

## **USDA ISO/IEC 17065 Program Accreditation for Certification Bodies**

### **1 Purpose**

This document provides the requirements to be met in designing a USDA ISO/IEC 17065 Program. It also provides the requirements used for the objective evaluation of programs submitted for accreditation by the Agricultural Marketing Service (AMS), Livestock and Poultry Program, Quality Assessment Division (QAD).

The USDA ISO/IEC 17065 Program is a voluntary conformity assessment and accreditation service provided by the QAD under the Quality Systems Verification Programs. 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 certification for livestock, meat, seed, and other agricultural products or services.

### **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 17065:2012 – Conformity Assessment - Requirements for Bodies Certifying Products, Processes, and Services*

QAD 1000 Procedure: *Quality Systems Verification Programs, General Policies and Procedures*

QAD 1115 Procedure: *Program Review Committee*

QAD 1102 Procedure: *Selection of Audit Team Members*

QAD 1012 Certificate: *USDA ISO 17065 Program*

QAD 1012AA Checklist: *USDA ISO 17065 Program for Clients*

QAD 1012BB Checklist: *USDA ISO 17065 Program for Auditors*

GU7183CCA - *USDA ISO 17065 Program, Guidance on Requirements*

[USDA, AMS: Auditing and Accreditation website](#)

[USDA, AMS: ISO/IEC website](#)

[Official Listing of Certification Bodies Approved under the USDA ISO 17065 Program](#)

### **4 Definitions**

The following definitions apply to this document:

**4.1 Foreign Supplier:** a supplier who is located outside of the U.S. and its territories, whose products are certified under the USDA ISO/IEC 17065 Program.

**4.2 Key Activities:** policy formulation, process and/or procedure development, contract review, planning conformity assessments, review, approval, and decision on the results of conformity assessments.

**4.3 Supplier:** an entity that is separate from the certification body and is certified to a standard by the certification body. Types of suppliers include, but are not limited to:

- a) Crop producers
- b) Wild crop producers
- c) Livestock producers
- d) Processing/Handling operations

**4.4 Witness Audit:** the witnessing of the certification body's conformity assessment activities during an inspection of a supplier, including an examination of the inspector's preparation for the inspection and the implementation of the certification body's inspection procedures. The inspection of the supplier may be a demonstration when it is not possible to conduct an actual inspection.

## **5 Responsibilities**

**5.1** Certification bodies must meet all applicable policies, procedures, and requirements outlined in this document, ISO/IEC 17065:2012, and QAD 1000 Procedure.

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

**5.3** 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.

**5.4** Certification bodies must arrange witness audits when requested by the QAD.

**5.5** The QAD must meet all applicable policies, procedures, and requirements outlined in this document, QAD 1000 Procedure, and referenced documents, as applicable.

## **6 QAD Websites**

**6.1** The [USDA: Auditing and Accreditation website](#) provides information on all QAD audit and accreditation activities, including:

The [USDA: ISO/IEC website](#). This website provides information regarding the USDA ISO/IEC 17065 Program, including relevant documents and standards, guidance, and the Official Listing.

## **7 Accreditation Period**

**7.1** The accreditation period is a four-year period.

**1st 4-Yr Period**

**Subsequent 4-Yr Periods**

<b>Year 0</b>	<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>	<b>Year 4</b>	<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>	<b>Year 4</b>
Initial (\$11)	Surveillance. (\$12)	Update (\$13)	Surveillance (\$12)	Reassess (\$14)	Update (\$13)	Surveillance (\$12)	Update (\$13)	Reassess (\$14)

*\*Activities are further described in the Sections referenced.*

**8 Application for Service**

**8.1** By applying for service, the certification body agrees to meet the requirements outlined in this document, ISO/IEC 17065:2012, and QAD 1000 Procedure.

**8.2** Certification bodies must apply for service in accordance with the requirements outlined in QAD 1000 Procedure.

**8.3** 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 17065:2012;
- d) A completed QAD 1012 Checklist, if applicable;
- e) A current list of clients certified by the certification body covered under the scope of the assessment, including locations and products certified and standard if the certification body offers multiple certifications;
- 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 report 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.

