

EXHIBIT 12

Presidential Memorandum

Creating a Preference for Meat and Poultry

Produced According to Responsible Antibiotic-Use Policies

Background

On June 2, 2015, the White House released a Presidential Memorandum entitled, "Creating a Preference for Meat and Poultry Produced According to Responsible Antibiotic-Use Policies" (Attachment A) encouraging responsible uses of medically important antibiotics in the meat and poultry supply chain by supporting the emerging market for meat and poultry that has been produced according to responsible antibiotic-use policies. This policy builds on the important work of the Food and Drug Administration (FDA) and antibiotic manufacturers which are already taking substantial steps to phase out the use of medically important antibiotics in food animals. Reducing antibiotic resistance requires stewardship practices in the use of antibiotics in medical and agricultural settings.

Scope of Work (SOW)

The contractor shall offer to the maximum extent possible, to the extent such an option is available and cost effective, meat and poultry sourced from animals that have been raised using responsible antibiotic-use policies as described in the above referenced Presidential Memo. The United States Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) is the Government entity responsible for overseeing the audit verification program for meat and poultry. More information about the certified responsible antibiotic-use standard, including a list of certified responsible antibiotic-use poultry producers, is available on USDA's website (<http://www.ams.usda.gov/services/auditing/crau>).

The Presidential Memorandum specifically targets meat and poultry that are raised using responsible antibiotic-use policies, which may include the use of antibiotics, if approved and administered by a licensed veterinarian. Meat and poultry that are specifically raised without ever using antibiotics or hormones are in a different category of meat and poultry offerings. The contractor shall not use organic, antibiotic-free or hormone-free meat and poultry to meet the requirements described in this SOW. In addition to the requirements of this SOW, the contractor may also provide:

- Organic, antibiotic-free or hormone-free meat and poultry; and
- Conventional meat and poultry.

The contractor shall be:

- Allowed 90 calendar days after the effective date of this modification to implement the requirements of this SOW.
- Strongly encouraged to increase its offerings of certified responsible antibiotic-use meat and poultry as the price point becomes more equivalent to conventional meat and poultry;
- Required to promote certified responsible antibiotic-use meat and poultry items on the menu to customers patronizing the facility. The consumer certified responsible antibiotic-use meat and poultry promotion and education campaign shall publicize the availability and importance of certified responsible antibiotic-use meat and poultry.
- Required to submit Quarterly Certified Responsible Antibiotic-Use Reports, utilizing the Quarterly Certified Responsible Antibiotic-Use Report Template (Attachment D), to the CO and GSA Regional Concessions Manager (RCM). The Quarterly Certified Responsible Antibiotic-Use Report shall include the following data points:
 - Certified responsible antibiotic-use meat and poultry was purchased from a supplier audited through either the USDA's:
 - Process Verified Program (PVP); or
 - Quality System Assessment (QSA) Program.

The PVP and QSA Program is defined in the GVD 1001 (Attachment E) and the GVD 1002 (Attachment F) procedures, respectively. Both programs ensure the certified responsible antibiotic-use standard is supported by a documented quality management system;

- Total pounds (i.e. pre-cooked) of certified responsible antibiotic-use meat and poultry purchased, prepared and sold, by meal, per month;
- Contractor's quarterly average purchasing cost of the certified responsible antibiotic-use meat and poultry, per pound;
- Customer's quarterly average purchase price, per portion, for each item that utilized certified responsible antibiotic-use meat and poultry;
- Total pounds (i.e. pre-cooked) of the equivalent conventional meat and poultry purchased, prepared and sold, by meal, per month;

- Contractor's quarterly average purchasing cost of equivalent conventional meat and poultry, per pound;
- Customer's quarterly average purchase price, per portion, for each item that utilized equivalent conventional meat and poultry; and
- Description and copies of the consumer marketing and education campaigns utilized to advertise the availability and benefits of certified responsible antibiotic-use meat and poultry.

Certified Responsible Antibiotic-Use Extensions and Waivers

If the contractor requires additional time for implementation or cannot comply with the requirements of the SOW, then the contractor shall:

- Seek an extension from the CO utilizing the Certified Responsible Antibiotic-Use Extension Template (Attachment B); or
- Seek a waiver from the CO utilizing the Certified Responsible Antibiotic-Use Waiver Template (Attachment C).

