

Peer Review Report

Background:

- 7 CFR 205.509 requires Administrator to establish a Peer Review Panel to annually review NOP adherence to accreditation procedures.
- NOP contracted with American National standards Institute (ANSI) in 2005 and 2014, and with National Institute of Standards and Technology (NIST) in 2010.
- Foreign governments have also conducted Peer Reviews of the NOP: EU in 2010 & 2014; Canadian FIA in 2011 and 2013; Korea in 2014.

- NOSB made recommendations to the NOP on peer review in 2001, 2005 and 2009.
- In 2010 OIG found that using third party organizations to conduct peer review did not satisfy 205.509
- NOP in 2014 asked NOSB for recommendation to establish a repeatable and transparent process.
- CACS sought public comment, and provided a recommendation to NOP in April 2015
- 2016 NOP established Peer Review Panel and contracted with ANSI

Panel Members

- **Robert (Bob) Miller PE**– ANSI/ANAB Lead Assessor, ISO/IEC 17011, 17020, 17025 and 17065.
- **Jean Richardson Ph.D.**, Professor Emerita, University of Vermont, Environmental Law and Environmental Studies; Independent Organic Inspector; NOSB (2012-2017) - Chair 2014-2015 and NOSB Certification and Accreditation Subcommittee 2012- 2017.
- **James Riddle**, Organic Independents LLP; Founding President, International Organic Inspectors Association; ISO training; Former board member, International Organic Accreditation Service; and Former chair, National Organic Standards Board.
- **Susan Ranck**, IOIA trained organic inspector, IFT Certified Food Scientist, ANSI technical assessor.
- **Elizabeth Okutuga**, Program Coordinate 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.

Methodology

- Panel meetings by conference call and face to face over period May-August 2016
- Selection of Certifier files to Review
- Detailed Review of files selected
- Detailed analysis of all NOP Documents, site evaluation reports, policies and procedures which are referenced and used in Accreditation process.
- Lead Auditor prepared ISO /IEC 17011 analysis
- Preparation of Individual Reports
- Critical Review of each other's analyses,
- September 2016 Lead Auditor Report and all individual reports to NOP

- The findings will be considered part of the NOP quality management system and corrective actions will be made as necessary and appropriate.
- Findings will be presented to NOSB



2016 Peer Review Panel Presentation
for
United States Department of Agriculture
Agricultural Marketing Service

National Organic Program- Peer Review

Prepared by ANSI Lead Evaluator

USDA-AG6395S150169-2016NOSB-Rev00



Scope:



Procedure outlined in NOP 1031 (5/12/16), Peer Review of National Organic Program (NOP) and instructions from Miles McEvoy dated 5/19/2016.

The panel was tasked with the following:

- evaluate the NOP's policies processes and procedures for conformance to NOP regulations and ISO/IEC 17011,
- review implementation of certification body accreditation processes through selected file review of five files and
- reporting the peer review panel findings to the NOP Deputy Administrator and the National Organic Standards Board.

Key Findings



- NOP and its staff are in general compliance with ISO/IEC 17011
- Opportunities for Improvement
 - The accreditation body's procedures lack clarity to verify that the auditors are reviewing the regulatory status of ingredients and processing aids.
 - During file review an isolated instance of the NOP not following NOP 2000 for notification to certification body of a suspension was observed.
 - Consistent accreditation records are not being used and retained in order for the NOP to be in full compliance with 205.502

Key Findings Continued



- NOP 2005-4 Witness Audit Checklist is not complete. The NOP 2005 procedure does not provide the control needed to approve the document for adequacy prior to use.
- The accreditation body does not ensure there is immediate notification to the NOP for potential changes by certified bodies that may affect compliance.
- The accreditation body is required to ensure a balanced representation of interested parties with no single party predominating. Balanced representation of interested parties is not described for Accreditation Committee, NOP 2012 clause 2 qualifications

Key Findings Continued



- ISO/IEC 17011, Clause 4.3.2 requires the Accreditation Body to document the relationship with related bodies and identify potential conflicts of interest. Where conflicts are identified, appropriate action shall be taken; however, the procedure does not identify the procedure to determine the appropriate action.
- ISO/IEC 17011, Clause 5.3 requires all documents to be controlled. Not all documents are adequately controlled.
- NOP indicates it has procedures for identification, collection, indexing, accessing, filing, storage, maintenance and disposal of its records, but specific procedures are not identified.
- ISO/IEC Guide 65 has been superseded by ISO/IEC 17065; however, some documents and procedures still refer to Guide 65.

USDA Agricultural Marketing Service
National Organic Program

NOP's Response to Peer Review

Miles McEvoy
NOP Deputy Administrator

Fall 2016 NOSB Meeting



Peer Review Process



- American National Standards Institute (ANSI); panel of 4 independent auditors
- Process driven by Memo to NOSB (November 2014): “Peer Review of NOP Accreditation”
- A vital component of NOP’s commitment to continuous improvement

Context for Peer Review



- NOP's goal is to align with ISO/IEC 17011, a quality standard that applies to accreditation bodies like NOP
- NOP is a small program serving a large and growing industry
- We have strong, robust accreditation procedures
- We have a skilled pool of auditors who receive ongoing training – several are new to NOP
- NOP provides annual training to certifiers
- Our tools include the regulations, checklists, guidelines, procedures, and the NOP Handbook

NOP's Corrective Actions



- Audit found that not all NOP documents are adequately controlled.
 - NOP is actively improving processes that will make it more consistent in how the team applies its accreditation procedures and checklists – this will avoid inconsistencies
 - NOP is inventorying where document controls are lacking, and in FY 2017 will implement a process improvement project for document management and control
 - In the FY 2017 audit season, NOP will make sure that all auditors consistently use the correct version of checklists
 - NOP recognizes the importance and value of records management – we have made significant progress, and will continue to improve in this area.

NOP's Corrective Actions



- NOP will update out-of-date references to quality standards. Example: replace ISO/IEC Guide 65 with ISO/IEC 17065.
- As government employees, NOP staff adhere to strict conflict of interest and ethics laws. These rules and any necessary enforcement steps are detailed in USDA Directives, but are not included in NOP's quality manual.
- NOP will continue to strictly follow all federal laws related to conflict of interest and ethics – this is part of our oath when we become Federal employees and civil servants.
- NOP will update its quality manual to explicitly document these existing requirements.

NOP's Corrective Actions



- In FY 2017, NOP will update its procedures to help auditors more clearly document how they perform ingredient and processing aid reviews when auditing certifiers
 - The review is being done – we need to document it better
- Certifiers need to notify the NOP when changes occur that could impact compliance. NOP will provide more examples to certifiers of when this applies.
 - Example: Certifier adds a satellite office

In Closing ...



- NOP appreciates the constructive feedback from ANSI.
- NOP will continue to refine its records management practices, improve accreditation processes, and continue to regularly train auditors and certifiers.
- By further strengthening accreditation procedures, NOP continues to support the organic community and maintain organic integrity for all.