Product Certification Accreditation

2014 Peer Review Report
FINAL

For

United States Department of Agriculture
Agricultural Marketing Service
National Organic Program

1400 Independence Avenue, NW
Room 2646 South Building
Washington DC 202 50 USA

Dates of the on-site review:
May 12-15, 2014

Prepared by

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

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I. TABLE OF CONTENTS

II. GENERAL INFORMATION

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	**On-site Peer Review Visit**
Dates	**May 12 – 15, 2014**
Peer Review Standard(s)	ISO/IEC 17011:2004C*onformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*, US 7 CFR Part 205, National Organic Program

Evaluation Team

Team Members	Lead Evaluator: **Marlene Moore**
	Technical Assessor: **Gary Sherlaw**
Observer:	ANSI Senior Program Director: Reinaldo Figueiredo

Document Review Report

Prepared by	**Marlene Moore**
Submitted to Client on	**June 18, 2014**
Revised and Resubmitted:	**July 25, 2014**
Revised and Resubmitted:	**August 13, 2014**

III. INTRODUCTION

The scope of this Peer Review includes activities related to NOP's accreditation and oversight of certifying agents (conformity assessment bodies – CABs). There are approximately ninety (90) certifying agents accredited by the National Organic Program. The U.S. Department of Agriculture National Organic Program carries out activities relating to the development, implementation, and administration of the USDA organic regulations.

The location of the peer evaluation review was the NOP office in Washington, DC and included remote interviews with field locations as necessary to conduct the peer review. The witness audits are to be completed in June 2014 as part of the ANSI Peer Review process. The technical assessor will report on these audits in separate reports.

The NOP also performs additional activities under the NOP Regulation that are outside the scope of the ISO/IEC 17011 accreditation process. These include:

- Developing and maintaining the USDA organic standards
- Investigating complaints and regulatory violations
- Managing the National Organic Standards Board, a citizen advisory committee
- Administering organic cost share programs, export certification, recognition agreements, equivalency agreements, and State Organic Program reviews

Processes to be reviewed include: all phases of NOP accreditation from initial application through final decision; ongoing surveillance and renewal and operation of a management system in conformance to ISO/IEC 17011. Key activities of the onsite review included: review of documents available to the public and internal operation personnel; records review of certifying agents and auditors, interviews with staff and demonstration of implementation of the management system.

The NOP requested ANSI to review the outcome of the National Institute of Standards and Technology – National Voluntary Conformity Assessment Evaluation Program (NIST/NVCASE) document review performed and reported in 2011. See the Appendix 1 to this report for the outcome of this review.

Program and Scopes of Accreditation

The United States Department of Agriculture (USDA), Marketing and Regulatory Program (MRP), Agricultural Marketing Service (AMS) administers the general policies and procedures for certifying agents (CA) seeking accreditation to the National Organic Program Regulations.

The National Organic Program (NOP) accredits certifying agents under the authority of the Organic Foods Production Act of 1990, as amended (7 U.S.C 6501 et seq), as described in the Code of Federal Regulation Title 7, Part 205 NOP Regulations. NOP Regulations assign the Agricultural Marketing Service (AMS) Administrator the responsibility for execution of the National Organic Program. The AMS Administrator delegated certain responsibilities as described in the NOP Regulations and the procedure NOP 2000 Accreditation Procedures Rev 07. The Regulations, NOP Handbook and other information are available to the public on the NOP website: http://www.ams.usda.gov/AMSv1.0/nop.

Opening and Closing Meetings

The opening meeting was held on the morning of May 12 2014. In the opening meeting, NOP personnel indicated other commitments during the scheduled time for the evaluation so the agenda

was modified to accommodate these changes. The ANSI technical assessor interviewed three (3) QAD auditors, two accreditation managers and the Assistant Deputy Administrator. The ANSI lead evaluator interviewed the Deputy Administrator, The Assistant Deputy Administrator, AIA Division Director, Compliance and Enforcement Division Director, two accreditation managers, quality manager, the QAD supervisor, and three program specialists.

There were fourteen (14) OFIs identified during this peer review and posted to ANSICA. These were reviewed with the staff at the closing meeting. Responses to the OFIs are to be posted to ANSICA by August 1, 2014. The ANSI Peer review team will review the responses within 15 days of posting. Work under this agreement is to be completed in September 2014. The attendees of the opening and closing meetings are presented in the rosters uploaded to ANSICA.

Additional Comments

The peer reviewers, Marlene Moore and Gary Sherlaw, completed ANSI form PRO-FR-300 ISO/IEC 17011, which presents the notes from the office visit. Included in this completed form is the peer reviewer's identification of the certification body document location and the scheme document location. The reviewers were able to find the majority of the information. Some items identified on the Form PRO-FR-300-ISO/IEC17011, where changed or other documents noted during the office visit. The form includes the Opportunities for Improvement (OFIs) identified for elements of ISO/IEC 17011 that require improvement for demonstration of full conformance to ISO/IEC 17011. The checklist PRO-FR-300-ISO/IEC17011 indicates "No" in the column titled conformance since these elements were lacking. The checklist was updated after the document review to present observations from the technical and lead peer review team members.

IV. REVIEW OF SUBMITTED DOCUMENTATION

The following documents are the significant documents used in the document review performed in January to February 2014. The specific documents addressing the requirements are identified on the FORM FR-300 ISO/IEC 17011. The effective dates of several of the documents were found to be revised in the early part of 2014 and are not reflected in this table. The current versions are listed on the NOP website for public documents and internal documents are found on the server. The NOP has been working on external documents and updates with internal documents to be updated during 2014 and 2015 after the addition of resources in 2014.

New Document Number	Title	Effective Date
1000 Series	**Quality Management System**	
N/A	Quality Management System Manual	08-08-12
NOP 1001	NOP Organizational Chart	02-06-13
NOP 1002	Duties, Responsibilities, and Authorities	12-09-11
NOP 1003	Quality Policies and Quality Objectives	10-01-11
NOP 1006	NOP Document Control Master List	08-16-12
NOP 1010	Document and Record Control	05-17-10
NOP 1010-1	NOP QMS Document Naming Protocol	07-13-10
NOP 1010-2	NOP Naming Protocol for NOP Division Activities	-
NOP 1010-3	NOP Division Activity Identifiers	07-13-10
NOP 1010-5	Document History Summary	12-15-11
NOP 1010-6	QMS Deviation History	05-26-11

New Document Number	Title	Effective Date
NOP 1010-7	NOP Communication Tool Matrix	07-15-12
NOP 1010-8	NOP Internal Document Review Process	07-15-12
NOP 1020	NOP Corrective and Preventive Action Procedure	07-13-10
NOP 1020-1	NOP Corrective and Preventive Action Work Plan	07-13-10
NOP 1020-2	NOP Corrective and Preventive Action Summary	07-13-10
NOP 1030	NOP Internal Audit Procedure	07-13-10
NOP 1030-1	NOP Internal Audit Plan	07-13-10
NOP 1030-2	NOP Internal Audit Checklist	08-10-10
NOP 1030-3	NOP Internal Audit Report	07-13-10
NOP 1030-4	Internal Audit Work Instruction	08-10-10
NOP 1040	NOP Management Review Procedure	12-10-11
NOP 1040-1	NOP Management Review Report	07-13-10
NOP 1040-2	NOP Management Review Work Plan	07-13-10
2000 Series	**Accreditation and International Activities (AIA) Division**	
NOP 2000	General Accreditation Policies and Procedures	07-22-11 (revised Feb 2014)
NOP 2000-1	Accreditation Work Flow Procedures	05-29-07
NOP 2000-2	Processing Applications Review and Assessment	
NOP 2000-3	Processing and Generating Reports	04-15-11
2100 Series	**Equivalence Activities**	
2200 Series	**Recognition Activities**	
2500 Series	**Auditor Qualifications and Performance**	
	NOP Auditor Criteria	02-17-12
NOP 2501	Evaluating Auditor Performance	02-17-12
NOP 2501-1	Auditor-in-Training Performance Evaluation Worksheet	05-17-12
NOP 2501-2	Auditor Performance Evaluation Worksheet	05-17-12
2600-2900 Series	**Certification**	
NOP 2601	Five Steps to Certification	07-22-11
NOP 2602	Recordkeeping of Certified Operations	07-22-11
NOP 2603	Organic Certificates	07-22-11
NOP 2604	Certifying Operations Changing Certifying Agents	06-14-12
NOP 2605	Reinstating Suspended Operations	06-14-12
NOP 2606	Processing Requests for Temporary Variances	07-22-11
NOP 2607	Disclosure of Information Concerning USDA ACAs and Certified Operations to the NOP	11-23-11
NOP 2608	Responding to Noncompliance's	01-13-12
NOP 2609	Unannounced Inspections	
NOP 2610	Sampling Procedures for Residue Testing	11-08-12
NOP 2611	Laboratory Selection Criteria for Pesticide Residue Testing	11-08-12
NOP 2611-1	NOP Target Pesticide List	07-22-11
NOP 2612	Penalty Matrix Instruction	-
NOP 2612-1	Penalty Matrix Instructions by Violation Category	
NOP 2613	Responding to Detections from Periodic Residue Testing	-
NOP 2614	Technical Assistance	
5600 Series	**National List Documents**	
	National List Petition Process	07-13-00

