A critical part of the National Organic Program's (NOP) mission is to accredit and oversee the work of third party accredited certifying agents (certifiers). The USDA organic regulations and NOP's quality system requires periodic peer reviews to assess NOP's accreditation program and to see how well it aligns with the requirements of ISO/IEC 17011 (which describes standards for accreditation programs).

In 2014, the NOP contracted with the American National Standards Institute (ANSI) to conduct its peer review. ANSI reviewed all phases of NOP accreditation from initial application through final decision, NOP's ongoing surveillance and renewal activities, and management system. ANSI's onsite review included: reviewing public and internal documents, interviewing personnel, reviewing certifying agent and auditor records, and reviewing NOP's management system.

#### **Opportunities for Improvement**

The 2014 ANSI peer review identified 14 opportunities for improvement, which included evidence that some NOP procedures need revisions or do not exist. As a result, the NOP will be taking the actions listed below.

- The NOP will ensure that the qualification for personnel performing internal audits includes knowledge in ISO/IEC 17011 and auditing skills per ISO 19011. In August 2014, several new and current staff members underwent a three-day training on the international standards governing the NOP's accreditation process.
- The NOP is committed to maintaining impartiality by both staff members and certifiers, and will continue to address its importance in its policy documents.
- The NOP will schedule an internal audit pursuant to current NOP policies and procedures.
- The NOP will continue to improve its quality management system by updating and revising its internal and external procedural documents to accurately reflect the NOP's policies and procedures.

- The NOP's internal procedures will specify a timeframe for updating all internal and external documents.
- The NOP is continually improving its quality management system, and will continue to review the system to remove outdated documents and determine when document revisions are necessary.
- The NOP has developed a procedure for record retention and file disposition, but has been seeking AMS approval for the last year. In the meantime, the NOP follows National Archives and Records Administration (NARA) record retention policies, but will continue to work on finalizing its own procedure.
- The NOP will revise its Terms of Accreditation to require certifiers to notify the NOP of any changes to scope or other activities that would affect their accreditation.
- The NOP will revise its procedures to identify which NOP personnel are responsible for reviewing applications for accreditation.
- The NOP is developing a procedure for extending its activities.
- The NOP will develop a procedure for addressing complaints related to the NOP's operations and what actions are needed when the complaint requires the NOP to make changes.
- The NOP will revise its procedures to clarify the steps to be performed to extend a certifier's scope of accreditation.
- The NOP will revise its procedures to clarify which NOP Division is responsible for actions related to suspension, withdrawal and reduction of accreditation when the decision is made by the Accreditation and International Activvities (AIA) Division.
- The NOP is revising its procedures to clarify renewal assessment processes. AIA staff will be trained on this procedure at a future AIA staff meeting.

Peer reviews evaluate NOP's accreditation process and provide information for continual improvement to the NOP accreditation system. We look forward to reporting our progress on the activities above, and thank ANSI for its work on this peer review project.

ANSI's Executive Summary is on the following pages.... Full Peer Review Report at: http://www.ams.usda.gov/NOP Look for Link: "About Us + Reports"



Product Certification Accreditation

# 2014 Peer Review Executive Summary FOR NOP REVIEW

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

1400 Independence Avenue, NW Room 2646 South Building Washington DC 202 50 USA

Dates of the on-site Peer Review: May 12-15, 2014

Prepared by

American National Standards Institute 1899 L Street, 11<sup>th</sup> Floor Washington, DC 20036

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## **II. GENERAL INFORMATION ON THE PEER REVIEW**

Accreditation Body Name of the Accreditation Body	United States Department of Agriculture Agricultural Marketing Service (AMS), National Organic Program (NOP)		
Address	1400 Independence Avenue SW Room 2646-South Building, Washington DC 20250		
Peer Review			
Type of Process	On-site Peer Review Visit		
Dates	May 12 – 15, 2014		
Peer Review Standard(s)	ISO/IEC 17011:2004Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies, US 7 CFR Part 205, National Organic Program		
Evaluation Team			
Team Members	Lead Evaluator: Marlene Moore		
Observer:	Technical Assessor: Gary Sherlaw ANSI Senior Program		
	Director: Reinaldo Figueiredo		
Desument Deview Dement			
Document Review Report Prepared by	ANSI Assessment Team		
Revised and Resubmitted:	August 26, 2014		

### **III. INTRODUCTION**

The scope of this Peer Review includes activities related to NOP's accreditation and oversight of certifying agents (conformity assessment bodies – CABs). There are approximately ninety (90) certifying agents accredited by the National Organic Program. The U.S. Department of Agriculture National Organic Program carries out activities relating to the development, implementation, and administration of the USDA organic regulations.

The location of the peer evaluation review was the NOP office in Washington, DC and included remote interviews with field locations as necessary to conduct the peer review. The witness assessments were completed in June 2014 as part of the ANSI Peer Review process.

The NOP also performs additional activities under the NOP Regulation that are outside the scope of the ISO/IEC 17011 accreditation process. These include:

- Developing and maintaining the USDA organic standards
- Investigating complaints and regulatory violations
- Managing the National Organic Standards Board, a citizen advisory committee
- Administering organic cost share programs, export certification, recognition agreements, equivalency agreements, and State Organic Program reviews

Processes to be reviewed include: all phases of NOP accreditation from initial application through final decision; ongoing surveillance and renewal and operation of a management system in conformance to ISO/IEC 17011. Key activities of the onsite review included: review of documents available to the public and internal operation personnel; records review of certifying agents and auditors, interviews with staff and demonstration of implementation of the management system.

