



**2019 Peer Review Panel
Evaluator Report**

For

**Agricultural Marketing Services (AMS)
National Organic Program (NOP)**

**Dates of Review Panel:
December 10 - 12, 2019**

Prepared by

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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 S.W.
Room 2648 South Building
Washington, DC 20250

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202-720-3252

Review

Type of Review

Peer Review Panel Evaluation

On-site Review Dates

December 10 to 12, 2019

Review Standard(s)

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:

Milan Neupane

Technical Reviewer:

Jean Richardson

ANSI Staff:

Reinaldo Figueiredo, ANSI Senior Program Director
Elizabeth Okutuga, ANSI, Program Coordinator

Report Prepared by:

**Milan Neupane
Mario Llerenas
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Submitted to ANSI on:

January 2, 2020

II. SCOPE

The NOP is establishing a peer review panel to satisfy adherence to internal and regulatory requirements. American National Standards Institute (ANSI) has convened this panel on July 30, 2019.

The peer review panel is tasked to:

- Evaluate the NOP's policies processes and procedures for conformance to NOP regulations (7 CFR Part 205) and ISO/IEC 17011:2017
- Focus on the updated ISO 17011:2017 standard and the revised risk-based changes to the standard
- Review implementation of certification body accreditation processes through select file review including a review of three accreditation decisions issued by the NOP - one for a certifier applicant, one renewal and one midterm assessment
- The USDA oversight process
- USDA process for assessing risk in their current management system
- Area for system improvements

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

III. 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 of 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

Panel Members

Milan Neupane – 17011 Expert; Risk Assessment Evaluator; ANSI Lead Assessor.

Jean Richardson - Professor Emerita, University of Vermont, Environmental Law and Environmental Studies; Independent organic inspector, IOIA qualified; NOSB 2012-2017; ISO/IEC trained.

Mario Llerenas, 17011 Expert (Qualified Peer Assessor); Risk Assessment Evaluator; ANSI Food Safety Lead Assessor.

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

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

Document Review - The review panel conducted a Document Review and completed a working document before the on-site evaluation.

The working document was created on November 7, 2019 and send to USDA NOP, including the tentative schedule of the personnel to interview during the on-site visit. The working document was used by the Peer Review Team for taking notes during the on-site assessment, and the findings are included in this report.

Assessment Plan

The on-site Assessment Plan revision 01 was issued on October 4, 2019; this version was approved and signed by USDA NOP in October 8, 2019; The assessment plan approved by USDA NOP is uploaded to ANSICA, the ANSI database.

Opening / Closing Meetings

The opening meeting was conducted on Tuesday 10 of December, 2019 at 8:30 am with 5 NOP senior staff in attendance and the two members of the ANSI Peer Review team (Milan Neupane has a travel issues and arrived at 10:30am). At the end of the opening meeting, the NOP Deputy Administrator, Jennifer Tucker, explained the proposed changes in the organizational structure of the NOP and its relationship with other governmental dependencies.

The closing meeting for the on-site assessment was done on Thursday 12 of December at 12:00 pm with the same five NOP persons in attendance and the three assessors of the Peer Review team. The results of the on-site assessment were discussed during the closing meeting: Six opportunities for improvement (OFIs) and three Comments were documented, as presented in the Section IV of this report.

Additional Comments

The Management System of USDA NOP is very well implemented and in accordance with the ISO/IEC 17011 version 2017 and the US 7 CFR Part 205, National Organic Program requirements, with the exception of the six OFIs identified.

The Peer Review team was well impressed on the improvements in the organization, resources and accreditation process since the last Peer Review in 2018.

The NOP personnel demonstrated good knowledge in both, technical requirements and the management system requirements.

The NOP program management also demonstrated commitment to continuous improvement.

