

USA ACCREDITED FIELD INSPECTION PROGRAM

USDA Process Verified Program-Seed USA Accredited Field Inspection Program (AFIP) Specified Program Requirements

1 Purpose

The purpose of this document is to set forth the policies, procedures, and requirements of the USA Accredited Field Inspection Program (AFIP) and for the independent process verification of participants in the AFIP. The AFIP is a voluntary, user-fee service available to field inspecting entities or individuals. Field inspectors, who meet all requirements of this program and successfully pass a USDA Process Verified Program Audit, will be able to represent themselves as a USA Accredited Field Inspector.

2 Scope

- 2.1 The AFIP applies to field inspectors seeking accreditation under this program. The USDA Agricultural Marketing Service (AMS) will conduct independent process verification audits of the field inspector's documentation and procedures with regard to the AFIP.
- 2.2 This document describes the requirements for accreditation for field inspecting only.

3 Objective

The objective of the USA AFIP is to provide uniform procedures and methodology for inspecting fields. The AFIP will enhance seed movement both domestically and globally through standardized, verified processes. Adherence to the program requirements and quality standards of the USDA Process Verified Program will further enhance the quality and consistency of field inspections in the U.S.

4 Additions to the USDA Process Verified Program (PVP) Requirements

The specific program requirements listed in Section 7 of this Procedure must be met through an approved USDA Process Verified Program. The USDA PVP ensures that the specified program requirements are supported by a documented quality management system. In addition to the requirement listed in the ARC 1001 Procedure, companies/entities must incorporate all of the following reference documents, definitions, and program requirements into their USDA Process Verified Program:

5 Reference Documents

5.1 ARC Procedure 1000 Quality Systems Verification Program General Policies and Procedures

5.2 ARC Procedure 1001 Process Verified Program

5.3 US OECD Procedures Guide

5.4 OECD Seed Schemes, Appendix 8

5.5 Documents referenced above may be obtained from the USDA web site:

www.ams.usda.gov/lsg/seed.htm

6 Definitions

6.1 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.

6.2 Accreditation Auditor Authority: AMS will have the authority to approve, deny or suspend a field inspector's accreditation in accordance with the USA AFIP guidelines.

6.3 Program Documentation: Documents and records prepared and maintained by accredited field inspectors that describe and record the inspecting procedures that conform to the AFIP requirements. This documentation must be in the form of a well-defined quality manual, including controlled program documents and records that meet all AFIP requirements.

6.4 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.

6.5 Surveillance Audit: A review of accredited field inspector's facilities, procedures and records (1) to determine conformance with this Program, and (2) to verify the accredited field inspector's ability to meet all of the requirements of the USA AFIP. These audits will be conducted by the USDA-AMS Livestock and Seed Program, Audit, Review, and Compliance (ARC) Branch or by AMS recognized auditors.

7 Specified Program Requirements

- 7.1 Participation in this program is voluntary.
- 7.2 Accredited field inspectors must maintain an approved Quality Management System and Standard Operating Procedures that meet all the applicable elements as outlined in ARC Procedure 1001 Process Verified Program. All program documentation must be available for review by the USDA Auditor or its designee.
- 7.3 Conformance with the AFIP requirements will be determined through fee-for-service, process verified, surveillance audits conducted by AMS, or its designee using the USA AFIP, ARC Procedure 1000 Quality Systems Verification Program General Policies and Procedures, and ARC Procedure 1001 Process Verified Program.
- 7.4 Accredited field inspectors will be accountable to inspect fields in accordance with US OECD Seed Schemes Procedures Guide.

8 Field Inspectors or Inspecting Entities Responsibilities

- 8.1 Accredited field inspectors must conduct an internal audit annually and supply the results of the internal audit to AMS 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 field inspector or by an outside agency.
- 8.2 Accredited field inspectors will be audited to determine expertise and implementation during actual field inspections.
- 8.3 A portion of the fields entered for official certification for OECD shall be check inspected by official field inspectors. That portion shall be at least 5 percent.
- 8.4 Comply with all provisions of this program and applicable elements of ARC Procedures 1001, Process Verified Program.
- 8.5 Maintain complete records demonstrating conformance with the AFIP. Records shall 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.
- 8.6 Immediately notify AMS of any significant changes in the approved program documentation used to verify conformance to the AFIP.

8.7 Notify AMS to cancel service prior to the next surveillance audit when service is no longer desired.

9 USDA-AMS Responsibilities

9.1 Conduct audits according to this Procedure, ARC Instruction 1000 Quality Systems Verification Program General Policies and Procedures, and ARC Instructions 1001 Process Verified Program.

