



Product Certification Accreditation

2016 Peer Review Executive Summary

United States Department of Agriculture Agricultural Marketing Service National Organic Program

1400 Independence Avenue, NW
Room 2646 South Building
Washington DC 20250 USA

Dates of the Peer Review:
May 16 – August 5, 2016

Prepared by

American National Standards Institute
1899 L Street, 11th Floor
Washington, DC 20036

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Document: Executive Summary

USDA-AG6395S150169-2016-EXS-ANSI-REV00

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I. 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
Dates

**Remote Assessment Peer Review
May 16 – August 5, 2016**

Peer Review Standard(s)

*ISO/IEC 17011:2004 Conformity Assessment – General requirements
for accreditation bodies accrediting conformity assessment bodies,
US 7 CFR Part 205, National Organic Program*

Evaluation Team

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 Coordinator, 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.

Document Review Report

Prepared by

ANSI Assessment Team

Revised and Resubmitted:

September 13, 2016

II. 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 in accordance with 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

Program and Scopes of Accreditation

The NOP established a peer review panel to satisfy internal requirements regarding adherence to internal and regulatory requirements. American National Standards Institute (ANSI) has convened this panel effective May 16, 2016 to fulfill the expectation of this requirement.

This Peer Review was conducted pursuant to 7 CFR 205.509, Peer Review Panel, of the USDA Organic Regulations. This Peer Review follows a procedure outlined in NOP 1031 (5/12/16), *Peer Review of National Organic Program* (NOP) and as modified by letter of 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 in writing to the NOP Deputy Administrator and the National Organic Standards Board.

III. 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.

IV. SUMMARY

The report covers NOP's compliance with ISO/IEC 17011 and review of NOP's accreditation procedures and decisions, The Review Panel members find that NOP and its staff are in general compliance with ISO/IEC 17011 and NOP's own policies and procedures. Opportunities for Improvement have been identified and are recorded in the individual reports and also in ANSI's Conformity Assessment portal, ANSICA. The opportunities for improvement include:

- The accreditation body's procedures lack clarity to ensure that the auditors are reviewing the regulatory status of ingredients and processing aids.
- The NOP did not follow NOP 2000 for notification to certification body of a suspension.
- Consistent accreditation records are not being used and retained in order for the NOP to be in full compliance with 205.502.
- NOP 2005-4 Witness Audit Checklist is not complete. The NOP 2000 procedure does not provide the control needed to approve the document for adequacy prior to use.
- Some NOP regulations allow NOP to be involved with CAB functions such as suspension, revocation and appeal; these regulations do not comply with ISO/IEC 17011 clause 4.3.6 A.
- 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.
- 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.



Product Certification Accreditation

2016 Peer Review Panel Lead Evaluator Report For

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

**Dates of Review Panel:
May 16 – August 5, 2016**

Prepared by
Robert Miller

American National Standards Institute
1899 L Street, 11th Floor
Washington, DC 20036

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**Document: Lead Evaluator Report
USDA-AG6395S150169-2016-Rev00**

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I. GENERAL INFORMATION

Accreditation Body

Name of reviewed Body

Agricultural Marketing Services (AMS)

Address

**1400 Independence Avenue, NW
Room 2646 South Building
Washington DC 20250 USA**

Telephone

202-720-3252

Review

Type of Review

Peer Review Panel

Review Dates

May 16 - 18, 2016

Review Standard(s)

**7 CFR Part 205 National Organic Program Final Rule
ISO/IEC 17011 “Conformity assessment – General
requirement for accreditation bodies accrediting
conformity assessment bodies**

Review Team

Lead Reviewer:

Robert Miller

Technical Reviewer:

Susan Ranck

Technical Reviewer:

Jean Richardson

Technical Reviewer:

Jim Riddle

ANSI Observer(s)

**Reinaldo Figueiredo
Elizabeth Okutuga**

Report

Review Report Prepared by:

Robert Miller

Submitted to ANSI on:

August 5, 2016

II. SCOPE

The NOP is establishing a peer review panel to satisfy internal requirements regarding adherence to internal and regulatory requirements. American National Standards Institute (ANSI) has convened this panel effective May 16, 2016 to fulfill the expectation of this requirement.

This Peer Review is conducted pursuant to 7 CFR 205.509, Peer Review Panel, of the USDA Organic Regulations. This Peer Review follows a procedure outlined in NOP 1031 (5/12/16), *Peer Review of National Organic Program* (NOP) and as modified by letter of Miles McEvoy dated 5/19/2016.

The panel is 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 select file review and
- reporting the peer review panel findings in writing to the NOP Deputy Administrator and the National Organic Standards Board.

III. INTRODUCTION

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- Accrediting, auditing, and training third-party organic certifying agents

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 Coordinator, 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.

Meetings - The review panel met on the following dates:

Date	Type of Meeting
May 4, 2016	Kick-off conference call
May 16-18, 2016	Initial Meeting
May 26, 2016	Conference Call
July 11, 2016	Assessor meeting to discuss technical findings
July 22, 2016	Review of Technical Reports
August 5, 2016	Review of Lead Assessor's report

IV. DOCUMENTATION

The following documentation were used by the Review Panel:

Document Name	Document No. & Revision Date
Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies	ISO/IEC 17011:2004
National Organic Program Profile	Not a Controlled Document
Quality Manual	NOP 1000 9/1/2015
Organizational Chart	NOP 1001 (Not a Controlled Document)
Duties, Responsibilities, and Authorities	NOP 1002 10/27/2015
Quality Policy & Quality Objectives	NOP 1003 5/9/2014
Quality Management System: Document Development, Review, and Distribution Process	NOP 1010 6/9/2015
Communication Tool Matrix	NOP 1010-7 4/8/2014
Project Kickoff Meeting Guide	NOP 1010-9 7/10/2015
Corrective and Preventive Action Procedure	NOP 1020 8/26/2015
Corrective and Preventive Action Summary Report	NOP 1020-2 8/26/2015
Internal Audit Procedure	NOP 1030 5/7/2015
Procedure: Peer Review of National Organic Program (NOP) Accreditation	NOP 1031, 5/12/16
Processing Freedom of Information Requests	NOP 1032 8/10/2010

Document Name	Document No. & Revision Date
Management Review	NOP 1040 8/11/2015
NOP Handbook - Introduction	NOP 1100 3/9/2011
NOP Instruction Accreditation Policies and Procedures	NOP 2000, 12/8/15
NOP Accreditation Assessment Checklist	NOP 2005, 10/29/15
NOP Certification File Review Checklist – Supplement for Grower Groups	NOP 2005-3, 5/15/13
NOP Witness Audit Checklist	NOP 2005-4, 8/25/14
NOP Witness Audit Checklist for Grower Group	NOP 2005-5, 8/25/14
NOP Audit Checklist – Review Audit (RA)	NOP 2005-6, 5/29/14
NOP Instruction Separation of Duties in Certification Decisions	NOP 2006, 4/7/14
Accreditation Committee Instruction	NOP 2012 7/8/2015
Accreditation Committee Timeline	NOP 2012-1 7/9/2015
Accreditation Committee Evaluation Checklist	NOP 2012-4 7/9/2015
NOP Information Submission Requirements for Certifying Agents	NOP 2024, 5/29/14
NOP Annual Report Checklist	NOP 2024-1, 1/13/12
Internal Program Review Requirements	NOP 2025 8/2/2015
Submitting Annual Lists of Certified Operations	NOP 2026 12/8/2015
Personnel Performance Evaluations	NOP 2027 3/31/2015
Extending Accreditation Activities Procedure	NOP 2039 10/13/2015
NOP Import Certificate	NOP 2110-1, OMB 0581-0191, undated
Assessing ACA's for TM-11	NOP 2402 6/19/2015
Auditor Criteria	NOP 2500 12/8/2015
Evaluating Auditor Performance	NOP 2501 12/8/2015

Document Name	Document No. & Revision Date
Auditor-In-Training Performance Evaluation Worksheet	NOP 2501-1 05/07/2015
Auditor Evaluation Worksheet	NOP 2501-2 10/23/2013
Organic Certificates	NOP 2603 9/3/2013
Reinstating Suspended Organic Operations	NOP 2605 2/17/2015
Disclosure of Information: USDA-Accredited Certifying Agents and Certified Operations to the National Organic Program	NOP 2607 11/23/2011
NOP Instruction Responding to Noncompliances	NOP 2608, 1/13/12
Instruction: Unannounced Inspections	NOP 2609 9/12/2012
Sampling Procedures for Residue Testing	NOP 2610 11/8/2012
Laboratory Selection Criteria for Pesticide Residue Testing	NOP 2611 11/8/2012
Prohibited Pesticides for NOP Residue Testing	NOP 2611-1 7/22/2011
Instruction - Responding to Results from Pesticide Residue Testing	NOP 2613, 3/4/13
Technical Assistance	NOP 2614 4/8/2013
NOP Instruction Enforcement of the USDA Organic Regulations: Penalty Matrix	NOP 4002, 1/20/15
Adverse Action Appeal Process	NOP 4011 12/23/2014
Wildcrop Harvesting-Response to Comments	NOP 5022 7/22/2011
Certification requirements for Handling Unpackaged Organic Products and Response	NOP 5031 1/22/2014 NOP 5031-1
Evaluation of Materials...	PM 11-4 8/6/2013
NOP Policy Memorandum "Calculating the Percentage of Organically Produced Ingredients"	PM-11-9, 1/31/11
NOP Guide for Organic Processors	Un-numbered, November 2012
National Organic Program Final Rule	7 CFR Part 205
Organic Foods Production Act	Title XXI

Document Name	Document No. & Revision Date
Proposed Rule	AMS–NOP–10–0083; NOP–10–09PR, 1/12/12
Interim Rule	77 FR 59287, 9/27/12
Memorandum to the National Organic Standards Board – NOP Accreditation Peer Review Process	Un-numbered, 11/19/14
Memorandum to the Chair of the National Organic Standards Board	Un-numbered, 4/26/10
NOP Fact Sheet - Proposed Rule for Vitamins and Minerals in USDA Organic Products	Un-numbered, 1/9/12
Memo to Accredited Certifying Agents – Periodic Residue Testing of Organic Products	Rev01 02/28/13
NOSB Recommendation: Criteria for Certification of Grower Groups	October 20, 2002
NOSB Recommendation: Certifying Operations with Multiple Production Units, Sites, and Facilities under the National Organic Program.	November 18, 2008
NOP Organic Integrity Quarterly Newsletter - https://www.ams.usda.gov/sites/default/files/media/2012-Organic-October-Newsletter.pdf	October 2012
National Organic Program - Notice to Stakeholders and Interested Parties	Notice 11-1, Jan. 6, 2011
NOSB Recommendation to NOP on National Organic Program Accreditation Peer Review Process	April 30, 2015
Memorandum to NOSB, NOSB Recommendations	September 3, 2015
NAQS Import Certificate	Not a controlled document
NOP Program Handbook	Web-based Content Listing

V. RECORDS

The following criteria were used to select accredited certification body (CB) files:

- One government CB within US (G)
- One CB Outside US (F)
- One ISO/IEC 17065 accredited CB (C)
- One small CB (S)

- One large CB (L)
- Suspension or Proposed suspension (U)
- One New CB applicant (N)
- One Renewal (R) CB applicant
- One Mid-term or on-going (O) CB

A list of Certification Bodies was provided by the USDA and the panel made the following selections based upon the above criteria:

Selection List with Criteria

Audit ID	Audit Type	Accreditation	Decision Date	Selection Criteria
NP5264EEA	Pre-decisional	New	1/28/16	Size S, N
NP5152EEA	Satellite	Continued	11/12/15	Size L, O
NP4132LCA	Renewal	Proposed Suspension	12/18/15	Size S, C, R, F, U
NP5166NNA	Mid-term	Continued	3/10/16	Size L, O
NP4342ZZA	Mid-term	Continued	10/6/15	Size S, G, O