New Document Number	Title	Effective Date
	Internal Procedures for National List Petition Process	09-30-05
NOP 3005-1	NOP Petitioned Substance Checklist for OFPA Exemptions and §205.600(b)	04-08-11
NOP 3005-2	NOP Substance Petition Checklist	04-08-11
NOP 5611	National List Sunset Dates	10-24-12
7000 Series	**National Organic Standards Board**	
	NOSB Policy and Procedures Manual	04-29-10
8000 Series	**NOP Administrative Functions**	
	National Organic Program Functional Statement	December 2009-
	NOP LS Program Work Agreement	10-01-10
	NOP CA Program MOU *(Need to Update)*	
	NOP Employee Handbook	03-11-11
8500 Series	**Communications and Outreach**	
8510	NOP Inquiry Routing Flowchart	03-11-11
	NOP Policy Memos	
	NOP Notices	

In February 2014, after the ANSI document review was underway, NOP requested ANSI to provide feedback on the NIST/NVCASE document review report. This was included as part of the on-site peer review and reported in Appendix I attached. The NIST/NVCASE Document review report is dated July 31, 2011. The accreditation body, NOP, worked toward addressing the NIST/NVCASE concerns and this was evident in the documents and information submitted as part of this peer evaluation. In late 2012 and 2013, NOP management and staff found the documents to be overwhelming and decided to implement operational controls without the extensive number of documented procedures. Although the operational controls have improved services offered by NOP including the updating of public information, the management system remains undocumented. The need for a documented management system that is implemented remains a concern for demonstration of conformance to ISO/IEC 17011.

V. RESULTS OF DOCUMENT REVIEW

Outcome from Document Review with input from NOP

The following is a summary of the outcome of the document review for conformance to ISO/IEC 17011. The document review was presented in February 2014. A conference call was held on March 31, 2014 to discuss the outcome and answer any questions from NOP personnel. The AB provided formal comments to the evaluation team on May 1, 2014. These items were further reviewed during the office visit on May 12 to 15, 2014. The following presents the outcome of the document review results.

Sections 1.0 to 3.0 Scope, References, Definitions

1. The documents are identified for internal NOP activities. External documents are not presented in the master document listing (ISO/IEC 17000, ISO/IEC 17065, etc.). **May 2014:** The AB maintains the documents on a separate server and this is available to all NOP personnel.
2. The transition to ISO/IEC 17065 is not identified or presented in the scope of the accreditation. **May 2014:** The law is not expected to change to address the change to this document. The AB does not anticipate any change to the updated requirements.

3. The commitment by top management is not clearly presented for the current AMS Administrator. **May 2014:** The policy was signed on May 9, 2014 by the current AMS Administrator and presented to the team on the first day of the assessment, May 12, 2014.
4. Program terms and definitions are found in the scheme documents (NOP regulation 7CFR Part 205 and Handbook). Definitions or terms used in ISO/IEC 17000 do not appear to be adopted by the accreditation body (AB). **May 2014:** Regulations are the adopted terms.

Section 4.0 Accreditation Body

1. The documentation submitted does not indicate the process for review of impartiality of the organization and its operations. **May 2014:** NOP 2012 and NOP 2000 indicate some items related to handling of impartiality and restrictions on certain activities defined by the law. NOP impartiality is related to personnel and not to organizational risks to impartiality. See ANSICA 2013-USDA NOP-01-O-MOOM-(17011)4.3.2.
2. The NOP 2000 procedure indicates the ARC Branch performs audits or evaluations. The ARC Branch is no longer the audit group. The assigned group (GVD) performs evaluations, but the separation and other activities are not presented in the documents submitted. Some of the personnel listing indicates the auditors are Accreditation and International Activities (AIA) personnel and that a sister agency Quality Assessment Division (QAD) is under the direction of the same administrator, but the functions are not clearly presented in the documents. It appears recent reorganizations are not in the current documentation. **May 2014:** The documents do not reflect current operations. NOP 2000 was updated in February 2014 and presented at the start of the on-site assessment. The document presents the current organizational names. Other documents are not always updated and authorized prior to initiating a change to the operation. The AB works with other USDA programs to perform NOP services. Due to recent administrative changes to these programs documents identifying organizational partners are not always clear. See ANSICA 2013-USDA NOP-02-O-MOOM-(17011)5.2.2
3. Website indicates USDA helps organic farmers, but the extent of this help is not presented or detailed in the program documents. It is unclear if the related body (GVD) is a certifying agent or an inspection body. It is unclear if this body is within the accreditation body or operates outside the accreditation body by performing servicers for the NOP. The records of the National Organic Standards Board (NOSB) and other management minutes do not indicate a review of the impartiality of these related bodies within USDA, AMS. **May 2014:** The NOSB does not perform nor are they tasked with a review of the risk to impartiality. Divisions, outside of the NOP operations, perform the farmer assistance and other assistance programs. This and other risks to impartiality must be more formally reviewed by NOP as required in ISO/IEC 17011. See ANSICA 2013-USDA NOP-01-O-MOOM-(17011)4.3.2.
4. Confidentiality of individuals is well defined. Confidentiality of information by NOP is not clearly presented. **May 2014:** Due to the nature of the accreditation body being a government entity, the confidentiality of business matters are defined by law. The release of information is controlled and managed as defined in the Freedom of Information Act (FOIA).
5. The process for extending activities or ensuring competency for new endeavors is not stated in the documents. (e.g. updating to new International standard ISO/IEC 17065) **May 2014:** The AB is not updated to ISO/IEC 17065, but is planning to extent its accreditation to other technical activities, such as aquaculture. The process for extending activities is not formally defined. See ANSICA 2013-USDA NOP-07-O-MOOM-(17011)4.6.3.