IV. RESULTS OF PEER REVIEW PANEL EVALUATION

1. **METHODOLOGY**.- The Peer Review team verified the compliance of USDA NOP to 7 CFR 205 and ISO/IEC 17011:2017 based on the sampling of documents, interviews and records; the Peer Review team selected accreditation files and NOP qualified assessors in order to verify the accreditation process and competency. The conclusions of the Peer Review team is based on objective evidence collected and observed during the assessment, and is contained in this report as compiled by the lead and technical evaluators.
2. **PREVIOUS OFIs**.- The OFIs cited from 2018 were both, documented and reviewed by the Peer Review team during the 2019 on-site assessment in order to verify the effectiveness of the actions implemented by NOP. The outcome of this review is presented below:

2018 Opportunity for Improvement	2019 Verification of the effectiveness
2018-USDA NOP-01-O-LLEM-(17011 v. 2004) 4.2.8	The OFI identified in 2018 was reviewed and is effective. [ref: 2018-USDA NOP-01-O-LLEM-(17011 v. 2004) 4.2.8]

<p>The NOP Organizational Chart does not show the Quality Manager position</p>	
<p>2018-USDA NOP-02-O-LLEM-(17011 v.2004) 4.3.7</p> <p>There is not documentation for the relationships with related bodies; as well, there is no evidence of the participation of the interested parties.</p>	<p>One OFI identified in 2018 was reviewed and remains open. 2018-USDA NOP-02-O-LLEM-(17011) 4.3.7</p>
<p>2018-USDA NOP-03-O-ricj-(ISO 17011 v. 2004) 6.1.2</p> <p>The NOP does not have a sufficient number of auditors.</p>	<p>One OFI identified in 2018 was verified and effective. 2018-USDA NOP-03-O-ricj-(17011)6.1.2</p> <p>The NOP has increased the number of Auditors to 11 total: 4 Full time Auditors; 3 Full time Auditors in Training and 6 part time Auditors.</p> <p>In addition the NOP is in the process of hiring a full time Auditor Supervisor</p>
<p>2018-USDA NOP-05-O-ricj-(ISO 17011 v. 2004) 7.5.7.</p> <p>Satellite offices of certifiers, especially international locations, are not audited on a frequent enough basis to reduce risk and prevent potential fraud.</p>	<p>One OFI identified in 2018 was verified and effective. 2018-USDA NOP-05-O-ricj-(17011) 7.5.7</p> <p>With the increase in number of staff available to conduct audits, both domestically and internationally there is now a Schedule of planned visits in place for more frequent auditing of Satellite offices.</p>
<p>2018-USDA NOP-06-O-ricj-(ISO 17011 v. 2004) 7.7.2.</p> <p>Procedures for residue sampling are not clearly understood or followed by international CAB and satellite offices.</p>	<p>One OFI identified in 2018 was verified and the Peer Review team has the following comment: 2018-USDA NOP-06-O- ricj-(ISO 17011 v. 2004) 7.7.2.</p> <p>Procedures for residue sampling are not clearly understood or followed by international CAB and satellite Offices.</p> <p>In response to this OFI from 2018, the NOP, in February 2020, will be conducting a training on residue sampling procedures at BIOFACH, and there will be a training module developed for residue sampling in the Organic Integrity Learning Center. This is scheduled.</p>
<p>2018-USDA NOP-08-O-ricj-(ISO 17011 v. 2004) 6.1.1.</p> <p>There is insufficient NOP personnel to handle the number of complaints and enforcement actions required of the C&E division.</p>	<p>One OFI identified in 2018 was verified and effective. 2018-USDA NOP-08-O-ricj-(17011) 6.1.1</p> <p>The total number of NOP staff has increased to accommodate the growth in the Complaints program. Presently there are 45 total NOP staff, with a goal of increasing to at least 59 positions in the next few months. This staff increase includes additional Auditors.</p> <p>The Compliance and Enforcement Division has added six new FTE which has allowed a much more streamlined procedure with procedures in place.</p>