File Content Table

Form/ Audit ID	NP5264EEA	NP5152EEA	NP4132LCA	NP5166NNA	NP4342ZZA
Letter of Engagement NOP 1031 Section 3.5 Not Listed	Yes	Yes	Yes	Yes	Yes
TM -10CG Application for Accreditation or Renewal NOP 1031 Section 3.5a	Yes	No	Yes	No	No
LPS 109 Application for Service NOP 1031 Section 3.5a	Yes	No	No	No	No
LS 313	No	Yes	Yes	Yes	Yes

Form/ Audit ID	NP5264EEA	NP5152EEA	NP4132LCA	NP5166NNA	NP4342ZZA
Application for Service (Grading and Verification Division) NOP 1031 Section 3.5a					
AIA Document Review Summary Sheet NOP 1031 Section 3.5b	Yes	No	No	No	No
QAD1415 Form 3/2014) NOP Audit Plan NOP 1031 Section 3.5c	Desk audit – Yes Site audit - Yes	Yes	Yes	Yes	Yes
NOP 2005 National Organic Program Accreditation Assessment Checklist NOP Audit Report NOP 1031 Section 3.5d	Desk Audit – Yes Site Audit - Yes	Yes	Yes	Yes	Yes
Notice of Noncompliance NOP 1031 Section 3.5e	Yes	Yes	Yes	Yes	Yes
Noncompliance Report NOP 1031 Section 3.5e	Yes	Yes	Yes	Yes	Yes

Form/ Audit ID	NP5264EEA	NP5152EEA	NP4132LCA	NP5166NNA	NP4342ZZA
Proposed corrective action from the applicant NOP 1031 Section 3.5f	Yes	Yes	Yes	Yes	Yes
Corrective Action Report (showing corrective action receipt and acceptance) NOP 1031 Section 3.5e	Yes	Yes	Yes	Yes	Yes
Certificate NOP 1031 Section 3.5j	Yes	Yes	Yes (Not up to Date)	Yes	Yes
Terms of accreditation NOP 1031 Section 3.5h	Yes	No	No	Yes	No
Notice of Continued Accreditation NOP 1031 Section 3.5i	Yes	Yes	No	Yes	Yes
NOP2012-4 Accreditation Committee Evaluation Checklist NOP 1031 Section 3.5g	Yes	No	No	No	No
Certifier Policy and Procedure (Quality)	Yes	Yes	No	Yes	No

Form/ Audit ID	NP5264EEA	NP5152EEA	NP4132LCA	NP5166NNA	NP4342ZZA
Manual					

Refer to the individual technical reports for an assessment of the records review.

VI. RESULTS OF PEER REVIEW PANEL ASSESSMENT

1. The objective evidence obtained during this assessment related to ISO/IEC 17011 requirements are in the Annex 1 of this report. Objective evidence related to observations from the review of accreditation procedures and selected files is contained in the individual technical reports.
2. The following are the consolidated key observations of the review panel which have been recorded in ANSICA with objective evidence; refer to ANSICA for details:
 - **2016-USDA NOP-01-O-RANS-(17011)7.8.1** - The accreditation body's procedures are inadequate to ensure that the auditors are reviewing the regulatory status of ingredients and processing aids.
 - **2016-USDA NOP-03-O-RANS-(17011)7.13.2** - During file review an isolated instance of the NOP not following NOP 2002 for notification to certification body of a suspension was observed.
 - **2016-USDA NOP-04-O-RANS-(17011)7.14.1** - Consistent accreditation records are not being used and retained in order for the NOP to be in full compliance with 205.502.
 - **2016-USDA NOP-05-O-MILR-(17011) 5.3 A** - NOP 2005-4 Witness Audit Checklist is not complete. The NOP 2002 procedure does not provide the control needed to approve the document for adequacy prior to use.
 - **2016-USDA NOP-07-O-RANS-(17011)7.8.1** - The accreditation body does not ensure there is immediate notification to the NOP for potential changes by certified bodies that may affect compliance.
 - **2016-USDA NOP-08-O-MILR-(17011) 4.3.2** - 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
 - **2016-USDA NOP-09-O-MILR-(17011) 4.3.7** - 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.
 - **2016-USDA NOP-10-O-MILR-(17011) 5.3** - Clause 5.3 requires all documents to be controlled. Not all documents are adequately controlled.
 - **2016-USDA NOP-11-O-MILR-(17011) 5.4** - NOP indicates it has procedures for identification, collection, indexing, accessing, filing, storage, maintenance and disposal of its records, but specific procedures are not identified.

VII. OTHER OBSERVATIONS

- <https://www.ams.usda.gov/sites/default/files/media/LSoOfficialListingISOGuide65.pdf> is the Official Listing of Certification Bodies Approved under the USDA ISO Guide 65 or ISO 17065 Programs. One Certification Body is identified as being approved under the ISO/IEC Guide 65 program. The ISO/IEC Guide 65 document has been sunseted and replaced with ISO/IEC 17065. The certification body is ANSI accredited to ISO/IEC 17065; this page and the linking page (<https://www.ams.usda.gov/?dDocName=STELDEV3004346>) should delete all references to ISO/IEC Guide 65.
- Some documents, such as NOP 1030 clause 2.1, reference ISO/IEC Guide 65. All references to ISO/IEC Guide 65 must be changed to ISO/IEC 17065 which is the current standard.
- Guidance is used to identify permissive or desired actions and are not required to be followed. Guidance documents use the words “should” or “may”. Mandatory actions are requirements or Directives and not guidance. Requirements use the words “shall” or “must”. Some guidance documents contain mandatory language. For example, NOP2610 clause 4.5 covering Chain of Custody.
- Questions and Answers to the Quality Assessment Division (QAD) are not auditable. QAD documents are identified as Policy; however, Q&A for the QAD is Guidance and not enforceable.
- NOP indicates personnel and training records are maintained to demonstrate specific technical competency. Consider developing a Competency Matrix which identifies the competency for each individual auditor.

VIII. CONCLUSION

This completes the work of the ANSI Peer Review Panel for the USDA NOP accreditation body.

This report covers NOP’s compliance with ISO/IEC 17011 clauses 4, 5, 6 and 8. The individual technical reports cover review of NOP’s accreditation procedures and decisions, and compliance with ISO/IEC 17011 clause 6.

The Review Panel members find that NOP and its staff are in general compliance with ISO/IEC 17011 and NOP’s own policies and procedures. Opportunities for Improvement have been identified and are recorded in the individual reports and also in ANSI’s Conformity Assessment portal, ANSICA.

IX. ANNEX I – ISO/IEC 17011 CHECKLIST

17011 Clause	Requirement	Evidence of Fulfillment	Comment
4.1 Legal responsibility			
4.1	The accreditation body shall be a registered legal entity.	N/A	Governmental accreditation bodies are deemed to be legal entities on the basis of their governmental status.
4.2 Structure			
4.2.1	The structure and operation of an accreditation body shall be such as to give confidence in its accreditations.	The NOP Structure is outlined in NOP 1001 Organizational Chart and NOP 1002 Duties Responsibilities & Authorities.	No conflicts of interest were observed in the structure & operation.
4.2.2	The accreditation body shall have authority and shall be responsible for its decisions relating to accreditation, including the granting, maintaining, extending, reducing, suspending and withdrawing of Accreditations.	7 CFR 205	Authority & Responsibility are defined by the regulation.
4.2.3	The accreditation body shall have a description of its legal status, including the names of its owners if applicable, and, if different, the names of the persons who control it.	7 CFR 205	As a government entity, there are no owners.
4.2.4	The accreditation body shall document the duties, responsibilities and authorities of top management and other personnel associated with the accreditation body who could affect the quality of the accreditation.	NOP Functional Statement	The NOP Profile identifies staff positions that could affect the quality of the accreditation.
4.2.5	The accreditation body shall identify the top management having overall authority and responsibility for each of the following: a) development of policies relating to the operation of the accreditation body; b) supervision of the implementation of the policies and procedures; c) supervision of the finances of the accreditation body; d) decisions on accreditation; e) contractual arrangements; f) delegation of authority to committees or individuals, as required, to undertake defined activities on behalf of top management.	Top Management is identified in NOP 1001 Organizational Chart and NOP 1002 Duties, Responsibilities and Authorities	The referenced documents adequately identify individuals having overall authority and responsibility for the listed functions.
4.2.6	The accreditation body shall have access to necessary expertise for advising the accreditation body on matters related to accreditation.	Expertise is obtained through its staff and advisory committees.	A review was made of the qualifications of three staff members. The individuals have the necessary education, training and experience for the positions they hold.
4.2.7	The accreditation body shall have formal rules for the appointment, terms of reference and operation of committees that are involved in the accreditation process, and shall identify the parties participating.	NOP 2012 Accreditation Committee Instructions NOP 2012-2 List of Approved Accreditation Committee Members	The referenced documents adequately describe the composition, scope and operation of the Accreditation Committee and members are identified.
4.2.8	The accreditation body shall	NOP 1001 Organizational Chart and	The referenced documents

17011 Clause	Requirement	Evidence of Fulfillment	Comment
	document its entire structure, showing lines of authority and responsibility.	NOP 1002 Duties, Responsibilities and Authorities	adequately identify the structure, responsibilities & lines of authority.
4.3 Impartiality			
4.3.1	The accreditation body shall be organized and operated so as to safeguard the objectivity and impartiality of its activities.	NOP 1001 Organizational Chart NOP 1002 Duties, Responsibilities and Authorities NOP 2500 Auditor Criteria	Decisions on accreditation are made by persons different from those who assessed accreditation.
4.3.2	For safeguarding impartiality and for developing and maintaining the principles and major policies of operation of its accreditation system, the accreditation body shall have documented and implemented a structure to provide opportunity for effective involvement by interested parties. The accreditation body shall ensure a balanced representation of interested parties with no single party predominating.	NOP 1001 Organizational Chart NOP 1002 Duties, Responsibilities and Authorities NOP 2500 Auditor Criteria https://www.ams.usda.gov/rules-regulations/organic/nosb	NOP 1000 4.3.2 indicates NOP ensures a balanced representation of interested parties with no single party predominating. National Organic Standards Board (NOSB) is a Federal Advisory Board having 15 members with a defined balance of interest. Balanced representation of interested parties is not described for Accreditation Committee, NOP 2012 clause 2 qualifications.
4.3.3	The accreditation body's policies and procedures shall be non-discriminatory and shall be administered in a non-discriminatory way. The accreditation body shall make its services accessible to all applicants whose requests for accreditation fall within the activities (see 4.6.1) and the limitations as defined within its policies and rules. Access shall not be conditional upon the size of the applicant CAB or membership of any association or group, nor shall accreditation be conditional upon the number of CABs already accredited.	USDA Departmental Regulation 4070-735-001, Employee Responsibilities and Conduct. NOP 2000 Accreditation Policies & Procedures	The USDA prohibits discrimination in all its programs.
4.3.4	All accreditation body personnel and committees that could influence the accreditation process shall act objectively and shall be free from any undue commercial, financial and other pressures that could compromise impartiality.	USDA Departmental Regulation 4070-735-001, Employee Responsibilities and Conduct 5 CFR Part 2635 Standards of Ethical Conduct for Employees of the Executive Branch 5 CFR Part 8301 Supplemental Standards of Ethical Conduct for Employees of the Department of Agriculture NOP 2012 Accreditation Committee Instructions QAD 1102, 1450 and 1455 Procedures AD-1202 Confidential Conflict of Interest Certification	Managers & Supervisors are required to file an annual report of their financial interests and outside employment.
4.3.5	The accreditation body shall ensure that each decision on accreditation is taken by competent person(s) or committee(s) different from those who carried out the assessment.	Decision on accreditation is made by the Accreditation Committee. NOP 2012 Accreditation Committee Instructions	Accreditation Committee members are different from those who assessed accreditation.
4.3.6	The accreditation body shall not offer or provide any service that affects its impartiality, such as a) those conformity assessment services that CABs perform, or	NOP 2000 Accreditation Policies and Procedures NOP 2500 Auditor Criteria	NOP does not offer or provide consulting services. NOP does not direct certifiers to specific persons or consultants or require the use of any persons or consultants.