**8.4** 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.

**9 Desk Audit**

**9.1** A desk audit (i.e. document review) is conducted prior to the initial assessment in accordance with the requirements for desk audits as outlined in QAD 1000 Procedure. The certification body may not request to forego this desk audit.

**9.2** A desk audit (i.e. document review) is also conducted prior to each surveillance assessment and reassessment to prepare for the assessment. The scope of the desk audit is based on the scope of the assessment.

## **10 Preliminary Visit**

**10.1** Prior to initial assessment, a preliminary visit may be conducted with the agreement of the certification body.

**10.2** This visit may result in the identification of deficiencies in the system of the applicant certification body or its competencies. These deficiencies must be adequately addressed before an initial assessment can be conducted.

**Note:** *The QAD does not consult and exercises due care to avoid consultancy during such a visit.*

## **11 Initial Assessment**

**11.1** Initial assessments are conducted in accordance with the requirements for on-site audits as outlined in QAD 1000 Procedure.

**11.2** Initial assessments include the entire quality management system, including associated documents and records, a review of certification files, and witness audits.

**11.3** In addition to visiting the main office, visits are made to all other premises of the certification body from which one or more key activities are performed and which are covered by the scope of accreditation.

## **12 Surveillance Assessments**

**12.1** Surveillance assessments are conducted in accordance with the requirements for on-site audits as outlined in QAD 1000 Procedure. The purpose of the surveillance assessment is to verify that the approved quality management system continues to be implemented, to consider the implications of changes to that system, and to confirm continued conformity to the requirements.

**12.2** Surveillance assessments are conducted during the four-year accreditation period as follows:

- a) After initial accreditation, the first surveillance assessment is conducted within 12 months of the initial accreditation date (Year 1).
- b) The second surveillance assessment is conducted during Year 3 of the first four-year accreditation period.
- c) During subsequent four-year accreditation periods, the surveillance assessment is conducted during Year 2.



- d) Additional surveillance assessments are conducted (1) if numerous non-conformances were identified during the previous assessment; (2) for failure to submit annual update reports; (3) as the result of complaints whose root cause is related to deficiencies in the certification body's quality system; (4) as the result of significant changes that have affected the certification body's operations at any time during the accreditation period; and/or (5) as directed by the QAD Branch Chief.

**12.3** In circumstances where the certification body operates a program spread across multiple offices, every effort is made to assess all offices from which key activities are conducted during the four-year accreditation period. The selection of offices is based on the following criteria:

- a) An obligatory visit to the main office;
- b) A selection of other offices based on the total number of offices with an effort to ensure that all offices are assessed during the four-year accreditation period; and
- c) Any additional office(s) deemed necessary by the QAD.

**12.4** A surveillance assessment includes, at least:

- a) A review of actions taken on non-conformances identified during the previous assessment;
- b) Review of any changes to the documented system;
- c) Effectiveness of the management system about achieving the objectives;
- d) Continuing operational control;
- e) Progress of planned activities aimed at continual improvement;
- f) Internal audits;
- g) Management reviews;
- h) Corrective and preventative actions;
- i) Appeals, complaints, and disputes;
- j) Use of marks and/or any other reference to approval;
- k) A review of the certification process, including applicable certification files; and
- l) Witness audits.

**12.5** The surveillance assessment may include other areas, as necessary, to verify conformance to the requirements.

**12.6** Prior to the surveillance assessment and upon the request of the QAD, the certification body must submit the following information relevant to the accreditation:

- a) 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 17065:2012*;
- b) An updated QAD 1012 Checklist, if applicable;
- c) Identification of major changes to the certification body's policies, procedures and protocols, since the most recent assessment or review;



