



## **2020 ANAB Peer Review Report**

**For**

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

**Dates of Review Panel:  
September 15 - 17, 2020**

Prepared by

ANSI NATIONAL ACCREDITATION BOARD  
1899 L Street, 11<sup>th</sup> Floor  
Washington, DC 20036

**Document: 2020-USDA-PeerReviewPanel-1-0-LLEM**

**I. TABLE OF CONTENTS**

**TABLE OF CONTENTS ..... 2**

**I. GENERAL INFORMATION ..... 3**

**II. SCOPE ..... 4**

**III. INTRODUCTION..... 4**

**IV. REPORT OF PEER REVIEW PANEL EVALUATION..... 5**

**Previous OFIs..... 5**

**2020 Opportunities for Improvement ..... 8**

**2020 Strengths.....8**

**V. CONCLUSION ..... 9**

## 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

Telephone

202-720-3252

### Review

Type of Review

Peer Review Panel Evaluation

On-site Review Dates

September 15 to 17, 2020

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**

Technical Reviewer:

**Susan Ranck**

Technical Reviewer:

**Jean Richardson**

### ANSI Staff:

Reinaldo Figueiredo, ANSI Senior Program Director  
Elizabeth Okutuga, ANSI, Accreditation Manager

### Report Prepared by:

**Mario Llerenas  
Jean Richardson  
Susan Ranck**

Submitted on:

**October 22, 2020**

## II. SCOPE

The NOP is establishing a peer review panel to satisfy adherence to internal and regulatory requirements. ANSI National Accreditation Body (ANAB) convened this panel on August 12, 2020.

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/IEC 17011:2017 standard and the revised risk-based changes to the standard
- Review implementation of certification body accreditation processes through select file review
- Include a review of three accreditation decisions issued by the NOP
- Review the USDA NOP oversight process
- Review the NOP accreditation division process, focused on sections 6 and 7 of the ISO/IEC 17011 standard
- Identify area(s) 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

Susan Ranck – Risk Assessment Evaluator; ANAB Technical Expert Assessor in Food

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; ANAB Food Safety Lead Assessor

ANAB Staff - Elizabeth Okutuga, Accreditation Manager, ANAB staff, ISO/IEC 17011 process knowledge and project coordinator.

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

**Document Review** - The review panel conducted a Document Review and completed a working document before the remote evaluation. The working document including the tentative schedule of the personnel to interview during the remote assessment was created on September 4, 2020 and sent to USDA NOP. The Peer Review Team used the working document for taking notes during the remote assessment, and the findings are included in this report.

### Assessment Plan

The Remote Assessment Plan was issued on September 3, 2020; this version was approved and signed by the Quality Manager of USDA NOP. The assessment plan approved by USDA NOP is uploaded in ANSICA, the ANAB database.

### Opening / Closing Meetings

In accordance with the assessment plan, an opening meeting was conducted on Tuesday, the 15th of September, 2020 at 11:00 am with five NOP senior staff in attendance and the members of the ANAB Peer Review team. At the end of the opening meeting, the NOP Deputy Administrator, Jennifer Tucker, explained the key changes in the organizational structure of the NOP, the accreditation process, and its relationship with other governmental departments.

The closing meeting for the remote assessment was conducted on Thursday, 17th of September 2020 at 4:00 pm with six NOP persons in attendance and the three assessors of the Peer Review team. The results of the remote assessment were discussed during the closing meeting: Two new opportunities for improvement (OFIs) were documented and three OFIs remain open from the 2019 Peer Review as presented in the Section IV of this report

### Additional Comments

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

The Peer Review team was very impressed by the improvements in the organization, resources and accreditation process since the last Peer Review in 2019. Significant improvements have been implemented since the last Peer Review in both the QMS and the Accreditation Process. The NOP personnel demonstrated sound knowledge in both management system and technical 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 Part 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 are 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 2019 were both documented and reviewed by the Peer Review team during the 2020 remote assessment in order to verify the effectiveness of the actions implemented by NOP. The outcome of this review is presented below:

2019 Opportunity for Improvement	2020 Verification of the effectiveness
<p><b>2019-USDA NOP-01-O-LLEM-(17011) 4.4.5 and 4.4.6</b></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>The OFI identified in 2019 was reviewed and remains open: <b>2020-USDA NOP-01-O-LLEM-(17011) 4.4</b></p> <p>The NOP is updating its Quality Manual including the Risk Analysis Methodology in accordance with the ISO/IEC 17011:2017 requirements; however, these documents were not completed at the time of this Peer Review.</p> <p>The NOP's revised Quality Manual NOP 1000 is in the process of being finalized and states in the section 4.4 "The NOP identifies, evaluates, mitigates and documents potential risks to impartiality including conflicts of interest arising from its relationship and the relationships of its personnel on an ongoing basis. The NOP records identified perceived risks to the impartiality of the NOP's operations and accreditation activities, in NOP 1009 Risk Mitigation Table"</p> <p>The draft of the NOP 1009 Risk Mitigation Table was reviewed.</p>