Section 5.0 Management

1. The documentation includes policies and statements about most of the items. The location of the objectives that are measureable was not found and it is not clear when documents are required to be updated. **May 2014:** The management system is not fully documented as implemented in the documents presented. See ANSICA 2013-USDA NOP-02-O-MOOM-(17011)5.2.2. The objectives for the management system are presented in the strategic plans which are not part of the management review process and do not always reflect on the objectives found in the policy.
2. The procedures for records management are not clear if all records are held for five year. One document indicates quality records are maintained for one year which is not sufficient. Interviews with staff and clarity on the procedure are needed to determine documents used for record management (AMS Handbook, NOP 1010). **May 2014:** The procedure for records is being developed but is not completed. See ANSICA 2013-USDA NOP-14-O-MOOM-(17011)5.4.
3. Qualification of personnel performing internal audits is not clearly defined. **May 2014:** NOP does not currently have qualifications for internal auditors. A trained auditor did not conduct the informal internal audit of the AIA division performed in 2013. The internal auditors are not required to have training in ISO/IEC 17011. See ANSICA 2013-USDA NOP-04-O-MOOM-(17011)5.7.3.a.
4. Management review was presented for June 2012, but no review was presented for 2013. **May 2014:** A management review was performed on May 7 2014. A draft report was presented to the ANSI team, but the report did not include the outputs as specified in ISO/IEC 17011 or the improvement summary template defined by the NOP procedure. Some of the elements listed for inputs on the template were not completed. The review does include action items for implementation. See ANSICA 2013-USDA NOP-02-O-MOOM-(17011)5.2.2.
5. The complaints process and complaints log are for the suppliers handling of complaints and does not appear to be related to NOP activities. The records and procedure for handling complaints related to the NOP accreditation body activities needs to be identified. **May 2014:** No complaints process is documented related to NOP operations. The records and procedures for handling complaints related to suppliers are administered by the Compliance and Enforcement Division. Complaints related to personnel are handled by human resources and accreditation managers are contacted by the certifying agents for complaints or appeals. Appeals on decisions may also be submitted to the AMS administrator. Records were tracked with some legal investigations taking over 1 year for completion. Some of these complaints are outside the scope of the accreditation body and are for regulatory activities. It is not always clear when the action relates to NOP certifying agent complaints and when the information is for regulatory action by USDA. See ANSICA 2013-USDA NOP-09-O-MOOM-(17011)5.9.c.

Section 6.0 Human Resources

1. The documentation does not indicate how the AB determines a sufficient number of personnel. **May 2014:** The strategic planning process used by the AB determines plans and ways for making improvements with available resources. Resources are dependent upon Congressional appropriations. Currently NOP uses personnel from the QAD in addition to its own auditors. QAD personnel have performed the audits for NOP for several years. Over time, the NOP plans to have NOP staff perform more audits.
2. It is unclear how the AB has commitment from all personnel to follow the NOP procedures including related body personnel from GVD. **May 2014:** NOP and QAD personnel signed Form used in the past. It is available for current staff but is no longer

used. The NOP considers the commitment as part of being a federal employee to follow the operational procedures. NOP Assistant Deputy Administrator is working with Human Resources to determine need for additional form beyond current ethics statement and commitment when hired.

3. The job descriptions and responsibilities of all AB staff are not presented in the documents. The auditors are clearly presented but all other support activities were not able to be located. The formal approval, monitoring of non-audit staff and evaluation of competency was not identified in the documentation. **May 2014:** This information was reviewed by the technical assessor and found that performance reviews are performed for all staff. Job functions are defined for all federal staff in position descriptions. NOP auditors, specialists and others located in the DC office and at other locations such as Malaysia for the quality manager and Virginia for the program specialist.

Section 7.0 Accreditation Process

1. Attachment to application was not submitted to allow review of all elements of Section 7.2. **May 2014:** The LS-313 is the attachment referred to on the applications. This was submitted with the response to the document review. The LS-313 is for other programs and is not applicable to NOP. It is for payment processing only by QAD.
2. No information is available on how the review of the application is completed and recorded to demonstrate AB has competency to perform work. (Section 7.3) **May 2014:** Checks are received by QAD and completeness of LS-313 is reviewed. The NOP staff review the information submitted on the TM-10CG except as noted in OFI 2013-USDA NOP-08-MOOM-(17011)7.2.3. This is followed by an NOP accreditation manager (auditor) review of the completeness of the materials submitted and assignment of the auditor. The AIA Division Director and Supervisor in the QAD Group assign the client an auditor either from within the NOP or QAD staff. In most cases the auditor performs the document review and the on-site audit. The accreditation manager supervises or performs the process.
3. The process for equivalency requires further review and explanation to determine if this is subcontracting or accepting the work of another AB (recognition). **May 2014:** As stated in the quality manual the equivalency process is outside the scope of the ISO/IEC 17011 accreditation body activities.
4. No process was identified for pre-assessment in the documentation. It is unclear if this is applicable in the NOP accreditation. **May 2014:** Pre-assessment is not currently part of the NOP process. No pre-assessment as defined in ISO/IEC 17011 is performed. A pre-decisional audit is performed following document review when a new applicant does not have any clients, but is seeking accreditation. The process is defined NOP 2000 Section 4.
5. The NOP procedures do not indicate if all elements of Section 7.5.4 are submitted to the certifying agent. **May 2014:** These elements are found in letters sent to the CAB. The objection of auditors is found in NOP 2000 paragraph 2.5b.
6. The selection and sampling process for key locations is not defined in the procedures. **May 2014:** This remains a concern that a detailed procedure is not provided. The ANSI technical assessor found sampling procedures for testing of residues and witness assessments, but the sampling of the CAB for key locations was not stated in the procedures.
7. Specific items to address during the opening meeting are not found in the procedures. Reference is made to ISO/IEC 17011 requirements, but it is unclear how the auditor is made aware of the specific elements. **May 2014:** The checklist (NOP 2005) used by the auditors for the assessment present this information.

8. The process for handling issues identified during the assessment by referring back to the AB is not stated in the procedure. It is unclear how this is handled by the auditors. **May 2014:** NOP has a process as identified by the ANSI technical assessor.
9. It is unclear if a closing meeting is performed and what is to be addressed in the closing meeting. **May 2014:** The checklist (NOP 2005) used by the auditors for the assessment presents this information.
10. The handling of insufficient corrective action responses is not presented in the SOP. The procedure is unclear if the certifying agent is allowed two or more responses with corrective actions. **May 2014:** NOP 2000-3 indicates revisions of practices and accuracy is required. The ANSI technical assessor indicated additional information is requested with time limits established for the responses.
11. The information presented to the decision maker is defined in the Rule or Regulation, but does not address all the ISO/IEC 17011 requirements in Section 7.8.6. **May 2014:** ANSI technical assessor identified location of this information in various locations. The procedure does not clearly present the location of these requirements.
12. The timeframe for making the decision is not stated in the procedures. **May 2014:** Decision to grant or extend must be made within 1 week from completion of review of information received. See NOP 2012-1 procedure.
13. The oversight of the certifying agents is not performed within the timeframe defined by ISO/IEC 17011. No surveillance is performed at least every 2 years on the 5-year cycle. **May 2014:** No on-site surveillance is performed however annual reports are required by the certifying agents and reviewed. If changes are noted and determined to be significant additional surveillance may be performed before the 2.5 year surveillance visit.
14. Strict timelines are not presented in the procedures for responding to nonconformities during surveillance and reassessment. **May 2014:** Template letters indicate 30 day response period required.
15. The process for a scope extension is not specific and requires clarification during the office visit. **May 2014:** See ANSICA 2013-USDA_NOP-10-O-MOOM-(17011)712

Section 8.0 Responsibilities of the accreditation body and the CAB

1. The certifying agents sign an Office of Management and Budget form designed for the program that is in conformance to the Rule. All the elements of ISO/IEC 17011 related to obligations of the CAB are not presented. This may be handled by referencing the NOP notices and handbook, but the information was not clearly stated in these documents. **May 2014**: The form (TM-10CG) requires the CAB to meet the regulatory requirements in 7 CFR 205.. This clause requires the CAB to meet the NOP Handbook and notices as presented on the website. Following the document review the document "Terms of Accreditation" was also submitted that addresses these elements. These other documents include all the requirements of this section of ISO/IEC 17011.
2. The process for the accreditation body to obtain input from interested parties for changes made to internal procedures is not stated in the documents submitted. **May 2014:** The regulatory public announcement and hearing process is used to gain input. In addition specific information may be obtained from the National Organic Standards Board (NOSB), a Federal Advisory Committee Act group of stakeholders.
3. The actions to be taken by NOP for improper use of the NOP symbol by the certifying agents are not clear. Investigations are identified, but appear to be related to the certified operations and not the certifying agents. Further clarification is required. **May 2014:** The rule 7 CFR 205 section 600 addresses the actions for improper use of the NOP symbol. This is used by the Compliance and Enforcement Division to take actions as needed to ensure proper use based on interviews with the Division Director. The AB

indicated that a policy is needed to ensure the use of the seal is appropriate and the policy is being developed.