- d) Changes in the certification body's information, since the most recent assessment or review;
- e) A copy of the most recent internal audit report;
- f) A copy of the most recent management review report;
- g) The number of complaints, appeals, and disputes, along with a copy of each, since the most recent assessment or review;
- h) A copy of corrective and preventative actions taken since the most recent assessment or review that are the result of management reviews, internal audits, complaints, or other means and related to the certification body's program;
- i) All reported misuses of logos received by the certification body, since the most recent assessment or review;
- j) All changes in the certification body certification personnel that are critical to the operation of its certification activities, since the most recent assessment or review;
- k) A current list of suppliers certified by the certification body covered under the scope of the surveillance assessment, including locations and products certified and standard if the certification body offers multiple certifications; and
- l) Samples of brochures, advertisements, labels, or other publicly available documents describing the certification services offered that reference accreditation by the USDA.

### **13 Annual Update Reviews**

**13.1** Annual update reviews are conducted during the four-year accreditation period as follows:

- a) During the first four-year accreditation period, and annual review is conducted during Year 2.
- b) During subsequent four-year accreditation periods, annual update reviews are conducted during Years 1 and 3.

**Note:** *A surveillance assessment may be conducted in lieu of an annual update review.*

**13.2** To facilitate the annual update review, the certification body must submit an annual update report upon the request of the QAD. The report must include the following:

- a) An updated QAD 1012 Checklist;
- b) Changes in the certification body's information, since the most recent assessment or review;
- c) Major changes to the certification body's policies, procedure and protocols, since the most recent assessment or review;
- d) A copy of the most recent internal audit report;
- e) A copy of the most recent management review report;
- f) The number of complaints, appeals, and disputes, along with a copy of each, since the most recent assessment or review;
- g) A copy of corrective and preventative actions taken since the most recent assessment or review that are the result of management reviews, internal audits, complaints, or other means and related to the certification body's program;
- h) All reported misuses of logos received by the certification body, since the most recent assessment or review;



- i) All changes in the certification body personnel that are critical to the operation of its certification activities, since the most recent assessment or review;
- j) The number of certified suppliers per type including location (state/country) and standard if the certification body offers multiple certifications.

## 14 Reassessments

**14.1** Reassessments are conducted in accordance with the requirements for initial assessments as outlined above in Section 11, except for Section 11.3. Instead, the selection of offices is in accordance with Section 12.3.

**14.2** Reassessments are conducted during Year 4 of the four-year accreditation period. Reassessments should be conducted prior to the expiration date; however, an extension of the accreditation period may be granted to allow for the timely conduct of the reassessment.

**14.3** Prior to the reassessment and upon the request of the QAD, the certification body must submit the following information relevant to the accreditation:

- a) 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 17065:2012*;
- b) An updated QAD 1012 Checklist, if applicable;
- c) Identification of major changes to the certification body's policies, procedures and protocols, since the most recent assessment or review;
- d) Changes in the certification body's information, since the most recent assessment or review;
- e) A copy of the most recent internal audit report;
- f) A copy of the most recent management review report;
- g) The number of complaints, appeals, and disputes, along with a copy of each, since the most recent assessment or review;
- h) A copy of corrective and preventative actions taken since the most recent assessment or review that are the result of management reviews, internal audits, complaints, or other means and related to the certification body's program;
- i) All reported misuses of logos received by the certification body, since the most recent assessment or review;
- j) All changes in the certification body certification personnel that are critical to the operation of its certification activities, since the most recent assessment or review;
- k) A current list of suppliers certified by the certification body covered under the scope of the reassessment, including locations and products certified and standard if the certification body offers multiple certifications; and
- l) Samples of brochures, advertisements, labels, or other publicly available documents describing the certification services offered that reference accreditation by the USDA.

## 15 Witness Audit

**15.1** Witness audits are conducted throughout the four-year accreditation period. They are normally conducted in conjunction with an assessment but may be conducted independent of one. The witness audit provides a means of verifying that the accredited certification body is satisfactorily implementing its procedures.

