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 voluntary, user-fee funded, audit and accreditation programs. The QSVP are designed to provide suppliers of agricultural products or services independent third-party verification of defined processes and process points.

The QSVP are provided by the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), Science and Technology (S&T), Seed Regulatory and Testing Division (SRTD) under the authority of the Agricultural Marketing Act (AMA) of 1946, as amended; the Code of Federal Regulations (CFR) Title 7, Part 62.

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 AMS Web site at http://www.ams.usda.gov/services/auditing. As appropriate, the S&T Program uses subject matter experts to ensure audits are conducted with the necessary expertise.

International entities that would like to pursue an AMS-S&T verification program will do so through a USDA Process Verified Program.

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 19011:2011 Guidelines for quality and/or environmental management systems auditing
AMS Auditing Services Web site: http://www.ams.usda.gov/services/auditing

4 Responsibilities
4.1 Applicants and S&T must meet all applicable requirements outlined in this document.

4.2 Applicants are required to maintain and implement their programs as described in their approved program documentation. Applicants must inform S&T, without delay, of significant changes relevant to program approval.

*The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, age, disability, and where applicable sex, marital status, familial status, parental status, religion, sexual orientation, genetic information, political beliefs, reprisal, or because all or part of an individual's income is derived from any public assistance program (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, 1400 Independence Avenue, S.W., Washington, D.C. 20250-9410, or call (800) 795-3272 (voice) or (202) 720-6382 (TDD). USDA is an equal opportunity provider and employer.* (Updated July 18, 2005)
4.3 S&T conducts audit activities in accordance to ISO 19011:2011 Section 6 Audit Activities. Audit documentation is retained by S&T in an electronic format. S&T does not consult with applicants regarding the development, implementation, and maintenance of programs.

4.4 S&T provides due notice of any changes to its requirements, and verifies that applicants carry out any necessary adjustments.

5 Application for Service
5.1 To request service, submit the following information to todd.erickson@usda.gov

   a) S&T 109, Application for Service. Applicants who have a S&T Form 109 on file do not need to resubmit the document unless the information must be updated.

   b) A complete copy (hard copy or in electronic form) of the applicant's program documentation as described in the individual program procedure, as applicable. Email the documentation to Todd.Erickson@usda.gov

5.2 An applicant may cancel the application process at any time. Applicants are responsible for fees accrued prior to canceling their application.

6 Receiving Applications for Service
6.1 The Program Manager, or designee, notifies the applicant upon receiving the application for service. If the submitted application is inadequate, the Program Manager, or designee, contacts the applicant to request additional documentation. The application is withheld from further processing until the necessary documentation is received.

6.2 Once the application is complete, the Program Manager, or designee, assigns an auditor to conduct the desk audit and forwards the application to the auditor.

6.3 The Program Manager, or designee, notifies the applicant of the assigned auditor. The applicant has 5 business days from receipt of notification to submit written objections regarding the auditor to the Program Manager.

6.4 When applicable, the Program Manager, or designee, also notifies the Program Review Committee. Refer to Section 8.

7 Use of the Program Review Committee
7.1 The final decision authority regarding program status for the USDA Process Verified Program is transferred from the Program Manager to the Program Review Committee.

   a) Program status includes the following: program inquiries (including process points), new applications, approvals, denials, suspensions, withdrawals, reinstatements, and significant changes.
b) The Program Review Committee makes the final decision regarding program status, except for decisions regarding reduction of scope; which may be made by the Program Manager.

7.2 Program Manager(s) of Quality Systems Verification Programs (QSVP) not included in Section 8.1, retain final decision authority regarding program status; however, they may use the Program Review Committee when determined appropriate. Refer to the individual program procedures for specific information on the use of the Program Review Committee.

7.3 The Program Review Committee may also be used to address complaints.

8 Desk Audit

8.1 The applicant may request to forego a desk audit for audit programs. This request must be submitted in writing to the Program Manager and must be approved. If the request is approved, an on-site audit must be conducted prior to approval of the program or any significant change.

8.2 The auditor conducts a desk audit of the applicant’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.

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

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

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

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 19011:2011 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 applicant of the assigned auditor(s) and/or expert(s). The applicant has 5 business days from receipt of notification to submit written objections regarding any team member(s) to the Program Manager. (Refer to Section 27 Objections of Audit Team Members.)
9.3 Once the date and schedule are arranged between the applicant and the audit team, the audit team leader prepares an audit plan and cost estimate. The documents are submitted to the applicant prior to the scheduled on-site audit.

9.4 The on-site audit is conducted in accordance to *ISO 19011:2011 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 applicant's conformance to the audit criteria.