VI. RESULTS OF THE ONSITE VISIT

ISO/IEC 17011 Requirements

Section 4.0 Accreditation Body

The general requirements for assessing and accrediting conformity assessment bodies (CAB), referred to as certifying agents (CA), is performed under the United States Department of Agriculture (USDA), Marketing and Regulatory Programs (MRP), Agricultural Marketing Service (AMS), National Organic Program Regulation (7 CFR Part 205)

Section 203 of the Agricultural Marketing Act of 1946, and Section 2115 of the Organic Foods Production Act of 1990, establish the legal authority and framework for accrediting organizations to the Regulation cites in 7 CFR Part 205. The Secretary of Agriculture delegated the responsibility of establishing and implementing the Regulation to the AMS Administrator. The AMS Administrator has the responsibility and authority to make decisions on accreditation appeals. The National Organic Program (NOP) Deputy Administrator has the responsibility and authority to accredit a governing State official, and any private person, as a certifying agent for the purpose of certifying a farm or handling operation as a certified organic farm or handling operation. Note that the NOP also performs additional activities under the NOP Regulation that are outside the scope of the ISO/IEC 17011; these activities include export certification, recognition agreements, equivalency agreements, and State Organic Program reviews.

The program does disclose specific information about the certified organization as specified in the regulation 7 CFR Part 205. In addition, government programs are open to Freedom of Information Act Requests (FOIA). A procedure is available to handle these requests. All information is considered confidential and personnel are required to maintain this confidentiality for all information presented to the NOP. Only information defined by law is made available to outside parties and only information is released to outside parties if a formal FOIA request is received.

The accreditation body is a government agency that ensures its impartiality by requiring all personnel to declare any conflicts and training staff to understand ethical practices and assurance of work that is impartial. NOP has not developed a process as required by ISO/IEC 17011 for evaluating risks to impartiality based on other USDA activities and possible influences from these activities. See ANSICA 2013-USDA-NOP-01-O-MOOM-(17011)4.3.2.

During 2014 – 2015 the NOP is expanding is operations to include aquaculture and other areas. The extending of its programs to these new technical areas does not include a document review. See ANSICA 2013-USDA-NOP-07-O-MOOM-(17011)4.6.3. The accreditation body provides information on the expansion of categories and its accreditation activities on its website. The NOP has worked to ensure external documents are up to date and provide the producers and certifying agents with current information.

Section 5.0 Management

AMS administers the Regulation primarily through three Divisions within the NOP. The Divisions include: Standards Division, Accreditation and International Activities Division, and the Compliance and Enforcement Division. One related body assists NOP with assessment activities; this is the AMS, Quality Assessment Division (QAD). The AIA Division accreditation managers administer client files and all certifying agents' activities.

The most recent organization chart dated April 14, 2014 was used for the office visit. The accreditation body documented a significant number of processes in 2011 to 2012. During this extensive document development period, operational staff found the implementation difficult to follow so the documents were not followed. During 2013 the Office of Deputy Administrator took over the role for quality system management from the AIA Director. In mid-2013 a new quality manager was assigned but hiring administration resulted in the person not being able to be fully effective until spring 2014. During the interim a NOP Standards Division staff person was acting as Quality Manager. The quality manager and Associate Deputy Administrator along with other staff hired within the last two years have not had training in ISO/IEC 17011. Therefore the management system elements from ISO/IEC 17011 were not fully implemented as identified in the seven (7) Opportunities for Improvement presented in ANSICA. See ANSICA 2013-USDA-NOP-02-O-MOOM-(17011)5.2.2, 2013-USDA-NOP-03-O-MOOM-(17011)5.7.2, 2013-USDA-NOP-04-O-MOOM-(17011)5.7.3, 2013-USDA-NOP-06-O-MOOM-(17011)5.3.b, 2013-USDA-NOP-09-O-MOOM-(17011)5.9.c, 2013-USDA-NOP-13-O-MOOM-(17011)5.3.b, 2013-USDA-NOP-14-O-MOOM-(17011)5.4.

Section 6.0 Human Resources

The program requires competency and integrity for all staff performing work within the NOP. The policy is presented and the auditor process for qualification of competency and integrity is identified. The competency and integrity of other staff is not as clearly presented but was found to be available based on job performance plans, descriptions and reviews that are completed for all federal employees. The integrity is part of the government hiring process and requirements for federal employees. The availability of this information should be more clearly presented in the NOP documents.

The accreditation body has a sufficient number of competent personnel having the education, training, technical knowledge, skills and experience necessary for handling the type, range and volume of work performed. There are position descriptions with required minimum qualifications given. The limits of their duties, responsibilities and authorities are noted. Each assessor was required to sign a statement of Commitment, Confidentiality Agreement, and Conflict of Interest Disclosure. The Human Resources Office and Office of Deputy Administrator are reviewing the need for this form based on the documents signed by federal employees.

Staff qualifications, experience and competence are verified. Initial and ongoing training is required. There are procedures for assessors and experts used in the assessment process. NOP has identified the specific scopes in which each assessor and expert has to demonstrate competence and be familiar with accreditation procedures, accreditation criteria. Each assessor has to undergo training and demonstrate knowledge of the relevant assessment methods. They must be able to communicate effectively, both in writing and orally and have appropriate personal attributes.

NOP has procedures for monitoring the performance and competence of personnel to identify training needs. Monitoring is conducted by on-site observations, review of assessment reports, feedback from CABs and peer monitoring. Each assessor is observed on-site regularly, normally every three years, unless there is sufficient supporting evidence that the assessor is continuing to perform competently.

NOP has records for each person involved in the accreditation process. Records of relevant qualifications, training, experience and competence are maintained.

Section 7.0 Accreditation Process

Since the document review in January/February 2014, some documents were updated these include:

Accreditation Policies and Procedures NOP 2000 dated February 28, 2014 (after document review)

The general criteria for accreditation of certifying agents set out in the NOP program is made publicly available via the USDA, AMS, NOP website. Detailed information about assessment and the accreditation processes are available. General information about the fees relating to the accreditation; a description of the rights and obligations of certifying agents; information on procedures for receiving and handling complaints and appeals; information about the authority under which the accreditation program operates; and, description of its rights and duties are available on the website. Information about the means by which NOP obtains financial support and information about its activities and stated limitations under which it operates are also available.

NOP requires a duly authorized representative of the applicant certifying agents to make a formal application. The application requests general features of the certifying agent, including corporate entity, name, addresses, legal status and human and technical resources. Information about the CAB, such as its activities, its relationship in a larger corporate entity if any; addresses of all its physical location(s) to be covered by the scope of accreditation; and, scope of accreditation

NOP requires the applicant CAB to provide information as required by the NOP regulations. NOP reviews its ability to carry out the assessment, in terms of the availability of suitable assessors and experts. The review of completeness of the application form is not specified in the documents as presented in ANSICA 2013-USDA-NOP-08-O-MOOM-(17011)7.2.3. The review also includes NOP's ability to carry out the initial assessment promptly. All assessments by NOP are performed by NOP personnel or personnel from within the USDA AMS Quality Assurance Division (QAD) and not contracted to another entity. Work is done by agreement with QAD (formerly ARC Branch and GVD). Many of the NOP documents are not updated to current organizational names. NOP has clear rules and exercises care to avoid consultancy during accreditation activities. NOP ensures team members act in an impartial and non-discriminatory manner.

