



Product Certification Accreditation

**2018 Peer Review Executive Summary**

**For**

**United States Department of Agriculture  
Agricultural Marketing Service  
National Organic Program**

**Dates of Review Panel:  
May 15 – May 17, 2018**

Prepared by

American National Standards Institute  
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## I. GENERAL INFORMATION

### Accreditation Body

Name of Reviewed Body

**United States Department of Agriculture  
Agricultural Marketing Services (AMS)  
National Organic Program**

Address

**1400 Independence Avenue SW,  
Room 2648 South Building  
Washington, DC 20250**

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**202-720-3252**

### Review

Type of Process

**On-site Assessment Peer Review**

On-site Review Dates

**May 15 to May 17, 2018**

Review Standard(s)

*ISO/IEC 17011:2004 Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*  
US 7 CFR Part 205, National Organic Program  
*ISO/IEC 17011:2017 Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*

### Review Team

Lead Reviewer:

**Mario Llerenas**

Co-Lead Reviewer:

**Susan Cadorette**

Technical Reviewer:

**Jean Richardson**

ANSI Observer(s)

**Reinaldo Figueiredo, ANSI Senior Program Director  
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Submitted to USDA on:

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## II. INTRODUCTION

The National Organic Program (NOP) is part of the Agricultural Marketing Service (AMS), U.S. Department of Agriculture (USDA), and is the organization responsible for activities relating to the development, implementation, and administration in accordance with the Organic Foods Production Act of 1990 (OFPA) and the USDA organic regulations. Key functions of the NOP include:

- Developing, reviewing, implementing, and interpreting the organic standards
- Enforcing organic production, handling, and labeling standards
- Accrediting, auditing, and training third-party organic certifying agents

The NOP established a peer review panel to satisfy internal requirements regarding adherence to internal and regulatory requirements. American National Standards Institute (ANSI) has convened this panel effective February 8, 2018 to fulfill the expectation of this requirement.

This Peer Review was conducted pursuant to 7 CFR 205.509, Peer Review Panel, of the USDA Organic Regulations. This Peer Review follows a procedure outlined in NOP 1031, and Peer Review of the National Organic Program (NOP).

The panel was tasked with the following:

- evaluate the NOP's policies, processes, and procedures for conformance to NOP regulations and ISO/IEC 17011 version 2004 and 2017;
- review implementation of certification body accreditation processes through selected review of five files: and
- report the peer review panel findings in writing to the NOP Deputy Administrator and the National Organic Standards Board.

## III. PURPOSE OF THE PEER REVIEW

Accreditation is the independent evaluation of conformity assessment bodies against recognized standards to ensure their impartiality and competence. Through the application of national and international standards, government, purchasers, and consumers can have confidence in the certifications provided. Accreditation bodies are established in many countries with the primary purpose of ensuring that conformity assessment bodies are subject to oversight by an authoritative body.

Accreditation bodies are evaluated by peers in order to reduce trade barriers and demonstrate the competence of the accreditation body operations. Accreditation reduces risk for business and its customers by assuring that accredited Conformity Assessment Bodies (CABs) are competent to carry out the work they undertake within their scope of accreditation. The purpose of the peer evaluation is to provide confidence in the operation of the accreditation process, thus providing acceptance in the market place of the conformity assessment outcome.

## IV. SUMMARY

The report covers NOP's compliance with ISO/IEC 17011 and review of NOP's accreditation procedures and decisions. The Review Panel members find that NOP and its staff are in general compliance with ISO/IEC 17011 and NOP's own policies and procedures. During the 2018 on-site peer review, the ANSI team identified 10 OFIs, and two recommendations. The following are the 2018 OFIs identified by the 2018 Peer Review Panel, which are recorded with objective evidence in ANSICA:

- **2018-USDA NOP-01-O-LLEM-(17011 v. 2004) 4.2.8** *The accreditation body shall document its entire structure, showing lines of authority and responsibility.*

The NOP Organizational Chart does not show the Quality Manager position.

**Evidence:** The Organizational Chart does not include a Quality Manager. However, there are several references in the procedures for the responsibilities of the Quality Manager. For example: 1) NOP 1030 Internal Audit Procedure Rev 04 clause 2.1: The Quality Manager schedules... 2) NOP 1000 clause 4.3 Management System: The Quality Manager is designated as the responsible member.

- **2018-USDA NOP-02-O-LLEM-(17011 v.2004) 4.3.7** *The accreditation body, with the participation of the interested parties as described in 4.3.2, shall identify, analyze and document the relationships with related bodies to determine the potential for conflict of interest, whether they arise from within the accreditation body or from the activities of the related bodies. Where conflicts are identified, appropriate action shall be taken.*

There is no documentation for the relationships between the NOP and related bodies; and no evidence of the participation of the interested parties.