17011 Clause	Requirement	Evidence of Fulfillment	Comment
	<p>b) consultancy. The accreditation body's activities shall not be presented as linked with consultancy. Nothing shall be said or implied that would suggest that accreditation would be simpler, easier, faster or less expensive if any specified person(s) or consultancy were used.</p>		
4.3.7	<p>The accreditation body shall ensure that the activities of its related bodies do not compromise the confidentiality, objectivity and impartiality of its accreditations. A related body may, however, offer consultancy or provide those conformity assessment services the accreditation body accredits, subject to the related body having (with respect to the accreditation body)</p> <p>a) different top management for the activities described in 4.2.5, b) personnel different from those involved in the decision-making processes of accreditation, c) no possibility to influence the outcome of an assessment for accreditation, and d) distinctly different name, logos and symbols.</p> <p>The accreditation body, with the participation of the interested parties as described in 4.3.2, shall identify, analyse and document the relationships with related bodies to determine the potential for conflict of interest, whether they arise from within the accreditation body or from the activities of the related bodies. Where conflicts are identified, appropriate action shall be taken.</p>	<p>NOP 2012 Accreditation Committee Instructions NOP 2500 Auditor Criteria QAD 1102 Procedure, Selection of Audit Team Members and personnel files</p>	<p>Related bodies that provide consultancy are outside of the NOP management structure. A person from these bodies who provides consultancy to a certifier may not participate in the assessment or accreditation decision for that certifier. Any conflicts are identified and kept in NOP files.</p> <p>Relationships with related bodies are documented and any conflicts of interest are identified. A description of the process to determine appropriate action to be taken is not described.</p>
4.4 Confidentiality			
4.4	<p>The accreditation body shall have adequate arrangements to safeguard the confidentiality of the information obtained in the process of its accreditation activities at all levels of the accreditation body, including committees and external bodies or individuals acting on its behalf. The accreditation body shall not disclose confidential information about a particular CAB outside the accreditation body without written consent of the CAB, except where the law requires such information to be disclosed without such consent.</p>	<p>NOP 2000 Accreditation Policies and Procedures NOP 2012 Accreditation Committee Instruction NOP 1010 Quality Management System Document and Record Control Procedure NOP 1032 Processing Freedom of Information Requests</p>	<p>The NOP meets the confidentiality requirements in 5 C.F.R. 2635.703 Use of nonpublic information, 5 U.S.C. § 552 The Freedom of Information Act, 5 U.S.C. § 552a Privacy Act of 1974; AMS Directive 160.1 Freedom of Information, and AMS Directive 160.2 Privacy Act</p>

17011 Clause	Requirement	Evidence of Fulfillment	Comment
4.5 Liability and financing			
4.5.1	The accreditation body shall have arrangements to cover liabilities arising from its activities.	NOP maintains adequate financial reserves to cover liabilities arising from its operations and/or activities.	Liabilities that cannot be covered by NOP funds would be covered by the Marketing Services account and the AMS budget reserves.
4.5.2	The accreditation body shall have the financial resources, demonstrated by records and/or documents, required for the operation of its activities. The accreditation body shall have a description of its source(s) of income.	The NOP receives financial resources through appropriated funds and is able to collect user fees for accreditation activities through QAD.	Fees for accreditation costs are published in NOP 2000 and the NOP federal budget appropriation is available online
4.6 Accreditation activity			
4.6.1	The accreditation body shall clearly describe its accreditation activities, referring to the relevant International Standards, Guides or other normative documents.	NOP 2000 Accreditation Policies and Procedures and other 2000 Series documents referenced in the Quality Manual.	QMS Handbook describes General Accreditation Policies and Procedures.
4.6.2	The accreditation body may adopt application or guidance documents and/or participate in the development of them. The accreditation body shall ensure that such documents have been formulated by committees or persons possessing the necessary competence and, where appropriate, with participation of interested parties. Where international application or guidance documents are available, these should be used.	ISO/IEC 17011: 2004 and guidance documents developed and issued by the NOP. USDA Organic Regulations	The NOP Handbook identifies adopted guidance issues. Some guidance contains mandatory language. For example: NOP2610 clause 4.5 covering Chain of Custody
4.6.3	The accreditation body shall establish procedures for extending its activities and to react to demands of interested parties. Possible elements to be included in the procedures are: a) analysis of its present competence, suitability of extension, resources, etc. in the new field, b) accessing and employing expertise from other external sources, c) evaluating the need for application or guidance documents, d) initial selection and training of assessors, and e) training accreditation body's staff in the new field.	NOP 2500	NOP provides staff training for auditors as necessary when the regulations are revised.
5.1 General Management			

17011 Clause	Requirement	Evidence of Fulfillment	Comment
5.1.1	The accreditation body shall establish, implement and maintain a management system and continually improve its effectiveness in accordance with the requirements of this International Standard. Requirements for the management system that take into account the particular nature of accreditation bodies are defined in 5.2 to 5.9.	NOP maintains its management system and continually improves its effectiveness through the use of internal and external audits, management reviews, corrective and preventative actions, and customer feedback.	A management system is in place.
5.1.2	Where this International Standard requires the accreditation body to have or establish procedures, this means that they shall be documented, implemented and maintained, and shall be based on formulated policies wherever suitable.	NOP 1006 NOP Document Control Master List	Procedures are documented, implemented and maintained.
5.2 Management system			
5.2.1	The accreditation body's top management shall define and document policies and objectives, including a quality policy, for its activities, and it shall provide evidence of commitment to quality and to compliance with the requirements of this International Standard. The management shall ensure effective communication of the needs of interested parties. The management shall also ensure that the policies are understood, implemented and maintained at all levels of the accreditation body. The objectives should be measurable and shall be consistent with the accreditation body's policies. NOTE Those accreditation bodies that are signatories to a mutual recognition arrangement may refer to the obligations of the mutual recognition arrangement in their policies.	NOP 1003 Quality Policy & Quality Objectives	Objectives are measured through employee performance and training, customer feedback including that from the NOSB, and the timeframes for providing services, addressing appeals, and addressing complaints.
5.2.2	The accreditation body shall operate a management system appropriate to the type, range and volume of work performed. All applicable requirements of this International Standard shall be addressed either in a manual or in associated documents. The accreditation body shall ensure that the manual and relevant associated documents are accessible to its personnel and shall ensure effective implementation of the system's procedures.	NOP 1010 Quality Management System Document and Record Control Procedure.	The manual and relevant associated documents (NOP document series 1000, 2000, 4000, 5000 and 8000) are maintained on the NOP server, which is accessible by all NOP personnel.
5.2.3	The accreditation body's top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that	NOP 1002 Duties, Responsibilities, and Authorities.	The Quality Manager is designated as the responsible member.

17011 Clause	Requirement	Evidence of Fulfillment	Comment
	includes a) ensuring that procedures needed for the management system are established, and b) reporting to top management on the performance of the management system and any need for improvement.		
5.3 Document control			
5.3	The accreditation body shall establish procedures to control all documents (internal and external) that relate to its accreditation activities. The procedures shall define the controls needed a) to approve documents for adequacy prior to issue, b) to review and update as necessary and re-approve documents, c) to ensure that changes and the current revision status of documents are identified, d) to ensure that relevant versions of applicable documents are available to personnel, subcontractors, assessors and experts of the accreditation body and CABs at points of use, e) to ensure that documents remain legible and readily identifiable, f) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose, and g) to safeguard, where relevant, the confidentiality of documents.	NOP 1010 Quality Management System Document and Record Control Procedure NOP 1006 NOP Document Master Control List.	In general, documents are uniquely identified and controlled by effective date. Some documents are not controlled such as NOP 1001 Organizational Chart.
5.4 Records			
5.4.1	The accreditation body shall establish procedures for identification, collection, indexing, accessing, filing, storage, maintenance and disposal of its records.	NOP 1000, 5.4.1	NOP 1000, 5.4 indicates NOP has procedures but specific procedures are not identified.
5.4.2	The accreditation body shall establish procedures for retaining records for a period consistent with its contractual and legal obligations. Access to these records shall be consistent with the confidentiality arrangements.	NOP 1000, 5.4.2	NOP 1000, 5.4 indicates NOP has procedures but specific procedures are not identified. It appears that individual documents contain records retention periods. Access to records follows confidentiality agreements.
5.5 Nonconformities and corrective actions			

5.5	<p>The accreditation body shall establish 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:</p> <ul style="list-style-type: none"> a) identifying nonconformities (e.g. from complaints and internal audits); b) determining the causes of nonconformity; c) correcting nonconformities; d) evaluating the need for actions to ensure that nonconformities do not recur; e) determining the actions needed and implementing them in a timely manner; f) recording the results of actions taken; g) reviewing the effectiveness of corrective actions. 	NOP 1020 Corrective and Preventive Action Procedure.	The Corrective Action system addresses the factors required by the standard.
5.6 Preventive actions			
5.6	<p>The accreditation body shall establish procedures to identify opportunities for improvement and to take preventive actions to eliminate the causes of potential nonconformities. The preventive actions taken shall be appropriate to the impact of the potential problems. The procedures for preventive actions shall define requirements for:</p> <ul style="list-style-type: none"> a) identifying potential nonconformities and their causes, b) determining and implementing the preventive actions needed, c) recording results of actions taken, and d) reviewing the effectiveness of the preventive actions taken. 	NOP 1020 Corrective and Preventive Action Procedure.	The Preventative Action system addresses the factors required by the standard.
5.7 Internal audits			

5.7.1	The accreditation body shall establish procedures for internal audits to verify that they conform to the requirements of this International Standard and that the management system is implemented and maintained. NOTE As an indication, ISO 19011 provides guidelines for conducting internal audits.	https://www.ams.usda.gov/services/auditing NOP 1030 Internal Audit Procedure	AMS utilizes the International Organization for Standardization (ISO) 19011:2011 guidelines for quality and/or environmental management systems auditing as the format to evaluate program documentation, to ensure consistent auditing practices, and to promote international recognition of audit results.
5.7.2	Internal audits shall be performed normally at least once a year. The frequency of internal audits may be reduced if the accreditation body can demonstrate that its management system has been effectively implemented according to this International Standard and has proven stability. An audit programme shall be planned, taking into consideration the importance of the processes and areas to be audited, as well as the results of previous audits.	NOP 1030 Internal Audit Procedure	The internal audit procedure is satisfactory.
5.7.3	The accreditation body shall ensure that: a) internal audits are conducted by qualified personnel knowledgeable in accreditation, auditing and the requirements of this International Standard, b) internal audits are conducted by personnel different from those who perform the activity to be audited, c) personnel responsible for the area audited are informed of the outcome of the audit, d) actions are taken in a timely and appropriate manner, and e) any opportunities for improvement are identified.	NOP 1030 Internal Audit Procedure	The internal audit procedure is satisfactory.
5.8 Management reviews			
5.8.1	The accreditation body's top management shall establish procedures to review its management system at planned intervals to ensure its continuing adequacy and effectiveness in satisfying the relevant requirements, including this International Standard and the stated policies and objectives. These reviews should be conducted normally at least once a year.	NOP 1040 Management Review	Management reviews are conducted annually after the internal audit and peer review.