All requests must be accompanied by supporting documentation, such as:

- Evidence of the cause of the delay in implementation; or
- Evidence that demonstrates certified responsible antibiotic-use meat and/or poultry is unavailable or cost-prohibitive.

Extension and waiver requests and corresponding supporting documentation will be reviewed and verified by the CO before any requests are granted.

Presidential Memorandum -- Creating a Preference for Meat and Poultry Produced According to Responsible Antibiotic-Use Policies

SUBJECT: Creating a Preference for Meat and Poultry Produced According to Responsible Antibiotic-Use Policies

Antibiotics support nearly all of modern medicine -- including care for premature babies, cancer patients, and people who need surgery. Yet, overuse and misuse can reduce the effectiveness of these miracle drugs. Antibiotic resistance -- when bacteria change so that they are able to grow in the presence of an antibiotic that would normally kill them or limit their growth -- threatens to return us to a time when many people died from common infections, posing a serious threat to public health and the economy. Reducing antibiotic resistance will require stewardship practices in the use of antibiotics in medical and agricultural settings, including eliminating the practice of feeding medically important antibiotics to food-producing animals for growth promotion.

It is the policy of the Federal Government to encourage responsible uses of medically important antibiotics in the meat and poultry supply chain by supporting the emerging market for meat that has been produced according to responsible antibiotic-use policies. This policy will build on the important work of the Food and Drug Administration (FDA) and antibiotic manufacturers, which are already taking substantial steps to phase out the use of medically important antibiotics in food animals.

By the authority vested in me as President by the Constitution and the laws of the United States of America, and to protect the health of the American people, I hereby direct as follows:

Section 1. Making Available in Certain Federal Cafeterias Meat and Poultry Produced According to Responsible Antibiotic-Use Policies. The Administrator of General Services, in consultation with the Secretary of Agriculture, the Secretary of Health and Human Services, and the Director of the Office of Management and Budget (OMB), shall take the following steps to make meat and poultry produced according to responsible antibiotic-use policies available in Federal cafeterias that the General Services Administration (GSA) manages (GSA cafeterias):

(a) within 120 days of the date of this memorandum, GSA shall initiate a process in which vendors, under new contract awards (including renewals), offer in GSA cafeterias, as an option, meat and poultry from animals that have been raised according to responsible antibiotic-use

policies, to the extent such an option is available and cost effective. (b) In conducting this effort, GSA shall:

- i. take steps to minimize price impact through:
 - A. using competitive procedures, consistent with law, in the selection of vendors; and
 - B. continuing to make available alternative food options, in addition to meat and poultry from animals that have been raised according to responsible antibiotic-use policies;
 - ii. work to develop, for inclusion in food-service contracts in GSA cafeterias, appropriate contractual requirements to verify that vendors are providing meat and poultry produced according to responsible antibiotic-use policies;
 - iii. analyze, in consultation with the Department of Agriculture and the Department of Health and Human Services, customer demand, product supply, and market prices; and
 - iv. ensure that GSA cafeteria vendors appropriately identify meat and poultry items from animals that have been raised according to responsible antibiotic-use policies.
- c. For 3 years after the initiation of the process described in this section, GSA shall report annually on the customer demand, product supply, and market prices of meat and poultry produced according to responsible antibiotic-use policies to the Director of OMB and the Task Force for Combating Antibiotic-Resistant Bacteria (Task Force) established by Executive Order 13676 of September 18, 2014.
 - d. During this 3-year period, executive departments and agencies (agencies) that contract for food in their own cafeterias and make meat and poultry produced according to responsible antibiotic-use policies available in their own cafeterias, may choose to similarly submit customer demand, product supply, and market price information to the Director of OMB and the Task Force, subject to the requirements of this section and under their own authorities.

Sec. 2. Broadening the Availability of Meat and Poultry Produced According to Responsible Antibiotic-Use Policies in Federal Cafeterias. By 2020, each agency shall develop and implement a strategy that creates a preference for awarding contracts to vendors that offer, as an option, meat and poultry produced according to responsible antibiotic-use policies for sale in domestic Federal cafeterias to civilian Federal employees and visitors, to the extent such an option is available and cost effective. In furtherance of this requirement, I hereby direct that:

- a. The Task Force shall:

- i. on an ongoing basis, review the data received pursuant to section 1 of this memorandum as it becomes available and, considering such data and other relevant data sources, conduct an ongoing analysis of the customer demand, product supply, and market prices of meat and poultry produced according to responsible antibiotic-use policies; and
- ii. develop a recommended strategy for creating the preference described in the opening paragraph of this section.

b. Agencies operating cafeterias in the United States for the primary purpose of serving civilian employees and visitors shall:

- i. consider the recommended strategy developed by the Task Force and, subject to their own authorities, develop a strategy that creates a preference as described in the opening paragraph of this section; and
- ii. implement the strategy developed under section 2(b) (i) of this memorandum for poultry by 2018 and for meats by 2020.

