



USDA ISO Guide 65 Program Accreditation for Certification Bodies

1 Purpose

This document provides the requirements to be met in designing a USDA ISO Guide 65 Program. It also provides the requirements used for the objective evaluation of programs submitted for accreditation by the Agricultural Marketing Service (AMS), Livestock and Seed (LS) Program, Audit, Review, and Compliance (ARC) Branch.

The USDA ISO Guide 65 Program is a voluntary conformity assessment and accreditation service provided by the ARC Branch under the Quality Systems Verification Program. This Program facilitates the marketing and distribution of certified agricultural products.

2 Scope

This Program is available to U.S. and international certification bodies that perform conformity assessment activities, such as certification, inspection, testing, and calibration, for livestock, meat, seed, and other agricultural products or services within the scope of the LS Program.

NOTE: The European Union (EU) designated the ARC Branch as a competent authority for the assessment of organic certification bodies under ISO/IEC Guide 65:1996. Accreditation under the USDA ISO Guide 65 Program allows U.S. organic products to be exported to the EU provided that the products conform to the EU organic standards (ECC 2092/91).

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/IEC Guide 65:1995 – General requirements for bodies operating product certification systems

ARC 00 QM Accrediting Conformity Assessment Bodies (ISO 17011)

ARC 1000 Procedure, Quality Systems Verification Programs General Policies and Procedures

ARC 1115 Procedure, Program Review Committee

ARC 1102 Procedure, Selection of Audit Team Members

ARC 1012 Certificate, USDA ISO Guide 65 Program

ARC 1012A Checklist, USDA ISO Guide 65 Program for Clients

ARC 1012B Checklist, USDA ISO Guide 65 Program for Auditors

ARC Branch Auditing Services Web site: www.ams.usda.gov/arcaudits

ARC Branch USDA ISO Guide 65 Program Web site

ARC Newsroom Web site

ARC Branch Questions and Answers Web site

ARC Branch Official Listing of Approved USDA ISO Guide 65 Programs

"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 Responsibilities

4.1 Certification bodies must meet all applicable policies, procedures, and requirements outlined in this document, *ISO/IEC Guide 65:1996*, and *ARC 1000 Procedure*.

4.2 Certification bodies must provide access to information, documents, and records as necessary for the assessment and maintenance of the accreditation.

4.3 Certification bodies must provide access to those documents that provide insight into the level of independence and impartiality of the certification body from its related bodies, where applicable.

4.4 Certification bodies must arrange the witnessing of certification activities when requested by the ARC Branch.

4.5 The ARC Branch must meet all applicable policies, procedures, and requirements outlined in this document ~~Procedure~~, *ARC Branch Quality Manual for Accrediting Conformity Assessment Bodies*, *ARC 1000 Procedure*, and referenced documents, as applicable.

5 ARC Branch Web Sites

5.1 The *ARC Branch Auditing Services Web site* provides information on all ARC Branch audit and accreditation activities, including:

- a) The *USDA ISO Guide 65 Program Web site*. This Web site provides information regarding the USDA ISO Guide 65 Program, including relevant documents and standards, guidance, the *Official Listing*.
- b) The *ARC Newsroom Web site*. This Web site provides notice to stakeholders and interested parties regarding the USDA ISO Guide 65 Program including proposed changes, approved changes, and timeframes for implementation of approved changes.
- c) The *Questions and Answers Web site*. This Web site provides answers to frequently asked questions regarding various Programs and subjects, including the USDA ISO Guide 65 Program.

6 Desk Audit

The certification body may not request to forego a desk audit. A desk audit is conducted prior to each assessment. The scope of the desk audit is based on the scope of the assessment.

7 Preliminary Visit

Prior to initial assessment, a preliminary visit may be conducted with the agreement of the certification body. This visit may result in the identification of deficiencies in the system of the applicant certification body or its competencies. The ARC Branch does not consult and exercises due care to avoid consultancy during such a visit.

8 Initial Assessment

Initial assessments are conducted in accordance with *ARC 1000 Procedure*. Initial assessments include the witnessing of certification activities at one or more suppliers of the certification body. A representative sample of suppliers is selected to ensure proper evaluation of the certification body's competence.

