



Quality Systems Verification Programs General Policies and Procedures

1 Purpose

This document outlines the responsibilities and requirements for services provided under the Quality Systems Verification Programs (QSVP). The QSVP are designed to provide independent verification that special processes and/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.

The 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 (AMA) of 1946, as amended; the Code of Federal Regulations (CFR) Title 7, Part 62; and as detailed in individual program procedures.

2 Scope

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

Note: All provisions do not apply to all programs as outlined in the individual program procedures.

3 References

The following referenced documents are used for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

4 Responsibilities

4.1 Clients must meet all applicable requirements outlined in this document.

4.2 Clients must inform the ARC Branch, without delay, of significant changes relevant to program approval.

4.3 The ARC Branch must meet all applicable requirements outlined in this document.

4.4 The ARC Branch conducts audit activities in accordance to *ISO 19011:2002 Section 6 Audit Activities*. Audit documentation is retained by the ARC Branch in an electronic format. The ARC Branch does not consult with clients regarding the development, implementation, and maintenance of programs.

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4.5 The ARC Branch provides due notice of any changes to its requirements, and verifies that clients carry out any necessary adjustments.

5 Contact Information

For additional information about the QSVP, please contact the Program Manager.

QSVP Program Manager
USDA, AMS, LS Program, ARC Branch
100 Riverside Parkway, Suite 135
Fredericksburg, VA 22406
Phone: 540-361-7640
Fax: 202-690-1038
Email: ARCBranch@usda.gov

6 Application for Service

6.1 Clients must submit an application for service to the Program Manager in the Fredericksburg, VA office. To submit an application, the client must complete and submit the following documents:

6.1.1 *LS Form 313, Application for Service.* The original form must be mailed to the ARC Branch. However, for faster service, clients may also fax the form to the office. Clients who have a *LS Form 313* on file do not need to resubmit the document unless the information must be updated.

6.1.2 Cover letter (hard copy or in electronic form) requesting services for each program in which the client wishes to participate. The cover letter must include the following:

- a) The program for which the client is seeking approval;
- b) A clearly defined, requested scope;
- c) General information concerning the client such as its activities, human and technical resources, and its relationships in a larger corporate entity, if any;
- d) Information concerning all outsourced processes used by the client that will affect the program;
- e) Addresses of all physical location(s) to be covered by the scope of the program; and
- f) Information concerning the use of consultancy relating to the management system.

6.1.3 A complete copy (hard copy or in electronic form) of the client's program documentation as described in the individual program procedure, as applicable.

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

7 Receiving Applications for Service

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



7.2 Once the application is complete, the Program Manager, or designee, assigns an auditor to conduct the desk audit. The application is forwarded to the auditor.

7.3 The Program Manager, or designee, notifies the client of the assigned auditor. The client may submit written objections regarding the auditor. Written objections must be submitted to the Program Manager and be received within 5 business days after notification.

7.4 When applicable, the Program Manager, or designee, also notifies the Program Review Committee.

8 Desk Audit

8.1 The client may choose to forego a desk audit. This request must be submitted in writing to the Program Manager.

8.2 The auditor conducts a desk audit of the client'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.

8.2.1 If the program documentation is adequate and the majority of the program requirements are met, then the auditor notifies the Program Manager that the initial on-site audit may be scheduled.

8.2.2 If the program documentation requires minimum clarification or additional information, then the auditor obtains the clarification or additional information. Once the program documentation is adequate and the majority of the program requirements are met, the auditor notifies the Program Manager that the initial on-site audit may be scheduled.

8.2.3 If the client's program documentation does not meet the majority of the program requirements or if the auditor identifies that the client would not pass the initial on-site audit, then the auditor prepares and submits a desk audit report itemizing the deficiencies. This report is submitted to the Program Manager, or designee. The Program Manager, or designee, sends the report to the client discussing the action that the client must take before continuing the audit process.

