



Quality Systems Verification Programs General Policies and Procedures

1 Purpose

This Procedure outlines the policies and procedures for services under the Quality Systems Verification Programs (QSVP). The QSVP are designed to provide independent verification that special processes or marketing claims are clearly defined and verified by an independent third party. The QSVP are voluntary, user-fee programs that are available to suppliers of agricultural products or services.

QSVP are provided by the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), Livestock and Seed (LS) Program, Audit, Review and Compliance (ARC) Branch, under the authority of the Agricultural Marketing Act of 1946, as amended; the Code of Federal Regulations (CFR) 7, Part 54; and as detailed in individual program procedures.

2 Scope

The provisions of this Procedure apply to all QSVP. Specific program requirements are set forth in individual program procedures. Individual program procedures are available on the ARC Branch website at <http://www.ams.usda.gov/lsg/arc/audit.htm>.

Note: All provisions of this Procedure do not apply to the Commodity Purchase Programs or the National Organic Program, as outlined in the individual program procedures.

3 References

ISO 19011:2002 Guidelines for quality and/or environmental management systems auditing

4 Responsibilities

Suppliers must meet all applicable policies and procedures outlined in this Procedure.

The ARC Branch must meet all applicable policies and procedures outlined in this Procedure. All audit activities are conducted in accordance to *ISO 19011:2002 Section 6 Audit Activities*. The ARC Branch must not consult with suppliers regarding the development, implementation, and maintenance of programs.

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

5 Contact Information

Program Manager
USDA, AMS, LS Program, ARC Branch
STOP 0294, Room 2627-S,
1400 Independence Avenue, S.W.
Washington, D.C. 20250.

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6 Requirements (Clauses 1 to 17)

The following clauses apply when applying, receiving, or providing service for the QSVP.

1 Application for Service

Suppliers must submit an application for service for the QSVP. To submit an application, supplier must complete and submit to the ARC Branch Washington, DC office the following documents:

- 1.1 *LS Form 313, Application for Service.* The original form must be mailed to the ARC Branch Washington, DC office. However, for faster service, suppliers may also fax the form to the ARC Branch Washington, DC office.
- 1.2 Cover letter requesting QSVP services for each program in which the supplier wishes to participate.
- 1.3 A complete copy of the supplier's program documentation as described in the applicable program procedure.

The supplier may withdraw from the application process at any time. Suppliers are responsible for fees accrued prior to withdrawing their application.

2 Receiving Applications for Service

The Program Manager or designee notifies the supplier upon receiving the application for service. If the submitted application is inadequate, the Program Manager or designee contacts the supplier to request the additional documentation. The Program Manager withholds the application from further processing until the necessary documentation is received.

Once the Program Manager has determined that the application is complete, it is forwarded to the assigned auditor. The Program Manager or designee notifies the supplier of the assigned auditor.

3 Initial Desk Audit

The assigned auditor conducts a desk audit of the supplier's program documentation to ensure that all program requirements as outlined in the individual program procedure are fully addressed. The auditor uses the appropriate program checklist to conduct the desk audit.

- 3.1 If the program documentation is adequate and the majority of the program requirements are met, then the auditor arranges an on-site audit with the supplier.
- 3.2 If the program documentation requires clarification or additional information that can be easily obtained by working directly with the supplier, then the auditor obtains the clarification or additional information. Once the program documentation is adequate, then the auditor arranges an on-site audit with the supplier.
- 3.3 If the supplier's program documentation does not meet the majority of the program requirements or identifies that the supplier would not pass an on-site audit, then the auditor prepares and submits a desk audit report itemizing the deficiencies. This report is submitted to the Program Manager. The Program Manager sends the report, along with a cover letter, to the supplier discussing the action that the supplier must take before continuing the audit process.



4 Pre On-site Audit Activities

The size and composition of the audit team is determined in accordance to *ISO 19011:2002 Section 6 Audit Activities*. An audit plan and cost estimate must be prepared by the team leader and submitted to the supplier prior to the scheduled on-site audit.

5 On-site Audits

On-site audits are conducted in accordance to *ISO 19011:2002 Section 6 Audit Activities*. The frequency of on-site audits is outlined in the individual program procedures.

The objective of on-site audits is to verify the supplier's conformance (compliance) to the audit criteria.

- 5.1 *Conformance*: The condition or fact of a supplier being in agreement with the requirements of a quality or environmental standard.
- 5.2 *Compliance*: The condition or fact of a supplier being in agreement with regulatory requirements

6 Post On-site Audit Activities

Corrective action audits and any other post on-site audit activities are conducted in accordance to *ISO 19011:2002 Section 6 Audit Activities*. All audit documentation is retained by the ARC Branch in an electronic format.

7 Audit Findings

All audit findings, including identified non-conformances, continuous improvement points, and recommendations, are discussed with the supplier at the conclusion of the on-site audit. The audit findings are outlined in the audit report, which is submitted to the Program Manager for final review and disposition. The Program Manager has the discretion to modify the audit findings.