**Evidence:** The identification and analysis of the relationship with related bodies to determine the potential conflict of interest is not documented. As well, there is no evidence of the participation of the interested parties in the identification and analysis (NOP does not have an Impartiality Committee).

- **2018-USDA NOP-03-O- ricj-(ISO 17011 v. 2004) 6.1.2** *The accreditation body shall have access to a sufficient number of assessors, including lead assessors, and experts to cover all of its activities.*

The NOP does not have a sufficient number of auditors.

**Evidence:** The number of certifiers accredited by the NOP has increased in recent years. In 2018 there are 81 CABs, plus 12 new CAB applications, and 54 Satellite Offices, making a total of 147 entities which require regular audits. There are seven auditors, of whom one is full time, and two are subcontracted from the USDA's Quality Assessment Division (QAD). NOP 2000, *Instruction - Accreditation Policies and Procedures* indicates that the total number of auditors and days for on-site renewal and mid-term assessment are established based on the total number of producers and scopes for each CAB. Many CABs are very large, with satellite offices in several countries. The number of NOP auditors is inadequate to provide regular assessments, prevent potential fraud, and minimize risk in a timely manner.

- **2018-USDA NOP-05-O- ricj-(ISO 17011 v. 2004) 7.5.7.** *For initial assessments, in addition to visiting the main or head office, visits shall be made to all other premises of the CAB from which one or more key activities are performed and which are covered by the scope of accreditation.*

Satellite offices of certifiers, especially international locations, are not audited on a frequent enough basis to reduce risk and prevent potential fraud.

**Evidence:** File review indicates that some certifiers have many additional satellite offices in numerous countries, and these numbers are increasing each year. NOP 2000 requires that all CAB must have both a mid-term and five-year site visit with witness audits, although Section 7 of NOP 2000 indicates that witness audits are not conducted for every satellite office with each assessment. Section 7 states: “A site visit and on-site visit will ultimately take place”. NOP Lead Auditor prepared a five-year plan to conduct audits of satellite offices, but at least two large CABs have over 20 satellite offices in several countries, which will result in increased risk if they are not more regularly audited, including witness audits.

A risk-based approach to identify and prevent fraud suggests that some satellite offices could apply to become a separate CAB, and that an additional number of auditors are needed to conduct regular audits of the growing number of satellite offices.

Fraud prevention could be addressed by conducting a number of audits, both unannounced and regular audits, in a specific geographic area where risk has been identified, such as Eastern European countries, or Texas/California. See also OFI above for 6.1.2 for additional full-time NOP Auditors.

- **2018-USDA NOP-06-O- ricj-(ISO 17011 v. 2004) 7.7.2.** *The assessment team shall conduct the assessment of the conformity assessment services of the CAB at the premises of the CAB from which one or more key activities are performed and, where relevant, shall perform witnessing at other selected locations where the CAB operates, to gather objective evidence that the applicable scope the CAB is competent and conforms to the relevant standard(s) and other requirements for accreditation.*  
**7 CFR §205.670** *Inspection and testing of agricultural products to be sold or labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).”*

Procedures for residue sampling are not clearly understood or followed by international CAB and satellite offices.

**Evidence:** All certifiers are required to conduct at least 5% residue sampling (205.670(d)). NOP 2613 *Responding to Results from Pesticide Residue Testing* does not address the full range of potential residues or drift, and is not written in manner which is readily understood or appropriately interpreted by foreign certification bodies and foreign satellite offices. This increases the potential for fraud. A risk-based review of procedures related to residue and other sampling should be implemented.

- **2018-USDA NOP-08-O- ricj-(ISO 17011 v. 2004) 6.1.1.** *The accreditation body shall have a sufficient number of competent personnel (internal, external, temporary, or permanent, full time or part-time) having the education, training, technical knowledge, skills and experience necessary for handling the type, range and volume of work performed.*

There is insufficient NOP personnel to handle the number of complaints and enforcement actions required of the C&E division.

**Evidence:** There were 349 complaints received by the NOP between May 2017 and 2018. The trend is

an increase in complaints and a need for enforcement. There are presently 11 NOP staff in C&E which is an inadequate number to address, in a timely manner, the increased need for investigations, fraud prevention, and enforcement activities. A Quality Manager may help streamline complaint handling.

- **2018-USDA NOP-09-O-CADS-(17011 v.2004) 5.2.1** *The accreditation body's top management shall define and document policies and objectives, including a quality policy, for its activities, and it shall provide evidence of commitment to quality and to compliance with the requirements of this International standard. The management shall ensure effective communication of the needs of interested parties. The management shall also ensure that the policies are understood, implemented and maintained at all levels of the accreditation body. The objectives should be measurable and shall be consistent with the accreditation body's policies.*

NOP should establish stronger quantitative objectives and key performance indicators for effective measurement and monitoring to achieve the Administration's goals.