5.8.2	Inputs to management reviews shall include, where available, current performance and improvement opportunities related to the following: a) results of audits; b) results of peer evaluation where relevant; c) participation in international activities, where relevant; d) feedback from interested parties; e) new areas of accreditation; f) trends in nonconformities; g) status of preventive and corrective actions; h) follow-up actions from earlier management reviews; i) fulfilment of objectives; j) changes that could affect the management system; k) appeals; l) analysis of complaints.	NOP 1040 Management Review	Key performance factors are identified and reviewed.
5.8.3	The outputs from the management review shall include actions related to a) improvement of the management system and its processes, b) improvement of services and accreditation process in conformity with the relevant standards and expectations of interested parties, c) need for resources, and d) defining or redefining of policies, goals and objectives.	NOP 1040 Management Review	Required outputs are addressed in the procedure.
5.9 Complaints			
5.9	The accreditation body shall establish procedures for dealing with complaints. The accreditation body a) shall decide on the validity of the complaint, b) shall, where appropriate, ensure that a complaint concerning an accredited CAB is first addressed by the CAB c) shall take appropriate actions and assess their effectiveness, d) shall record all complaints and actions taken, and e) shall respond to the complainant.	NOP 4001 5.3 5.4 5.6.2 a 5.6.2 c & d 5.11 b-h 5.5, 5.6.1 b, 5.11.1 a	NOP Complaint Handling Process Compliance Coordinator function Referrals to ACA ACA reports findings to CE Division. Compliance Specialist follow-up. Done during case opening & closing process Done initially during referrals and during case closing process
6.1 Personnel associated with the accreditation body			
6.1.1	The accreditation body shall have a sufficient number of competent personnel (internal, external, temporary, or permanent, full time or part time) having	NOP 1002 Duties, Responsibilities and Authorities NOP 2500 Auditor Criteria QAD 1102, 1405, 1450 and 1455 procedures.	The procedures identify the functional duties and responsibilities.

	the education, training, technical knowledge, skills and experience necessary for handling the type, range and volume of work performed.		
6.1.2	The accreditation body shall have access to a sufficient number of assessors, including lead assessors, and experts to cover all of its activities.	NOP 1001 NOP Organizational Chart NOP 1002 Duties, Responsibilities and Authorities NOP 2500 Auditor Criteria QAD 1102, 1405, 1450 and 1455 procedures and personnel records	
6.1.3	The accreditation body shall make clear to each person concerned the extent and the limits of their duties, responsibilities and authorities.	NOP 1001 NOP Organizational Chart NOP 1002 Duties, Responsibilities and Authorities NOP 2000 Accreditation Policies & Procedures NOP 2500 Auditor Criteria and personnel records	
6.1.4	The accreditation body shall require all personnel to commit themselves formally by a signature or equivalent to comply with the rules defined by the accreditation body. The commitment shall consider aspects relating to confidentiality and to independence from commercial and other interests, and any existing or prior association with CABs to be assessed.	Departmental Regulation NUMBER: 4070-735-001	During the AMS onboarding process, new employees are also provided with a link to the Department Regulation, "Employee Responsibilities and Conduct," and must reaffirm their commitment to this regulation each year when signing their performance appraisal.
6.2 Personnel involved in the accreditation process			
6.2.1	The accreditation body shall describe for each activity involved in the accreditation process a) the qualifications, experience and competence required, and b) initial and ongoing training required.	NOP 1002 Duties, Responsibilities, and Authorities NOP 2012 Accreditation Committee Instruction NOP 2500 Auditor Criteria and QAD procedures numbered 1405, 1450, 1450A, 1450B, and 1455.	The NOP determines requirements for persons participating in the accreditation process to have initial training on the procedure and ongoing training, as determined necessary. The NOP AIA Division Director reviews the expertise of auditors and approves the audit team prior to the audit being conducted.
6.2.2	The accreditation body shall establish procedures for selecting, training and formally approving assessors and experts used in the assessment process.	NOP 2500 Auditor Criteria, and QAD procedures numbered 1450 and 1455.	Auditor criteria are satisfactory.
6.2.3	The accreditation body shall identify the specific scopes in which each assessor and expert has demonstrated competence to assess.	NOP personnel and training records.	Consider developing a Competency Matrix which identifies the competency for each individual auditor.
6.2.4	The accreditation body shall ensure that assessors and, where relevant, experts a) are familiar with accreditation procedures, accreditation criteria and other relevant requirements, b) have undergone a relevant accreditation assessor training, c) have a thorough knowledge of the relevant assessment methods, d) are able to communicate	NOP 1002 Duties, Responsibilities, and Authorities, NOP 2500 Auditor Criteria, QAD procedures numbered 1405, 1450, and 1455, and NOP personnel and training records.	An annual performance appraisal is conducted for all staff.

	effectively, both in writing and orally, in the required languages, and e) have appropriate personal attributes. NOTE Guidance on personal attributes may be found in publications such as ISO 19011.		
6.3 Monitoring			
6.3.1	The accreditation body shall ensure the satisfactory performance of the assessment and the accreditation decision-making process by establishing procedures for monitoring the performance and competence of the personnel involved. In particular, the accreditation body shall review the performance and competence of its personnel in order to identify training needs.	NOP 2004-6 Annual Review of NOP Accreditation Audits and NOP 2501 Evaluating Auditor Performance	The NOP uses performance reviews to monitor the performance of its personnel involved in the assessment and accreditation decision-making process. These performance reviews are conducted at least annually during each fiscal year (October 1 to September 30) and may be conducted more frequently as necessary.
6.3.2	The accreditation body shall conduct monitoring (e.g. by on-site observations, or by using other techniques such as review of assessment reports, feedback from CABs and peer monitoring of assessors) to evaluate an assessor's performance and to recommend appropriate follow-up actions to improve performance. Each assessor shall be observed on-site regularly, normally every three years, unless there is sufficient supporting evidence that the assessor is continuing to perform competently.	NOP 2004-6 Annual Review of NOP Accreditation Audits NOP 2501 Evaluating Auditor Performance	Performance of NOP personnel involved in the assessment and accreditation decision-making process is monitored through performance reviews. These performance reviews are conducted at least annually during the fiscal year (October 1 to September 30) and may be conducted more frequently as necessary. Refer to NOP 2004-6 Annual Review of NOP Accreditation Audits and NOP 2501.
6.4 Personnel records			
6.4.1	The accreditation body shall maintain records of relevant qualifications, training, experience and competence of each person involved in the accreditation process. Records of training, experience and monitoring shall be kept up to date.	NOP personnel and training records.	Due to the nature of this remote peer review and the confidentiality of personnel records, this was not covered by ANSI's assessment. NOP represents that it has personnel records covering the training, experience and competence of staff.
6.4.2	The accreditation body shall maintain up-to-date records on assessors and experts consisting of at least the following: a) name and address; b) position held and for external assessors and experts, the position held in their own organization; c) educational qualifications and professional status; d) work experience; e) training in management systems, assessment and conformity assessment	NOP personnel and training records.	Due to the nature of this remote peer review and the confidentiality of personnel records, this was not covered by ANSI's assessment. NOP represents that it has personnel records covering the training, experience and competence of staff.

	activities; f) competence for specific assessment tasks; g) experience in assessment and results of their regular monitoring.		
7 Accreditation process – Refer to the individual Technical Reports			
8 Obligations of the CAB			
1.1	The accreditation body shall require the CAB to conform to the following. a) The CAB shall commit to fulfil continually the requirements for accreditation set by the accreditation body for the areas where accreditation is sought or granted. This includes agreement to adapt to changes in the requirements for accreditation, as set out in 8.2.4. b) When requested, the CAB shall afford such accommodation and cooperation as is necessary to enable the accreditation body to verify fulfilment of requirements for accreditation. This applies to all premises where the conformity assessment services take place. c) The CAB shall provide access to information, documents and records as necessary for the assessment and maintenance of the accreditation. d) The CAB shall provide access to those documents that provide insight into the level of independence and impartiality of the CAB from its related bodies, where applicable. e) The CAB shall arrange the witnessing of CAB services when requested by the accreditation body. f) The CAB shall claim accreditation only with respect to the scope for which it has been granted accreditation. g) The CAB shall not use its accreditation in such a manner as to bring the accreditation body into disrepute. h) The CAB shall pay fees as shall be determined by the accreditation body.	NOP 2000 Accreditation Policies and Procedures, TM-10CG Application for Accreditation, and the USDA organic regulations.	The TM-10CG is the legal agreement covering obligations of the CAB. Item c of this clause is not specifically identified. Consider adding this to the application rather than depending on the catchall language in clause 6 of the application.
8.1.2	The accreditation body shall require that it is informed by the accredited CAB, without delay, of significant changes relevant to its accreditation, in any aspect of its status or operation relating to a) its legal, commercial, ownership or organizational status, b) the organization, top management and key personnel, c) main policies, d) resources and premises, e) scope of accreditation, and f) other such matters that may affect the ability of the CAB to fulfil requirements for accreditation.	NOP 2000 Accreditation Policies and Procedures and the USDA organic regulations.	Attachment A of NOP 2000 covers changes due to business relocations, personnel changes or other events.
8.2 Obligations of the accreditation body			
8.2.1	The accreditation body shall make	NOP 2000 Accreditation Policies	Required information is on the

	publicly available information about the current status of the accreditations that it has granted to CABs. This information shall be updated regularly. The information shall include the following: a) name and address of each accredited CAB; b) dates of granting accreditation and expiry dates, as applicable; c) scopes of accreditation, condensed and/or in full. If only condensed scopes are provided, information shall be given on how to obtain full scopes.	and Procedures and the USDA organic regulations. https://www.ams.usda.gov/resources/organic-certifying-agents	certificate.
8.2.2	The accreditation body shall provide the CAB with information about suitable ways to obtain traceability of measurement results in relation to the scope for which accreditation is provided.	7 C.F.R. §§ 205.670(d) and (e). NOP 2611 Laboratory Selection Criteria for Pesticide Residue Testing is a best practices document.	NOP 2611 Laboratory Selection Criteria for Pesticide Residue Testing requires laboratories to be accredited to ISO/IEC 17025 or to comply to a standard acceptable to the NOP.
8.2.3	The accreditation body shall, where applicable, provide information about international arrangements in which it is involved.	NOP 2100 Equivalence Determination Procedure, NOP 2101 Peer Review Procedure, NOP 2200 Recognition and Monitoring of Foreign Government Conformity Assessment Systems, NOP 2402 Assessing Certifying Agents to Issue TM-11 Organic Export Certificates, and NOP 2403 Certifying Agents Approved to Issue TM-11 Export Certificate under an Export Arrangement Between the USDA and a Foreign Government.	The referenced documents adequately address this requirement.
8.2.4	The accreditation body shall give due notice of any changes to its requirements for accreditation. It shall take account of views expressed by interested parties before deciding on the precise form and effective date of the changes. Following a decision on, and publication of, the changed requirements, it shall verify that each accredited body carries out any necessary adjustments.	NOP Program Handbook and NOP 2000 Accreditation Policies and Procedures.	The procedures address changes in requirements.
8.3 Reference to accreditation and use of symbols			
8.3.1	An accreditation body, as proprietor of the accreditation symbol that is intended for use by its accredited CABs, shall have a policy governing its protection and use. The accreditation symbol shall have, or be accompanied with, a clear indication as to which activity (as indicated in Clause 1) the accreditation is related. An accredited CAB is allowed to use this symbol on its reports or certificates issued within the scope of its accreditation.	N/A	The NOP does not specifically have an accreditation symbol. Certifiers may, however, use the USDA organic seal to signify accreditation to the USDA organic regulations. Additionally, the NOP allows certifiers to use the USDA organic seal on reports, certificates, and advertisements.