Sec. 3. Developing a Strategy for Federal Acquisition of Meat and Poultry Produced According to Responsible Antibiotic-Use Policies. (a) The Task Force shall recommend a strategy for consideration by the Federal Acquisition Regulatory Council (FAR Council) for applying a preference in Federal acquisitions for meat and poultry produced according to responsible antibiotic-use policies served or sold in all Federal facilities. The strategy shall include criteria for appropriate exceptions, including exceptions to ensure acquisitions of such products can be made at fair and reasonable prices and within a reasonable timeframe.

(b) By 2020, to the extent permitted by law, the FAR Council shall issue a proposed rule to amend the Federal Acquisition Regulation to implement a preference, with appropriate exceptions, for acquisitions of meat and poultry produced according to responsible antibiotic-use policies served or sold in all Federal facilities.

Sec. 4. Definitions. (a) "Medically important antibiotics" shall have the meaning it is given in FDA's Guidance for Industry (GFI) 213, Appendix A.

(b) "Responsible antibiotic-use policies," such as FDA GFI 209 and 213, are those policies under which meat and poultry producers use medically important antibiotics only under veterinary oversight and only when needed to prevent, control, and treat disease -- but not for growth promotion.

Sec. 5. General Provisions. (a) This memorandum shall be implemented consistent with applicable law, including international trade obligations, and subject to the availability of appropriations.

b. Nothing in this memorandum shall be construed to impair or otherwise affect:

- i. the authority granted by law to a department, agency, or the head thereof; or
 - ii. the functions of the Director of OMB relating to budgetary, administrative, or legislative proposals.
- c. This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

BARACK OBAMA

Attachment B - Certified Responsible Antibiotic-Use Extension Template; dated September 10, 2015

Name of Vendor Requesting Waiver	Date of Request	Address of Food Service Facility	
GSA Contract Number	Name of Contracting Officer	Name of GSA Regional Concessions Manager	
Reason/Justification For Requested Extension (attach supporting documentation)			
Required Signatures	Signature	Date	Approved yes/no
Vendor			n/a
GSA Regional Concessions Manager			
Contracting Officer			
Reason for Declining Extension Request :			
Additional Comments:			

Attachment C - Certified Responsible Antibiotic-Use Waiver Template; dated September 09, 2015

Name of Vendor Requesting Waiver	Date of Request	Address of Food Service Facility	
GSA Contract Number	Name of Contracting Officer	Name of GSA Regional Concessions Manager	
Reason/Justification For Requested Waiver (attach supporting documentation)			
Required Signatures	Signature	Date	Approved yes/no
Vendor			n/a
GSA Regional Concessions Manager			
Contracting Officer			
Reason for Declining Waiver:			
Additional Comments:			

Attachment D - Quarterly Certified Responsible Antibiotic-Use Report Template, Dated
9/10/2015

Name of Vendor	Date of Request		Address of Food Service Facility	
GSA Contract Number	Name of Contracting Officer		Name of GSA Regional Concessions Manager	
Description of the consumer marketing and education campaigns utilized to advertise the availability and benefits of certified responsible antibiotic-use meat and poultry. (attach supporting documentation).				
Data Metric	Certified Responsible Antibiotic-Use Meat and Poultry		Conventional Meat and Poultry	
Name of Certified Responsible Antibiotic-Use Certified Farm			N/A	
Name of Food Distributor / Supplier				
Total pounds (i.e. pre-cooked) of meat and poultry purchased per quarter	Meat lbs.		Meat lbs.	
	Poultry lbs.		Poultry lbs.	
Total pounds (i.e. pre-cooked) of meat and poultry prepared by meal per quarter	Meat lbs.	B* L*	Meat lbs.	B L
	Poultry lbs.	B L	Poultry lbs.	B L
Total pounds (i.e. pre-cooked) of meat and poultry sold by meal per quarter	Meat lbs.	B L	Meat lbs.	B L
	Poultry lbs.	B L	Poultry lbs.	B L
Average purchasing cost of meat and poultry, per pound	Poultry \$/lb		Poultry \$/lb	
	Meat \$/lb		Meat \$/lb	
Customer's average purchase price, per portion, for each item that utilized Certified Responsible Antibiotic Use meat and poultry	Item Type/Description			Price
Customer's average purchase price, per portion, for each item that utilized equivalent conventional meat and poultry	Item Type/Description			Price
* B = Breakfast L= Lunch				



Attachment E - GVD 1001; dated April 16, 2004

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*.