9.5 The on-site audit is conducted at the premises of the applicant from which one or more key activities are performed. Where relevant, the on-site audit includes other selected locations where the applicant operates to gather objective evidence that the applicant 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 applicant 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 applicant 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. 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. A minor non-conformance 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, excluding CIPs, are outlined in the audit report, which is submitted to the Program Manager for final review and disposition. The Program Manager, or designee, has the discretion to modify the audit findings; however, changes must be shared with the auditor(s). S&T is responsible for the content of the audit report.

10.4 CIPs are provided to the applicant during the closing meeting and are not outlined in the audit report.

11 Correcting Identified Non-conformances
11.1 Applicants 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. Applicants 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 applicant must identify the non-conforming product and make corrections 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 applicant, 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 applicant’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. Corrective action audits are normally conducted via a document review. However, 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 19011:2011 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, or designee, has the discretion to modify the audit findings; however, changes must be shared with the auditor(s).

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. Refer to Section 8 for final decision authorities regarding Program Approval.

13.2 Program approval status is applicable to all QSVP services and may be one of the following:

a) Approval: No non-conformances were identified during the audit. No actions are necessary by the applicant.

b) Approval with Conditions: Non-conformances were identified during the audit. Applicants 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 applicant's expense.

c) Denied Approval: Denied approval may be issued prior to the initial program approval for any of the reasons outlined below. Applicants must submit corrective actions and corrections 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 applicant's expense.

13.3 Upon reaching a decision, the Program Manager, or designee, sends the applicant the audit report and any additional documentation. The audit report includes the "Notification of Audit Results" section, which details the approval status and any terms and conditions, as appropriate.

13.4 When appropriate, the Program Manager, or designee, adds the applicant's program to the official listing on the applicable AMS Business Listing Web site in accordance with the individual program procedure.

14 Program Suspension
14.1 Program suspension is the temporary removal of an applicant's approved program, or a portion of it, pending corrective action by the applicant or formal program withdrawal by S&T. The applicant must cease all activities upon notification of program suspension. However, agricultural products or services verified under the program prior to suspension remain verified.

14.2 Program suspension is applicable to all QSVP services, except for the accreditation programs like USDA ISO/IEC 17065 Program and the COR and A&M Program and may occur for any of the following reasons:

a) Failure to adequately address any program requirement, including audit findings that compromise the integrity of the program or product to the extent that program approval should be suspended

b) Failure to demonstrate capability to meet any program requirement

c) Failure to follow the applicant's approved program

d) Failure to maintain the applicant's approved program

e) Failure to provide corrective actions and correction as applicable in the timeframe specified

f) Persistently failing to meet the requirements of the program or to abide by S&T policies and procedures

g) Implementing significant changes to an approved program without prior written notification to and approval by (if applicable) the Program Manager

h) Failure to pay S&T fees
NOTE: The applicant may request suspension.

14.3 Refer to Section 8 for final decision authorities regarding Program Suspension.

14.4 Upon reaching a decision, the Program Manager, or designee, notifies the applicant in writing of the suspension and the details of actions required to be reinstated. The details of actions do not include specific remedies to barriers of reinstatement.

14.5 The official listing on the applicable AMS Business Listing Web site is updated to reflect the status of the applicant's program.

14.6 Recurring suspension of an applicant's program may result in program withdrawal or a reduction in the scope of the approval to exclude those parts where the applicant has persistently failed to meet the requirements of the program, including competence.

15 Reinstatement of a Suspended Program

15.1 Reinstatement of a suspended program is applicable to all QSVP services. Refer to Section 8 for final decision authorities regarding Reinstatement of a Suspended Program.

a) A program suspended due to the applicant failing to adequately address any program requirement 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 applicant's expense.

b) A program suspended due to the applicant failing to demonstrate capability to meet any program requirement 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 applicant's expense.

c) A program suspended due to the applicant failing to follow the applicant's approved program 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 applicant's expense.

d) A program suspended due to the applicant failing to maintain the applicant's approved program 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 applicant's expense.

e) A program suspended due to the applicant failing to provide corrective actions and/or corrections within the timeframe specified is reinstated upon submission of acceptable corrective actions and corrections, as applicable. Additional desk audits and/or on-site audits may be conducted at the applicant's expense.

f) A program suspended due to the applicant persistently failing to meet the requirements of the program or to abide by S&T policies and procedures 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 applicant's expense.

g) A program suspended due to the applicant implementing significant changes to the approved program without prior written notification and approval, if applicable, 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 applicant's expense.

h) A program suspended due to the applicant failing to pay S&T fees is reinstated upon notification that all outstanding fees and interest have been paid in full. Additional restrictions may be put in place to ensure future payments for services.