8.3.2	<p>The accreditation body shall take effective measures to ensure that the accredited CAB</p> <p>a) fully conforms with the requirements of the accreditation body for claiming accreditation status, when making reference to its accreditation in communication media such as the Internet, documents, brochures, or advertising,</p> <p>b) only uses the accreditation symbols for premises of the CAB that are specifically included in the accreditation,</p> <p>c) does not make any statement regarding its accreditation that the accreditation body may consider misleading or unauthorized,</p> <p>d) takes due care that no report or certificate nor any part thereof is used in a misleading manner,</p> <p>e) upon suspension or withdrawal of its accreditation (however determined), discontinues its use of all advertising matter that contains any reference to an accredited status, and</p> <p>f) does not allow the fact of its accreditation to be used to imply that a product, process, system or person is approved by the accreditation body.</p>	<p>NOP 2000 Accreditation Policies and Procedures, the USDA organic regulations, TM10CG Application for Accreditation, And the NOP 4000 Series (Compliance and Enforcement) documents, which address the misuse of statements, symbols, etc., relating to accreditation or certification of non-accredited or non-certified entities.</p>	<p>The referenced documents are satisfactory to demonstrate fulfillment of this requirement.</p>
8.3.3	<p>The accreditation body shall take suitable action to deal with incorrect references to accreditation status, or misleading use of accreditation symbols found in advertisements, catalogues, etc. NOTE Suitable actions include request for corrective action, withdrawal of accreditation, publication of the transgression and, if necessary, other legal action.</p>	<p>NOP 2000 Accreditation Policies and Procedures, the USDA organic regulations, and the NOP 4000 Series (Compliance and Enforcement) documents</p>	<p>The referenced documents are satisfactory to demonstrate fulfillment of this requirement.</p>

END OF REPORT



Product Certification Accreditation

ANNEX 2
TECHINCAL EVALUATOR REPORT-
SUSAN RANCK
2016 Peer Review Panel
Individual Report 1

For

United States Department of Agriculture
Agricultural Marketing Service
National Organic Program
1400 Independence Avenue, NW
Room 2646 South Building
Washington DC 20250 USA

Dates of Review Panel:
May 16 - 18, 2016

Prepared by

American National Standards Institute
1899 L Street, 11th Floor
Washington, DC 20036

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Document: Technical Evaluator's Report
USDA-AG6395S150169-2016-ANNEX2-Rev00

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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

Telephone

202-720-3252

Review

Type of Review

Peer Review Panel

Review Dates

May 16 - 18, 2016

Review Standard(s)

ISO/IEC 17011:2004 Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies
US 7 CFR Part 205, National Organic Program

Review Team

Lead Reviewer:

Robert Miller

Technical Reviewer:

Susan Ranck

Technical Reviewer:

Jean Richardson

Technical Reviewer:

Jim Riddle

ANSI Observer(s)

**Reinaldo Figueiredo
Elizabeth Okutuga**

Report

Prepared by:

Susan Ranck

Submitted to ANSI on:

June 7, 2016

II. SCOPE

The NOP is establishing a peer review panel to satisfy internal requirements regarding adherence to internal and regulatory requirements. American National Standards Institute (ANSI) has convened this panel effective May 16, 2016 to fulfill the expectation of this requirement.

The panel is tasked with the following:

- evaluate the NOP's policies, processes and procedures for conformance to the NOP statute and regulations and ISO/IEC 17011; and
- review implementation of certification body accreditation processes through file review.

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 in accordance with 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

Jean Richardson, Professor Emerita, University of Vermont, independent organic inspector, and Law Clerkship, Member NOSB (term expires: January 2017)

James Riddle, Organic Research Grants Program Manager, Ceres Trust, Organic inspector with training in ISO 9000, Former member NOSB

Susan Ranck – IOIA-trained organic inspector, IFT Certified Food Scientist, ANSI technical assessor

Elizabeth Okutuga, Program Coordinator, 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

Records

The following criteria were used to select accredited certification body (CB) files:

- One government within US (G)
- One Certifier Outside US (F)
- One ISO/IEC 17065 accredited CB (C)
- One small CB (S)
- One large CB (L)
- Suspension (Surrender) or Proposed suspension (U)
- One New (N)
- One Renewal (R)
- One Continued or on-going (O)

Selection List with Criteria

Entity	Audit ID	Audit Type	Accreditation	Decision Date	Selection Criteria
Basin and Range Organics	NP5264EEA	Pre-decisional	New	1/28/16	Size S, N
Primus Labs	NP5152EEA	Satellite	Continued	11/12/15	Size L, O
Ecological Farming Control Organization	NP4132LCA	Renewal	Proposed Suspension	12/18/15	Size S, C, R, F, U
Ecocert ICO, LLC	NP5166NNA	Mid-term	Continued	3/10/16	Size L, O
Texas Department of Agriculture	NP4342ZZA	Mid-term	Continued	10/6/15	Size S, G, O

IV. 7 CFR Part 205 National Organic Program

7 CFR §205.400(c) General Requirements for Certification

§205.401 Application for Certification

Collection of the client application by the accredited certification body is reviewed during the on-site visit and is documented by the NOP auditor on NOP 2005. Section II covers this section and collects information on the certification body including information provided as part of the application, certification fees and documentation collected. No issues were noted with the 5 clients reviewed.

§205.402 Review of Application

Application review is assessed and documented in II of NOP 2005. Included in the review is confirmation of who reviews the application, who conducts material review and how the application information is verified correct. The 5 client files presented for review were adequately documented to provide detail of this evaluation.

§205.403 On-site Inspection

The Accreditation Assessment Checklist (NOP 2005) Section III in detail captures all information required to document assessment of this criteria. File review indicated adequate documentation including unannounced audits, trace back reviews as part of the audits and exit interviews with the most senior responsible party. File review supported NOP assessor review of the criteria. NOP findings were well documented and evidence supported the NOP assessor decision.

§205.404 Granting Certification

Section IV of the NOP 2005 captures all necessary information for review of this criteria. Certificate decision and content is reviewed and documented. Findings were consistent in severity and evidence for observations in all files reviewed.

§205.405 Denial of Certification

The assessor completes Section V of the NOP 2005 to document the certification denial of certification. Files reviewed are detailed in the table section of 2005 and are well documented in both the checklist and the supporting documentation.

§205.406 Continuation of Certification

Section VI of the NOP 2005 is used to document the body program's process of certification for all clients. Evidence presented was consistent with decisions made.

7 CFR §205.500 Areas and Duration of Accreditation

§205.501 General Requirements for Accreditation

Section VII of the NOP 2005 provides information on the certification body regarding their expertise, competency and number of staff. The assessor includes details on specific qualifications and annual performance evaluations in Table 8. Auditor confidentiality and maintenance of records are also provided in this section.

§205.503 Applicant Information

Section VIII is completed to provide information relevant to Section 205.503. This section is completed only for initial or renewal assessments. This section documents the organizational information. Completion of this section was found to be consistent with the requirements.

§205.504 Evidence of Expertise and Ability

Section IX is completed to provide personnel information. This section is completed only for initial or renewal assessments. Information provided includes training and evaluation policies, a listing of all personnel and their qualifications and administrative activities. Completion of this section was found to be consistent with the requirements.

§205.510 Annual Report, Recordkeeping and Renewal of Accreditation

The NOP 2005 Section X documents the annual certification body update and details any changes to the program including internal annual review, application of fees and maintenance of records.

7 CFR §205.660 Compliance

§205.661(a) Investigation of Certified Operations

§205.662 Non-compliance Procedure for Certified Operations

Section XII references the following NOP documents for investigation of complaints and adverse actions. File reviews are detailed client by client in Table 4 of the check sheet.

NOP 2607 Disclosure of Information Concerning Operations Certified Under the NOP

NOP 4001 Complaint Handling Procedure

NOP 4002 Enforcement of the USDA Organic Regulations by Accredited Certifying Agents

NOP Appeals Procedure: Adverse Action Appeal Process – Certified Operation or Applicant for Certification

§205.663 Mediation

Mediation activities are documented, if they have occurred, in Section XIII of the checklist.

§205.670 Inspection & Testing of Agricultural Products

§205.671 Exclusion from Organic Sale

Section XIV is used to capture all applicable information for sampling and testing by the certification body. Tables 7a and 7b provide granular detail on the body's activity with regard to lab selection, chain of custody, 5 of the clients tested and communication of results.

§205.672 Emergency Pest or Disease Treatment

Documented in Section XV as applicable to the certification body scope of accreditation

NOP 2005 National Organic Program Accreditation Assessment Checklist Effective Date: 10/29/2015

Worksheets & Findings (11 Tables and 1 Findings Template)

The worksheets and tables were found to contain objective, detailed evidence to support the notes and findings in Sections I – XVI of the NOP 2005 checklist. All worksheets were included with each checklist and tables not used were noted as not applicable. This aided in confirmation of the assessors' use of the application items and consideration of those not to be completed.

Other Observations

On the whole, the documents reviewed provided a consistent and complete documentation of the process followed for the accreditation process. There were many ancillary documents cited and provided that provide duplicate information and do not present added value to the process. There was inconsistent use of different applications with none seeming to be the one that 'must' be used to be considered for accreditation. The NOP 2005 document was consistently completed and submitted by the assessor and is a vital portion of the documentation chain. Documentation of review and decision with NOP 2002 was required by procedure for all assessments but found in practice to only be used for initial accreditation.

V. CONCLUSION

This completes the review by a member of ANSI Peer Review Panel of the NOP Accreditation Process. With the exception of the findings identified, the program is being consistently implemented pursuant to the regulatory and procedural requirements cited herein.



Product Certification Accreditation

ANNEX 3- TECHNICAL EVALUATOR REPORT- JEAN RICHARDSON

**2016 Peer Review Panel
Individual Report 2**

For

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

**1400 Independence Avenue, NW
Room 2646 South Building
Washington DC 20250 USA**

**Dates of Review Panel:
May 16 - 18, 2016**

Prepared by

American National Standards Institute
1899 L Street, 11th Floor
Washington, DC 20036

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**Document: Technical Evaluator's Report
USDA-AG6395S150169-2016-ANNEX3-Rev00**

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I. GENERAL INFORMATION

Accreditation Body

Name of Review Body

Agricultural Marketing Services (AMS)

Address

1400 Independence Avenue S.W.
Room 2648 South Building
Washington, DC 20250

Telephone

202-720-3252

Assessment

Type of Review

Peer Review Evaluation

Review Dates

May 4, 16 - 18, 26, 2016
July 11, 22, 2016
August 5, 2016

Review Standard(s)

7 CFR 205
ISO/IEC 17011

Assessment Team

Lead Reviewer:

Robert Miller

Technical Reviewer:

Susan Ranck

Technical Reviewer:

Jean Richardson

Technical Reviewer:

Jim Riddle

ANSI Observer(s)

Reinaldo Figueiredo
Elizabeth Okutuga

Report

Review Report Prepared by: **Jean Richardson**

Submitted to ANSI on: July 24, 2016

II. SCOPE

This Peer Review is conducted pursuant to Section 7 USC 6516 of the Organic Food Production Act (OFPA) and 7 CFR 205.509, Peer Review Panel, of the USDA Organic Regulations. This Peer Review follows a procedure outlined in NOP 1031 (5/12/16), *Peer Review of National Organic Program* (NOP) and as modified by letter of Miles McEvoy dated 5/19/2016.

“The NOP is establishing a peer review process to implement the peer review section (7CFR 205.509) of the USDA organic regulations. This peer review panel will “evaluate the NOP’s policies, processes and procedures for conformance to ISO/IEC 17011:2001 Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies, which replaced ISO/IEC Guide 61, and the accreditation procedures in subpart F of the USDA organic regulations. The panel will report its findings in writing to the NOP Deputy Administrator and the National Organic Standards Board (NOSB). The findings will be considered part of the NOP quality management system, and the Deputy Administrator will make corrective actions to the NOP accreditation processes as necessary and appropriate. The panel’s findings will neither bind the NOP to take any action nor affect the NOP’s decisions. The findings will be published and presented at public meetings of the National Organic Standards Board.” (NOP 1031 May 12, 2016).

III. INTRODUCTION

Background:

In November 2014 the NOP sent a Memorandum (*NOP Accreditation Peer Review Process*) to the National Organic Standards Board (NOSB) requesting that the NOSB review a proposed Peer Review of NOP Accreditation, and provide feedback. This NOP memorandum was attached to the Scope of Work for this contract. The NOSB subcommittee on Certification and Accreditation (CACS) reviewed the NOP document, wrote a proposal (1/7/15), and sought public comment from all organic stakeholders through its public comment procedures and Posting prior to the April 2015 meeting of the NOSB. At that meeting the NOSB unanimously approved the recommendation. The NOSB Recommendation for a Peer Review process which is repeatable and transparent was accepted by the NOP in its 9/3/15 Response to the NOSB on its Recommendations and subsequently clarified in NOP 1031 first distributed internally at the NOP on May 12, 2016.