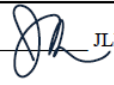
Any suggested changes to this Procedure should be submitted via email to the GVD Program Manager.

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.

"The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, sexual orientation, marital or family status, political beliefs, parental status, or protected genetic information. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at 202-720-2600 (voice and TDD). To file a complaint of discrimination, write USDA, Director, Office of Civil Rights, Room 326-W, Whitten Building, 14th and Independence Avenue, SW., Washington, DC 20250-9410 or call 202-720-5964 (voice and TDD). USDA is an equal opportunity provider and employer."

Date Issued 04/16/04
Date Revised N/A

Approved by  JLR



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.



Attachment F - GVD 1002; dated March 4, 2004 USDA Quality System Assessment (QSA) Program

1 Purpose

This Procedure provides the requirements of a USDA Quality System Assessment (QSA) Program. It also provides the criteria used in the objective evaluation of USDA QSA Programs that are submitted for approval. Evaluations are conducted by the Agricultural Marketing Service (AMS), Livestock, Poultry, and Seed (LPS) Program, Quality Assessment Division (QAD), Audit Services (AS) Branch.

2 Scope

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

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

3 References

QAD 1000 Procedure, Quality Systems Verification Programs General Policies and Procedures
Applicable QAD Program Procedure

4 Responsibilities

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

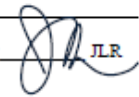
The QAD must meet all applicable policies and procedures outlined in this Procedure, the applicable Program Procedure, and *QAD 1000 Procedure, Quality Systems Verification Program General Policies and Procedure*.

5 Audit Frequency

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

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of color, race, national origin, gender, religion, age, disability, sexual orientation, marital or family status, political beliefs, parental status, or protected genetic information. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at 202-720-2600 (voice and TDD). To file a complaint of discrimination, write USDA, Director, Office of Civil Rights, Room 326-W, Whitten Building, 14th and Independence Avenue, SW., Washington, DC 20250-9410 or call 202-720-5964 (voice and TDD). USDA is an equal opportunity provider and employer.

Date Issued 03/04/04
Date Revised N/A

Approved by  JLR



6 Listing of Approved Programs

Approved programs will be listed on the applicable Program website or on the USDA QSA Program website at

<http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateQ&navID=GradingCertificationandVerification&leftNav=GradingCertificationandVerification&page=LSAuditingServices&description=Audit%20Review%20and%20Compliance%20Services>.

Information about the approved program will be in accordance with the applicable Program Procedure. The approved program listing on the USDA QSA Program website will include the following information:

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

7 Program Requirements (Clauses 1 to 5)

Companies must submit a documented program that addresses the program requirements as outlined in the following clauses (Clauses 1 to 5).

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, the applicable Program Procedure, and to specified product requirements.

1.2 Documentation Requirements

1.2.1 General

The company must prepare and maintain a QMS that includes:

- a) Documented specified product requirements;
- b) A quality manual;
- c) Documented procedures required by this Procedure;
- d) Documents necessary to ensure the effective operation and control of its processes; and
- e) 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 product requirements;
- d) Documented procedures established for the QMS;
- e) A master document list that shows the most current issue of all QMS procedures, forms, tags, and labels used to track or demonstrate conformance; and
- f) All other documentation as required by 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.

Control of documents includes at a minimum:

- a) All documents must contain the current revision status of the document.
- b) The company must ensure that relevant versions of applicable documents are available at all associated sites where activities are conducted.
- c) The company must prevent the use of obsolete or unapproved documents.
- d) All documents must be retained for a minimum of 1 year.

Substantive changes to QMS documentation must be submitted to the QAD 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 product requirements, and of the effective operation of the QMS.