16 Program Withdrawal

16.1 Program withdrawal is the removal of an applicant's approved program, or a portion of it. Partial withdrawal may apply where an applicant is approved for multiple scopes that may be treated individually for approval purposes. The applicant must cease all activities upon notification of program withdrawal. In addition, agricultural products or services verified under the program prior to the withdrawal are no longer verified.

16.2 An applicant’s program may be permanently withdrawn if the applicant deliberately misrepresented the eligibility of agricultural products or services, introduced prohibited compounds or substances, or used program approval in a manner that brings S&T into disrepute. S&T will not provide service to the applicant during the timeframe that the permanent withdrawal is in effect.

16.3 Program Withdrawal applies to all QSVP services.

16.4 Program withdrawal may occur for any of the following reasons:

a) Audit findings that compromise the integrity of the program or product to the extent that program approval should be withdrawn

b) Deliberate misrepresentation of the eligibility of agricultural products or services distributed under an approved program

c) Confirmed finding of any prohibited compounds or substances or other violations as described in the individual program procedure. Upon confirming the violation, AMS withdraws all approvals for applicants in the product’s chain of custody pending a complete investigation in cooperation with appropriate regulatory agencies

d) Denying access to applicant's facilities and records within the scope of the program

e) Use of program approval in such a manner as to bring S&T into disrepute

NOTE: The applicant may request withdrawal.

16.5 Refer to Section 8 for final decision authorities regarding Program Withdrawal.
16.6 Upon reaching a decision, the Program Manager, or designee, notifies the applicant in writing of the withdrawal and the details of actions required to be reinstated. The details of actions do not include specific remedies to barriers of reinstatement.

16.7 The official listing on the applicable AMS Business Listing Web site is updated to reflect the status of the applicant's program. Reference to the applicant's program is removed from the official listing after a period of 60 calendar days or the end of the appeals process, whichever is longer.

*Note: Withdrawal has the same meaning as revocation.*

17 **Reinstatement of a Withdrawn Program**

Reinstating a Withdrawing Program is applicable to all QSVP services. Refer to Section 8 for final decision authorities regarding Reinstatement of a Withdrawn Program.

17.1 Reinstatement of a withdrawn program may be granted only after the applicant has successfully completed an onsite audit. Additionally, a program may be withdrawn:

a) Due to the audit findings - must provide corrective actions and correction, as applicable, which specifically address the audit findings that resulted in the program withdrawal.

b) Due to deliberate misrepresentation - must provide corrective actions and correction, as applicable, which specifically address the deliberate misrepresentation.

c) Where the applicant'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.

d) Where the applicant is found to be responsible for the introduction of prohibited substances into the affected products remains withdrawn until such a time as (1) the applicant 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.

e) Due to the denial of access - must provide access.

18 **Significant Changes**

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

a) Legal, commercial, ownership, or organizational status

b) Organization, top management, and key personnel

c) Policies and procedures
d) Resources and premises

e) Addition or reduction of the scope of the program

f) Other matters that may affect the ability of the applicant to fulfill requirements for the program

18.2 Refer to Section 8 for final decision authorities regarding Significant Changes to an approved program. The significant changes may require approval by the Program Review Committee or the Program Manager depending upon the nature and extent of the changes. A complete or partial on-site audit of the program may be required prior to approval of the significant changes. 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.

19 Surveillance
19.1 All approved programs are audited on an on-going basis as listed in the individual program procedures unless the program is suspended, withdrawn, or cancelled.

19.2 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 or withdrawing approval.

20 Extension of Scope
Extension of Scope is considered a significant change to an approved program. Applicants with approved programs may request to extend the scope of their programs at any time by applying to the Program Manager. When an application is received, S&T undertakes the necessary activities to determine whether or not the extension may be granted. These activities are outlined in Section 8 through Section 13. Refer to Section 8 for final decision authorities regarding Extension of Scope to an approved program.

21 Reduction of Scope
Reduction of Scope is considered a significant change to an approved program. Applicants with approved programs may request to 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 to reflect the reduced scope on the applicable AMS Business Listing Web site. Refer to Section 8 for final decision authorities regarding Reinstatement of a Withdrawn Program.

22 Cancellation
22.1 Applicants with approved programs may cancel service at any time by submitting a written notification to the Program Manager. When applicable, applicants who cancel service are removed from the listing on the applicable AMS Business Listing Web site.