	<p>NOP should finalize the new version of the Quality Manual as well as the Risk Mitigation Table.</p> <p>ANAB recommends for NOP to review the ISO 31000 Risk Management – Principles and Guidelines for improving the creation of the Risk Mitigation methodology.</p>
<p><b>2019-USDA NOP-02-O-NEUM-(17011) 5.6, 5.7</b></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>One OFI identified in 2019 was reviewed and remains open: <b>2020-USDA NOP-02-O-LLEM-(17011) 5.6</b></p> <p>The NOP is in the process of updating the Quality Manual and several documents related to the management system; However, at the time of this Peer Review, the responsibilities and authorities of all NOP positions of the expanded organizational chart (NOP 1001 May 28, 2020) are not consistent with the current document NOP 1002.</p> <p>During the revision of the Quality Manual and other QMS documents, the NOP is archiving and combining some documents in order to have a more efficient QMS documentation. One of the documents to be archived is NOP 1002 Duties, Responsibilities and Authorities.</p> <p>NOP should finalize the revision and release of the new QMS documents, verifying that the duties, responsibilities and authorities are consistent with positions in the Organizational Chart.</p>
<p><b>2019-USDA NOP-03-O-NEUM-(17011) 9.3</b></p> <p>The NOP has an opportunity to improve the effectiveness of its implemented document control procedure.</p>	<p>One OFI identified in 2019 was verified and remains open: <b>2020-USDA NOP-03-O-LLEM-(17011) 9.3</b></p> <p>The Peer Review Team reviewed the drafts of the new version of the Quality Manual and NOP 1010 Document Development, Review and Distribution Process, and both of these are still in process and not yet completed.</p> <p>The control of the documents was improved and now the documents are in PDF files.</p> <p>The draft version of NOP 1010 includes the Control of Records and External documents; however, this section is not yet finalized. NOP should finalize NOP 1010 new version and complete the release process.</p>
<p><b>2019-USDA NOP-04-O-NEUM-(17011) 9.5 b)</b></p> <p>The NOP has an opportunity to record the identification of the root cause when addressing corrective actions.</p>	<p>One OFI identified in 2019 was verified and is effective: <b>2019-USDA NOP-04-O-NEUM-(17011) 9.5 b)</b></p> <p>As a result of the QMS documental revision, NOP has archived the NOP 1020-1 Corrective and Preventive Action Work Plan and the NOP 2010-2 Corrective and Preventive Action Summary.</p> <p>NOP 1020 Corrective Action Procedure section 4, clause 4.2 states the NOP will determine the cause of each nonconformance or OFI.</p> <p><b>Closed</b></p>

<p><b>2019-USDA NOP-05-O-NEUM-(17011) 9.7.1, 9.7.4, 6.3</b>                  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>One OFI identified in 2019 was verified and is effective:  <b>2019-USDA NOP-05-O-NEUM-(17011) 9.7.1, 9.7.4, 6.3</b></p> <p>The new procedure NOP 1030 Internal Audit Procedure Rev05 (dated July 30, 2020) addresses the policies and procedures for internal audits conducted by the National Organic Program (NOP) of its accreditation activities.</p> <p>The implementation and effectiveness of the new NOP 1030 Internal Audit Procedure was verified during remote review.</p> <p>All records of the last Internal Audit are in accordance with the NOP policies and procedures and complies with the ISO/IEC 17011 requirements.</p> <p><b>Closed</b></p>
<p><b>2019-USDA NOP-06-O-NEUM-(17011) 9.8.2</b>                  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>One OFI identified in 2019 was verified and effective.  <b>2019-USDA NOP-06-O-NEUM-(17011) 9.8.2</b></p> <p>The new procedure NOP 1040 NOP Management Review Rev06 (July 29, 2020) addresses the policies, procedures, and responsibilities for conducting NOP management reviews.</p> <p>NOP 1040 requires that the NOP conducts a management review at least once each calendar year to ensure its continuing adequacy and effectiveness in satisfying the requirements of the USDA organic regulations, ISO/IEC 17011, and the NOP's stated policies and objectives.</p> <p>The agenda is included in the new version of the Quality Manual NOP 1000.                  The inputs and outputs are also included in the new version of the NOP 1040 and are according to the ISO/IEC 17011 requirements.</p> <p>The records of the last Management Review were evaluated during this Peer Review and found to be in accordance with the NOP procedure and the ISO/IEC 17011 requirements.</p> <p><b>Closed</b></p>