Documentation reviewed by this panel member:

The scope of work for this Peer Review specifically cites conformance with ISO/IEC 17011, 7 CFR 205.509, and accreditation procedures in subpart F which comprises Sections 205.500-205.510 of the USDA Regulations in addition to NOP policies, processes and procedures.

Numerous policy documents have been promulgated by the NOP over the last several years to augment the regulations and guide the accreditation process. Some of these policies, such as NOP 1031 were developed with public comment, while many were written without the benefit of public comment. Some of these policy documents are for distribution to the public, are in the NOP Handbook, easily found on the NOP Website, and transparent to the public. Others are for internal NOP distribution only and were provided upon request by NOP staff to this panel.

The table below indicates NOP documents reviewed by this panel member.

The policy document numbering convention used is generally as follows:
1000 – General NOP/Office of Deputy Administrator

- 2000 – Accreditation and Certification related documents
- 3000 – Standards related documents
- 4000 – Compliance and enforcement related documents.

IV. 7 CFR Part 205 National Organic Program

Peer Review requires verification of compliance with 7 CFR 205 subpart F, *Accreditation of Certifying Agents*, which comprises Sections 205.500 - 205.510. However, when reviewing the representative accreditation decisions, full compliance with NOP policies and procedures can only be determined by including review of how the Certifier audited certified operations utilizing both Subpart E, *Certification*, and Subpart G, *Administrative, Compliance*.

Subpart E refers to requirements for certified operations, not certifiers, but for audit purposes, accrediting certifiers must demonstrate, pursuant to 205.501(a)3 and (4), that they have reviewed all aspects of Subpart E in auditing actions of certified operations.

Subpart G is referenced in several subsections of 205.501 and must be reviewed in order to verify compliance, for example, with possible non compliance procedures per 205.602, inspection and testing per 205.670, or unannounced inspections. Certifier files were specifically selected to include suspension of a certifier which necessitates review for compliance with 205.665, 205.680 and 205.681.

7 CFR 205 Sub Part E. - Certification

§205.400 General Requirements for Certification and

§205.401 Application for Certification and

§205.402 Review of Application

- All 5 files indicate that a standard procedure was used by NOP auditors to verify that Certifiers followed a transparent application procedure for certified operations seeking organic certification in compliance with 205.400, 205.401 and 205.402. To a large extent, this was accomplished utilizing a comprehensive 102-page Checklist-style document, NOP 2005 (10/29/2015), which includes live links to the Regulations and relevant policy documents.
- One file, the most recent, new applicant certifier, was notably complete in application detail and documentation.
- The regulations at 7 CFR 205 have been greatly augmented by a number of policy documents such as NOP PM 11-4, NOP 5031, NOP 2605, NOP 2603, NOP 2000, NOP 2006, and review of the 5 files indicated that these policies and procedures were followed, with the exceptions of those items identified in this report.
- File review indicated that NOP auditors reviewed certifiers' policies and procedures to ensure that staff and inspectors are appropriately qualified, trained and evaluated.

§205.403 On-site Inspection

- All 5 of the files reviewed indicated that auditors reviewed certifier files to verify that both annual and unannounced on-site inspections took place. (See also discussion under the Observations section on use of NOP 2069 policy document.)
- The NOP has written and distributed several policy documents to augment the regulations relating to on-site inspections, 205.403 (c) - (e), including NOP 2000, NOP 2005, NOP 2004-4, NOP 2005-3, and NOP 2005-5. Review of certifier files indicated that these policy documents are followed.
- All 5 files indicated that NOP auditors verified Exit Interviews and noted non-compliances in Exit Interviews, and in related follow up correspondence with certifiers.

§205.404 Granting Certification

- All 5 files reviewed indicated that auditors had reviewed certifier files to determine compliance with 205.404 and NOP 2603 which clarifies this Section.

§205.405 Denial of Certification

- All 5 files indicate NOP auditors had reviewed certifier files to determine if denial of certification had been handled correctly.
- In one file, NOP auditors identified a non-compliance in the procedures used by certifier to address denial and reinstatement of a certified operator. This was noted in their file review, with appropriate follow up documentation of corrective actions.

§205.406 Continuation of Certification

- All 5 files indicate NOP auditors reviewed certifier files to verify compliance with 205.406.

7 CFR 205 Sub Part F – Accreditation of Certifying Agents

§205.500 Areas and Duration of Accreditation

- File review indicates that NOP actions are in accordance with 205.500.

§205.501 General Requirements for Accreditation

- This Section includes a comprehensive list of requirements for certifiers to meet, including expertise and training of staff which is further covered in 205.504.
- All files reviewed indicated that NOP auditors had reviewed levels of expertise of staff and inspectors, per 205.501(a) (1) – (5).
- It was clear from all files reviewed that NOP verified that certifiers had conducted annual evaluations per 205.501(a)(6) and NOP auditors identified one issue of concern.
- NOP 2000 and NOP 2027 provide clarification of 205.501 (a)(6) on personnel evaluation.
- Section 501(a)(4) also indicates that verification of adequately trained personnel must comply with Subpart E.

- One file indicated that the NOP auditors correctly noted that there was a lack of expertise on the certifier staff to conduct materials review, citing 205.501(a)(5), and PM 11-4. Follow up in this file indicated that prior to accreditation of this new applicant, this issue was appropriately addressed.
- NOP 2000 requires use of NOP 2005 to implement 205.501 and in all five files reviewed, there was a completed NOP 2005 Checklist and tables as necessary to the specific audit.
- Certifying agents must demonstrate compliance with NOP 2024 on Information Submission Requirements of certifying agents and this was verified in file review.
- NOP 2025 also augments 205.501(a)(21) to instruct ACA's to establish and conduct annual program review of its certification activities, and this policy was verified as being followed.
- One file reviewed was an application from a new certifier which included the pre-decisional required documentation. In this file, it was noted that where inadequate detail or inaccuracies in documents were provided by the new applicant, the NOP auditors correctly referenced 205.501(a) (8) in providing sufficient information to the certifier to "enable them to comply with the applicable requirements of the Act and regulations".
- Four files included policies and procedure manuals for the certifier which enabled verification that conflict of interest and other related policies were in place as required at 205.501 (a) (11), and the required annual program review of certification activities per 205.5019a(7).
- Certifying agents must also comply with NOP 2025 in order to meet requirements of 205.501(a)(7), and this was verified in file review.
- All files indicated that certifiers have systems in place to comply with 205.501(a)(8).
- Verified that COI were reviewed for all staff per 205.501(a)(11).
- One file indicated that it was verified that the ACA provides all notices of approval and denial to the Administrator per 205.501(a)(15)(i) and that these are in their Procedures Manual.
- Verified that seals and logos were reviewed to ensure compliance with 205.501(b)(1)(3).

§205.503 Applicant Information

- All 5 files reviewed indicate that they meet the general requirements set out in 205.503.
- NOP 2000 provides specificity to augment 205.503 and some discrepancies were noted in file review suggesting some inconsistencies in cross referencing between the many policy documents in use.
- NOP 2000 Section 4.1 requires that form TM-10CG, Application for Accreditation (Attachment A) must be included in the Accreditation Application Package "for both initial

and renewal applications”. File review indicated an inconsistency with this. Only 2 out of the 5 files included TM-10CG.

- NOP 2000 Section 4.1 requires that form LPS-109, Application for Service (Attachment B) must be included in the Accreditation Application Package “for both initial and renewal applications”. File review indicated that only one file includes LPS -109, and instead the other 4 files utilize form LS 313 Application for Service (Grading and Verification Division). LPS 313 is noted in NOP 2005, but not in NOP 2000.
- Verified that certifiers submitted lists of each state and foreign country per 205.503(e).

§205.504 Evidence of Expertise and Ability

- Policies and Procedures manuals for certifiers were provided for 4 out of the 5 files reviewed. These allowed verification of procedures in place as they apply to qualifications, evaluations and training of staff and inspectors, COI and other policies.
- File review indicated that NOP auditors had reviewed the policies and procedures of all certifiers. The Pre-Decisional application file review indicated that auditors had identified errors in the proposed policies and procedures of the certifier, and records indicate that this issue was fully addressed prior to accreditation of certifier.
- Personnel reviews and evaluations were found in all files except one where it was not applicable as this was only a Satellite Audit.
- Verified that all files were reviewed to confirm lists of certified operations and lab results from pesticide testing per 205.504(b)(ii)(iii).

§205.505 Statement of Agreement

- Verified in each file. See also notes above under 205.501.

§205.506 Granting Accreditation

- There were 4 files which included Notice of Continued Accreditation; one file did not include this.
- All files included Certificates of Accreditation although one was not up to date.
- NOP 2000 indicates that the audit review process of certifiers must take place in a timely manner. Review of the 5 files indicated a reasonable time line for 2 files. One file was complicated in that it not only involved a number of years of non-compliances but that it is in an international location, involving certified operations in several countries, and involved Notice of Proposed Suspension and Settlement.

§205.507 Denial of Accreditation

- Of the 5 files reviewed, none were denied accreditation although one file included a lengthy period of noncompliance procedures, proposed suspension and settlement, all of which was well documented and met the policies set out in NOP 2608.

- One file included discussion of a possible suspension, but the issue was resolved to give the certifier additional time to come in to compliance.

§205.508 Site Evaluations

- Witness Audits and site evaluations were conducted and well documented in all files as relevant.
- Several NOP policy documents amplify 205.508, such as NOP 2000, NOP 2005-6 and these were verified as being followed.

§205.509 Peer Review Panel

- The NOP has complied with Section 205.509 with the exceptions noted in the associated OFI.

§205.510 Annual Report, Recordkeeping and Renewal of Accreditation

- Copies of Annual Reports and record keeping were verified as having been reviewed during audit.
- NOP 2025 augments 205.501(a)(21) and 205.510 to instruct ACA's to establish and conduct annual program review of its certification activities, and was verified as being followed.
- Documents related to renewal of accreditation were reviewed. Only one file included Terms of Accreditation.

7 CFR Subpart G - Administrative Compliance

§205.660 General

- Verified that documents were mailed to correct addresses in all cases.

§205.661(a) Investigation of Certified Operations

- Provides authority to ACA's

§205.662 Non-compliance Procedure for Certified Operations

- Verified that non-compliances, proposed suspension and related procedures were handled following appropriate procedures as outlined in this section and as augmented in NOP 2608, and NOP 2000.

§205.663 Mediation

- No files were reviewed where mediation was required although one file did include a Settlement Agreement.

§205.665 Non-compliance Procedure for Certifying Agents

- Of the 5 files reviewed, 4 appear to have been completed in a reasonable time while one file seemed to take an excessive time to complete per NOP 2000.
- Verified that correct procedures were followed in handling non-compliances and proposed suspension except as noted in other observations.
- NOP 2012, NOP 2012-1, NOP 2012-4, NOP 2000, NOP 2024 augment this section and were found to have been used during the NOP audit of the 5 files reviewed.
- Proposed corrective action plans and corrective action reports were present in all files.

§205.670 Inspection & Testing of Agricultural Products

- Verified correct use of appropriate documentation in sampling and testing procedures, per 205.504, and with use of policies found in NOP 2610, NOP 2611, NOP 2611-1, NOP 2614, and NOP 2613-1.
- All 5 files indicated that inspection and testing conducted by clients were undertaken and appropriate labs were being used.
- One file indicated that a non-compliance was correctly issued when, during a witness audit, samples were gathered by hands rather than using appropriate SOP scientific methods.

§205.671 Exclusion from Organic Sale

- No files were reviewed where this applied.

§205.672 Emergency Pest or Disease Treatment

- No files were reviewed where emergency treatment was an issue.

§205.680 General

§205.681 Appeals

- One file reviewed involved a complex Appeal process conducted in accordance with these sections, and as augmented by use of NOP 2000 and NOP 4011.