22.2 Applicants who cancel service must reapply to regain program approval. When an application is received, S&T undertakes the necessary activities, as outlined in Section 8 through Section 13, before program approval may be re-granted.

22.3 Applicants are responsible for fees accrued prior to cancellation of the approved program.
23 Reference to Approval

23.1 Applicants with approved programs may refer to approval by S&T in communication media, such as the internet, documents, brochures, or advertising, and including product labels.

23.2 Upon request by S&T, applicants must submit communication media for review by S&T prior to its use.

23.3 Applicants must ensure that references are complete and not misleading or ambiguous.

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

23.5 If a program is suspended, withdrawn, or cancelled, the applicant must discontinue its use of all communication media that contains any reference to their approved status.

Note: Reference to program approval is distinctly separate from approval of promotional materials associated with the USDA Process Verified Program.

24 Appeals

24.1 An appeal is a request from the applicant for reconsideration of any adverse audit findings, assessment findings, or decisions issued by the Program Manager related to the applicant's program.

24.2 Applicants have the right to appeal any adverse audit findings, assessment findings, or decisions issued by the Program Manager.

24.3 Appeals, other than those described in 25.4, must be submitted in writing to the Program Manager within 30 days of the date of the official report or letter rendering the findings or decisions.

24.4 Appeals dealing with Objections to Audit Team Members must be submitted in writing to the Program Manager within 5 business days of the date of the decision notification.

24.5 Appeals must include:

   a) The basis for the appeal
   b) The requested alternative decision or actions

24.6 For appeals other than those described in 25.7, the Program Manager reviews any appeal and notifies the applicant of the final decision within 30 calendar days from receipt of the appeal. If the final decision cannot be determined within this timeframe, the applicant is provided with a progress report.

24.7 For appeals dealing with Objections to Audit Team Members, the Program Manager reviews the appeal and notifies the applicant of the final decision within 5 business days from receipt of the appeal.

24.8 Suspensions, withdrawals, and/or denied approvals remain in effect pending the outcome of the appeal.
25 Complaints

25.1 A complaint is an objection to the policies, procedures, and/or performance of S&T. A complaint may also be an objection to the performance or activities of an approved Program submitted to S&T by a third party.

25.2 Applicants have the right to submit a complaint regarding S&T policies, procedures, and/or performance, including performance of S&T officials. Any third party also has the right to submit a complaint regarding the performance or activities of applicants with approved Programs.

25.3 Complaints may be submitted in any format to the Program Manager. Complaints should provide enough information to allow S&T to investigate the complaint.

26 Objections of Audit Team Member(s)

26.1 Applicants have the right to object to any audit team members(s).

26.2 Objections must be submitted in writing to the Program Manager within 5 business days after notification of the audit team.

26.3 Objections must include:
   a) The basis for the objection
   b) The requested alternative decision or actions

26.4 The Program Manager reviews any objections and notifies the applicant of the final decision within 5 business days from receipt of the objection.

26.5 The applicant has the right to appeal the decision issued by the Program Manager.

26.6 The appeal must be submitted in writing to the Program Manager within 5 business days of the date of the official report or letter rendering the decision.

26.7 Appeals must include:
   a) The basis for the appeal
   b) The requested alternative decision or actions

26.8 The Program Manager reviews the appeal and notifies the applicant of the final decision within 5 business days from receipt of the appeal.

27 Fees for Services

27.1 The QSVP are user-fee programs. The fees for service are the responsibility of the applicant requesting service. Fees are charged according to the approved hourly rate published in applicable parts of 7 CFR Parts 56, 62, and 70.

27.2 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 applicants, charges will be prorated between the applicants.

d) **Review of Promotional Materials**: Time associated with the review of USDA Process Verified Program promotional materials, including labels, packaging, and other marketing materials.

e) Other expenses related to providing services.

27.3 Auditors document all hours of service charged to applicants. Charges are submitted to S&T Gastonia, NC, office for billing purposes.

28 **Confidentiality**

28.1 Documentation submitted by applicants and maintained by S&T 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.

28.2 Any portion of the program documentation that the applicant considers proprietary must be identified to S&T at the time the information is submitted. S&T makes appropriate provisions to protect the information from disclosure to the extent possible under existing federal laws.

28.3 S&T officials must have a signed *S&T Conflict-of-Interest and Confidentiality Statement* and appropriate disclosure agreement on file prior to assignment to provide QSVP service to applicants.

29 **AMS Web Sites**

29.1 The [AMS Auditing Services Web site](#) provides information on the QSVP. It also provides links to all other Web sites.

29.2 In addition, each audit and accreditation program has its own Web site within the AMS Web site structure.