3. **2020 Opportunities for Improvement.** During this remote assessment, the Peer Review team identified two opportunities for improvement. The following are the 2020 opportunities for improvement (OFIs) documented by the review panel:

Requirement	Opportunity for Improvement	Evidence
<p><b>17011:2017 7.6</b>                  The accreditation body shall have documented procedures for describing the assessment techniques used, the circumstances in which they are to be used and the rules for determining assessment durations. The procedures shall</p>	<p><b>2020-USDA NOP-05-O-RANS-(17011)7.6</b>                  The accreditation body does not have a documented policy/procedure for the timely completion of assessments.</p>	<p>File reviews and discussion with the management staff indicate there is no formal policy for the completion of assessment activities. This lack of definition makes it difficult for the organization to determine adequate resources to meet assigned deliverables.</p>

include how the accreditation body will report the assessment findings to the conformity assessment body.		
<p><b>ISO/IEC 17011:2017, section 7.4.7</b></p> <p>The accreditation body shall develop an assessment plan to cover the activities to be assessed, the locations at which activities will be assessed, the personnel to be assessed where applicable and the assessment techniques to be utilized including witnessing where appropriate or applicable. The accreditation body shall justify where witnessing is not appropriate or applicable.</p>	<p><b>2020-USDA NOP-06-ORANS-(17011)7.11.2</b></p> <p>The organization does not have a defined process for completion of certifier satellite offices as part of the accreditation cycle.</p>	<p>There is no formal policy for satellite office visits as part of the accreditation cycle. A tracking document was presented as an historical illustration but was not currently in use.</p>

**2020 Strengths.** The Peer Review team identified positive processes and activities during the 2020 remote assessment. The following are the strengths identified by the team:

<b>NOP PROCESS</b>	<b>COMMENTS</b>
<b>2019 Peer Review responses and actions taken</b>	<p>The NOP made a complete analysis of the findings documented in 2019 by the ANAB Peer Review team and presented an action plan.</p> <p>During this remote assessment, the NOP demonstrated the implementation of the actions in accordance with the action plans.</p> <p>There are three OFIs from 2019 where the actions are not yet completed; however, the action plan appears to be adequate to avoid the recurrence of the findings.</p>
<b>Organic Integrity Learning Center</b>	<p>Records indicate a high level of attendance at training sessions conducted by the Organic Integrity Learning Center (OILC) established in May 2019. Data indicates 3144 persons presently enrolled in the OILC. This includes certifier staff and inspectors worldwide. Additional training modules will be developed in 2021 to improve competency of inspectors and certifiers.</p>
<b>Auditors</b>	<p>The NOP has addressed the need to conduct audits worldwide in a timely manner through the restructuring of the Accreditation Division to include both Accreditation Managers and Auditors. With additional resources, the NOP has been able to eliminate the outsourcing of Auditors to QAD, and move to a group of in-house, full time Auditors with the goal of increasing to 8 full time Auditors in the next fiscal year.</p>
<b>Residue Sampling</b>	<p>The NOP has taken actions to address the issue of inconsistencies in residue sampling in different countries around the world through training and a new course in the OILC. Previous Trainings were well attended by all except 4 of the 77 certifiers. The trainings will continue to be available and be updated as necessary.</p>
<b>Materials Review</b>	<p>The NOP seeks to assure consistency in materials review including inert materials and is in the process of hiring a Materials Specialist for the</p>



	Standards Division. The NOP plans to hire two additional Materials Specialists in the next fiscal year.
<b>ACCREDIT System</b>	The NOP has established a system to ensure ease of access for all staff to documents remotely. Evidence indicates that this system is streamlining work and eliminating inconsistencies.
<b>Documentation and Control of Documents</b>	<p>The NOP has worked over the last three years to update its document control system.</p> <p>At this time, the documentation of the Quality System remains under revision. The new Quality Manual in accordance with ISO/IEC 17011 is the key document in the QMS remains in draft form, but is very well documented.</p> <p>Additionally, several documents were archived and/or combined, an action that will lead to more effectiveness in the system</p>
<b>Complaint Process</b>	The NOP demonstrated a sound improvement in handling complaints. The Compliance & Enforcement Division acts in a more robust manner and the effectiveness of the complaint process has been improved.

## V. CONCLUSION

This report completes the work of the 2020 ANAB 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, 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 remote 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 commitment during the Peer Review assessment.

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