9 On-site Audit

9.1 The Program Manager, or designee, appoints the audit team to conduct the on-site audit. The audit team consists of a suitable number of auditor(s) and/or technical expert(s). The size and composition of the audit team is determined in accordance to *ISO 19011:2002 Section 6 Audit Activities*. After the audit team is appointed, the program documentation is forwarded to the audit team leader, if necessary.

9.2 The Program Manager, or designee, notifies the client of the assigned auditor(s) and/or expert(s). The client may submit written objections regarding any team member(s). Written objections must be submitted to the Program Manager and be received within 5 business days after notification.

9.3 Once the date and schedule is arranged between the client and the audit team, the audit team leader prepares an audit plan and cost estimate. The documents are submitted to the client prior to the scheduled on-site audit.



9.4 The on-site audit is 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 an on-site audit is to verify the client's conformance to the audit criteria.

9.5 The on-site audit is conducted at the premises of the client from which one or more key activities are performed. Where relevant, the on-site audit includes other selected locations where the client operates, to gather objective evidence that the client is competent and conforms to the requirements of the audit criteria. Additionally, the audit team reviews the performance of a representative number of staff of the client to gather objective evidence.

10 Audit Findings and Audit Report

10.1 All audit findings, including identified non-conformances, continuous improvement points, and recommendations, are discussed with the client at the conclusion of the on-site audit. If the audit team cannot reach a conclusion about an audit finding, the audit team refers to the Program Manager for clarification.

10.2 Audit findings may consist of the following:

- a) *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.
- b) *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.
- c) *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.

10.3 The audit findings are outlined in the audit report, which is submitted to the Program Manager, or designee, for final review and disposition. The Program Manager has the discretion to modify the audit findings. The ARC Branch is responsible for the content of the audit report.

11 Correcting Identified Non-conformances

11.1 Clients must address all non-conformances and respond to all requests for corrective actions and corrections, as applicable, within the time frame specified in the audit report.

11.2 Requests are based on non-conformances identified during the audit. Clients 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 client must identify the non-conforming product and make correction appropriate to the non-conformance. Written corrective action responses must be submitted in hard copy or electronic form.



11.3 The following actions must be taken by the client, when applicable:

- a) *Corrective Action*: Action to eliminate the cause of a detected non-conformance. Corrective action is taken to prevent recurrence.
- b) *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.
- c) *Preventative Action*: Action to eliminate the cause of a potential non-conformance. Preventative action is taken to prevent occurrence.

12 Corrective Action Audit

12.1 The audit team leader conducts a corrective action audit to ensure that the client's responses are sufficient in addressing the non-conformance(s). If the responses are found not to be sufficient, further information is requested. Evidence of effective implementation of actions taken may be requested. Additionally, an on-site corrective action audit may be conducted to verify effective implementation of the corrective actions. Corrective action audits and any other post on-site audit activities are conducted in accordance to *ISO 19011:2002 Section 6 Audit Activities*.

12.2 The findings of the corrective action audit are outlined in an audit report. The report is submitted to the Program Manager, or designee, for final review and disposition. The Program Manager has the discretion to modify the audit findings.

13 Program Approval

13.1 Program approval is based upon the audit findings and the recommendation of the audit team. The approval is 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.

13.2 Program approval status may be one of the following:

- a) *Approval*: No non-conformances were identified during the audit. No actions are necessary by the client.
- b) *Approval with Conditions*: (1) Non-conformances, and any non-conforming product, were corrected prior to the decision of approval; or (2) only minor non-conformances were identified during the audit. Clients must submit corrective actions and corrections as applicable within the time frame specified in the audit report. Additional desk audits and/or on-site audits may be conducted at the client's expense.
- c) *Denied Approval*: Denied approval may be issued prior to the initial program approval for any of the reasons outlined below. Clients 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 client's expense.



- 1) Failure to adequately address any program requirement resulting in a major non-conformance.
- 2) Failure to demonstrate capability to meet any program requirement resulting in a major non-conformance.
- 3) Finding of objective evidence of a major non-conformance within the scope of the program.
- 4) An accumulation of minor non-conformances that result in the assignment of a major non-conformance for the program.
- 5) Presenting false or misleading information to any ARC Branch official.
- 6) Denying access to client's facilities and records within the scope of the program.