	<p>A tiered system of complaint handling (3 tiers) is now in place and is quickly seen to be allowing for a streamlined approach to complaints resolution in a very timely manner. The newly updated system in place also includes the use of external contractors, other divisions of USDA and other Federal and international agencies.</p>
<p>2018-USDA NOP-09-O-CADS-(17011)</p> <p>NOP should establish stronger quantitative objectives and key performance indicators for effective measurement and monitoring to achieve the Administration's goals.</p>	<p>One OFI identified in 2018 was verified and effective. 2018-USDA NOP-09-O-CADS-(17011)</p> <p>The NOP has documented 2020 objectives and measurable goals:</p> <ol style="list-style-type: none"> 1.- Deepen risk-based Organic Control Systems, leading to trusted people, processes, and rules 2.- Expand Farm to Market Traceability, increasing supply chain integrity around the world 3.- Protect Organic Integrity through Robust Enforcement, creating a consistent and fair market for all organic participants 4.- Support the existing organic standards and collaborate with organic stakeholders 5.- Support AMS-wide initiatives to facilitate agricultural marketing 6.- Increase communication and efficiency of compliance and enforcement mission
<p>2018-USDA NOP-10-O-CADS-(17011) 5.3</p> <p>Several documents were found to be out of compliance with the document control procedure.</p>	<p>The OFI identified in 2018 [ref: 2018-USDA NOP-10-O-CADS-(17011) 5.3] was reviewed and the Peer Review team has the following comments:</p> <p>Following improvements are noted during on-site peer review:</p> <ol style="list-style-type: none"> a) NOP 1006 Document Control Master List has been updated to Rev.57. b) National Organic Program Handbook: Guidance and Instructions for Accredited Certifying Agents and Certified Operations has been updated (e.g. NOP 5611 National list Sunset Dates – a regulation has been updated on 11/22/2019 and approved by NOP Deputy Administrator). c) All Guidance documents, Policy Memos, and Instructions undergo Office of General Counsel review as part of the review process. d) The NOP 4000 series of quality management procedure is under review, which focuses on Compliance and Enforcement topics. e) NOP procedures are referred in NOP 1000 Quality Manual, Rev. 04. f) The Quality Manager has demonstrated commitment in continued oversight and active facilitation of the quality management system improvement.

<p>2018-USDA NOP-11-O-CADS-(17011) 7.9.4</p> <p>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.</p>	<p>One OFI identified in 2018 was verified and the Peer Review team has the following comment: 2018-USDA NOP-11-O-CADS-(17011) 7.9.4</p> <p>The NOP is developing a mechanism with the accreditation database to accommodate the necessary additional information. This is not yet fully complete.</p>
<p>2018-USDA NOP-12-O-CADS-(17011) 8.3.2</p> <p>There is an opportunity for NOP to provide further protections for its USDA Organic seal.</p>	<p>One OFI identified in 2018 was verified and is effective: 2018-USDA NOP-12-O-CADS-(17011) 8.3.2</p> <p>The NOP has the added support of the Custom & Border Protection (CBP) on the control of the USDA Seal.</p>

3. **2019 Opportunities for Improvement.**- During this on-site assessment, the Peer Review team identified six opportunities for improvement. The following are the 2019 opportunities for improvement (OFIs) made by the review panel:

Requirement	Opportunity for Improvement	Evidence
<p>17011:2017 4.4 Impartiality requirements <i>4.4.5 The accreditation body shall document and implement a process to provide opportunity for effective involvement by interested parties for safeguarding impartiality. The accreditation body shall ensure a balanced representation of interested parties with no single party predominating.</i></p> <p><i>4.4.6 The accreditation body shall have a process to identify, analyse, evaluate, treat, monitor and document on an ongoing basis the risks to impartiality arising from its activities including any conflicts arising from its relationships or from the relationships of its personnel.</i></p>	<p>2019-USDA NOP-01-O-LLEM-(17011) 4.4.5 and 4.4.6</p> <p>The NOP can improve their risk identification and analysis process. The NOP does not document the process for identification, analysis, control and mitigation actions for all potential risks.</p> <p>There is no evidence of a documented and implemented structure with participation of the interested parties.</p>	<p>1) NOP demonstrated to have the impartiality controls implemented; however, NOP can improve the risk identification and analysis process for the assessors conducting assessments of International certifiers. NOP should document the process for identification, analysis, controls and mitigation actions for all potential risks.</p> <p>2) The Quality Manual NOP 1000 dated December 18, 2017 clause 3.3 Impartiality, states the NOP has documented and implemented a structure to provide the opportunity for effective involvement by interested parties. The NOP ensures a balanced representation of interested parties with no single party predominating; however, there is no evidence of the documented and implemented structure with participation of the interested parties.</p>