**15.2** Enough witness audits are conducted to ensure that sufficient objective information is collected to verify that documented procedures are implemented and effective. A representative sample of suppliers, including foreign suppliers if applicable, is selected to ensure proper evaluation of the certification body's competence. The number of witness audits is based on the following criteria:

**15.2.1** During initial assessments and reassessments, a minimum of one witness audit for each type of supplier per standard is conducted. One supplier may be witnessed for multiple standards.

**15.2.2** During surveillance assessments, a minimum of three witness audits are conducted. If only two types of suppliers are certified by the client, then a minimum of one witness audit may be conducted. Additional witness audits may be conducted based on the findings of certification file reviews, non-conformances identified during the previous assessment or annual update review, the number of suppliers certified considering the types and standards, complaints received, or as directed by the QAD.

**NOTE:** *Witness audits may be conducted throughout Years 2 and 3 rather than all for one year.*

## **16 Review of Certification Files**

**16.1** Certification files are reviewed during the four-year accreditation period. They are normally reviewed in conjunction with an assessment but may be conducted independent of one. The review of certification files ensures that:

- a) The documentation found in a case file is complete and up to date;
- b) The evaluation methods are sufficient to ensure evaluation of suppliers against all standards applicable to their operations;
- c) The inspection reports include a sufficient quantity of information elements needed to make a certification decision;
- d) The decision made is congruous with the evaluation of the production/preparation plan as submitted by the operator and the report resulting from inspection visits to operations sites;
- e) The certification body has monitored the implementation of all necessary corrective measures that it requested from each operator having products certified; and
- f) The certification body is operating in accordance with the relevant sections of *ISO/IEC 17065*.

**16.2** Enough certification files are reviewed to ensure that sufficient objective information is collected to verify that documented procedures are implemented, and program requirements are met. The typical quantity and selection of certification files reviewed during initial and reassessments is based on the criteria in the following table:



<b>Number of Certified Suppliers</b>	<b>Number of Files Reviewed*</b>
100 or less	Between 7 and 10 files, 6 of which must be full reviews
101 - 240	Between 10 and 12 files, 10 of which must be full reviews
241 - 400	Between 12 and 15 files, 10 of which must be full reviews
401 - 1000	Between 15 and 20 files, 10 of which must be full reviews
More than 1000	Between 20 and 25 files, 10 of which must be full reviews

*\*In cases where the certification body certifies to multiple standards, a representative sample of files for all standards is selected to ensure proper evaluation of the certification body's competence. One file may be reviewed for multiple standards. In cases where the certification body certifies foreign suppliers, if the reviewed files do not include at least one foreign supplier per type, then additional files of foreign suppliers for that type is selected and a full review is conducted.*

**16.3** The typical quantity and selection of certification files reviewed during surveillance assessments is based on the criteria in the following table:

<b>Number of Certified Suppliers</b>	<b>Number of Files Reviewed*</b>
100 or less	Between 5 and 7 files, 5 of which must be full reviews
101 - 240	Between 7 and 10 files, 6 of which must be full reviews
241 - 400	Between 10 and 12 files, 6 of which must be full reviews
401 - 1000	Between 12 and 15 files, 6 of which must be full reviews
More than 1000	Between 15 and 20 files, 6 of which must be full reviews

*\*In cases where the certification body certifies to multiple standards, a representative sample of files for all standards is selected to ensure proper evaluation of the certification body's competence. One file may be reviewed for multiple standards. In cases where the certification body certifies foreign suppliers, if the reviewed files do not include at least one foreign supplier per type, then additional files of foreign suppliers for that type is selected and a full review is conducted.*

## **17 Extension of Scope**

**17.1** Assessments for extension of certification scope requests are conducted in accordance with the requirements for initial assessments as outlined above in Section 11. The scope of these assessments is limited to the extension request.

**17.2** The certification body must submit the following information relevant to an extension of scope request:

- a) A description of the extension of scope request;
- b) A list of new 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 relevant associated documents that were updated to address the extension of scope;

- d) Evaluation documents used for reviews and inspections;
- e) A list of additional locations and the activities conducted at the locations;
- f) A list of new certification body personnel, including committees, their qualifications and responsibilities;
- g) Records of training and qualifications for current certification body personnel, including committees, involved in activities related to the extension of scope request, including reviews, inspections, and decision making; and
- h) Samples of brochures, advertisements, labels, or other publicly available documents describing the new service offered that reference accreditation by the USDA.