Control of records includes at a minimum:

- a) The company must control all records required by this Procedure.
- b) Records must be stored in a manner so as to prevent loss, damage, or alteration.
- c) Records must be legible, easily accessible, and readily available.
- d) All records must be retained for a minimum of 1 year.

2 Management Responsibility

Management must ensure that specified product requirements are established at relevant functions and levels within the company.

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.

A management representative, who has the authority to act on behalf of the company at all locations where program activities are conducted, must be designated.

The management representative must have the responsibility and authority for ensuring that processes needed for the QMS are established, implemented, and maintained.



3 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, as applicable.

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

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

The documented procedure must define the methods for:

- 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 personnel 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, and experience, as applicable. These records must include the scope of the training received.

4 Product Realization

4.1 General

Where any program requirements within *Clause 4 Product Realization* can not be applied due to the nature of a company and its product, 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 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 and used in the program conform to specific receiving requirements.

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



The documented procedure must describe:

- a) All product purchased and/or received from outside establishments regardless of its use within the program;
- b) The specified receiving requirements for acceptance 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 purchased product and/or product 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.

4.3 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; 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.

4.4 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.

4.5 Control of Monitoring and Measuring Devices

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

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



The company must establish processes to ensure that monitoring and measurement can be conducted and are 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.

The plan must include a 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.



5.2.3 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 meet product requirements.

When product requirements 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.

The company must ensure that product requirements have been met 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 to 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:

- The identification of non-conforming product;
- The controls used to ensure the segregation of non-conforming product; and
- 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:

- By taking action to eliminate the detected non-conformity;
- By authorizing its use, release, or acceptance under concession by a relevant authority and, where applicable, by the customer; or
- 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 product 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 Improvement

5.4.1 Continual Improvement

The company must continually improve the effectiveness of the QMS through the use of the quality objectives, customer feedback, audit results, and corrective and preventative actions.

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

5.4.2 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 maintain records of the results of any actions taken.

5.4.3 Preventative Action

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



Appendix A - Definitions

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

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.

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

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

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.

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

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

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

Date Approved 03/04/04
Date Revised N/A

Approved by _____ JLR



Appendix B – Documentation Requirements

1. Clause 1.2.2 - Quality Manual
2. Documented Procedures:
 - 1) Clause 3 – training of personnel
 - 2) Clause 4.2 – receiving of product from outside sources
 - 3) Clause 4.3 – identification and traceability
 - 4) Clause 5.3 – control of non-conforming product
3. Records:
 - 1) Clause 3 – training, education, skills and/or experience
 - 2) Clause 4.2 – results of supplier evaluations and any necessary actions
 - 3) Clause 4.2 – evidence of conformity to the receiving process and it's effective operation
 - 4) Clause 4.3 – product identification and changes of identities
 - 5) Clause 4.5 – results of calibration and verification
 - 6) Clause 5.2.1 – customer perception
 - 7) Clause 5.2.4 – evidence of conformity to specified product requirements
 - 8) Clause 5.3 – non-conforming product and subsequent actions taken
 - 9) Clause 5.4.2 – corrective actions
 - 10) Clause 5.4.3 – preventative actions
4. Any other documents necessary to ensure the effective operation and control of the QMS.

Attachment G - Definitions, dated September 10, 2015

Agricultural Marketing Service (AMS) – A U.S. Department of Agriculture agency, AMS facilitates the strategic marketing of agricultural products in domestic and international markets while ensuring fair trading practices and promoting a competitive and efficient marketplace. AMS constantly works to develop new marketing services to increase customer satisfaction.

Antibiotics - A type of drug that kills or stops the growth of bacteria. Examples include penicillin and ciproflaxin.

No Antibiotics Added (Meat and Poultry) -The terms "no antibiotics added" may be used on labels for meat or poultry products if sufficient documentation is provided by the producer to the Food Safety Inspection Service (FSIS) demonstrating that the animals were raised without antibiotics.

Antibiotic Resistance - Occurs when bacteria change so that they are able to grow in the presence of an antibiotic that would normally kill them or limit their growth.

Antibiotic-Use Policies - A course or principle of action adopted or proposed by the Government or subsidiary (e.g. "Presidential Memorandum" dated, June 2, 2015, "Draft Guidance for Industry (GFI) on New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI 209; Guidance 213." and "Veterinary Feed Directive", etc.) that encourage judicious use of antibiotics.