NOP 2005 NOP Accreditation Checklist. Effective date 10/29/2015 With Worksheets & Findings (11 Tables and 1 Findings Template)

- This comprehensive document was used in all 5 files, together with completed tables as relevant to specific inspection. This detailed Checklist fulfills a critical function in ensuring requisite consistency and transparency in tracking and reviewing audit procedures. (See also notes in the Observation section of this report.)

Other Observations:

- Auditor Qualifications: NOP 2500 provides Auditor Selection Criteria, and Assessment, together with additional documents NOP 2501-1, NOP 2501-2, and NOP 2000 that appear to meet international standards. The Review Panel was provided with short resumes for

each of the NOP auditors and reviewers. No evaluations or training logs per se were provided, but the resumes and quality of written documents in each file reviewed indicate qualified personnel.

- Management System: Although NOP 2000 (revised 12/8/15), *General Accreditation Policies and Procedures*, forms the foundation document clarifying the regulations at 7 CFR 205 for NOP accreditation process, there are numerous additional documents which are critical to this accreditation process. Each document, such as NOP 2012 (rev. 7/9/15), NOP 2608 (rev 1/13/2012), and Checklists such as NOP 2005 (rev 10/29/15), plus Policy memos such as PM-11-4, Instructions such as NOP 2069, and NOSB Recommendations, such as for Grower Groups, must all be used by Auditors, Certifiers and Reviewers in order to make this accreditation procedure work. A single foundation document which incorporates all of the diverse documents, and which is reviewed and updated quarterly as recommended in NOP 1100, or at least once a year on a regular basis, would make this accreditation process more transparent, more efficient, and easier to replicate on a regular basis as part of the Peer Review process, and provide internal consistency in policies and procedures.
- Numbering Convention: Although there is some rationale to Document numbering conventions between Standards and Accreditation, etc., the numbering convention is not clear to this external reviewer. NOP 1100 clearly states that the Handbook is prepared and maintained up to date under auspices of the OMB's GGP's and identifies 3 Levels of documents to be in the Handbook. This concordance is not clear.
- Transparency - documents used in certification procedure: It was not always clear why some documents which the Peer Review Panel needed to use in connection with this Review were for internal NOP distribution only, as opposed to being available to the public in the NOP Handbook which is easily found on the NOP website. For example, NOP 2005 is in the Handbook and thus publically available, but many of the documents linked within that document are only distributed within NOP which reduces transparency of process and may result in lack of information necessary to accurately complete the processes required. NOP 1100 clearly states that "program guidance documents are developed with adequate public participation, and are readily available to the public".
- Inconsistencies in use of precise words: There were a number of inconsistencies in use of specific words which have legal interpretation, such as "recommend", "require", "should", "shall", "must", and "may". Use of the incorrect word through poor citation or interpretation of a policy or procedure can lead to confusion for certifiers or create a legally non-enforceable compliance issue. For example, in one file the non-compliance asserted NOP 2609 as "requiring" certifying agents to conduct unannounced inspections ... when in fact NOP 2609 states ..."*We **recommend** that certifying agents conduct unannounced inspections of 5% their total certified operations per year.....*". The NOP Reviewer completing NOP 2005 under Section 205.403 is prompted to assume non-compliance when the certifier has not conducted 5% unannounced inspections. This leads to unenforceable non-compliances being issued.
- Legally enforceable documents: NOP 1100 (3/9/11), indicates that program guidance documents "are not applied as binding requirements". Thus, Guidance, Instruction and Policy Memo documents do not themselves establish legally enforceable rights or responsibilities and are not legally binding on the public or program (NOP 1100 - *Legal Effects*), and yet NOP 2609 is used in findings of non-compliance in unannounced Inspections, as are NOSB Recommendations from October 20, 2002 and November 19, 2008 regarding Grower Groups.

- Signatures: Records and required forms in files reviewed do not consistently include the required signature of an NOP official. For example, form LPS 109, dated 8/26/15, in one file does not include the required NOP signature.
- Document NOP 2012-4 (8/9/15) Accreditation Committee Evaluation Checklist was found in only one file although it appears that it is a required document.
- Dates: Not all letters or documents included dates, making it somewhat difficult to be sure of chronology in the review process, although internal Chronology logs provided useful verification of steps taken.
- NOP 1031: Procedure: Peer Review of National Organic Program (NOP) Accreditation was authorized for distribution within the NOP on May 12, 2016. Full transparency would be accomplished by placing this in the publically available sections of the Handbook.
- NOP 1001: National Organic Program Organizational Chart does not include the National Organic Standards Board (NOSB) which has specific, unique amongst FACA, statutory authority under OFPA, and Accreditation Checklists and documents such as NOP 2005 specifically include reference to NOSB Recommendations such as the Grower Group Recommendation dated November 19, 2008.
- Previous Peer Review Panel Reports were specifically excluded from this Peer Review, per letter from Deputy Administrator dated May 19, 2016, although a review of them may have allowed this Panel to determine what progress has been made implementing any recommendations made by those previous review panels.

V. CONCLUSION

- This individual Panel member finds that NOP and its staff are in general compliance with their own policies and procedures.
- There are an inordinate number of NOP documents, NOP Instructions, NOP Policies, NOSB Recommendations and diverse tables, each with differing legal weight, which amplify the language in 7 CFR 205 and combine to make the accreditation process comprehensive, albeit cumbersome and at times inconsistent.
- The National Organic Standards Board (NOSB), in response to a request from the NOP (11/19/14), voted unanimously to recommend that the NOP establish a repeatable and transparent Peer Review Process (4/30/15). The NOP responded in a timely manner in a Memorandum to the NOSB (9/3/15). NOP 1031, *Procedure: Peer Review of National Organic Program (NOP) Accreditation*, was authorized for distribution within the NOP on May 12, 2016.
- This individual panel member finds that the Peer Review Process followed meets the NOSB Recommendation of 4/30/15 and Procedures in NOP 1031 of May 12, 2016, and provides a repeatable and transparent Peer Review Process.

This completes the DRAFT ANSI Peer Review Panel by a member of the Peer Review Panel



Product Certification Accreditation

ANNEX 4- TECHNICAL EVALUATOR REPORT- JIM RIDDLE

**2016 Peer Review Panel
Individual Report 3**

For

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

**1400 Independence Avenue, NW
Room 2646 South Building
Washington DC 20250 USA**

**Dates of Review Panel:
May 16 - 18, 2016**

Prepared by

American National Standards Institute
1899 L Street, 11th Floor
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**Document: Technical Assessor's Report
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I. GENERAL INFORMATION

Accreditation Body

Name of reviewed Body

Agricultural Marketing Services (AMS)

Address

**1400 Independence Avenue, NW
Room 2646 South Building
Washington DC 20250 USA**

Telephone

202-720-3252

Review

Type of Review

Peer Review Panel

Review Dates

May 16 - 18, 2016

Review Standard(s)

**7 CFR Part 205 National Organic Program Final Rule
ISO/IEC 17011 “Conformity assessment – General
requirement for accreditation bodies accrediting
conformity assessment bodies**

Review Team

Lead Reviewer:

Robert Miller

Technical Reviewer:

Susan Ranck

Technical Reviewer:

Jean Richardson

Technical Reviewer:

Jim Riddle

ANSI Observer(s)

**Reinaldo Figueiredo
Elizabeth Okutuga**

Report

Review Report Prepared by:

**Jim 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**

Submitted to ANSI on:

August 5, 2016

II. SCOPE

The NOP established a peer review panel to satisfy internal requirements regarding adherence to internal and regulatory requirements. The American National Standards Institute (ANSI) convened this panel effective May 16, 2016 to fulfill the expectation of this requirement.

This Peer Review is conducted pursuant to 7 CFR 205.509, Peer Review Panel, of the USDA Organic Regulations. This Peer Review follows a procedure outlined in NOP 1031 (5/12/16), *Peer Review of National Organic Program (NOP)*, and as modified by letter to ANSI from the NOP Deputy Administrator dated 5/19/2016.

The panel is tasked with the following:

- evaluate the NOP's policies, processes and procedures for conformance to NOP regulations and ISO/IEC 17011; and
- review implementation of certification body accreditation processes through select file review.

The panel is reporting their findings in writing to the NOP Deputy Administrator and the National Organic Standards Board.

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 the development, implementation and administration in accordance with 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; and
- Accrediting, auditing, and training third-party organic certifying agents.

IV. 7 CFR Part 205 National Organic Program

Observations and Discussion

Subpart E – Certification

§205.400 General Requirements for Certification

1. Background: The review of NOP accreditation procedures and five accreditation files revealed that the general requirements for certification stated in 205.400(a-e) are consistently assessed during NOP audits. However, no evidence was observed indicating that the requirements of 205.400(f) (1-2) are assessed during NOP audits.

205.400(f)(1-2) requires that certified operators and applicants must “immediately notify the certifying agent regarding any: (1) application, including drift, or a prohibited substance to any field, production unit, site, facility, livestock, or product that is part of the operation; and

(2) change in a certified operation or any portion of a certified operation that may affect compliance...”

Observation 1: A review of NOP 2005 “Accreditation Assessment Checklist” reveals no questions under section 205.400 to assess certifying agents’ procedures and performance requiring certified operations and applicants to immediately notify the certifier regarding the application of prohibited substances or changes to their operations that may affect compliance, as required by 205.400(f)(1-2).

§205.401 Application for Certification

Observation 2: The review of NOP accreditation procedures and five accreditation files revealed that applications for certification, known as organic system plans, are consistently reviewed by NOP auditors. Deficiencies are identified as noncompliances and corrective actions have been taken by accredited certifying agents to improve their application forms and procedures.

§205.402 Review of Application

3. Background: All labels making “organic” claims are to be reviewed by certifying agents to determine that the products’ composition, percentage of organic ingredients, and market information are in full compliance with all applicable requirements. NOP 2005 “Accreditation Assessment Checklist” contains detailed “Label Review Worksheets 6a, 6b and 6c”. The worksheets contain extensive instructions to auditors regarding the review of labels making “organic” claims. However, the worksheets contain no instructions for the review of product composition or the review of calculations used by certifying agents to determine the percentage of organic ingredients. Such calculations of organic content directly affect the label claim that can be used on a product making an “organic” label claim.

All five accreditation files reviewed indicate NOP auditors use the label review worksheets in NOP 2005 to determine if label reviews are handled correctly by certifying agents. The comments entered on the worksheets revealed that NOP auditors do not assess product composition or the method used to calculate the percentage of organic ingredients. One of the NOP auditors recognized this point by stating, “Composition was not reviewed for this product.” In spite of this, the NOP auditor stated, “No issues noted by the auditor regarding the label.”

Observation 3a: Worksheets 6a, 6b and 6c in the NOP 2005 Accreditation Assessment Checklist contain no questions requiring NOP auditors to review product composition or the calculations used by certifying agents to determine the percentage of organic ingredients. Product composition and calculations of percentage of organic ingredients directly affect the label which can be used on a product making an “organic” claim.

Observation 3b: Reviewed accreditation files indicate that NOP auditors, during label reviews, do not assess product composition or the method used by certifying agents to calculate percentage of organic ingredients.

§205.403 On-site Inspection

Observation 4a: The review of five accreditation files, including witness and review audits, revealed that inspections and inspection reports are assessed during NOP audits. Deficiencies are noted as noncompliances and corrective actions are undertaken by certifying agents. Of the five certifying agents reviewed, four had conducted on-site inspections in a timely manner, as required by 205.403(a)(1) and (b).

205.403(a)(1) and (b) require that “on-site inspections shall be conducted annually,” and “must be conducted within a reasonable time.” “The initial inspection may be delayed for up to 6 months.” One of the certifying agents reviewed had not conducted on-site inspections of every certified operation in over a year. At the time of the NOP audit, the certifying agent had 219 certified operations with 113 crop, 6 livestock, 50 handlers, 32 distributors, 13 fiber processors, and 5 retailers. The NOP Audit Checklist reported, “Annual on-site inspections were not conducted at 49 operations (38 crop and 11 handling) in 2014.” The NOP cited the certifying agent for noncompliance with this requirement. The certifying agent submitted a plan to correct the noncompliance by inspecting all remaining operations. The corrective action was accepted by the NOP.

