



2021 ANAB Peer Review Report

For

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

**Dates of Review Panel:
October 5 - 7, 2021**

Prepared by

**ANSI NATIONAL ACCREDITATION BOARD
1899 L Street, 11th Floor
Washington, DC 20036**

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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 by:

Type of Review

Peer Review Panel Evaluation

On-site Peer Review Dates

October 5 to 7, 2021

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*

Peer Review Team

Lead Reviewer:

Mario Llerenas

Technical Reviewer:

Susan Ranck

Technical Reviewer:

Jean Richardson

ANSI Staff:

Reinaldo Figueiredo, ANAB Senior Program Director
Nikki Jackson, ANAB Accreditation Director
Elizabeth Okutuga, ANAB, Accreditation Manager
Ron Hicks, Food technical expert

Report Prepared by:

**Mario Llerenas
Jean Richardson
Susan Ranck**

Submitted on:

November 24, 2021

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 18, 2021.

The peer review panel is tasked to:

- Evaluate NOP policies processes and procedures for conformance to NOP regulations 7 CFR Part 205 and ISO/IEC 17011;
- 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 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 – ISO/IEC 17011 Expert (Qualified Peer Assessor); Risk Assessment Evaluator; ANAB Food Safety Lead Assessor

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

ANAB Staff – Nikki Jackson, Director, Product Certification Accreditation Program

ANAB Staff – Ron Hicks, Food Expert

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 October 3, 2021 and sent to USDA NOP. The Peer Review team used the working document to take notes during the remote assessment, and the findings are included in this report.

Assessment Plan

The remote assessment plan was issued on September 10, 2021; 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 5th of October 2021 at 8:30 am with six NOP senior staff and the members of the ANAB Peer Review team in attendance. 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, 7th of October 2021 at 4:00 pm with the same six NOP persons and the three assessors of the Peer Review team in attendance. The results of the remote assessment were discussed during the closing meeting: One opportunity for improvement (OFI) was documented and two comments with observations for NOP to consider in its management system were identified during this remote Peer Review.

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 one Opportunity for Improvement (OFI) identified.

The Peer Review team was very impressed by the improvements in the organization, resources, and accreditation process since the last Peer Review in 2020. 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 5 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 are contained in this report as compiled by the lead and technical evaluators.
2. **PREVIOUS OFIs** - The three OFIs open from 2019 and two OFIs cited from 2020 were documented and reviewed by the Peer Review team during the 2021 remote assessment to verify the effectiveness of the actions implemented by NOP. The outcome of this review is presented below:

2020 Opportunity for Improvement	2021 Verification of the effectiveness
<p>2020-USDA NOP-01-O-LLEM-(17011) 4.4 (2019 OFI)</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” 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>The Quality Manual NOP 1000 was finalized on January 4, 2021 under revision 05.</p> <p>The structure of the manual is in accordance with the requirements of the ISO/IEC 17011:2017 standard.</p> <p>The NOP Quality Manual is well documented and complies with the requirements. This part of the 2020 OFI has been closed.</p> <p><u>CLOSED</u></p> <p>Note: The NOP 1009 Risk Mitigation Table was not finalized at the time of the 2021 Peer Review and one OFI was identified (see below 2021 opportunities for improvements).</p>

<p>2020-USDA NOP-02-O-LLEM-(17011) 5.6 (2019 OFI)</p> <p>During the revision of the Quality Manual and the QMS documentation, 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>NOP 1002 document was archived.</p> <p>The duties, responsibilities and authorities for NOP employees are documented in Position Descriptions.</p> <p>Sampling of staff and technical personal were reviewed and compliant with the requirements.</p> <p><u>CLOSED</u></p>
<p>2020-USDA NOP-03-O-LLEM-(17011) 9.3 (2019 OFI)</p> <p>The control of documents was improved and now documents are in PDF files. The new version of the NOP 1010 includes the Control of Records and External documents; however, this section is not yet finalized. NOP should finalize the NOP 1010 new version and complete the release process.</p>	<p>NOP 1010 NOP Quality Management System: Document Development, Review, and Distribution Process was finalized on November 26, 2020 under the revision 03.</p> <p>Section 4.8 Control of Records and External Documents was reviewed and complies with the requirements.</p> <p><u>CLOSED</u></p>
<p>2020-USDA NOP-05-O-RANS-(17011)7.6 (2020 OFI)</p> <p>The accreditation body does not have a documented policy/procedure for the timely completion of assessments. 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>	<p>A timeline of assessment activities was established including individual steps throughout the process. The total time frame from audit through accreditation decision is five months. Assignment of a KPI based upon this timeline is under consideration.</p> <p><u>CLOSED</u></p>
<p>2020-USDA NOP-06-O-RANS-(17011)7.11.2</p> <p>The organization does not have a defined process for completion of certifier satellite offices as part of the accreditation cycle. There is no formal policy for satellite office visits as part of the accreditation cycle. A tracking document was presented as a historical illustration but was not currently in use.</p>	<p>Satellite office audit scheduling has been incorporated into the five-year accreditation cycle through the utilization of a pilot project the NOP is conducting in 2022. The NOP will be piloting its risk-based approach for certifier oversight, including satellite offices. .</p> <p><u>CLOSED</u></p>

3. **2021 Opportunities for Improvement.** During this remote assessment, the Peer Review team identified one opportunity for improvement. The following is the 2021 opportunity for improvement (OFI) documented by the review panel:

Requirement	Opportunity for Improvement	Evidence
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<p>ISO/IEC 17011:2017 4.4.6 The accreditation body shall have a process to identify, analyze, 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. The process shall include identification of and consultation with appropriate interested parties as described in 4.4.5 to advise on matters affecting impartiality including openness and public perception.</p>	<p>2021-USDA NOP-01-OLLEM-(17011) 4.4.6</p> <p>NOP has the opportunity to improve its risk analysis matrix developed to document potential threats to the impartiality of the NOP's operations and activities.</p>	<p>The draft of NOP 1009 Risk Mitigation Table was reviewed, and the methodology complies with the expectations of ISO/IEC 17011. However, the following observations on the document should be considered by NOP to improve the process: 1) Finalize NOP 1009 document; 2) document the methodology including the criteria for impact, likelihood, and residual risk levels; and 3) include other sources of potential threats to Impartiality, such as: + Commercial + Finances + Related Bodies + Training + Marketing</p>
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4. **2021 Comments.** During this remote assessment, the Peer Review team identified two observations classified as Comments. These comments originated from the technical Peer Review team and can be considered by NOP as examples of good practices in the accreditation process.

COMMENT # 1
<p>As part of the response to the pandemic, certification bodies implemented various approaches to complete inspection requirements, while ensuring the safety of both their inspectors and the sites to be inspected. These methods included remote inspections, offsite document review, and alternative onsite inspections. The NOP maintains the requirement that certifiers conduct an annual inspection and allows the certifier to determine the best method. This process would be improved if the certifier conducted a risk-based assessment of the operation prior to determining if remote inspection activities are appropriate.</p>

COMMENT # 2
<p>As part of the NOP internal pandemic response, the program transitioned to positions with the option for remote work. Over the past year the NOP has hired and onboarded new staff in a remote setting and no longer requires that all NOP positions are based in the DC area. The review of recent hires indicates this transition has positively impacted the applicant pool in terms of both number of applicants and the qualifications of said applicants. It is the current intent of the NOP to continue this allowance of remote work positions.</p>

2021 Strengths. The Peer Review team identified positive processes and activities during the 2021 remote assessment. The following are the strengths identified by the team:

NOP PROCESS	COMMENTS
<p>Quality Management System totally in accordance with 17011 requirements.</p>	<p>NOP has finalized the documents related to the Quality Management System and demonstrated that the system is well documented and implemented.</p>

	The documentation complies with the requirements of the International Standard for accreditation bodies, ISO/IEC 17011:2017.
Software application for managing the complaints process	<p>NOP developed a software application for handling complaints. The application considers many possibilities for tracking complaints, allowing for an in-depth analysis of sources, types, impact, etc.</p> <p>Due to the effectiveness of the application, NOP is now addressing complaints in a timely manner.</p>
NOP objectives and goals go beyond expectations	<p>NOP develops goals and objectives annually which informs the program's projects and strategic planning. .</p> <p>During this peer review, NOP demonstrated compliance with its goals and objectives, and exceeded some expectations set for 2021.</p>
Team work approach	<p>NOP has created a competent and effective executive team. During this peer review, ANAB collected evidence that the NOP team works from the foundation of its clearly defined purpose and goals.</p> <p>All NOP personnel interviewed demonstrated understanding and commitment to NOP business goals.</p>
Organic Integrity Learning Center	NOP has continued to expand the Organic Integrity Learning Center and increased the number of attendees world-wide. The increased participation has strengthened the technical training of inspectors and certifiers with demonstrated improvement in the consistency of certification.
Personnel and cross-divisional collaboration	NOP hired 21 key personnel in the last 12 months. These hires were balanced among all divisions so additional experts are now available in both the Standards Division and the Compliance and Enforcement Division to support and strengthen the work of the Accreditation Division. There is a documented system in place to facilitate the sharing of expertise, thereby supporting cross-divisional collaboration.
Stronger control systems and standardization	NOP has effectively strengthened its database and control systems through the standardization of systems resulting in improved communications, both within the NOP and externally through reports available to public stakeholders. This improvement has resulted in greater consistency, increased efficiencies, and transparency in public-facing program materials.
Strengthen Organic Standards	NOP strengthened the Standards Division by hiring additional Materials Specialists and moving forward with several rules. NOP is drafting final rules for Strengthening Organic Enforcement (SOE) and Origin of Livestock (OOL), and the proposed rule for Organic Poultry and Livestock Standards (OLPS). NOP actively engages the National Organic Standards Board, stakeholders, and partners in this process. These actions will strengthen consistency in organic certification.
Robust Enforcement	NOP continues to expand its safeguarding of organic integrity through the increased use of risk-based oversight approaches, surveillance, and

	enforcement actions world-wide. All of which will increase the integrity and consistency in the organic marketplace.
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V. CONCLUSION

This report completes the work of the 2021 ANAB Peer Review for the USDA NOP accreditation body. The review covers the NOP's compliance with ISO/IEC 17011:2017 as well as a review of NOP's accreditation procedures, decisions, and conformance with 7 CFR Part 205.

The Peer Review Panel members conclude that USDA NOP and staff continue to operate in conformance with ISO/IEC 17011:2017, 7 CFR Part 205 and with NOP's own policies and procedures. One OFI and two comments were identified 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** -----