USDA Process Verified Program

1 Purpose

This Procedure provides the requirements to be met in designing a USDA Process Verified Program. It also provides the requirements used for the objective evaluation of USDA Process Verified Programs that are submitted for approval and monitored by the Agricultural Marketing Service (AMS), Livestock and Seed (LS) Program, Grading and Verification Division (GVD).

2 Scope

The provisions of this Procedure apply to marketing programs for livestock, meat, and agricultural products that are submitted to the LS 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.

Where any program requirements can not be applied due to the nature of a company and its product, 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

GVD 1000 Procedure, Quality Systems Verification Programs General Policies and Procedures
GVD 1115 Procedure, Program Review Committee Procedures

4 Responsibilities

Companies must meet all applicable policies and procedures outlined in this Procedure and *GVD 1000 Procedure, Quality Systems Verification Program General Policies and Procedure*.

The GVD must meet all applicable policies and procedures outlined in this Procedure and *GVD 1000 Procedure, Quality Systems Verification Program General Policies and Procedure*.

Any suggested changes to this Procedure should be submitted via email to the GVD Program Manager.

5 Audit Frequency

All approved programs are audited at least once per year. However, more frequent 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 GVD Deputy Director.

6 Program Review Committee

Prior to the initial desk audit, the company's specified process verified points are reviewed by a Program Review Committee. The review is conducted in accordance to *GVD 1115 Procedure*. The Committee determines that the process verified points are auditable, feasible, factual, value-adding, and within the scope of the LS Program.

7 Listing of Approved Programs

Approved programs are listed on the USDA Process Verified Program website at http://processverified.usda.gov/. The listing includes the following information about the approved program:

a) Company name;
b) Company contact information;
c) Specified Process Verified Points;
d) Report reference number (approval number); and
e) Renewal date.

8 Certificate of Conformance

The Program Manager issues a *Certificate of Conformance* to all approved programs. The Certificate identifies the program, location, scope, certificate number, issue date, and renewal date.

9 Program Requirements (Clauses 1 to 6)

Companies must submit a documented program that addresses the program requirements as outlined in the following clauses (Clauses 1 to 6).

1 Quality Management System

1.1 General Requirements

A quality management system (QMS) must be established, documented, implemented, and maintained which ensures that products conform to the requirements of this Procedure and to specified process verified points.

The company must continually improve the effectiveness of the QMS in accordance with the requirements of this Procedure.

The company must

a) Identify the processes needed for the QMS and their application throughout the company;
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, and analyze these processes; and
f) Implement actions necessary to achieve planned results and continual improvement of these processes.

The company must manage these processes in accordance with the requirements of this Procedure.

Where a company chooses to outsource any process that affects product conformity with requirements, the company shall ensure control over such processes. Control of such outsourced processes must be identified within the QMS.

1.2 Documentation Requirements

1.2.1 General

The company must prepare and maintain a QMS that includes

a) Documented statements of a quality policy;
b) Documented statements of a quality objective;
c) A quality manual;
d) Documented procedures required by this Procedure;
e) Documents necessary to ensure the effective planning, operation, and control of its processes; and
f) Records required by this Procedure.

1.2.2 Quality Manual

The company must establish and maintain a quality manual that includes at a minimum

a) An organizational chart or similar document listing all personnel assigned to managerial positions within the program;
b) A description of the scope of the QMS, including details of and justification for exclusions;
c) The specified process verified points;
d) Documented procedures established for the QMS;
e) Reference to all forms, tags, and labels used to track or demonstrate product conformance,;
f) A master document list that shows the most current issue of all QMS procedures, forms, tags, and labels used to track or demonstrate conformance;
g) A description of the interaction between the processes of the QMS; and
h) All other documentation as required in this Procedure.

The quality manual must be controlled and available for review at all associated sites where activities are conducted.

1.2.3 Control of Documents

The company must control all documents required by this Procedure.

A documented procedure must be established to define the controls needed

a) To control all documents required by this Procedure;
b) To ensure that changes and the current revision status of documents are identified;
c) To ensure that relevant versions of applicable documents are available at points of use;
d) To ensure that documents remain legible and readily identifiable;
e) To prevent the use of obsolete or unapproved documents; and
f) To retain all documents for at least 1 year after the year in which the audit was performed.

Significant changes to QMS documentation must be submitted to the GVD for approval prior to implementation.

1.2.4 Control of Records

The company must establish and maintain records to provide evidence of conformity to program requirements, to specified process verified points, and of the effective operation of the QMS.