The AIA Division Director along with the Supervisor of the QAD formally appoints an assessment team consisting of a lead assessor and a suitable number of assessors and/or experts for the scope of the assessment. When selecting the assessment team, NOP ensures that all the expertise brought to each assignment was appropriate and have the understanding to make a reliable assessment of the competence of the certifying agent. NOP informs the certifying agent of the names of the members of the assessment team and the organization they belong to, sufficiently in advance to allow the certifying agent to object to the appointment of any particular assessor or expert. NOP defines the assignment given to the assessment team.

The NOP has established procedures for sampling based on the number of producers certified by the certifying agent. These procedures ensure that the assessment team witnesses a representative number of sites, client files and operation types to ensure proper evaluation of the competence of the certifying agent. For surveillance and reassessment, NOP has established procedures for sampling of key locations as defined by ISO/IEC 17011 to ensure all sites are visited at least once every five (5) years. NOP ensures the auditor team is provided with criteria documents, previous assessment records, current documents and records of the certifying agent.

The assessment team reviews all relevant documents and records supplied by the certifying agents to evaluate its system for conformity with the standard(s) and other requirements for accreditation. The assessment team reports to NOP accreditation manager if the information from the certifying agent is not acceptable. If NOP has decided not to proceed with an on-site assessment based on the nonconformities found during document review, the AIA Division Director reports the nonconformities in writing to the certifying agent.

The assessment team begins the on-site assessment with an opening meeting to outline the assessment and accreditation criteria, the assessment schedule and confirm the scope for the assessment. The assessment team conducts the assessment of the conformity assessment services at the premises of the certifying agent. The assessment team witnesses the performance of a representative number of staff of the certifying agent to provide assurance of the competence of the certifying agent across the scope of accreditation.

The assessment team reports all information and evidence gathered during the document and record review and the on-site assessment to NOP staff. NOP ensures that the analysis is sufficient to allow NOP to determine the extent of competence and conformity of the certifying agent with the requirements for accreditation. NOP procedures require that: a meeting takes place between the assessment team and the certifying agent to report on its observations obtained from the analysis prior to leaving the site. An opportunity is provided for the certifying agent to ask questions about the observations.

The NOP generates the written report, which contains comments on competence and conformity, and identifies nonconformities to be resolved in order to conform to all requirements for accreditation. The certifying agent is invited to respond to the report and to describe the specific actions taken or planned, within 30 days, to resolve any identified nonconformities. NOP remains responsible for the content of the assessment report, including nonconformities. NOP accreditation manager reviews the acceptance of all corrective actions prior to submittal to the accreditation committee. The accreditation manager submits information to the accreditation committee prior to the accreditation decision by the NOP Deputy Administrator.

NOP prior to making a decision satisfies itself that the information gathered is adequate to decide that the requirements for accreditation have been fulfilled through the review by the accreditation committee. The accreditation committee is composed of NOP staff members. The only members voting are those that were not involved in the accreditation process. As presented in the OFI, one example was observed where a person voting was involved in the document review. Although staff is aware of the requirement, it is not clearly obvious all the staff personnel involved in the accreditation process.

Some of the processes for extending, renewing, suspending and withdrawing accreditation are not sufficiently detailed to meet ISO/IEC 17011. See ANSICA 2013-USDA-NOP-10-O-MOOM-(17011)7.12. 2013-USDA-NOP-11-O-MOOM-(17011)7.13, 2013-USDA-NOP-12-O-MOOM-(17011)7.11. NOP does not use information from another accreditation body to make its decisions on accreditation.

NOP provide an accreditation certificate to the accredited certifying agent. The certificate identifies: all premises from which one or more key activities are performed and which are covered by the accreditation; the identity and logo of the accreditation body; the identity of the accredited certifying agent; the accreditation number of the accredited certifying agent; the effective date of granting of accreditation; the expiry date; reference to the regulation; a statement of conformity; and, a reference to the standard(s) or other normative document(s), including revision used for the assessment.

The NOP receives appeals from emails, letters and the website. Some appeals are received via the accreditation manager or auditor. Depending on the nature of the complaint the Office of Deputy Administrator, Compliance and Enforcement Division or the AIA Division Director handles the complaint. The lead ANSI team member reviewed the receipt, listing and follow-up of the appeals, complaints or investigations performed by the Compliance and Enforcement Division. The process used meets ISO/IEC 17011 however the process found in the current procedure is not consistent with the current handling. A draft procedure is in process (NOP 4000) that is updating current documents to actual practice. The draft document was reviewed and is consistent with ISO/IEC 17011 requirements.

Section 8.0 Responsibilities of the accreditation body and the CAB

The obligations of the certifying agents are stated in the regulation 7 CFR Part 205, NOP Handbook, Notices and other documents defined by NOP such as the Terms of Accreditation. The agreement (TM-10CG) indicates that by signing the application document, these requirements must be fulfilled by the certifying agent. All elements are addressed in these documents except the need for the certifying agent to notify NOP without delay of changes. See ANSICA OFI 2013-USDA NOP-05-O-MOOM-(17011)8.1.2. The certifying agent must notify NOP annually, which may not be sufficient to ensure current information is available.

The accreditation body, NOP maintains a website that provides certifying agents, producers and the public with information about the program as required by ISO/IEC 17011. NOP has controls and monitoring on the use of the Organic Mark. Other countries and ABs outside the United States use the symbol. Authorization comes from equivalency arrangements and recognition arrangements. This is not part of the NOP accreditation body activities, but is part of the scheme requirements of NOP. There is no obvious separation based on the display of the mark, but internal documents and agreements provide the needed detail. In all cases the mark signifies the product meets the requirements of the NOP 7CFR Part 205, NOP Handbook and Notices or have been considered equivalent by the regulatory program.

The NOP has a top priority to develop clear rules for use of its mark. When the mark is misused or allegations of misuse are identified, the Compliance and Enforcement Division lead the investigation with input from other NOP personnel. If initial requests to stop the use are not implemented by the certifying agent or the producer, the division takes further legal action to address the issue. The actions are defined in the regulations and in NOP 2024-1. Personnel are aware to notify NOP with appeals and complaints via the website. The Associate Deputy Administrator manages the appeals process with input from the Compliance and Enforcement Division Director, AIA Division Director and the Deputy Administrator.

VII. SUMMARY

This completes the office and document review for the peer evaluation review of the USDA AMS, NOP. The next step is for NOP personnel to review the report and fourteen (14) Opportunities for Improvements (OFIs) and provide comments to this final draft report and upload responses to the OFIs into ANSICA. In addition the ANSI technical assessor will plan and conduct two witness assessments and report on these under separate cover.

The NOP operations perform audit activities as defined by the regulations 7 CFR Part 205. The regulation specifies the accreditation body to work in conformance to ISO/IEC Guide 61 now known as ISO/IEC 17011. All elements of ISO/IEC 17011 are not implemented as presented in the Opportunities for Improvement (OFI). The NOP has not implemented a documented management system since the documented system developed in 2012 was not found to be efficient and effective. The lack of a documented system that reflects current practices is expected to be problematic as new staff is added to the NOP operations in 2014 to 2015.

The NOP administrator and personnel are committed to implementing ISO/IEC 17011. The current NOP operations are taking on additional responsibilities for the program. This change has occurred since 2012 and additional resources are being added to improve the administration of the NOP. The administrative and management staff has not been trained in ISO/IEC 17011 and the Office of the Deputy Administrator (ODA) has adopted an undocumented style of organizational management. Variations in the implementation were observed during the peer review, which is minimized at the present time due to the limited number of staff. This may become problematic as additional staff is added to the NOP operations.

The NOP accreditation system is specified under the USDA organic regulations. These regulations are not completely aligned with ISO Guide 65 or ISO/IEC 17065. The NOP is not planning on implementing full compliance with ISO/IEC 17065 for its certifying agents. The International Accreditation Forum (IAF) and conformity assessment bodies (CAB) have set the date of September 15, 2015 as the implementation date for all conformity assessment bodies in all certification schemes to be in conformance to ISO/IEC 17065.