9.2 Maintain and publish a listing for the AFIP at www.ams.usda.gov/lsg/seed.htm

9.3 Records should be maintained for five (5) calendar years after the year in which the external audit was conducted.

10 Surveillance Audits

10.1 ARC 1000 Procedure Quality Systems Verification Programs General Policies and Procedures and the requirements outlined in this program will be used to assess field inspectors and field inspecting entities.

10.2 All accredited field inspectors will be audited at least every three (3) years. More frequent audits may be conducted if either numerous minor non-conformances or a major non-conformance are identified during an audit.

10.3 AMS reserves the right to conduct a case specific surveillance audit 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.

10.4 Program audits will be conducted by AMS or its designee and will include both a technical and system auditing component.

11 Approval Procedures

ARC 1000 Procedure Quality Systems Verification Programs General Policies and Procedures, ARC Procedure 1001 Process Verified Program, and the requirements outlined in this procedure will be used to approve or deny field inspectors or field inspecting entities.

12 ARC Branch Contact Information

All program documentation, updates, and internal reviews should be submitted to the following address:

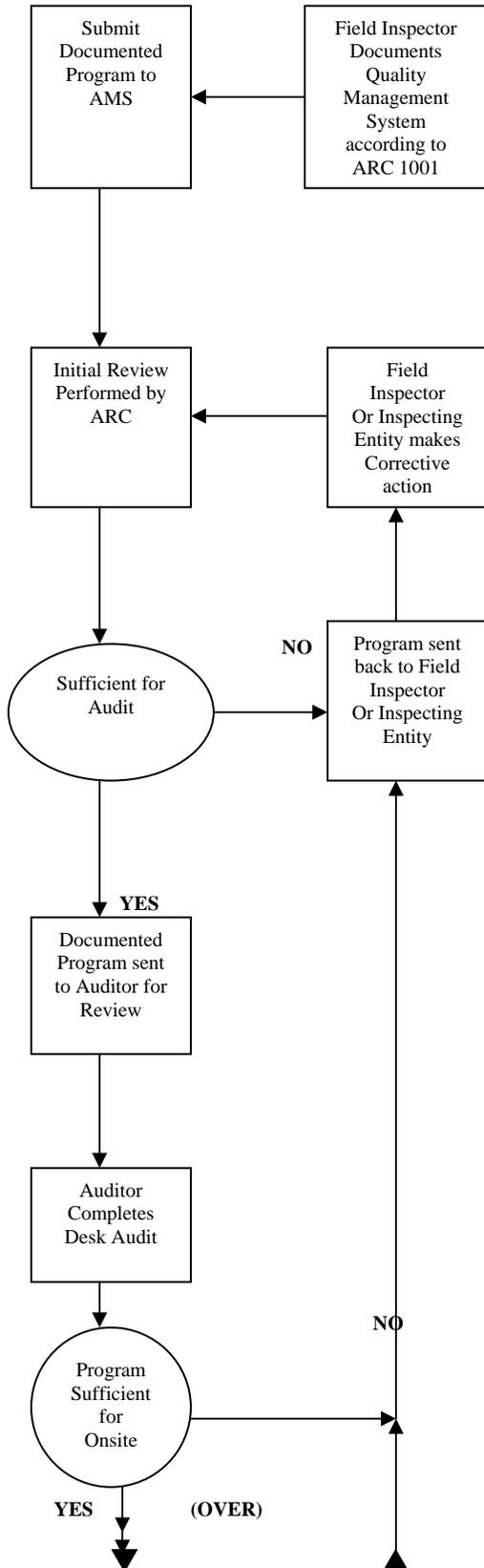
USDA, AMS, LS, ARC Branch
100 Riverside Parkway, Suite 135
Fredericksburg, VA 22406
Phone: (540) 361-7640
Fax: (540) 361-7859 or (202) 690-1038