A documented procedure must be established to define the controls needed

a) To control all records required by this Procedure;
b) To store records in a manner so as to prevent loss, damage, or alteration;
c) To ensure that records are legible, easily accessible, and readily available; and
d) To retain all records for at least 1 year after the year in which the audit was performed.

2 Management Responsibility

2.1 Management Commitment

Top management must provide evidence of its commitment to the development and implementation of the QMS.

Top management must continually improve the effectiveness of the QMS.

Top management must communicate to program personnel the importance of meeting customer as well as statutory and regulatory requirements

Top management must establish the quality policy.

Top management must ensure that quality objectives are established.

Top management must conduct management reviews of the QMS.

Top management must ensure the availability of resources.

2.2 Customer Focus

Top management must ensure that customer requirements are determined and are met with the main focus of enhancing customer satisfaction.

2.3 Quality Policy

Top management must ensure that the quality policy

a) Is appropriate to the purpose of the company's program;
b) Includes a commitment to conform to the requirements of the QMS;
c) Includes a commitment to continually improve the effectiveness of the QMS;
d) Provides a framework for establishing and reviewing quality objectives;
e) Is communicated and understood within the company; and
f) Is reviewed for continuing suitability.

2.4 Planning

2.4.1 Quality Objectives

Top management must ensure that quality objectives, including those necessary to meet specified process verified points, are established at relevant functions and levels within the company.

The objectives must be measurable and consistent with the quality policy.

2.4.2 Quality Management System Planning

Top management must ensure that the planning of the QMS meets the requirements given in *Clause 1.1 General Requirements*, as well as the quality objectives.

Top management must ensure that the integrity of the QMS is maintained when changes to it are planned and implemented.

2.5 Responsibility, Authority and Communication

2.5.1 Responsibility and Authority

Top management must ensure that QMS responsibilities and authorities are defined and communicated within the company.

The company must have an organizational chart or similar document listing all personnel assigned to managerial positions within the program.

All personnel listed must have their responsibilities and authorities outlined in an auditable method.

2.5.2 Management Representative

Top management must designate a management representative who, irrespective of other responsibilities must have responsibility and authority that includes

a) Ensuring that processes needed for the QMS are established, implemented, and maintained;
b) Reporting to top management on the performance of the QMS and any need for improvement; and
c) Ensuring the promotion of awareness of customer requirements and specified process verified points throughout the company.

The management representative must have the authority to act on behalf of the company at all locations where program activities are conducted.

2.5.3 Internal Communication

Top management must ensure that appropriate communication processes are established within the company.

Top management must ensure that communication takes place regarding the effectiveness of the QMS.

2.6 Management Review

2.6.1 General

Top management must review the company's QMS, at planned intervals, to ensure its continuing suitability, adequacy, and effectiveness.

The review must include assessing opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives.

The company must maintain records from the management reviews.

2.6.2 Review Input

The management review input must include information on

a) Results of audits (internal and third party);
b) Customer feedback;
c) Process performance and product conformity;
d) Status of preventative and corrective actions;
e) Follow-up actions from previous management reviews;
f) Changes that could affect the QMS; and
g) Recommendations for improvement.

2.6.3 Review Output

The management review output must include any decisions and actions related to

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

3 Resource Management

3.1 Provisions of Resources

The company must determine and provide the resources needed to implement and maintain the QMS and to continually improve its effectiveness.

The company must determine and provide the resources needed to enhance customer satisfaction by meeting customer requirements.

3.2 Human Resources - Competence, Awareness, and Training

Personnel performing work affecting product quality must be competent on the basis of appropriate education, training, skills, and/or experience.

The company must provide training to all persons with QMS responsibilities.

The company must have a documented procedure to ensure all persons performing work affecting product quality are properly trained in relevant aspects of the QMS.

The documented procedure must include

a) Determining the necessary competence for personnel performing work affecting product quality;
b) Determining the criteria for training;
c) Evaluating the effectiveness of the training; and
d) Ensuring that the persons are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

The company must maintain appropriate records of education, training, skills, or experience, as applicable. These records must include the scope of the training received.

3.3 Infrastructure

The company 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) Process equipment (both hardware and software); and
c) Supporting services (such as transport or communication).

3.4 Work Environment

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

4 Product Realization

4.1 General

If any program requirements within Clause 4 Product Realization can not be applied due to the nature of a company and its product, then these requirements may be considered for exclusion. Exclusions 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.

4.2 Planning of Product Realization

The company 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 QMS.