A complete list of the findings (Opportunity for Improvements - OFIs) from this peer review evaluation can be found in Appendix 2 of this report.

VIII. Appendix 1

NIST/NVCASE Document Review (July 2011) Corrective Actions Review

Clause of ISO/IEC 17011 or other standard/ requirement (specify)	Type # Auditor	Issues of Concern (IC)	ANSI Review May 2014
§3.0	IC-1 (MM)	*The AB does not use the same definitions as found in ISOIEC 17000.* *Evidence*: The QM references ISO/IEC 17000, but the regulations, 7 CFR Part 205, define accreditation and certification in a slightly different manner. The QM and related documentation do not state the hierarchy of the required documents. In the teleconference, July1, 2011, NOP indicated that the regulations are *required* and other items found in Level 1 and Level 2 documents are only *strongly suggested*. The reference to the terms used in the quality manual are not required, but are suggested and the terms in the regulation are required. Therefore it is not apparent that the AB adheres to the definitions cited in ISO/IEC 17011 and ISO/IEC 17000.	This continues to be a concern since the use of ISO/IEC 17000 is a normative reference needed to understand and implement ISOIEC 17011. Regulatory definitions are used and others are not incorporated into the management system. As found during the 2014 visit the regulations are followed, but not a documented management system as required by ISO/IEC 17011.
§4.2.1, §5.1.1, §5.2.2	IC-2 (MM)	*The AB structure and operation do not indicate the person(s) responsible for meeting the requirements of ISO/IEC 17011.* *Evidence*: The AB policy indicates conformance to ISO/IEC 17011, but the duties and responsibilities do not indicate the person responsible for ensuring the operations of the AB are in conformance to ISO/IEC 17011. Based on the verbal information presented by the NOP Deputy Director, the NOP is only required to adhere to the requirements of 7 CFR 205. Therefore it is unclear from the documents if all requirements of ISO/IEC 17011 are to be addressed or only the elements of 7 CFR Part 205 subpart F. The specific activities with NOP that are included in the ISO/IEC 17011 management system are not clearly stated such as the issuing of export certificates, review of International Agreements, State	The duties and responsibilities document states (NOP1002) the NOP Deputy Administrator is responsible. The Quality Manual from 2012 is updated and clearly states the activities not within the accreditation body activities such as export certificates, international agreements and State Organic Programs. Since the NOP has not fully adopted a documented management system in conformance to ISO/IEC 17011 a concern remains as presented in the Opportunities for Improvement (OFI)

Clause of ISO/IEC 17011 or other standard/ requirement (specify)	Type # Auditor	Issues of Concern (IC)	ANSI Review May 2014
		Organic Programs, etc. Based on the NOP request of NIST to perform a document review for conformance to ISO/IEC 17011, the structure and operations do not clearly reflect all the elements as presented in the OFIs and ICs that follow.	identified by ANSI during the 2014 visit. However the systems have improved and personnel involved in the NOP program attempted to implement a documented program in 2012-2013. The documented program was not effective for the operational staff. The NOP has improved external documents, but has not improved the documents for internal operations.
§4.2.8	IC-3 (MM)	*The AB has not documented the entire structure showing the lines of authority and responsibility for all activities.* *Evidence*: NOP 1001 presents the Compliance and Analysis Program on the chart, but does not indicate the lines of authority and areas of responsibility. It is not clear if this program must meet all or relevant parts of ISO/IEC 17011. Positions presented in NOP 1002 are not all identified on NOP 1001 organization chart. (e.g. Accreditation Manager, Accreditation Specialist, Regional Accreditation Managers, NOP Accreditation Committee and its members relationship in the organization.)	An improvement is noted since the NOP operations are more clearly defined as to the responsibilities of the program. The NOP 1002 and organization chart for the NOP are consistent. The only inconsistency is in the names of the operational units performing NOP activities such as QAD and the Compliance & Enforcements office names. Documents do not always reflect the current group name.
§4.3.7, 7.5.	IC-4 (MM)	*The AB does not clearly define the activities of related bodies and include a review to ensure the related body activities do not compromise the impartiality of the AB.* *Evidence*: Section 4.3.2 NOP 1000 indicates a review of impartiality is made by the NOSB, but the policies and procedures of the NOSB do not indicate that the NOSB reviews and makes decision on the impartiality of related activities or bodies of the USDA	As presented in the OFI 2013-USDA NOP-01-O-MOOM-(17011)4.3.2 during the 2014 visit, the risks to impartiality of the NOP AB operations from other NOP regulatory actions, other AMS activities and the QAD activities are not clearly defined. It is noted that the document review comments

Clause of ISO/IEC 17011 or other standard/ requirement (specify)	Type # Auditor	Issues of Concern (IC)	ANSI Review May 2014
		AMS. The April 2010 minutes from the NOSB do not show a review of impartiality of the program. The Accreditation Committee members are part of other activities or programs within USDA Accreditation & International Activities (AIA) and Standards Division (SD). Their job functions are not clearly defined in the documentation to ensure impartiality is maintained. Some activities within AMS performed by ARC Branch perform audits and inspection services that are similar to other CAB activities. Some activities within NOP may provide consultancy as part of training or standards interpretation. These groups all have the same top management for AMS. The relationship is not clearly presented to ensure no conflicts exist.	indicate that the NOSB is not the mechanism to review the impartiality of NOP.
§4.5.1 and 4.5.2	IC-5 (MM)	*The AB does not present information in the checklist to indicate the location of information to cover its liabilities and the financial resources needed for the operation of the program.* *Evidence*: The NOP 1000 document references the USC6522 appropriations documents. No information is presented or identified on where to find out how top management covers liabilities and determines the sufficiency of its financial resources.	The Quality Manual presents information on the appropriations from Congress as the source of income for the organization. The Quality Manual is available on the website.
§4.6.3.a	IC-6 (MM)	*The AB does not indicate that an analysis is available on the competence and resources review for extension to new fields.* *Evidence*: The NOP 1000 indicates the NOSB obtains the information, but no evidence is found in the NOSB reports or charters. NOP 2500 defines auditor criteria but does not present sector specific scope criteria. The procedure referenced does not address extension and resources for new fields (such as new organic crops or processing not previously assessed by NOP.)	The NOP is expanding into new areas. A strategic plan is used, but this is not inclusive of the elements required by ISOIEC 17011. See 2014 ANSI OFI 2013-USDA_NOP-07-O-MOOM-(17011)4.6.3

Clause of ISO/IEC 17011 or other standard/ requirement (specify)	Type # Auditor	Issues of Concern (IC)	ANSI Review May 2014
§5.2.1	IC-7 (MM)	*There is no documented evidence that top management has demonstrated commitment to quality and to comply with the requirements of ISO/IEC 17011.* *Evidence:* The Deputy Administrator signs the NOP 1003 Policy document. The Deputy Administrator of the NOP is not the top manager for the NOP section. The top manager is the AMS Administrator who makes decisions on appeals and accreditation decisions.	This commitment was presented to the ANSI team on the first day of the peer review. The policy statement was signed by the Administrator on May 9, 2014.
§5.3.b	IC-8 (MM)	*The AB document control procedure does not include the control needed to re-approve documents.* *Evidence:* Procedure 1010 does not address re-approving documents	Procedure 1010 has not been updated since the NIST document review. Document control process is not followed as presented in the OFI OFI 2013-USDA_NOP-13-O-MOOM-(17011)5.3.b and 2013-USDA_NOP-06-O-MOOM-(17011)5.3.b
§5.4.2	IC-9 (MM)	*The AB does not have a stated policy for retaining records.* *Evidence:* The referenced documents in NOP 1010 are not provided. Some records of the NOP are indicated as 1 year in this procedure. It is not clear if these reference records are considered part of the NOP accreditation body program. Records retention of emails and other certification body documents is not specified in NOP 1010.	Although a significant amount of work has been developed for the records retention policy it has not been completed as presented in the OFI 2013-USDA_NOP-14-O-MOOM-(17011)5.4. At this time all records are retained either electronically or hard copy.
§5.8.1	IC-10 (MM)	*The top manager of the accreditation program is not indicated as participating in the management review.* *Evidence:* The AMS Administrator is not identified as a member of the top management participating in the management review. The AMS Administrator is the person making the decision on accreditation and handling appeals.	The top management for NOP is the Deputy Administrator as defined in the quality manual and organizational structure. The management review minutes from May 2014 included the Deputy Administrator, Asst Deputy Administrator