<p>ISO/IEC 17011:2017, section 5.6 <i>The accreditation body shall document the duties, responsibilities and authorities of top management and other personnel associated with the accreditation body who are involved in the accreditation process.</i></p> <p>ISO/IEC 17011:2017, section 5.7 <i>The accreditation body shall identify the top management having overall authority and responsibility for each of the following:</i> <i>i) provision of adequate resources;</i> <i>k) safeguarding of impartiality.</i></p>	<p>2019-USDA NOP-02-O-NEUM-(17011) 5.6, 5.7</p> <p>The NOP has an opportunity to complete the documentation of responsibilities and authorities of NOP positions in its quality system as part of the expanded organizational structure.</p>	<p>The responsibilities and authorities of all NOP positions of the expanded organizational chart are not yet addressed in the NOP quality system documentation for all positions. For example: a) AMS Trade Systems Director b) Standards Assistant Director</p> <p>The responsibilities and authorities of Executive Management for safeguarding impartiality and provision of resources (other than financial resources) are unclear in the quality system documentation (ref: NOP 1002).</p>
<p>ISO/IEC 17011:2017, section 9.3 Document control.</p> <p><i>The accreditation body shall establish documented procedures to control all documents (internal and external) that relate to its accreditation activities. The procedures shall define the controls needed:</i> <i>a) to approve documents for adequacy prior to issue;</i> <i>b) to review and update as necessary and re-approve documents;</i> <i>c) to ensure that changes and the current revision status of documents are identified;</i> <i>d) to ensure that relevant versions of applicable documents are available at points of use;</i> <i>e) to ensure that documents remain legible and readily identifiable;</i> <i>f) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose;</i> <i>g) to safeguard, where relevant, the confidentiality of documents.</i></p>	<p>2019-USDA NOP-03-O-NEUM-(17011) 9.3</p> <p>The NOP has an opportunity to improve the effectiveness of its implemented document control procedure.</p>	<p>PART I: a) The NOP’s quality system documents are maintained as unlocked word documents. Users can make unintentional changes or unauthorized modifications to the documents. b) The procedure for the control of documents from external origin is not specified in NOP 1010. c) The NOP Records File Plan and Disposition Schedule (NOP XXXX, dated Dec 6, 2016) is still a draft document and not yet approved.</p> <p>PART II: 1) The reference to NOP 1010 Quality Management System Document and Record Control Procedure under NOP 1000 Quality Manual, section 4 appears to have the incorrect title. 2) The NOP’s quality system documents reference older versions of standards or normative documents, such as ISO/IEC 17011:2004 and ISO 19011:2011). 3) Reference to NOP Records File Plan and Disposition Schedule is missing in the NOP 1000 Quality Manual.</p>

<p>ISO/IEC 17011:2017, section 9.5 Nonconformities and corrective actions.</p> <p><i>The accreditation body shall establish documented procedures for the identification and management of nonconformities in its own operations. The accreditation body shall also, where necessary, take actions to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the impact of the problems encountered. The procedures shall cover the following:</i></p> <p><i>b) determining the causes of nonconformity;</i></p>	<p>2019-USDA NOP-04-O-NEUM-(17011) 9.5 b)</p> <p>The NOP has an opportunity to record the identification of the root cause when addressing corrective actions.</p>	<p>As a result of 2018-2019 internal audit a corrective action report was generated addressing findings identified during the internal audit. However, the identification of root cause was not recorded while developing the corrective action plan as per NOP 1020 Corrective and Preventive Action Procedure (Rev03), Section 4.2.</p>
<p>ISO/IEC 17011:2017, section 9.7.1 <i>The accreditation body shall establish documented procedures for internal audits to verify that the accreditation body conforms to the requirements of this document and that the management system is implemented and maintained.</i></p> <p>ISO/IEC 17011:2017, section 9.7.4 <i>The accreditation body shall ensure that:</i></p> <p><i>a) internal audits are conducted by competent personnel knowledgeable in accreditation, auditing and the requirements of this document;</i></p> <p>ISO/IEC 17011:2017, section 6.3 Personnel records.</p> <p><i>The accreditation body shall maintain records, including qualifications, training, competence, results of monitoring, experience, professional status and professional affiliations for personnel managing or performing accreditation activities.</i></p>	<p>2019-USDA NOP-05-O-NEUM-(17011) 9.7.1, 9.7.4, 6.3</p> <p>The NOP has an opportunity to ensure standard audit checklist and reporting templates are used while conducting internal audit, and relevant records are maintained as per NOP 1030.</p>	<p>a) NOP 1030-3 Internal audit report template and NOP 1030-2 Internal Audit Checklist were not used for the 2018-2019 internal audit, as per NOP 1030 Internal Audit Procedure (Rev04).</p> <p>b) The record of the internal auditor's training on ISO/IEC 17011:2017 and ISO/IEC 17065:2012, as per NOP 1030, section 2.1, was not available during the peer review.</p>

