



Product Certification Accreditation

**2017 Peer Evaluation Panel
Executive Summary**

For

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

1400 Independence Avenue, SW Room 2642 (Stop 0268)
Washington, DC 20250 USA

**Dates of Review Panel:
April 20 – June 30, 2017**

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I. GENERAL INFORMATION

Name of Reviewed Body United States Department of Agriculture
Agricultural Marketing Service (AMS)
National Organic Program

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Room 2642 (Stop 0268)
Washington, DC 20250

Telephone 202-720-3252

Type of Review Remote Peer Review Panel Evaluation

Review Dates April 20 to June 30, 2017

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

Peer Review Panel

Marlene Moore - Lead Evaluator, ISO/IEC 17011 PAC evaluator, past lead evaluator, NOP program, and ANSI/ANAB lead assessor for ISO/IEC 17065, 17025, 17043

Jean Richardson - Professor Emerita, University of Vermont, independent organic inspector, and Law Clerkship, Member NOSB (term expires: Jan 2017)

Susan Ranck, IOIA-qualified organic inspector, Institute of Food Technologists Certified Food Scientist, ANSI technical assessor

Elizabeth Okutuga, Program Coordinator, ANSI staff, ISO/IEC 17011 process knowledge and project coordinator

Reinaldo Balbino Figueiredo, Senior Program Director, ANSI staff, ISO/IEC 17011 evaluator. Contract/Project Manager

Report Prepared by: Marlene Moore
Susan Ranck
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Submitted to ANSI: August 9, 2017 (NOP review completed August 31)

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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; and
- accrediting, auditing, and training third-party organic certifying agents.

Program and Scope of Accreditation

The NOP is establishing a peer review panel to satisfy internal requirements regarding adherence to internal and regulatory requirements. The American National Standards Institute (ANSI) has convened this panel, effective April 20, 2017, to fulfill the expectation of this requirement. The peer review panel is tasked to:

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

The panel is reporting its findings in writing to the NOP Deputy Administrator and the National Organic Standards Board. The findings shall be considered part of the NOP management system.

III. PURPOSE OF PEER REVIEW PANEL

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 purpose of ensuring that an authoritative body oversees conformity assessment bodies.

Peers evaluate accreditation bodies to reduce trade barriers and demonstrate the competence of accreditation body operations. Accreditation reduces risks for businesses and their customers by assuring that accredited Conformity Assessment Bodies (CABs) are competent to carry out the work they undertake within their scope of accreditation. The peer panel evaluation provides confidence in the operation of the accreditation process and acceptance of the conformity assessment outcome in the market place.

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IV. EXECUTIVE SUMMARY

The Peer Review Panel Evaluation Report details the NOP's compliance with ISO/IEC 17011:2004 and the review of NOP's accreditation procedures and decisions. The report is presented separately from this Executive Summary.

The Peer Review Panel members find that NOP and its staff are in general compliance with ISO/IEC 17011 and NOP policies and procedures. Opportunities for Improvement have been identified and are detailed in the ensuing Peer Review Panel Evaluation Report and in ANSI's Conformity Assessment portal, ANSICA. The Opportunities for Improvement (OFIs) for 2016 were reviewed and are implemented for most of the items identified.

The Opportunities for Improvement (OFIs) for 2017 include:

- **2017-USDA NOP-01-O-MOOM-(17011)5.5:** The records do not indicate that the corrective action procedure is implemented.
Evidence: The form, NOP 1020-2, is no longer an active document. This document includes all the required elements of the procedure. The OFIs from the 2016 ANSI review are not listed. A few of the OFIs were submitted with a response but it is unclear if all were part of the planning. The Internal Audit from 2016 had seven findings and the corrective actions do not appear tracked as NOP 1020 states.
- **2017-USDA NOP-02-O-MOOM-(17011)5.6:** The 2016 OFIs are not listed on form 1020-2 as required by the procedure, NOP 1020. The status of implementation of the actions taken and a review of the effectiveness are not recorded as defined by the procedure.
Evidence: The Preventive Action system indicates Opportunities for Improvement are handled as defined in NOP 1020. The form NOP 1020-2 is no longer an active document. The Operating Plan document was cited as the replacement. The Operating Plan does not include the specific details cited in this clause (5.6). The plan does not include a record of the actions taken and the effectiveness of the actions.
- **2017-USDA NOP-04-O-RANS-(17011)7.2.3:** The accreditation body did not complete the review section of the application.
Evidence: There is an area of the application itself to indicate USDA review. This section was not completed for any of the files reviewed. The application review is documented on the NOP 2005 Checklist.
- **2017-USDA NOP-05-O-RANS-(17011)7.5.6:** The accreditation body did not provide evidence for determination of the number or geographic location(s) for audit(s) of satellite offices associated with a certification body. (As an example of previous evidence provided, NOP 2000 section 6.3, Section 8 was referred to by the NOP staff during the closing meeting.)
Evidence: There was no documented sampling procedure provided for instances of multiple offices (satellites of the certifier) working under the accreditation of one CAB. None of the files selected for review had satellite offices.

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- **2017-USDA NOP-06-O-RANS-(17011)7.9.4:** The accreditation body certificate does not meet requirements for: c) all premises from which one or more key activities are performed and which are covered by the accreditation; e) the effective date of granting of accreditation and, as applicable, the expiry date; g) a statement of conformity and a reference to the standard(s) or other normative document(s), including issue or revision used for assessment of the CAB.

Evidence: The full address of the certification body does not appear on the certificates. The certificate listed a date earlier than the decision. Accreditation body is using the statement 'as amended' to indicate current version of the 7 CFR 205. This does not meet the standard requirement of the date of issuance of the standard.

- **2017-USDA NOP-08-O-RANS-(17011)7.14.1:** The accreditation body did not consistently ensure records were sufficient to exhibit accreditation activities were completed as required.

Evidence: Isolated instances of incorrect or incomplete records were observed (Proposed Corrective Action not dated or signed; LPS 109 not signed by applicant; inconsistency in completion of NOP 2005 indicating activities completed via check mark (some auditors check boxes; others do not.).

Some files contain application versions other than those cited in NOP 2000. NOP 2000 Section 4.1 requires that forms, TM-10CG Application for Accreditation and LPS-109 Application for Service, be submitted for both initial and renewal applications.

- **2017-USDA NOP-09-O-MOOM-(17011)5.2.2:** Certifiers' corrective action submittal does not ensure that the implementation is completed in a timely manner.

Evidence: The evidence received for corrective action implementation is insufficient to ensure the non-conformance can be closed at the next visit. The number of non-conformities that are not cleared at subsequent visits for the files reviewed demonstrated the need for more frequent assessments or more timely submittals.

- **2017-USDA NOP-10-O-MOOM-(17011)7.11.3:** The AB performed surveillance on-site assessments that exceeded two years.

Evidence: The procedure, NOP2000 Table 1, indicates surveillance is performed within 24 - 36 months of the renewal assessment. ISO/IEC 17011 recommends a surveillance within one year of accreditation and for two years between assessments. The NOP lacks resources to perform on-site assessments to meet this recommendation. More frequent on-site visits will ensure the clearing of corrective actions.

END EXECUTIVE SUMMARY.