Clause of ISO/IEC 17011 or other standard/ requirement (specify)	Type # Auditor	Issues of Concern (IC)	ANSI Review May 2014
			and Division Directors.
§6.1.4	IC-11 (KW)	*The AB does not require all personnel involved in the AB to commit themselves to comply with the rules of the AB.* *Evidence:* The NOP 1008 and related documents do not indicate that all personnel sign the commitment document. The NOP document is for Conflict of interest and confidentiality, but does not address complying with the rules of the program.	The document defined by NOP is not signed by personnel since the human resources group has indicated to NOP Asst Deputy Administrator that it is not needed. This continues to be reviewed by NOP to determine the need for a separate document due to the requirements in place for federal employees.
§6.2.1, 6.2.2	IC-12 (KW)	*The qualifications, experience and competence along with initial and on-going training for all staff are not presented in the NOP documents listed on the checklist. The procedures also do not include the selection of assessors and formally approving assessors.* *Evidence:* NOP procedures identified do not indicate the qualification, experience and competence for staff other than auditors and Accreditation Committee members. The procedures also do not present initial and on-going training requirements for staff performing other functions beyond auditors and Accreditation Committee members. The current NOP 2500 document identified does not include the selection of auditors and the person responsible for approving auditors. The procedure does not provide sufficient detail to determine the activities performed by NOP to meet these requirements. A previous version of NOP 2500 (2010) included a section on selection.	The NOP presented performance plans and other personnel documents to show authorization and continued monitoring of personnel performing specified duties. The alignment of the plans and the NOP documented system was being further reviewed and developed as new personnel are added and the work of the NOP is being performed within the NOP operations. The NOP 2500 document does include the selection process.
§6.3.1	IC-13 (KW)	*The AB does not present the monitoring and review of competence for all personnel.* *Evidence:* The NOP procedures do not address the monitoring and performance review of	Performance plans and personnel monitoring was presented to the ANSI team. These are not identified in the NOP program documents, but do address the

Clause of ISO/IEC 17011 or other standard/ requirement (specify)	Type # Auditor	Issues of Concern (IC)	ANSI Review May 2014
		competence for all staff. The procedures are specific to the evaluation of auditors used by the ARC Branch and NOP. It does not address other personnel involved in the assessment and decision-making. The procedures also do not indicate how the AB reviews the performance and competence of its personnel in order to identify training needs.	monitoring and performance for all jobs within the NOP and related operations.
§7.1.2.e	IC-14 (MM)	*The current status of the accredited CBs is not presented on the website as required in ISO/IEC 17011 8.2.1.* *Evidence:* A random selection of listed certified CBs (5 – 3 domestic and two international) on the website identified one international accredited CB the does not indicate a renewal letter was issued. (Costa Rica EcoLogica S.A accredited in 2002, no renewal letter as of 2011. Renewal was due in 2007)	A random selection of CBs found letters and processes are correct on the status of the CBs. A spreadsheet tracks all CBs status and this is used to ensure renewal and surveillance audits are performed. It was noted that some were not up to date, but extension letters were issued by the AIA Division Director to address the delay in assessments. Some of these were noted as due to the government shutdown.
§7.1.2.k	IC-15 (MM)	*The AB does not include information on the public website about all the related bodies performing activities of NOP.* *Evidence:* The website presents information on the NOSB committee related to standards development, but does not define intergovernmental related bodies such as ARC Branch, Compliance and Analysis (C&A), Compliance & Enforcement Division (CE), etc. (See also IC-4)	The interrelationship is more clearly presented in the documents and public information since the Quality Manual from 2012 is presented and newer documents are updated to indicate renaming of other operations.
§7.2.1.d	IC-16 (MM)	*The AB does not have an agreement to address all ISO/IEC 17011 requirements for all areas in which NOP operates.* *Evidence:* The State Organic Programs and International Agreements are not required to meet all the elements defined in the	These programs are not defined as within the NOP accreditation program in the current Quality Manual. The NOP contracts require adherence to the regulations, the handbook and notices

Clause of ISO/IEC 17011 or other standard/ requirement (specify)	Type # Auditor	Issues of Concern (IC)	ANSI Review May 2014
		agreement TM-10CB (7-10). Some elements are excluded for State Organic Programs (e.g. 7, 8 and 9) and the arrangement for International Agreements is not clearly presented to evaluate if the requirement is to meet ISO/IEC 17011. The State Organic Program and International Agreements are consistent with the regulation, but it is unclear if they must also be consistent with ISO/IEC 17011.	which address all the elements of ISO/IEC 17011 for certifying agents.
§7.3	IC-17 (MM)	*The AB does not indicate that a resource review is performed including the ability to carry out the initial assessment in a timely manner.* *Evidence:* The NOP documents (2000 and 2012) do not indicate a resource review is performed including the ability to perform the assessment in a timely manner. A resource review is found in the ARC 1000 procedure, but not for the NOP operations.	The AB does perform a resource review but this is not identified in a procedure or policy. The AB performs a strategic plan and this was available for review by the ANSI team.
§7.4.1, 7.4.2, 7.4.3	IC-18 (MM)	*The AB agreement with ARC Branch does not include covering all arrangements such as NOP policies and procedures, confidentiality and conflict of interest, evaluating competency and obtaining consent of CB.* *Evidence:* The agreement signed in 2010 by both parties does not define the requirements to operate in accordance with NOP policies and procedures or ISO/IEC 17011. No specific requirements for confidentiality and conflict of interest are presented. The MOU does not define or reference the process to be implemented by NOP to evaluate the competence of ARC Branch auditors and assessment process. The checklist indicates the MOU and NOP 2000 define how the consent of the CB is obtained. The agreement (LS313 and TC-10CG) do not clearly indicate the use of the ARC Branch as a subcontractor for performing NOP assessments. It is not clear how the consent of the CB is	The AB has an agreement with QAD and the elements are addressed. This agreement was recently signed by the appropriate parties.

Clause of ISO/IEC 17011 or other standard/ requirement (specify)	Type # Auditor	Issues of Concern (IC)	ANSI Review May 2014
		obtained.	
§7.5.4	IC-19 (MM)	*The AB does not have procedures for NOP to notify the CB of the assessment team and for handling any objections* *Evidence:* The NOP may use its own auditors based on the MOU with ARC Branch. The NOP does not have specific procedures for meeting these requirements. The ARC Branch procedures do address this requirement.	This is addressed in the letter sent to the certifying agents and the certifying agent has the right to reject any member of the team for cause. The AIA Division Director handles any objections and this is found in NOP 2500.
§7.7.3	IC-20 (KW)	*The AB does not specify the number of witness assessments based on number of staff of the CB.* *Evidence:* The NOP procedures presented do not imply or indicate the selection of the number of witness audits is based on the number of CB auditors.	NOP 2005 indicates the selection process for the number and types of witness assessments.
§7.8.2	IC-21 (KW)	*The AB procedures do not indicate the process for the assessment team to refer back to the AB assessment findings for clarification.* *Evidence:* The NOP procedures do not indicate how the ARC Branch is to contact NOP when the assessment team cannot reach a conclusion about a finding. NOP 2005 indicates the ARC Branch is to list any unresolved issues that are referred to AIA. It is not clear if the information is forwarded to NOP.	This is handled by NOP following the review of the findings. This process is stated in NOP 2500 and the team reviews this with the accreditation manager or AIA Division Director, if needed.
§7.9.4	IC-22 (KW)	*The AB certificate does not include an issue or revision of the regulation used for assessment.* *Evidence:* The certification submitted on 07/07/11 indicates conformity to the regulation, but does not indicate an issue or revision used for the assessment.	This is now added to the certificate.
§7.10.2.a and	IC-23	*The AB does not ensure that all the*	The AMS Administrator