13.3 Upon reaching a decision, the Program Manager, or designee, sends the client 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.

13.4 When appropriate, the Program Manager, or designee, adds the client's program to the official listing on the applicable ARC Branch Program website in accordance with the individual program procedure.

14 Program Suspension

14.1 The Program Manager makes the final decision regarding program suspension. When appropriate, a Program Review Committee makes the final decision regarding program suspension, in accordance to the individual program procedure.

14.2 Program suspension may occur for any of the following reasons:

- a) Failure to adequately address any program requirement.
- b) Failure to demonstrate capability to meet any program requirement.
- c) Failure to follow the client's approved program.
- d) Failure to provide corrective actions and correction as applicable in the timeframe specified.
- e) Failure to maintain the client's approved program.
- f) Implementing significant changes to approved program without prior written notification to and approval by the Program Manager.
- g) Deliberate misrepresentation of the eligibility of agricultural products or services distributed under an approved program.
- h) Confirmed finding of any prohibited compounds or substances or other violations as described in the individual program procedure. Upon confirming the violation, AMS suspends all approvals for clients in the product's chain of custody pending a complete investigation, in cooperation with appropriate regulatory agencies.
- i) Denying access to client's facilities and records within the scope of the program.
- j) Use of program approval in such a manner as to bring the ARC Branch into disrepute.
- k) Failure to pay ARC Branch fees.



14.3 Prior to the suspension, the Program Manager, or designee, notifies the client 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.

14.4 Upon suspension, the client's program is removed from the official listing on the applicable ARC Branch Program website, when appropriate.

14.5 The continuous suspension of a client's program may result in the permanent suspension of the program, or a reduction in the scope of the approval to exclude those parts where the client has persistently failed to meet the requirements of the program, including competence.

15 Reinstatement of a Suspended Program

15.1 Final decisions regarding reinstatement of a suspended program is at the discretion of the Program Manager. When appropriate, a Program Review Committee makes the final decision regarding reinstatement, in accordance with the individual program procedures.

15.1.1 A program suspended due to the client implementing significant changes to the approved program without prior written notification and approval is 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 client's expense.

15.1.2 A program suspended where the client's program is within the chain of custody of products identified as containing or having been treated with any prohibited substance is reinstated only upon revalidation of the integrity of the program in cooperation with appropriate regulatory agencies.

15.1.3 A program suspended where the client is found to be responsible for the introduction of prohibited substances into the affected livestock or products remains suspended until such a time as (1) the client provides objective evidence that the program has been completely purged of all potentially affected products, and (2) an on-site audit verifies that effective corrective action and corrections, as applicable, have been taken.

15.1.4 A program suspended due to the client failing to follow the approved program is reinstated upon submission of acceptable corrective actions and corrections, as applicable, which address the failure to follow the approved program. Additional on-site audits may be conducted at the client's expense.

15.1.5 A program suspended due to the client failing to provide corrective actions and/or corrections within the timeframe specified is reinstated upon submission of acceptable corrective actions and corrections, as applicable.

15.1.6 A program suspended due to the client failing to pay ARC Branch fees is reinstated upon notification that all outstanding fees and interest have been paid in full.

15.1.7 Programs that are permanently suspended may be reinstated based upon the decision of the Program Review Committee.

16 Maintaining Programs



16.1 Clients are required to maintain and implement their programs as described in their approved program documentation.

16.2 Any significant changes, in any aspect of status or operation to the client's approved program must be submitted in writing to the Program Manager and approved prior to implementation. Such changes include the following:

- a) Legal, commercial, ownership, or organizational status;
- b) Organization, top management, and key personnel;
- c) Main policies;
- d) Resources and premises;
- e) Scope of program; and
- f) Other matters that may affect the ability of the client to fulfill requirements for the program.

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 is issued for an appropriate time period based on the findings of the audit.