## **18 USDA National Organic Program**

**18.1** Certification bodies may request accreditation to the USDA National Organic Program (NOP) production standards under the USDA ISO/IEC 17065 Program. Accreditation to these standards is contingent upon the certification body being in good standing as an USDA NOP accredited certifying agent. If the USDA NOP suspends or revokes a certification body's accreditation for any reason, then the QAD will also suspend or withdraw the certification body's accreditation specific to the NOP production standards. Certification bodies may remain accredited to other Standards.

**18.2** The QAD notifies the USDA NOP of any non-compliance to the NOP regulation that is found during USDA ISO 17065 Program assessment. This includes any non-compliance that may be identified even though outside the scope of the USDA ISO 17065 Program. In addition, the QAD also notifies the USDA NOP of the results of any corrective action audits specific to the NOP regulation. The USDA NOP may choose to take separate action based upon the information provided by the QAD.

**18.3** The QAD notifies the USDA NOP when a certification body's accreditation under the USDA ISO 17065 Program is suspended or withdrawn as the result of a non-compliance to the NOP regulation.

## **19 Program Review Committee**

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

- a) Applications for service and extension of scope requests are reviewed by a Program Review Committee. The purpose of the review is to determine the QAD's capabilities to conduct the assessment by evaluating the QAD's own policies and the availability of suitable auditors and experts with the appropriate competence to perform the assessment in a timely manner.



- b) The Program Review Committee reviews the results of initial assessments, reassessments, and extension of scope requests.
- c) A Program Review Committee reviews the results of surveillance assessments, annual update reviews, and independent witness audits only when program suspension or withdrawal may be necessary.

## **20 Listing of Accredited Programs and Programs Under Review**

**20.1** The QAD provides public information about the current status of accreditation of applicant certification bodies and accredited certification bodies in the *Official Listing of Certification Bodies Approved under the USDA ISO 17065 Program*. In addition, the QAD uses the Official Listing to solicit comments regarding the certification bodies' performance and conformance to relevant standards.

**20.2** The Official Listing is maintained on the USDA, AMS: ISO/IEC website and contains information including:

- a) Certification body's name;
- b) Certification body's address;
- c) Certification body's contact information including telephone number, fax number, and email address when available;
- d) Standards applied;
- e) Scope of accreditation;
- f) Countries of operation;
- g) Certificate number, as applicable;
- h) Issue date and renewal date related to the current accreditation period; and
- i) Original accreditation date.

**20.3** In addition, the Official Listing will also contain the following information if applicable:

- 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 withdrawal are no longer certified. No additional products may be certified."
- d) If the certification body has requested to cancel service, the following 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 next surveillance assessment or reassessment was to occur.

## 21 Certificate of Conformance

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

- a) Identity and logo of the QAD;
- 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) Issue date and renewal 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.

**Note:** *Individual certificates for different standards may be issued.*

**21.2** Certificates are valid for up to four years and may be renewed provided systems are maintained as described in program documentation and subsequent assessments provide objective evidence of ongoing conformance. An extension of the accreditation period may be granted to allow for the timely conduct of the reassessment.

**21.3** Companies that are withdrawn from the USDA ISO/IEC 17065 Program or cancel service must discontinue using the *Certificate of Conformance*.

## 22 References to Official Certificates and Accreditation

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

**Note:** *Acceptable references may include, for example, "[Certification body's] product certifications are accredited under ISO/IEC 17065:2012 by the U.S. Department of Agriculture."*

**22.2** References must be complete and not misleading or ambiguous.

**22.3** References must not imply that a product, process, system, or person is approved by the QAD.

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

**22.5** If a certification body continuously makes erroneous references, the QAD shall not allow the certification body to make any references until such time that the QAD is assured that references will be accurate.



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