9 Surveillance Assessments

9.1 Surveillance assessments are conducted on-site and are less comprehensive than the initial assessment and reassessment. All locations from which one or more key activities are performed are assessed during the



2-year period prior to reassessment. Surveillance assessments may include the witnessing of certification activities at one or more suppliers of the certification body to ensure proper evaluation of the certification body's competence.

9.2 Surveillance assessments are conducted at least once per year after accreditation. However, more frequent assessments may be conducted (1) if either numerous minor non-conformances or a major non-conformance are identified during the assessment; (2) if customer complaints indicate an ongoing problem; or (3) as directed by the ARC Branch Chief.

10 Reassessments

10.1 Reassessments are similar to initial assessments, as described in *ARC 1000 Procedure*, except that experience gained during previous assessments is taken into account. Reassessments include the witnessing of certification activities at one or more suppliers of the certification body. A representative sample of suppliers is selected to ensure proper evaluation of the certification body's competence.

10.2 Reassessments are conducted every 3 years prior to the expiration date. Extensions may be granted.

11 Program Review Committee

Applications are reviewed by a Program Review Committee. The purpose of the review is to determine the ARC Branch's capabilities to conduct the assessment by evaluating the ARC Branch's own policies and the availability of suitable auditors and experts with the appropriate competence to perform the assessment in a timely manner.

Decisions on accreditation, including approval, disapproval, extension of scope, suspension, and withdrawal are made by the Program Review Committee. **Decisions regarding reduction of scope may be made by the Program Manager.** Decisions regarding suspension and withdrawal are limited to those based on the findings of the assessment. The review is conducted in accordance to *ARC 1115 Procedure, Program Review Committee*. The Program Review Committee makes the final decision regarding accreditation status.

12 Listing of Accredited Programs and Programs Under Review

The ARC Branch provides public information about the current status of accreditation of applicant certification bodies and accredited certification bodies **in the *Official Listing of Approved USDA ISO Guide 65 Programs*. In addition, the ARC Branch uses the *Official Listing* to solicit comments regarding the certification bodies' performance and conformance to relevant standards.**

The *Official Listing* is maintained on the *ARC Branch USDA ISO Guide 65 Program Web site* at <http://www.ams.usda.gov/Asg/arc/iso65.htm>. The *Official Listing* **and** contains information including:

- a) Certification body's name;
- b) Certification body's address, and
- c) Certification body's contact information including telephone number, fax number, and email address when available;
- d) Certificate number, as applicable;
- e) Dates of granting accreditation and expiry dates, as applicable; and
- f) Scope of accreditation, condensed and/or in full. If only condensed scopes are provided, information shall be given on how to obtain full scopes.



In addition:

- a) If the certification body is undergoing an initial assessment, the statement "Under Review" is included.
- b) If the certification body is under suspension, the scope of the suspension, the effective date of the suspension and the following statement are included: "Under Suspension – Agricultural products certified under the program prior to suspension remain certified. No additional products may be certified while the suspension is in effect."
- c) If the certification body is under withdrawal, the effective date of the withdrawal and the following statement are included: "Under Withdrawal – Agricultural products certified under the program prior to suspension are no longer certified. No additional products may be certified."
- d) If the certification body has requested to cancel service, the following the statement is included: "Requested to Cancel Service – Agricultural products certified under the program are eligible until [date]." The date referenced is the date that cancellation is effective, normally the date that the surveillance or reassessment was to occur.

13 Certificate of Conformance

13.1 A *Certificate of Conformance* is issued to all accredited programs (hard copy and/or in electronic form). The Certificate identifies the following:

- a) Identity and logo of the ARC Branch;
- b) Certification body's name;
- c) All premises from which one or more key activities are performed and which are covered by the accreditation;
- d) Certificate number
- e) Effective date of granting of accreditation and expiry date;
- f) Reference to the scope of accreditation;
- g) Statement of conformity and a reference to the standard(s) or other normative document(s), including issue or revision used for the assessment;
- h) Type of certification
- i) Standards or normative documents, or regulatory requirements or types thereof, to which products, personnel, services, or management systems are certified as applicable
- j) Industry sectors, where relevant;
- k) Product categories, where relevant; and
- l) Personnel categories, where relevant.

13.2 Certificates are valid for up to three years and may be renewed provided systems are maintained as described in program documentation and subsequent assessments provide objective evidence of ongoing conformance. Extensions may be granted **on a case-by-case basis**.