17 Surveillance

17.1 All approved programs are audited on an on-going basis as listed in the individual program procedures unless a written cancellation request is received from the client or a program is suspended.

17.2 All approved programs are subject to unannounced audits. The audit team 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.

18 Extension of Scope

Clients with approved programs may extend the scope of their programs at any time by submitting an application to the Program Manager. When an application is received, the ARC Branch undertakes the necessary activities to determine whether or not the extension may be granted. These activities are outlined in Section 8 through Section 14. The Program Manager makes the final decision to grant the extension. When appropriate, a Program Review Committee makes the final decision, in accordance to the individual program procedure

19 Reduction of Scope

Clients with approved programs may reduce the scope of their programs at any time by submitting a written request to the Program Manager. Upon acceptance, the official listing is updated on the applicable ARC Branch Program website to reflect the reduced scope, when applicable.

20 Cancellation

20.1 Clients with approved programs may cancel service at any time by submitting a written notification to the Program Manager. When applicable, clients who cancel service are removed from the listing on the applicable ARC Branch Program website.



20.2 Clients who cancel service must reapply to regain program approval. When an application is received, the ARC Branch undertakes the necessary activities, as outlined in Section 8 through Section 14, before program accreditation may be re-granted.

20.3 Clients are responsible for fees accrued prior to cancellation of the approved program.

21 Reference to Approval

21.1 Clients with approved programs that make reference to approval by the ARC Branch in communication media, such as the internet, documents, brochures, or advertising.

21.2 Upon request by the ARC Branch, clients must submit communication media for review by the Branch prior to its use.

21.3 Clients must ensure that references are complete and not misleading or ambiguous.

21.4 Clients are responsible for correcting erroneous references in a sufficient manner that is appropriate to the situation.

21.5 If a program is suspended or cancelled, the client must discontinue its use of all communication media that contains any reference to an approved status.

22 Appeals

(Note: Refer to *ARC 1102 Procedure* to appeal the selection of an audit team member.)

22.1 Clients have the right to appeal any adverse audit findings or decisions issued by the Program Manager or Program Review Committee.

22.2 Appeals 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.

22.3 Appeals must include:

- a) The basis for the appeal, and
- b) The requested alternative decision or actions.

22.4 The ARC Branch Chief reviews any appeal and notifies the client of the final decision within 30 business days from receipt of the appeal. If the final decision can not be determined within this timeframe, the client is provided with a progress report.

22.5 Suspensions and/or denied approvals remain in effect pending the outcome of the appeal.

23 Complaints

23.1 Clients have the right to submit a complaint regarding ARC Branch activities, including processes or decisions, ARC Branch officials, or clients with approved programs.



23.2 Complaints may be submitted in any format to the ARC Branch. Complaints should provide enough information to allow the ARC Branch to investigate the complaint.

23.3 The ARC Branch Chief, or designee, provides the complainant with progress reports and the outcome, as applicable.

24 Fees for Services

24.1 The QSVP are user-fee programs. The fees for service are the responsibility of the client requesting service. Fees are charged according to the approved hourly rate published in 7 CFR Part 62.

24.2 The fees for the QSVP include the following:

- a) *Audit preparation:* Time to review the approved program documentation and records from previous audits, and to prepare checklists.
- b) *Audit time:* Time to conduct the audit, report the results of the audit, and conduct the corrective action audit, if applicable.
- c) *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 clients, charges will be prorated between the clients.
- d) Other expenses related to providing services.

24.3 Auditors document all hours of service charged to clients. Charges are submitted to the ARC Branch Fredericksburg, VA, office for billing purposes.

25 Confidentiality

25.1 Documentation submitted by clients and maintained by the ARC Branch is subject to disclosure under the Freedom of Information Act (FOIA) (5 USC §552). FOIA applies to documents that are in the control of or maintained by a government agency.

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

25.3 ARC Branch officials must have a signed *ARC Branch Conflict-of-Interest and Confidentiality Statement* and appropriate disclosure agreement on file prior to assignment to provide QSVP service to clients.