In planning product realization, the company 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, inspection, and test activities specific to the product and the criteria for product acceptance;
d) Records necessary to provide evidence that the realization processes and resulting product meet the requirements.

The output of this planning must be in a form suitable for the company's method of operations.

4.3 Customer-Related Processes

4.3.1 Determination of Requirements Related to the Product

The company must determine the specified process verified points.

The company must determine requirements specified by the customer, including the requirements for delivery and post-delivery activities.

The company must determine requirements not stated by the customer but necessary for specified or intended use, where known.

The company must determine statutory and regulatory requirements related to the product.

The company must determine any additional requirements determined by the company.

4.3.2 Review of Requirements Related to the Product

The company must review the requirements related to the product.

The review must be conducted prior to the company's commitment to supply a product to the customer.

The review must ensure that product requirements are defined.

The review must ensure that contract or order requirements differing from those previously expressed are resolved.

The review must ensure that the company has the ability to meet the defined requirement.

The company must maintain records of the results of the review and actions arising from the review.

The company must confirm the customer requirements before acceptance when the customer does not provide a documented statement of requirements.

The company must ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements when product requirements are changed.

4.3.3 Customer Communication

The company 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

The company must plan and control the design and development of product.

During the design and development planning, the company 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.

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

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

4.4.2 Design and Development Inputs

Inputs relating to product requirements must be determined.

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.

Inputs must be reviewed for adequacy.

Requirements must be complete, unambiguous, and not in conflict with each other.

The company must maintain records relating to product requirements.

4.4.3 Design and Development Outputs

The outputs of design and development must be provided in a form that enables verification against the design and development input.

The outputs must be approved prior to release.

Design and development outputs must

a) Meet the input requirements for design and development;
b) Provide appropriate information for purchasing, production, and for 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.

4.4.4 Design and Development Review

The company must perform systematic reviews of design and development at suitable stages.

The company must perform the systematic reviews in accordance with planned arrangements (1) to evaluate the ability of the results of design and development to meet requirements and (2) to identify any problems and propose necessary actions.

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

The company must maintain records of the results of the reviews and any necessary actions.

4.4.5 Design and Development Verification

The company must perform verification in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements.

The company must maintain records of the results of the verification and any necessary actions.

4.4.6 Design and Development Validation

The company must perform design and development validation in accordance with planned arrangements.

Validation must ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known.

The company must complete validation prior to delivery or implementation of the product, wherever practicable.

The company must maintain records of results of validation and any necessary actions.

4.4.7 Control of Design and Development Changes

The company must identify design and development changes.

The company must review, verify, validate and approve changes 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.

The company must maintain records of the results of the review of design and development changes and any necessary actions.

4.5 Receiving

4.5.1 Receiving Process

The company must ensure that product purchased or received from outside establishments and used in the program conform to specified receiving requirements.

The company must ensure the adequacy of specified receiving requirements prior to their communication to the supplier.

The company must evaluate and select suppliers based on their ability to supply product that conforms to the specified receiving requirements.

The company must establish and implement the inspection or other activities necessary for ensuring that product purchased or received from outside establishments conform to specific receiving requirements.

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

The company must have a documented procedure addressing products purchased or received from outside establishments.

The documented procedure must describe

a) All products purchased and/or received from outside establishments;
b) The specified receiving requirements for approval of products to be used in the program;
c) The criteria and process for supplier selection, evaluation, and re-evaluation; and
d) The process used to ensure that products purchased or received from outside establishments and used in the program conform to specific receiving requirements.

The company must maintain records of the results of supplier evaluations and any necessary actions arising from the evaluation.

The company must maintain records to provide evidence of conformity to the receiving process and of the effective operation of the receiving process.

4.6 Production and Service Provision

4.6.1 Control of Production and Services Provision

The company must plan and conduct production and service provision under controlled conditions.

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 devices;
e) The implementation of monitoring and measurement; and
f) The implementation of release, delivery, and post-delivery activities.

4.6.2 Validation of Processes for Production and Service Provision

The company 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.

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

The company 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 personnel;
c) Use of specific methods and procedures;
d) Requirements for records; and
e) Revalidation.

4.6.3 Identification and Traceability

The company must have a documented procedure to identify product (raw materials and/or 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;
b) Controlling and recording the unique identification of the product, including the use of the “USDA Process Verified” shield or the term “USDA Process Verified”, if applicable; and
c) Identifying the product status with respect to monitoring and measurement requirements.