**Evidence:** The NOP Strategic Plan for 2015-2018 lists four key performance measures; however, only two are currently regularly tracked, and there are new measures that are tracked that were not defined in the plan. Key performance measures change over time as Administration priorities shift.

- **2018-USDA NOP-10-O-CADS-(17011) 5.3** *The accreditation body shall establish procedures to control all documents (internal and external) that relate to its accreditation activities. The procedures shall define the controls needed.*

Several documents were found to be out of compliance with the document control procedure.

**Evidence:** NOP 1010 does not describe control of external documents in accordance with copyright laws as currently practiced by NOP management. NOP 1010 does not specify which types of documents must be forwarded by the program to Office of General Counsel for comment.

The NOP Records Plan and Disposition Schedule is still awaiting approval and formalized entry into the NOP management system. In the meantime, the records plan is being implemented in the program, except for the disposition schedule. All records are being retained; the disposition schedule will take effect when the procedure is approved.

The Master List NOP 1006 was not updated when NOP 4001 was reinstated and approved. NOP 4001-1, 4001-2 and 4001-3 have been archived but are still referenced in NOP 4001. According to management, new staff have not been fully trained on the document control process. C&E Internal Procedure "Complaints Regarding the National Organic Program's Accreditation Activities and Accredited Certifying Agents" effective 7/1/2015 is not traceable to the management system. Also refer to OFI #1 regarding Quality Manager.

- **2018-USDA NOP-11-O-CADS-(17011) 7.9.4** *The accreditation body shall provide an accreditation certificate to the accredited CAB. This accreditation certificate shall identify (on the front page, if possible) the following:*
  - *the unique identity of the accredited CAB;*
  - *all premises from which one or more key activities are performed and which are covered by the accreditation;*

The accreditation certificate does not identify all premises from which one or more key activities are performed and covered by the accreditation and the physical addresses associated with the certification body.

**Evidence:**

Organic Integrity Database:

- Satellite offices and their locations are not listed on the certificate.
- P.O. Box number is identified for the certifier rather than a physical address.
- **2018-USDA NOP-12-O-CADS-(17011) 8.3.2** *The accreditation body shall take effective measures to ensure that the accredited CAB*
  - a) *fully conforms with the requirements of the accreditation body for claiming accreditation status, when making reference to its accreditation in communication media such as the Internet, documents, brochures, or advertising,*
  - b) *only uses the accreditation symbols for premises of the CAB that are specifically included in the accreditation,*
  - c) *does not make any statement regarding its accreditation that the accreditation body may consider misleading or unauthorized,*
  - d) *takes due care that no report or certificate nor any part thereof is used in a misleading manner,*
  - e) *upon suspension or withdrawal of its accreditation (however determined), discontinues its use of all advertising matter that contains any reference to an accredited status, and*
  - f) *does not allow the fact of its accreditation to be used to imply that a product, process, system or person is approved by the accreditation body.*

There is an opportunity for NOP to provide further protections for its USDA Organic seal

**Evidence:** The use of the USDA Organic seal is prescribed by CFR 7 §205.311. NOP 200A February 2014 The Terms of Accreditation identify the contractual requirements for accreditation. It does not contain specific terms describing the obligations of the certification body to use the seal only as allowed by the regulations. NOP does not have a separate license agreement for the use of the seal.

Although probability of misuse is currently low and NOP has legal control of the use of the seal, and the impact of misuse and fraud of the seal represents a potential for risk. Additional measures, such as to add provisions in the existing terms of agreement could increase awareness with certification bodies of their obligations and further protect the NOP.

**Recommendation 1:**

Given the changing organic marketplace and increased complexities, it is recommended that the NOP provide additional training opportunities to NOP staff and auditors, specifically in the areas of risk assessment and investigative methods for fraud prevention. A Training Manager could ensure greater consistency, frequency, and depth of training for auditors.

**Recommendation 2:**

Training Manager position at the NOP could develop and provide NOP webinars for CAB staff and inspectors worldwide so everyone has easy access to a consistent source of educational training via the NOP. Certifier audit trail exercises do not always provide adequate detail to verify and fully document the audit trail including full supply chain. Certification bodies generate inspection /checklists for inspectors to use, and these checklists vary considerably between certifiers. For example, some inspector checklists may not prompt an inspector to conduct a mass balance over a specific time period, or a conduct a audit trail exercise with enough detail to verify full traceability of all locations in a supply chain. As a result, the inspector may not provide adequate information for the certifier.

----- **END OF REPORT** -----