- 7.1 *Major non-conformance*: A non-conformance that compromises the integrity of the program or product to the extent that program approval should be denied, revoked, or delayed until corrective action can be completed. Any absence or complete breakdown of a program requirement is considered a major non-conformance.
- 7.2 *Minor non-conformance*: A non-conformance that does not compromise the integrity of the program or product. Isolated incidences of non-conformance are considered a minor non-conformance. Minor non-conformances not corrected or addressed in a timely manner may be upgraded to a major non-conformance.
- 7.3 *Continuous improvement point (CIP)*: Observations or areas identified as opportunities for improvement. Although not identified as non-conformances, CIPs have the potential to become non-conformances if not corrected or addressed.

8 Correcting Identified Non-conformances

Suppliers must address all non-conformances and respond to all requests for corrective actions and corrections, as applicable, within the time frame specified by the Program Manager.



Requests are based on non-conformances identified during the audit. Suppliers must identify the cause(s) of the non-conformance, determine the necessary corrective action, and implement the corrective actions. Additionally, if the non-conformance resulted in the use or delivery of non-conforming product, the company must make correction appropriate to the non-conformance.

- 8.1 *Corrective Action*: Action to eliminate the cause of a detected non-conformance. Corrective action is taken to prevent recurrence.
- 8.2 *Correction*: Action to eliminate a detected non-conformance. Correction does not address the cause of the non-conformance but rather the specific non-conforming product.
- 8.3 *Preventative Action*: Action to eliminate the cause of a potential non-conformance. Preventative action is taken to prevent occurrence.

9 Approval Status

Program approval is based upon the audit findings and the recommendation of the auditor. The approval will be issued for the appropriate time period in accordance to the individual program procedure. The Program Manager makes the final decision regarding approval status. When appropriate, a Program Review Committee makes the final decision regarding approval status, in accordance to the individual program procedure.

Program approval status will be one of the following:

- 9.1 *Approval*: No non-conformances were identified during the audit. No actions are necessary by the supplier.
- 9.2 *Approval with Conditions*: Only minor non-conformances were identified during the audit. Suppliers must submit corrective actions and corrections as applicable within the time frame specified by the Program Manager. Additional desk audits and/or on-site audits may be conducted at the supplier's expense.
- 9.3 *Denied Approval*: Denied approval may be issued prior to the initial program approval for any of the reasons outlined below. Suppliers must submit corrective actions and correction as applicable to address any identified non-conformances before approval may be issued. Additional desk audits and/or on-site audits may be conducted at the supplier's expense.
 - 9.3.1 Failure to adequately address any program requirement resulting in a major non-conformance.
 - 9.3.2 Failure to demonstrate capability to meet any program requirement resulting in a major non-conformance.
 - 9.3.3 Finding of objective evidence of a major non-conformance within the scope of the program.
 - 9.3.4 An accumulation of minor non-conformances that result in the assignment of a major non-conformance for the program.
 - 9.3.5 Presenting false or misleading information to any ARC Branch official.
 - 9.3.6 Denying access to supplier's facilities and records within the scope of the program.



Upon reaching a decision, the Program Manager sends the supplier a cover letter, along with the audit report and any additional documentation. The cover letter details the approval status and any terms and conditions as appropriate. When appropriate, the Program Manager or designee will add the supplier's program to the listing on the applicable ARC Branch Program website in accordance with the individual program procedure.

10 Suspending Program Approval

The Program Manager may suspend program approval and remove a supplier's program from the listing on the applicable ARC Branch Program website for any of the following reasons:

- 10.1 Failure to adequately address any program requirement resulting in a major non-conformance.
- 10.2 Failure to demonstrate capability to meet any program requirement resulting in a major non-conformance.
- 10.3 Failure to follow the supplier's approved program.
- 10.4 Failure to provide corrective actions and correction as applicable in the timeframe specified.
- 10.4 Failure to maintain the supplier's approved program.
- 10.6 Implementing significant changes to approved program without prior written notification to and approval by the Program Manager.
- 10.7 Deliberate misrepresentation of the eligibility of agricultural products or services distributed under an approved program.
- 10.8 Confirmed finding of any prohibited compounds or substances or other violations as described in the specific program procedure. Upon confirming the violation, AMS suspends all approvals for suppliers in the product's chain of custody pending a complete investigation, in cooperation with appropriate regulatory agencies.
- 10.9 Denying access to supplier's facilities and records within the scope of the program.
- 10.10 Failure to pay ARC Branch fees.

Prior to the suspension, the Program Manager notifies the supplier in writing of the suspension, the effective date, and details of actions required to regain approval status. The details of actions do not include specific remedies to barriers of approval.

The continuous suspension of a supplier's approved program may result in the permanent suspension of the approved program.

