled.
5. **Measurement** – the actual determination of a value. Requires the use of a device to determine the numerical value of a product characteristic or process parameter at a given time.
6. **Monitoring** – a general term implying oversight over time. (Examples: normal process observation by employees, daily supervision by managers, automated alarms, etc.)
7. **Non-conforming Product** – product within the QMS that does not meet, or cannot be verified as meeting, the 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. Additionally, the company must take appropriate actions when non-conforming product is detected after delivery or use has started.
8. **Objective Evidence** – data supporting the existence or verity of something.
9. **Planned Arrangements** – arrangements that have been pre-determined.
10. **Planned Results** - includes, but is not limited to, the requirements of this document, the requirements outlined in the client's quality management system, and the specified process verified points.
11. **Preventative Action** – action to eliminate the cause of a potential non-conformance.
12. **Procedure** – a specified way to carry out an activity or a process. Procedures can be documented or not. The Process Verified Program requires 10 documented procedures.
13. **Process Verified Points** – the specified requirements of the product which are achieved through the implementation of a quality management system.
14. **Process** – a set of interrelated or interacting activities which transforms inputs into outputs.

15. Product - the result of a process. There are 4 product categories: (a) processed materials (e.g. a raw material or finished good); (b) services (e.g. transport); (c) software (e.g. computer programs); and (d) hardware (e.g. equipment).

- a) A product which is a processed material may change from within a quality management system depending upon where it is within the product realization process.
- b) A service is the result of at least one activity necessarily performed at the interface between the supplier and the customer and is generally intangible.
- c) Software consists of information and is generally intangible and can be in the form of approaches, transactions, or procedures.
- d) Hardware is generally tangible and its amount is a countable characteristic.

16. Product Realization – the process of developing a product from initial acceptance of the raw materials into the program through production to delivery to the customer.

17. 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 process verification points.

18. Quality Policy – the overall intentions and direction of a company related to quality and formally expressed by top management.

19. Quality Objective – something sought, or aimed for, related to quality. These are generally based on the quality policy and specified for relevant functions and levels in the company.

20. Record – a document that states results achieved or provides evidence of activities performed. The Process Verified Program requires 20 records.

21. Top Management – a person or group of people who direct and control the company at the highest level.

22. Validation – confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

23. Verification – confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.

Appendix B – Documentation Requirements of the USDA Process Verified Program

1. Documents
 - Clause 1.2.2.1 – Quality Manual
 - Clause 1.2.3.2 – Master Document List
 - Clause 2.3 – Quality Policy
 - Clause 2.4.1 – Quality Objectives
 - Clause 2.4.3 – Process Verified Points
2. Documented Procedures
 - 2.1 Clause 1.2.3.3 – Control of Documents
 - 2.2 Clause 1.2.4.2 – Control of Records
 - 2.3 Clause 3.2.2.3 – Competence, Awareness, and Training
 - 2.4 Clause 4.6.3.1 – Identification and Traceability
 - 2.5 Clause 5.2.2.3 – Internal Audit
 - 2.6 Clause 5.3.2 – Control of Non-conforming Product
 - 2.7 Clause 5.5.2.2 – Corrective Action
 - 2.8 Clause 5.5.3.2 – Preventative Action
 - 2.9 Clause 6.1 – Control of the “USDA Process Verified” Shield and Term
3. Records
 - 3.1 Clause 2.6.1.2 – Management Review
 - 3.2 Clause 3.2.2.5 – Human Resources - Competence, Awareness, and Training
 - 3.3 Clause 4.1.2 – Planning of Product Realization
 - 3.4 Clause 4.2.2.2 – Review of Requirements Related to the Product
 - 3.5 Clause 4.4.2.1 – Design and Development Inputs
 - 3.6 Clause 4.4.4.3 – Design and Development Review
 - 3.7 Clause 4.4.5.2 – Design and Development Verification
 - 3.8 Clause 4.4.6.2 – Design and Development Validation
 - 3.9 Clause 4.4.7.1 – Control of Design and Development Changes
 - 3.10 Clause 4.5.1.3 – Purchasing Process
 - 3.11 Clause 4.5.3.3 – Verification of Purchased Product
 - 3.12 Clause 4.6.2.3 – Validation of Processes of r Production and Service Provision
 - 3.13 Clause 4.6.3.4 – Identification and Traceability
 - 3.14 Clause 4.6.4.1 – Customer Property
 - 3.15 Clause 4.7.5 – Control of Monitoring and Measuring Equipment
 - 3.16 Clause 5.2.1.2 – Customer Perception
 - 3.17 Clause 5.2.2.4 – Internal Audit
 - 3.18 Clause 5.2.4.2 – Monitoring and Measurement of Product
 - 3.19 Clause 5.3.4 – Control of Non-conforming Product
 - 3.20 Clause 5.5.2.2 – Corrective Action
 - 3.21 Clause 5.5.3.2 – Preventive Action
4. Any other documents necessary to ensure the effective operation and control of the QMS.