Observation 4b: 205.501(a)(18) requires that a certifying agent provide the inspector with a copy of the previous on-site inspection report and notify the inspector of its certification decision and any requirements for correction of noncompliances. NOP 2005-4 “Witness Audit Checklist” contains a number of questions for inspectors, but does not direct the NOP auditor to ask if the inspector was provided a copy of the previous inspection report and notified of the certification decision and corrective action requirements.

§205.404 Granting Certification

5. Background: This review found no forms or instructions for auditors to assess the regulatory status of ingredients and processing aids allowed by certifying agents. Witness and review audits do not appear to address this issue, other than reference certifier general procedures for materials review, using OMRI, WSDA or other certifier approvals for inputs used in the production of organic products.

Observation 5a: An extensive review of NOP procedures and accreditation files finds no guidance for auditors regarding the use of minor ingredients, processing aids and other non-agricultural substances, including nutrient vitamins and minerals in infant formula and petitioned substances rejected by the NOSB, used during processing that do not appear on the National List.

Observation 5b: No evidence was observed demonstrating that auditors assess certifying agents to verify that only approved ingredients and processing aids appearing on the National List are used in the handling of organic products.

Observation 5c: No evidence was observed indicating that all ingredients and processing aids allowed by certifying agents were verified by auditors as in compliance with National List requirements (annotations).

Observation 5d: No evidence was observed demonstrating that the NOP has established procedures for auditors to assess certifying agents’ disallowance of substances rejected by the NOSB.

§205.405 Denial of Certification

Observation 6: The review of NOP accreditation procedures and five accreditation files revealed that NOP auditors consistently review certifying agents procedures and performance regarding denial of certification.

§205.406 Continuation of Certification

Observation 7: The review of NOP accreditation procedures and five accreditation files revealed that NOP auditors consistently review certifying agents procedures and performance regarding continuation of certification.

Subpart F – Accreditation of Certifying Agents

§205.500 Areas and Duration of Accreditation

Observation 8: The review of NOP accreditation procedures and five accreditation files revealed that the requirements of 205.500(a-b) are met. This review did not access the NOP's compliance with 205.500(c), which addresses the approval of foreign governments' accreditation programs and equivalency agreements.

§205.501 General Requirements for Accreditation

Observation 9: The review of NOP accreditation procedures and five accreditation files revealed that NOP auditors consistently and comprehensively assess certifying agents for compliance with the general requirements for accreditation found in 205.501.

§205.502 Applying for Accreditation

10. Background: The review of NOP accreditation procedures and five accreditation files revealed inconsistencies in the application information that the NOP has on file. Two of five files contained completed TM -10CG "Application for Accreditation or Renewal" forms. One of five had a completed LPS 109 "Application for Service" form. The other four had LS 313 "Application for Service (Grading and Verification Division)" forms. None of the files contained "AIA Document Review Summary Sheets," even though these documents are listed in NOP 1031 Section 3.5b as required documents. All certifying agents reviewed received "letters of engagement" from the NOP. These "letters of engagement" have not been assigned document control numbers and are not listed in NOP 1031 3.5b as required documents.

Observation 10: Consistent accreditation application forms are not being used and retained in order for the NOP to be in full compliance with 205.502.

§205.503 Applicant Information

Observation 11: The review of NOP accreditation procedures and five accreditation files revealed that applicant information was on file for all files reviewed, except as noted in the Opportunities for Improvement (OFIs).

§205.504 Evidence of Expertise and Ability

Observation 12: In order to be accredited, certifying agents must use qualified, trained and experienced staff and contracted service providers. They also must conduct annual performance reviews and make sure that conflicts of interest are avoided. These documents appear to be consistently checked by NOP auditors.

A review of resumes from eleven USDA auditors and staff involved in the NOP accreditation program revealed that all are qualified to perform described tasks. Most have at least some education or experience related to agriculture, but 2 of the 11 do not. Most have some

experience in organic production, processing, marketing, materials review or certification, although some had no organic experience prior to working for the NOP. Six have received at least some training by the International Organic Inspectors Association, but five have not. At least seven of the eleven have been trained in ISO quality management systems.

§205.505 Statement of Agreement

Observation 13: The review of NOP accreditation procedures and five accreditation files revealed inconsistencies in the information on file regarding statements of agreement. Two of the five files reviewed contained “Terms of accreditation” as listed on NOP 1031 Section 3.5h. Four of five files contained “Notices of Continued Accreditation” listed on NOP 1031 Section 3.5i.

§205.506 Granting Accreditation

14. Background: 205.506(b) requires that the NOP inform successful accreditation applicants, in writing, of the: 1) areas of accreditation; 2) effective date of accreditation; 3) terms and conditions for correction of minor noncompliances; and 4) for private entities, the type and amount of security to be provided.

Observation 14a: The review of NOP accreditation procedures and five accreditation files revealed that current accreditation certificates, with information described in 205.506(b), were on file for four of the five files reviewed. One accreditation certificate provided by the NOP expired on Jan. 22, 2013.

Observation 14b: All of the files reviewed contained “Corrective Action Reports” (showing corrective action receipt and acceptance), as listed on NOP 1031 Section 3.5e. Only two of the five contained the “Terms of Accreditation,” listed on NOP 1031 Section 3.5h. The “Terms of Accreditation” document appears to be a legally binding document which lists the specific requirements unique to a given certifying agent.

§205.507 Denial of Accreditation

Observation 15: The review of NOP accreditation procedures and five accreditation files revealed that procedures are in place to deny accreditation.

§205.508 Site Evaluations

16. Background: 205.508 requires that the NOP conduct site evaluations of accreditation applicants and accredited certifying agents. Site evaluations include desk audits, review audits and witness audits. For the most part, site evaluations appear to be well documented and follow Part 205 requirements and NOP procedures.

The NOP has created two lengthy forms, NOP 2005-3 “Certification File Review Checklist – Supplement for Grower Groups NOP” and NOP 2005-5 “Witness Audit Checklist for Grower Group”, that are to be used during audits of certifying agents that certify grower groups. Two of the five files reviewed were of certifying agents who certify grower groups.

Observation 16: The review of NOP accreditation procedures and five accreditation files revealed that site evaluations and witness audits are regularly conducted by NOP auditors.

§205.510 Annual Report, Recordkeeping and Renewal of Accreditation

Observation 17: The review of NOP accreditation procedures and five accreditation files revealed that accredited certifying agents are following the requirements of 205.510 for annual reports, recordkeeping and renewal. Compliance is assessed by NOP auditors and staff.

7 CFR §205.660 Compliance

§205.660 General

Observation 18: The review of NOP accreditation procedures and five accreditation files revealed that a notice of accreditation suspension was issued against one certifying agent (see Observation 21, below).

§205.661(a) Investigation of Certified Operations

Observation 19: The review of NOP accreditation procedures and five accreditation files revealed that NOP auditors review certifying agent complaint files during audits and report their findings. Complaint files were not provided for our review. This includes complaints against certifying agents and complaints against the NOP.

§205.662 Non-compliance Procedure for Certified Operations

Observation 20: NOP 2005 Accreditation Assessment Checklist states, “Are settlement agreements in accordance with the guidance provided by the NOP training module?” A link to the training module found on the Accreditation Checklist for two of the files reviewed was broken and did not connect to the module.

The term “settlement agreements” is not used in or defined by OFPA or by 7 CFR Part 205. The term does not appear in other NOP documents reviewed. The “guidance” referenced in question # 23 was not identified by file number, name or date and was not made available for review. The “NOP training module” referenced in question # 23 was not identified by file number, name, or date, and the linked URL was broken. The training module was not made available for review.

§205.665 Non-compliance Procedure for Certifying Agents

Observation 21: In one of the files reviewed, the NOP issued a notice of proposed suspension of an accredited certifying agent. In its notice of proposed suspension, the NOP gave three reasons: 1) the number and severity of noncompliances; 2) multiple and inadequate proposed corrective actions; and 3) suspensions by other accreditation bodies. The certifying agent appealed. The certifying agent claimed that the NOP has not established requirements for the number and severity of noncompliances allowed; was engaged with the certifying agent regarding proposed corrective actions; and suspensions issued by other accreditation bodies are irrelevant, since the NOP can only accredit certifying agents for compliance with the requirements of OFPA and 7 CFR Part 205. Despite the fact that the NOP’s auditor reported numerous noncompliances, the certifying agent won the appeal and its accreditation was reinstated by the NOP. In the letter of proposed suspension, the NOP did not provide sufficient details for the suspension, as required by 205.665(c1).

Observation 21a: No current or updated accreditation certificate for this certifying agent was issued or provided by the NOP for our review.

§205.663 Mediation

Observation 22: While it is apparent from files reviewed that NOP auditors assess a certifying agent's mediation records, where applicable, no mediations occurred between the NOP and any of the five certifying agents reviewed. So no mediation files were reviewed.

§205.670 Inspection & Testing of Agricultural Products

23. Background: 205.670(d)(1) requires that "results of all analyses and tests performed under this section must be promptly provided to the Administrator."

NOP 2024, "Information Submission Requirements for Certifying Agents," and NOP 2024-1, "Annual Report Checklist," itemize the information that must be submitted by certifying agents to the NOP. There is no mention of the submission of analyses and residue test results, as required by 205.670(d)(1).

NOP 2613 "Instruction - Responding to Results from Pesticide Residue Testing" provides detailed instructions regarding sampling and testing for residue analysis. It directs certifying agents to "Retain the test results, which must be made available to the public upon request and will be reviewed as part of the next audit."

§205.671 Exclusion from Organic Sale

Observation 24: The review of five accreditation files revealed no instances where residue testing detected prohibited substances at levels greater than 5 percent of the EPA tolerance. Therefore, no products excluded from organic sale were observed in this review.

§205.672 Emergency Pest or Disease Treatment

Observation 25: The review of NOP accreditation procedures and five accreditation files revealed that NOP auditors review certifying agents' policies and procedures for emergency pest or disease treatment, as well as any instances where emergency treatments have occurred and how these treatments have impacted organic operations' certification status.

Other Observations

26. Background: NOP 2402 "Assessing Certifier Applications to Issue TM-11 Export Certificates" describes the NOP's procedure for authorizing accredited certifying agents to issue TM-11 Export Certificates. The procedures described in NOP 2402 are not nearly as complete as the questions asked in NOP 2005 "Accreditation Assessment Checklist," which contains 10 pages of detailed issues that must be addressed for authorization to issue Export Certificates.

Further, NOP 2402, section 4.2 specifies two requirements for TM-11 Export Certificates issued for products being exported to Taiwan, while pages 72-82 of NOP 2005 contain numerous requirements that must be met for Export Certificates issued for the European Union, Switzerland, Canada, Korea, and Japan, in addition to Taiwan.

Finally, NOP 2402 states, "NOP officials will post all TM-11 authorizations issued on the NOP Web site."

Observation 26a: NOP 2402 is not as complete as NOP 2005 and does not address Export Certificate authorizations for products exported to the European Union, Switzerland, Canada, Korea, or Japan.

V. CONCLUSION

Except as otherwise noted, this review of NOP accreditation procedures and five accreditation files revealed that the NOP has established and operates an accreditation program which complies with the requirements of 7 CFR Part 205.

In a November 19, 2014 memo to the National Organic Standards Board, the NOP Deputy Administrator stated that a goal of the peer review was to establish a “repeatable and transparent peer review process.” In order for the review to be repeatable and transparent, future panels must be provided the following: 1) nonconformities identified during previous audits; 2) corrective actions undertaken in response to previous audits; 3) internal audit reports; 4) management review reports; 5) complaint files; 6) files to assess the NOP’s compliance with 205.500(c) regarding the approval of foreign governments’ accreditation programs and equivalency agreements; and 7) the ability to conduct site visits and interview NOP auditors and other staff members.

This completes the review by a member of the ANSI Peer Review Panel.