11 Reinstatement of Suspended Program Approval

Program approvals suspended for implementing significant changes to the supplier's approved program without prior written notification to and approval by the Program Manager are reinstated immediately upon receipt of appropriate corrective actions and corrections as applicable. Additional desk audits and/or on-site audits may be conducted at the supplier's expense.



AMS reinstates program approvals for suppliers whose programs are within the chain of custody of products identified as containing or having been treated with any prohibited substance only upon revalidation of the integrity of their program in cooperation with appropriate regulatory agencies.

Program approvals for suppliers found to be responsible for the introduction of prohibited substances into the affected livestock or products are suspended until such a time as the client provides objective evidence that the program has been completely purged of all potentially affected products and an on-site audit verifies that effective corrective action and corrections as applicable have been taken. Final decisions regarding the suitability of corrective action, corrections, and the supplier's eligibility for reinstatement are at the discretion of the Program Manager.

Program approvals for suppliers who fail to follow the approved program are reinstated upon submission of acceptable corrective actions and corrections as applicable that address the failure to follow the approved program.

Program approvals for suppliers who fail to provide corrective actions and/or corrections within the timeframe specified are reinstated upon submission of acceptable corrective actions and corrections as applicable.

Program approvals for suppliers suspended for failure to pay ARC Branch fees are reinstated upon notification that all outstanding fees and interest have been paid in full.

Suppliers who are permanently suspended may be reinstated based upon the decision of a Program Review Committee.

12 Maintaining Approved Programs

Suppliers are required to maintain and implement their programs as described in their approved program documentation. Any significant changes to the supplier's approved program must be submitted in writing to the Program Manager and approved prior to implementation. Depending upon the nature and extent of the changes, the Program Manager may require a complete or partial on-site audit of the program prior to approval. In situations where an additional on-site audit is required, a new approval will be issued for an appropriate time period based on the findings of the audit.

13 Surveillance

All approved programs are audited on an on-going basis as listed in the individual program procedures unless a cancellation request is received in writing or a program is suspended. All approved programs are subject to unannounced audits by ARC Branch representatives. The auditor documents the findings of unannounced audits in an audit report and submits the report to the Program Manager. Findings of unannounced audits are considered when determining conformance of the program for continued approval, or may provide the basis for suspending approval.

14 Cancellation

Suppliers with approved programs may cancel service at any time by notifying the Program Manager in writing. Suppliers who cancel service are removed from the listing on the applicable ARC Branch Program website. Suppliers who cancel service must reapply and be approved through an audit before they are returned to the list. Suppliers are responsible for fees accrued prior to cancellation of the approved program.



15 Appeals, Complaints, and Disputes

Suppliers have the right to appeal any adverse audit findings or decisions issued by the Program Manager or Program Review Committee. Appeals, complaints, and disputes must be submitted in writing to the ARC Branch Chief within 30 days of the date of the official report or letter rendering the findings or decisions.

Requests for appeals, complaints, and disputes must include:

- 15.1 The basis for the appeal, complaint, or dispute, and
- 15.2 The requested alternative decision or actions.

The ARC Branch Chief, or designee, reviews any request for action and notifies the supplier of the final decision within 30 working days of the receipt of the request. Any suspensions or denied approvals remain in effect pending the outcome of the appeal.

16 Fees for Services

All QSVP are user-fee programs. The fees for QSVP services are the responsibility of the supplier requesting the services. Fees will be charged according to the approved hourly rate published in 7 CFR Part 54.27 (http://www.access.gpo.gov/nara/cfr/waisidx_04/7cfr54_04.html) or as outlined in individual program procedures. The fees for QSVP services include the following:

- 16.1 *Audit preparation*: Time to review the approved program documentation and records from previous audits, and to prepare checklists.
- 16.2 *Audit Time*: Time to conduct the audit, report the results of the audit, and conduct post-audit activities.
- 16.3 *Travel*: Travel time and expenses to and from the assigned auditor's official duty location and between audit sites. When traveling to provide services to multiple suppliers, charges will be prorated between the suppliers.
- 16.4 Other related expenses

Auditors document all hours of service charged to the suppliers on *LS Form 5-3 (1-93), Agricultural Products Certificate*. The original and pink copies are submitted to the Meat Grading and Certification Branch Office of Field Operations (OFO) for billing. One green copy is submitted to the ARC Branch Washington, DC office. One green copy is retained by the auditor.

17 Confidentiality

All documentation submitted by suppliers and maintained by the ARC Branch is subject to disclosure under the Freedom of Information Act (FOIA). FOIA applies to documents that are in the control of or maintained by a government agency.

Any portion of the program documentation that the supplier considers proprietary must be identified to the ARC Branch at the time the information is submitted. The ARC Branch will make appropriate provisions to protect the information from disclosure to the extent possible under existing Federal laws.

All ARC Branch representatives have signed conflict of interest statements and appropriate disclosure agreements on file with the ARC Branch prior to assignment to provide QSVP service to suppliers.