13.3 Companies that withdraw from the USDA ISO Guide 65 Program or that are suspended must discontinue using the *Certificate of Conformance*.

14 References to Official Certificates and Accreditation

14.1 A certification body with a valid *Certificate of Conformance* may make references to accreditation by the ARC Branch in communication media.

NOTE: Acceptable references may include, for example, "[Certification body's] product certifications are accredited under ISO/IEC Guide 65:1996 by the U.S. Department of Agriculture."



14.2 References must be complete and not misleading or ambiguous.

14.3 References must not imply that a product, process, system, or person is approved by the ARC Branch.

14.4 Certification bodies are responsible for correcting erroneous references in a sufficient manner that is appropriate to the situation.

14.5 If a certification body continuously makes erroneous references, the ARC Branch may not allow the certification body to make any references until such time that the ARC Branch is assured that references will be accurate.

15 Program Requirements

15.1 Initial Assessment

15.1.1 The certification body must submit an application for service in accordance with *ARC 1000 Procedure*. In addition, the certification body must submit the following information relevant to the accreditation:

- a) A description of the conformity assessment services that the certification body undertakes;
- b) A list of standards, methods, or procedures for which the certification body seeks accreditation, including limits of capability where applicable;
- c) A hard copy and electronic copy of the certification body's quality manual and relevant associated documents and records. The quality manual and associated documents and records must meet the requirements of *ISO/IEC Guide 65:1996*;
- d) A completed *ARC 1012A Checklist*;
- e) A current list of clients certified by the certification body covered under the scope of the assessment, including locations and products certified;
- f) Samples of brochures, advertisements, labels, or other publicly available documents describing the certification services offered; and
- g) A copy of the most recent internal audit of the certification body's program. If all activities of the certification body's program are not implemented at the time of the internal audit, then the internal audit must cover those activities that are implemented.

The certification body may also be asked to submit the following information relevant to the accreditation:

- a) The standard(s) used to certify product;
- b) The source of the standard(s);
- c) The names of the members who developed the standard(s) and their qualifications; and
- d) The process used to develop the standard(s) if developed by the certification body.

15.2 Surveillance Assessments

15.2.1 Prior to the surveillance assessment, the certification body must submit the following information relevant to the accreditation:

- a) A description of the conformity assessment services that the certification body undertakes;
- b) A list of standards, methods, or procedures for which the certification body seeks accreditation, including limits of capability where applicable;



- c) A hard copy and/or an electronic copy of the certification body's quality manual and relevant associated documents and records, applicable to the scope of the surveillance assessment, and including any changes made since the previous assessment. The quality manual and associated documents and records must meet the requirements of *ISO/IEC Guide 65:1996*;
- d) An updated *ARC 1012A Checklist*;
- e) A current list of clients certified by the certification body covered under the scope of the surveillance assessment, including locations and products certified;
- f) Samples of brochures, advertisements, labels, or other publicly available documents describing the certification services offered;
- g) A copy of the most recent internal audit of the certification body's program;
- h) A copy of the most recent management review of the certification body's program;
- i) A copy of any corrective and preventative actions taken since the previous assessment; and
- j) A copy of any appeals, complaints, and disputes since the previous assessment.

15.3 Reassessments

15.3.1 Prior to the reassessment, the certification body must submit the following information relevant to the accreditation:

- a) A description of the conformity assessment services that the certification body undertakes;
- b) A list of standards, methods, or procedures for which the certification body seeks accreditation, including limits of capability where applicable;
- c) A hard copy and/or an electronic copy of the certification body's quality manual and relevant associated documents and records. The quality manual and associated documents and records must meet the requirements of *ISO/IEC Guide 65:1996*;
- d) An updated *ARC 1012A Checklist*;
- e) A current list of clients certified by the certification body covered under the scope of the reassessment, including locations and products certified;
- f) Samples of brochures, advertisements, labels, or other publicly available documents describing the certification services offered;
- g) A copy of the most recent internal audit of the certification body's program;
- h) A copy of the most recent management review of the certification body's program;
- i) A copy of any corrective and preventative actions taken since the previous assessment; and
- j) A copy of any appeals, complaints, and disputes since the previous assessment.