



USDA Process Verified Program for Seed General Requirements

1 Purpose

This document outlines the general requirements of the USDA Process Verified Program for Seed. These requirements are in addition to those outlined in *ARC 1000 Procedure, Quality Systems Verification Program General Policies and Procedures*. Companies must also incorporate the following reference documents, definitions, and program requirements, as applicable, and required into their USDA Process Verified Program for Seed.

Specific program requirements for the USA Accredited Seed Laboratory (ASL) Program, USA Accredited Seed Sampling Program (ASSP), and USA Accredited Field Inspection Program (AFIP) are outlined in Appendixes A, B, and C of this Procedure. The specific program requirements must be met through an approved USDA Process Verified Program. The requirements of the USDA Process Verified Program are defined in *ARC 1001 Procedure, USDA Process Verified Program*. The USDA Process Verified Program ensures that the specific program requirements are supported by a documented quality management system.

The USDA Process Verified Program for Seed is a voluntary, user-fee audit program. It is available to seed laboratories, seed samplers or sampling entities, and field inspectors. Services are provided by USDA AMS Audit, Review, and Compliance (ARC) Branch in Fredericksburg, VA.

2 Reference Documents

- 2.1 *ARC 1000 Procedure Quality Systems Verification Program General Policies and Procedures*
- 2.2 *ARC 1001 Procedure Process Verified Program*
- 2.3 USDA Process Verified Program Web site: <http://processverified.usda.gov>
- 2.4 *United States Seed Analyst Accreditation Standard*: <http://www.seedtechnology.net>
- 2.5 *AASCO Seed Sampling Handbook*, as amended
- 2.6 *US OECD Procedures Guide*
- 2.7 *OECD Seed Schemes, Appendix 8*
- 2.8 *Association of Official Seed Analysts (AOSA) Rules of Testing Seed*
- 2.9 *Federal Seed Act*

3 Definitions

- 3.1 Accredited Seed Sampler: Any seed sampler or sampling entity meeting all requirements of the ASSP. USDA deems samplers accredited who work under an approved documented program that addresses the requirements of ASSP and upon successful completion of an audit by USDA or by USDA, AMS Recognized Auditors.

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- 3.2 Accreditation Auditor Authority: USDA-AMS will have the authority to approve, deny or suspend accreditation in accordance with the USDA Process Verified Program for Seed guidelines.
- 3.3 Accredited Seed Laboratory (ASL): Any seed-testing laboratory meeting all requirements of the ASL Program. USDA deems laboratories accredited upon implementation of a documented program that addresses the requirements of the ASL Program and upon successful completion of an audit by USDA, or by USDA, AMS Recognized Auditors.
- 3.4 Accredited Field Inspector: Any field inspector meeting all requirements of the AFIP. USDA deems field inspectors accredited who work under an approved documented program that addresses the requirements of the AFIP and upon successful completion of an audit by USDA or by USDA, AMS Recognized Auditors.
- 3.5 Product: For the purpose of the accredited programs, product may mean samples, field inspection reports, testing reports, etc.
- 3.6 Program Documentation: Documents and records prepared and maintained by the accredited entity that describe and record the relevant procedures that conform to the requirements. This documentation must be in the form of a well-defined quality manual, including controlled program documents and records that meet all requirements.
- 3.7 Recognized Auditors: Audit, Review and Compliance Branch Quality Systems Auditors and audit programs that are approved by AMS using International Organization for Standardization (ISO) Guide 65, General requirements for bodies operating product certification systems. Audit systems must include both a technical and systems auditing component in accordance to ISO Guide 65 requirements.
- 3.8 Surveillance Audit: A review of the accredited entity's facilities, procedures and records (1) to determine conformance with this Program, and (2) to verify the participant's ability to meet the requirements of the USDA Process Verified Program for Seed. These audits are conducted by the AMS Livestock and Seed Program, Audit, Review and Compliance (ARC) Branch or by AMS recognized auditors.
- 3.9 Proficiency Testing: Accredited laboratories must satisfactorily participate annually in a recognized proficiency-testing program, within their chosen scope of crop accreditation. Recognized programs will include currently developed programs/or those to be developed and administered by *Association of Official Seed Analysis (AOSA)*, *Society of Commercial Seed Technologist (SCST)*, *Canadian Food Inspection Agency (CFIA)*, *International Seed Testing Association (ISTA)* or *United States Department of Agriculture (USDA)*. The laboratory may contract proficiency services if their chosen scope of crop accreditation is not offered in a recognized program or they may participate in a standard offered program that includes crop kinds beyond their chosen scope of accreditation.
- 3.10 Program Guidelines: Program Guidelines were developed by affiliated seed associations and USDA. Future changes to these programs will occur as necessary.



4 Audits

- 4.1 USDA Process Verified Programs for Seed are audited at least every three (3) years. More frequent audits may be conducted if either numerous minor non-conformances or a major nonconformance are identified during an audit.
- 4.2 The ARC Branch reserves the right to conduct a case specific surveillance audit at any time at the cost of the participant. A surveillance audit could be triggered by a written complaint, which has been investigated and deemed valid by USDA, or a non-conformance issue relating to the audit process.
- 4.3 Audits are conducted by the ARC Branch or an AMS-accredited USDA ISO Guide 65 Program.
- 4.4 If the applicant operates under a recognized ISO certification program, then audits will emphasize those technical components of the USDA Process Verified Program for Seed that are not specifically addressed within the ISO certification program.

5 Listing of Accredited Programs

Applicants that have an accredited USDA Process Verified Program for Seed are listed on the *Official Listing of Accredited USDA Process Verified Programs for Seed*. The Official Listing is available on the ARC Branch Web site at www.ams.usda.gov/arcaudits.

6 Applicants Responsibilities

Applicants must follow the policies and procedures outlined in the *ARC 1000 Procedure, Quality Systems Verification Programs General Policies and Procedures*, in addition to the following:

- 6.1 Programs must conduct an internal audit annually and supply the results of internal audit to the ARC Branch, prior to its anniversary date listed on the USDA web site. Internal audits must review all activities within the scope of the accreditation and can be performed by the accredited program or by an outside agency.
- 6.2 Maintain complete records demonstrating conformance with the USDA Process Verified Program for Seed. Records should be maintained for a minimum of five (5) years. Records can be disposed of at the beginning of the sixth year after the year in which they were created.
- 6.3 Accredited entities must immediately notify the ARC Branch of any significant changes in the accredited program. Depending on the nature of the significant change, it may be subject to approval prior to implementation.