The method for identifying the product must

a) Be unique to the Program. When applicable, animals must be identified with ear tags or other permanent identification; and
b) Be such that the identification will transfer through all phases of product realization, from receipt into the Program through production to delivery;

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

4.6.4 Customer Property

The company must exercise care with customer property while it is under the company's control or being used by the company.

The company must identify, verify, protect, and safeguard customer property provided for use or incorporation into the product.

The company must report to the customer and maintain records of any incidences where customer property is lost, damaged, or otherwise found to be unsuitable for use.

4.6.5 Preservation of Product

The company must preserve the conformity of product during internal processing and delivery to the intended destination.

The preservation must include identification, handling, packaging, storage, and protection. It must also apply to the constituent parts of a product.

4.7 Control of Monitoring and Measuring Devices

The company must determine the monitoring and measurement to be undertaken to provide evidence of conformity to product requirements.

The company must determine the monitoring and measurement devices needed to provide evidence of conformity to product requirements.

The company must establish processes to ensure that monitoring and measurement can be conducted and is conducted in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment must

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 must 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 adjustment that would invalidate the measurement result; and
e) Be protected from damage and deterioration during handling, maintenance, and storage.

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

The company must confirm the ability of computer software to satisfy the intended application when used in the monitoring and measurement of specified requirements. This must be performed prior to initial use and reconfirmed as necessary.

The company must maintain records of the results of calibration and verification.

5 Measurement, Analysis, and Improvement

5.1 General

The company must plan and implement the monitoring, measurement, analysis, and improvement processes needed

a) To demonstrate conformity of the product;
b) To ensure conformity of the QMS; and
c) To continually improve the effectiveness of the QMS.

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

When statistical methods are used to control product quality or integrity, the basis for those procedures must be clearly defined.

5.2 Monitoring and Measurement

5.2.1 Customer Satisfaction

The company must monitor information relating to customer perception as to whether the company has met customer requirements. This information must be reviewed as a performance measurement of the QMS.

The company must determine the methods for obtaining and using this information

The company must maintain records relating to customer perception.

5.2.2 Internal Audit

The company must conduct internal audits at planned intervals.

The internal audits must determine whether the QMS

a) Conforms to the planned arrangements, to the requirements of this Procedure, and to the QMS requirements established by the company; and
b) Is effectively implemented and maintained.

The company must have a documented procedure which defines

a) The planning of an audit program, which must consider the status and importance of the processes and areas to be audited, as well as the results of the previous audit;
b) The audit criteria, scope, frequency, and methods;
c) The selection of the auditors and conduct of auditors which must ensure objectivity and impartiality of the audit process (Auditors must not audit their own work.);
d) The responsibilities for planning and conducting audits;
e) The reporting of results;
f) The follow-up activities (Follow-up activities must include the verification of the actions taken and the reporting of the verification results.); and
g) The maintenance of records.

Within the area being audited, management must ensure that actions are taken without undue delay to eliminate detected non-conformances and their causes.

The company must review the results of internal audits during management reviews.

The company must maintain records of the internal audits.

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

5.2.3 Monitoring and Measurement of Processes

The company must apply suitable methods for monitoring and, where applicable, measurement of the QMS 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, to ensure conformity of the product.

5.2.4 Monitoring and Measurement of Product

The company must monitor and measure the characteristics of the product to verify that product requirements have been met. This must be conducted at appropriate stages of the product realization process in accordance with the planned arrangements.

The company must ensure that the planned arrangements have been satisfactorily completed prior to product release and service delivery, unless otherwise approved by a relevant authority and, where applicable, by the customer.

The company must maintain records to verify evidence of conformity with product requirements. Records must indicate the person(s) authorizing release of product.

5.3 Control of Non-conforming Product within the QMS

The company must ensure that non-conforming product (raw material and/or finished product) is identified and controlled to prevent its unintended use or delivery.

The company must have a documented procedure that defines

a) The identification of non-conforming product;
b) The controls used to ensure the segregation of non-conforming product; and
c) The related responsibilities and authorities for ensuring the segregation and disposition of non-conforming product.

The company must handle non-conforming product by one or more of the following methods:

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;
c) By taking action to preclude its original intended use or application.

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

The company must take appropriate actions when non-conforming product is detected after delivery or use has started.

The company must maintain records of all non-conforming product and any subsequent actions taken, including concessions obtained.

5.4 Analysis of Data

The company must determine, collect, and analyze appropriate data to demonstrate the suitability and effectiveness of the QMS.