Clause of ISO/IEC 17011 or other standard/ requirement (specify)	Type # Auditor	Issues of Concern (IC)	ANSI Review May 2014
d	(MM)	*requirements for handling appeals per ISO/IEC 17011 are addressed* *Evidence:* 7.10.2..a) the AB procedure does not clearly state that a person or group that is always independent of the subject of the appeal performs the appeal decision and investigation. The procedures indicate that AMS Administrator makes the decision on the appeal. The AMS administrator is also the person making the decision on accreditation for initial applications and therefore is not independent of this process. The procedures for Adverse Actions Appeals Process do not indicate the process used for the selection of the Appeals Team used to investigate the appeal. 7.10.2.d) the C&A procedures and NOP procedures do not indicate how follow-up actions relevant to the AB's operation are handled when identified.	is listed in the documents as responsible for appeal. The Compliance & Enforcement Division and the Assistant Deputy Administrator handle the appeal process. The appeals reviewed found the process to meet ISO/IEC 17011, but the documented procedures are not the ones followed.
§7.11.2, 7.11.3, 7.11.4, 7.11.5	IC-24 (MM)	*The AB procedures do not address all the requirements for surveillance and reassessments.* *Evidence:* The regulation and procedure do not define the procedure for performing surveillance on-site assessments or activities. The NOP 2000 procedure indicates surveillance assessments are performed, but no procedure on the process is found. The requirements of on-site surveillances are not documented in the procedures presented. The timeframes for response to corrective action are not presented in the referenced documents. 7.11.3 The frequency of the reassessment does not meet the requirements of ISO/IEC 17011. The frequency for reassessment is every 5 years with a mid-term assessment performed at 24 to 36 months. The procedures refer to this process as an assessment and if this is the surveillance it does not meet the	NOP procedure has been updated to address surveillance and reassessments. The information is not clear on the specific steps required for renewal. See ANSI OFI 2013-USDA_NOP-12-O-MOOM-(17011)7.11.1

Clause of ISO/IEC 17011 or other standard/ requirement (specify)	Type # Auditor	Issues of Concern (IC)	ANSI Review May 2014
		requirement of an on-site visit at least every two years. The initial assessment is two years after the pre-decisional assessment and meets the first two years requirement, but since the reassessment is not until three years after this assessment it will not meet the 2-year requirement.	
§ 7.12	IC-25 (MM)	*The AB procedures do not detail all the requirements for extending the scope of accreditation.* *Evidence:* The identified procedures do not indicate the information needed to extend the scope of accreditation.	The procedures do not clearly detail the steps needed for scope extension. See ANSI OFI 2013-USDA_NOP-10-O-MOOM-(17011)7.12
§ 8.1.1	IC-26 (MM)	*The AB does not clearly specify the requirements to be performed by the CB.* *Evidence:* The TC-10CG indicates the following: *"Complying with, implementing, and carrying out any other terms and conditions determined by the Administrator to be necessary*;" It is not clear if the policies and procedures identified in the NOP Handbook are required in addition to the 7 CFR Part 205 requirements where additional information is provided in the policy and procedures supplied.	A review of this was made with the Compliance & Enforcement Division Director. As presented in the regulations the NOP may include additional information which is found in the Handbook and Notices that are considered requirements.
§8.2.2	IC-27 (MM)	*The AB did not indicate in the submitted checklist the reference to the requirement for obtaining traceability of measurements.* *Evidence:* The NOP requires testing as part of the evaluation process used by CBs. The NOP 2611 is a level 2 document that is not required, but does provide guidance on measurement traceability. It is not clear if CBs are required to follow this Guide in order to meet the NOP testing requirements.	The NOP testing requires the use of accredited laboratories to ISO/IEC 17025. (See NOP1000) Therefore the traceability of measurement is assured.

Clause of ISO/IEC 17011 or other standard/ requirement (specify)	Type # Auditor	Issues of Concern (IC)	ANSI Review May 2014
§8.3	IC-28 (MM)	*The AB does not clearly define the policy and procedures for the use of the USDA Organic seal to reflect accreditation applicable programs only.* *Evidence:* The USDA Seal is used for identification of the program and can be used for other activities that may or may not be within the scope of the accreditation program. The seal does not indicate the activity that is represents, such as SOP or International Agreements. The clear requirements for the use of the AB symbol are not found in the referenced documents. The requirements do not indicate that the seal can only be used for the premises of the CB that are accredited. The requirements also do not state that the accreditation is not to be used to imply that a product is approved by the AB (8.3.2).	The AB indicated that development of a policy is top priority for the NOP. Some clarity is provided in the terms of accreditation and the regulations also provide some requirements. The NOP Organic Seal is authorized for use by certifying agents, state programs and equivalency programs.

Clause of ISO/IEC 17011 or other standard/ requirement (specify)	Type # Auditor	Opportunities for Improvement	ANSI Review May 2014
§5.3	OFI-1 (MM)	Several documents do not appear to be controlled in the same manner as other documents in the program. Two examples are presented. (1) The Assignment of Functions document dated December 2009 does not have a control number or person issuing the document. (2) The C&A documents related to appeals handling do not have a control number or person issuing the document. It appears that some documents used by NOP are outside of its document control program (external documents) and the procedure for handling, reviewing and authorizing for use by NOP is not defined.	The C&A documents are not updated since the identification of this OFI. The division named is now the Compliance and Enforcement (C&E) Division. Some procedures from C&E are being drafted and following the NOP process for document control. As presented in this review the use of a documented management system that is effective continues to be part of the improvements being developed for the NOP.
§6.1.4	OFI-2 (KW)	NOP 1008 and ARC 1420 do not address "prior" conflicts in the commitment documents and procedures. The NOP 1000 indicates this is addressed. Interviews with staff required to determine how "prior" conflicts are declared and handled. See also ISO/IEC 17011 7.5.1 for preliminary visit activities for state assistance programs that may result in "prior" conflicts requiring a declaration.	State assistance programs are outside the scope of the NOP ISO/IEC 17011 program. Staff are required by the federal employment of personnel to declare conflicts.
§6.3.2	OFI-3 (KW)	It is not clear from the procedures if NOP does a separate monitoring (witness) of the assessor's performance beyond the monitoring done by the ARC Branch. The monitoring of the assessment process by NOP as performed by the ARC Branch requires clarification from NOP personnel.	The NOP is performing witnessing of NOP staff and QAD (formerly ARC) personnel. Records are not always available, but the monitoring and feedback is performed.

IX. Appendix 2: List of Opportunities for Improvement

1. 2013-USDA NOP-01-O-MOOM-(17011)4.3.2
2. 2013-USDA NOP-02-O-MOOM-(17011)5.2.2
3. 2013-USDA NOP-03-O-MOOM-(17011)5.7.2
4. 2013-USDA NOP-04-O-MOOM-(17011)5.7.3.a
5. 2013-USDA NOP-05-O-MOOM-(17011)8.1.2
6. 2013-USDA NOP-06-O-MOOM-(17011)5.3.b
7. 2013-USDA NOP-07-O-MOOM-(17011)4.6.3
8. 2013-USDA NOP-08-O-MOOM-(17011)7.2.3
9. 2013-USDA NOP-09-O-MOOM-(17011)5.9.c
10. 2013-USDA NOP-10-O-MOOM-(17011)7.12
11. 2013-USDA NOP-11-O-MOOM-(17011)7.13.1
12. 2013-USDA NOP-12-O-MOOM-(17011)7.11.1
13. 2013-USDA NOP-13-O-MOOM-(17011) 5.3.b
14. 2013-USDA NOP-14-O-MOOM-(17011) 5.4