The NOP requested ANSI to review the outcome of the National Institute of Standards and Technology – National Voluntary Conformity Assessment Evaluation Program (NIST/NVCASE) document review performed and reported in 2011. See the Appendix 1 to this report for the outcome of this review.

#### **Program and Scopes of Accreditation**

The United States Department of Agriculture (USDA), Marketing and Regulatory Program (MRP), Agricultural Marketing Service (AMS) administers the general policies and procedures for certifying agents (CA) seeking accreditation to the National Organic Program Regulations.

The National Organic Program (NOP) accredits certifying agents under the authority of the Organic Foods Production Act of 1990, as amended (7 U.S.C 6501 et seq), as described in the Code of Federal Regulation Title 7, Part 205 NOP Regulations. NOP Regulations assign the Agricultural Marketing Service (AMS) Administrator the responsibility for execution of the National Organic Program. The AMS Administrator delegated certain responsibilities as described in the NOP Regulations and the procedure NOP 2000 Accreditation Procedures Rev 07. The Regulations, NOP Handbook and other information are available to the public on the NOP website: <a href="http://www.ams.usda.gov/AMSv1.0/nop">http://www.ams.usda.gov/AMSv1.0/nop</a>.

### **IV. 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.

The methodology used by ANSI during this Peer Assessment process is the one defined in ISO/IEC 17040:2005 and also in the IAF/ILAC procedures on how to conduct a Peer Assessment process of single accreditation bodies (IAF/ILAC A2:07/2010).

ISO/IEC 17040:2005 is applicable to peer assessment amongst accreditation bodies, which is also known as peer evaluation. This international standard also covers peer evaluation of accreditors of conformity assessment bodies (CABs) performing activities such as testing, product certification, inspection, management system certification (sometimes also called registration), and personnel certification. Peers from one accreditation body perform the evaluation of another accreditation body to determine the equivalence of the accreditation process between accreditation bodies.

The peer evaluation determines the following:

- Experience in the assessment of its accredited conformity assessment bodies (CAB) including document review, on-site assessment, witnessing and issuing decisions on accreditation,
- Experience in operating an accreditation body and
- Having access to technical expertise in all aspects of its accreditation activities.

### V. SUMMARY

This completes the peer evaluation review of the USDA AMS, NOP. The NOP personnel reviewed and responded to the report and fourteen (14) Opportunities for Improvements (OFIs). The final report includes the peer evaluation comments. In addition the ANSI technical assessor conducted two witness assessments in June 2014 and reported on these under separate cover. The witness assessment permitted the technical assessor to observe directly the NOP auditor conducting a renewal and mid-term assessment of a Certification Agents program and staff. The NOP auditors observed conducted the audit to the NOP requirements.

The NOP operations perform audit activities as defined by the regulations 7 CFR Part 205. The regulation specifies the accreditation body to work in conformance to ISO/IEC Guide 61 now known as ISO/IEC 17011.

The NOP administrator and personnel are committed to implementing ISO/IEC 17011. The current NOP operations are taking on additional responsibilities for the program. This change has occurred since 2012 and additional resources are being added to improve the administration of the NOP. The NOP has the required technical expertise for performing assessments as required by 7 CFR Part 205. Personnel and administrators are familiar with accreditation activities such as application review, on-site assessments, witness assessments and issuing certificates. Interviews conducted by the technical assessor during the on-site assessment of the Washington DC office showed personnel understand program requirements and have the specified education and management skills.

The administrative and management staff understands the principles of ISO/IEC 17011. The management and staff should receive formal training in ISO/IEC 17011 in order to further improve the NOP processes. In 2012, the Office of the Deputy Administrator (ODA) adopted a management style that is not fully compliant with ISO/IEC 17011 since the style was not based on documented processes. ISO/IEC 17011 is based on a documented organizational management operation. Variations in the implementation were observed during the peer review, which is minimized at the present time due to the limited number of staff. This may become problematic as additional staff is added to the NOP operation.

All elements of ISO/IEC 17011 are not implemented as presented in the Opportunities for Improvement (OFI). The NOP response to the OFIs indicates that a documented management system is planned with commitment to update and review documents to ensure consistent communication of the processes used by NOP staff and auditors. The NOP management review and internal audit processes should include the input from this report to ensure the program administration continues the development of a documented management system to meet the requirements of ISO/IEC 17011. As with all accreditation bodies, the NOP would benefit from a routine peer evaluation schedule.

The NOP accreditation system is specified under the USDA organic regulations. These regulations are not completely aligned with ISO/IEC Guide 65 or ISO/IEC 17065. The NOP is not planning on implementing full compliance with ISO/IEC 17065 for its certifying agents. The International Accreditation Forum (IAF) and conformity assessment bodies (CAB) have set the date of September 15, 2015 as the implementation date for all conformity assessment bodies in all certification schemes to be in conformance to ISO/IEC 17065. Since NOP is not aligned with the current international conformity assessment standard, the NOP accredited certification bodies may find the need to operate multiple accreditation programs which may result in added cost to the organic program.