<p>ISO/IEC 17011:2017, section 9.8.2 <i>Inputs to management reviews shall include, current performance and opportunities for improvement related to the following:</i></p> <p><i>c) participation in international activities, where relevant;</i> <i>d) safeguarding impartiality;</i> <i>e) feedback from interested parties;</i> <i>i) the status of actions to address risks and opportunities;</i></p>	<p>2019-USDA NOP-06-O-NEUM-(17011) 9.8.2</p> <p>The NOP has an opportunity to include additional agenda items into its management review procedure to comply with the updates in ISO/IEC 17011:2017.</p>	<p>NOP 1040 Management Review procedure, section 2.2 defines the requirements for inputs to the management review. However, it does not include the following inputs as per ISO/IEC 17011:2017, section 9.8.2:</p> <ol style="list-style-type: none"> 1. Participation in international activities, where relevant; 2. Safeguarding impartiality; 3. Feedback from interested parties (except Feedback from accredited certifying agents, as it is included as an input item) 4. The status of actions to address risks and opportunities. <p>None of the above agenda items were discussed during the management review for 2018.</p>
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2019 Comments.- In addition to the Opportunities for Improvement, the Peer Review team documented three comments for USDA NOP to consider:

NOP PROCESS	COMMENTS
Impartiality: Obligations of the accredited CBs	The NOP should encourage the certifiers to comply with the Impartiality Risk Analysis evaluated by an independent mechanism requirement of the ISO/IEC 17065 (ref. ISO/IEC 17065 clauses 4.2 (Management of Impartiality) and 5.2 (Mechanism for safeguarding impartiality)).
Competence of Personnel: 6.1.2.1	The NOP does not use IAF MD 20:2016, Annex 1, which is mandated for 17011. However, the detailed criteria used in hiring competent staff and evaluating them as required in the USDA's performance plans and processes for appraisal, as verified from completed documents reviewed during sampling, indicates that the present USDA/NOP system appears to contain the elements covered in the IAF MD20: 2016, Annex 1.
7 CFR 205.670	Procedures for residue sampling are not clearly understood or followed by international CAB and satellite offices. In response to this OFI from 2018, the NOP, in February 2020, will be conducting a training on residue sampling procedures at BIOFACH, and there will be a training module developed through the Organic Integrity Learning Center. This is scheduled.

2019 Strengths.- The Peer Review team identified positive processes and activities during the 2019 on-site assessment. The following are the strengths identified by the team:

NOP PROCESS	COMMENTS
2018 Peer Review responses and actions taken	The NOP has made a serious analysis of the findings documented in 2018 by the ANSI team elaborating an action plan. During this on-site assessment, the NOP demonstrated the implementation of the actions in accordance with the action plans (several actions already implemented and some of them in process).

2020 Objectives and Goals	The NOP developed Objectives and Goals for 2020. The document lists six general objectives including the measurable Goals related to each objective. These goals are part of the Performance Task and Appraisal document created for NOP staff person.
NOP Resources	The NOP has more resources (both, financial and personnel), appointed a Quality Manager, and is creating the Accreditation Assessment team, with three qualified auditors, and five in training at the time of this Peer Review.
Training	The creation and implementation of the Organic Integrity Learning Center is an improvement. Some training courses are still in development but the Learning Center is working and supporting the knowledge and calibration of the NOP personnel.
Complaints	Complaint and Enforcement introduction to a new complaints process with additional personnel. Additional improvements include data analysis, complaints classification, electronic complaints management system, and the pasture surveillance audit team. In addition, NOP 4001 is in revision for finalization.
Publicly Available Information	The NOP web-site contains more public information in comparison to other Accreditation Bodies. The NOP demonstrates transparency in the public information domain.

V. CONCLUSION

This completes the work of the 2019 ANSI Peer Review for the USDA NOP accreditation body. The review covers NOP's compliance with ISO/IEC 17011:2017. The report covers review of NOP's accreditation procedures and decisions, and conformance with ISO/IEC 17011:2017 and 7 CFR Part 205.

The Peer Review Panel members conclude that USDA NOP and staff operate in conformance with ISO/IEC 17011:2017, 7 CFR part 205, and NOP's own policies and procedures with the exception of the Opportunities for Improvement identified and documented above in this Report.

During this on-site assessment, NOP management consistently demonstrated their commitment to improvement to the Peer Review team.

The Peer Review team would like to express appreciation to USDA NOP personnel for their cooperation and hospitality during the Peer Review assessment.

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