Certified - Implies that the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) and the Agricultural Marketing Service (AMS) have officially evaluated a meat product for class, grade or other quality characteristics (e.g. "Certified Angus Beef").

Certified Responsible Antibiotic-Use (Meat and Poultry) - Meat and poultry raised using certified responsible antibiotic use standards audited and verified by the United States Department of Agriculture (USDA).

Certified Responsible Antibiotic-Use Waiver - A written document recording the vendor's request for the Government to waive the certified responsible antibiotic use standard entirely and/or for a specified period of time.

Conventional Meat and Poultry Meat and Poultry that is not "antibiotic-free", "organic", nor raised under a certified responsible antibiotic-use or similar standard.

Commercial Concession Contract - A negotiated contract between a vendor and the Government that gives the vendor the right to operate a specific business within the Government's jurisdiction and subject to certain conditions. The contract can be written,

verbal, or implied in a formal or an informal manner and include all aspects of a business, such as hiring, wages, leases, loans and employee safety. A breach of the contract takes place when a contracting party fails to live up to the agreements.

Effective Date - The date when the rights and obligations under a contract become operational. The effective date need not be the same as the execution date. In the absence of an effective date, the terms of the agreement become operational upon execution.

The Food Safety and Inspection Service (FSIS) -The Food Safety and Inspection Service is the public health agency in the U.S. Department of Agriculture responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged.

Food and Drug Administration (FDA) – The Food and Drug Administration is an agency within the US Department of Health and Human Services, responsible for protecting the public health by assuring that foods (except for meat from livestock, poultry and some egg products which are regulated by the U.S. Department of Agriculture) are safe, wholesome, sanitary and properly labeled; ensuring that human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective; protecting the public from electronic product radiation; assuring cosmetics and dietary supplements are safe and properly labeled; regulating tobacco products; advancing the public health by helping to speed product innovations. FDA's responsibilities extend to the 50 United States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, and other U.S. territories and possessions.

Hormones - A synthetic substance with an effect similar to that of an animal or plant hormone.

Hormone-Free – Animals that are not given hormones to promote growth.

Licensed Veterinarian - A professional operating in compliance with the licensing requirements in the state(s) in which he/she practices veterinary medicine by treating disease, disorder, and injury in non-human animals.

Meat - The flesh of an animal (especially a mammal) as food.

Meat and Poultry Supply Chain - The movement of meat and poultry through a number of processing steps, including packers, suppliers, distributors, retail grocers and foodservice operators, before delivery to retailers, wholesalers and/or distributors, foodservice or direct to consumers.

Modification - A generic term meaning any written change in the terms and scope of the contract.

Organic Meat and Poultry - Meat and poultry that contains a minimum of 95 percent organic ingredients (excluding salt and water). Up to 5 percent of the ingredients may be non-organic agricultural products that are not commercially available as organic and/or non-agricultural products.

Poultry - The flesh of chickens and other domesticated turkey, ducks, guineas, ratites, and squab (young pigeons) used as food.

Responsible Antibiotic-Use - All uses of medically important antibiotics must be (1) directed at treatment, control or prevention of specific diseases; and (2) only under veterinary oversight.

Statement of Work (SOW) - A formal document that captures and defines the work activities, deliverables and timeline a vendor must execute in performance of specified work for a client. The SOW usually includes detailed requirements and pricing, with standard regulatory and governance terms and conditions.

United States Department of Agriculture (USDA) - The U.S. federal executive department that is responsible for developing and executing federal government policy on farming, agriculture, forestry and food. It aims to meet the needs of farmers and ranchers, promote agricultural trade and production, work to assure food safety, protect natural resources, foster rural communities and end hunger in the United States and internationally. The USDA is also known as the Agriculture Department.

United States Department of Agriculture (USDA) Process Verified Program (PVP) - Utilizes the International Organization for Standardization's (ISO) 9000 series standards for (1) documented quality management systems as a format for evaluating program documentation to ensure consistent auditing practices; and (2) promote international recognition of audit results. It provides vendors that supply agricultural products or services the opportunity to assure customers of their ability to provide consistent quality products or services. It is limited to programs or portions of programs where specified process verified points are supported by a documented quality management system.

United States Department of Agriculture (USDA) Quality System Assessment (QSA) Program - Provides vendors that supply agricultural products and services the opportunity to assure customers of their ability to provide consistent quality products or services. It is limited to programs or portions of programs where specified product requirements are supported by a documented quality management system.