13 Publication

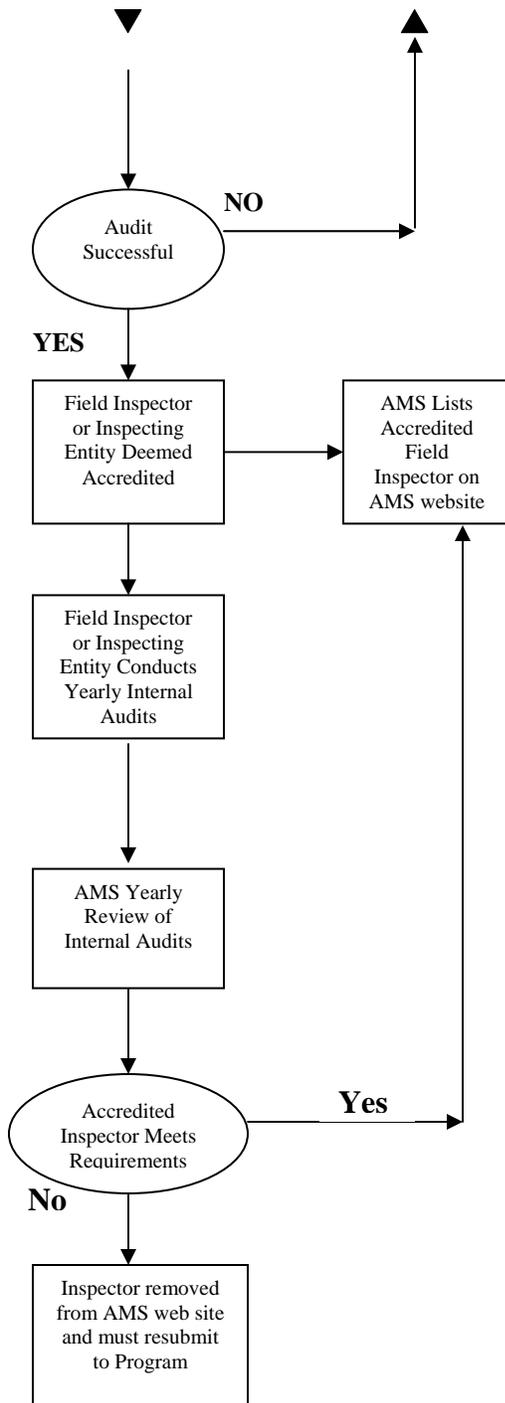
Information about each accredited field inspector program will be posted on the USDA-AMS Internet website at: www.ams.usda.gov/lsg/seed.htm
Information posted will include the name, address and scope of accreditation.

14 Confidentiality

All materials submitted by applicants and maintained by AMS are subject to disclosure under the Freedom of Information Act. The Freedom of Information Act applies to documents that are in the control of or maintained by a government agency. AMS does not maintain program manuals submitted by applicants. These manuals are reviewed by a branch auditor and returned to the applicant upon completion of the audit process. AMS will make appropriate provisions to protect proprietary information from disclosure to the extent possible under existing Federal laws. Any portion of the program documentation that the applicant considers proprietary must be identified at the time the information is submitted along with written justification why said documents should not be released to or reviewed by the public. Any information deemed a trade secret or confidential business information cannot be released to the public.



- USA ACCREDITED FIELD INSPECTION PROGRAM (AFIP)**
1. The applicant documents its Quality Management System (QMS) according to *ARC 1001, Process Verified Program* and current USA AFIP procedure.
 2. The inspecting entity requests an initial assessment by submitting the following to the ARC Branch.
 - A completed and signed *Application for Service, LS Form 313*.
 - A cover letter requesting an AFIP audit.
 - The Quality management program documentation used to ensure conformance to the applicable elements of *ARC Instruction 1001, Process Verified program* and the AFIP requirements.
 3. The ARC Branch performs the initial review. If the submitted program is sufficient, it is then sent to an auditor.
 4. AMS will assign a qualified ARC Branch auditor, or an approved recognized audit program chosen to perform an audit as soon as possible upon determining that the *Application – LS Form 313* and QMS program documentation is sufficient.
 5. An auditor will complete a desk audit of the program, interacting with the inspecting entity as necessary.
 6. The auditor will schedule the onsite visit once the program is determined to be sufficient.
 7. All audits will be conducted according to *ARC Instruction 1000 Quality Systems Verification Program General Policies and Procedures, and ARC Instructions 1001 Process Verified Program*.



8. AMS will prepare a detailed report of the audit observations, findings and a recommendation. AMS will then forward the audit report and the final decision to the accredited field inspector or inspecting entity. AMS will ensure surveillance audits are performed as required by this procedure and provides overall program review and approvals.

9. The field inspector or inspecting entity must address any non-conformances found during the audit within a reasonable time frame.

10. Approval. A field inspector or inspecting entity that conforms to the AFIP procedure and their approved QMS program documentation will be considered accredited. Once accredited, the ARC Branch will post the field inspector programs information.

11. Accredited field inspectors or field inspecting entities must conduct an internal audit yearly and supply a copy of the results to AMS prior to their anniversary date on the USDA official web listing. Internal audits must review all activities within the scope of the accreditation and can be self-performed or contracted with an outside agency.

12. Accredited field inspectors or inspecting entities will be audited every three (3) years. However, more frequent audits may be conducted if either numerous continuous improvement points or hold points are identified during any audit.

13. AMS reserves the right to conduct a case specific surveillance audit during the three (3) year period, 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 approval process.