The company must evaluate where continual improvement of the effectiveness of the QMS can be made. This must include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data must provide information relating to (1) customer satisfaction; (2) conformity to product requirements; (3) characteristics and trends of processes and products including opportunities for preventative action; and (4) suppliers.

5.5 Improvement

5.5.1 Continual Improvement

The company must continually improve the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventative actions, and management review.

5.5.2 Corrective Action

The company must take action to eliminate the cause of non-conformance in order to prevent recurrence.

Corrective actions must be appropriate to the effects of the non-conformances encountered.

The company must establish a documented procedure which defines the 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 corrective action taken to determine its effectiveness.

The company must maintain records of the results of any actions taken.

5.5.3 Preventative Action

The company must determine action to eliminate the causes of potential non-conformances in order to prevent their occurrence.

Preventative actions must be appropriate to the effects of the potential problems.

The company must establish a documented procedure which defines the 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 preventative action taken to determine its effectiveness.

The company must maintain records of the results of any actions taken.

6 Promotional Materials

6.1 Control of Promotional Materials

The company may use the "USDA Process Verified" shield or the term "USDA Process Verified" in promotional and advertising materials, which includes all labels, packaging, and other marketing materials.

The company must request the use of the shield or term within the QMS.

When applicable, the company must establish a documented procedure for promotional and advertising materials that

a) Addresses the development of the materials;
b) Ensures the specified process verified points are accurately represented in the materials;
c) Ensures the use of the "USDA Process Verified" shield or the term "USDA Process Verified" in direct association with a clear description of the specified process verified points in the materials;
d) Provides for the proper control and use of the shield or term on labels, packaging, and other marketing material on which it may appear.

All materials must be reviewed by the GVD prior to use.

Appendix A - Definitions

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.

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

Correction – action to eliminate a detected non-conformance.

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

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.

Monitoring – a general term implying oversight over time. (Examples: normal process observation by employees, daily supervision by managers, automated alarms, etc.)

Non-conforming Product – product within the QMS that does not meet, or can not 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.

Objective evidence – data supporting the existence or verity of something.

Planned Arrangements – arrangements that have been pre-determined.

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

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.

Process Verified Points – the specified requirements of the product which are achieved through the implementation of a quality management system.

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

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

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.

Appendix A – Definitions (continued)

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.

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

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.

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

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

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

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

Appendix B – Documentation Requirements

1. Clause 1.2.2 – Quality Manual

2. Documented Procedures
   - 2.1 Clause 1.2.3 – Control of Documents
   - 2.2 Clause 1.2.4 – Control of Records
   - 2.3 Clause 3.2 – Training of Personnel
   - 2.4 Clause 4.5.1 – Receiving of Product from Outside Sources
   - 2.5 Clause 4.6.3 – Identification and Traceability
   - 2.6 Clause 5.2.2 – Internal Audits
   - 2.7 Clause 5.3 – Control of Non-conforming Product
   - 2.8 Clause 5.5.2 – Corrective Action
   - 2.9 Clause 5.5.3 – Preventative Action
   - 2.10 Clause 6.1 – Control of Promotional Material

3. Records
   - 3.1 Clause 2.6.1 – Management Reviews
   - 3.2 Clause 3.2 – Human Resources - Competence, Awareness, and Training
   - 3.3 Clause 4.2 – Planning of Product Realization
   - 3.4 Clause 4.3.2 – Review of Requirements Related to the Product
   - 3.5 Clause 4.4.2 – Design and Development Inputs
   - 3.6 Clause 4.4.4 – Design and Development Review
   - 3.7 Clause 4.4.5 – Design and Development Verification
   - 3.8 Clause 4.4.6 – Design and Development Validation
   - 3.9 Clause 4.4.7 – Control of Design and Development Changes
   - 3.10 Clause 4.5.1 – Receiving Process (2)
   - 3.11 Clause 4.6.3 – Identification and Traceability
   - 3.12 Clause 4.6.4 – Customer Property
   - 3.13 Clause 4.7 – Control of Monitoring and Measuring Devices
   - 3.14 Clause 5.2.1 – Customer Satisfaction
   - 3.15 Clause 5.2.2 – Internal Audit
   - 3.16 Clause 5.2.4 – Monitoring and Measurement of Product
   - 3.17 Clause 5.3 – Control of Non-conforming Product within the QMS
   - 3.18 Clause 5.5.2 – Corrective Actions
   - 3.19 Clause 5.5.3 – Preventive Actions

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