NIST Report
Document Review

United States Department of Agriculture,
Agricultural Marketing Service
National Organic Program
(USDA-NOP)

Assessment of USDA's Organic Certifier Accreditation System

Document Review Dates: June 17, 2011 & July 5-8, 2011
Final Report Issue Date: July 31, 2011

National Institute of
Standards and Technology
U.S. Department of Commerce

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II. EXECUTIVE SUMMARY

The results of the document review are presented in this report as required by the agreement between NIST and USDA/AMS/NOP.

Overall the USDA/AMS/NOP program is designed to fulfill the requirements of the National Organic Program regulation 7 CFR Part 205. The program documentation is organized in accordance with theses requirements.

The ISO/IEC 17011 elements that are not required in the regulation are not always thoroughly presented in the documentation as noted in Section V of this report, Issues of Concern.

Information that is not clear as to the specific processes to be implemented in order to meet the requirements of ISO/IEC 17011 is presented in Section VI, Opportunities for Improvement.

The organizational operations and management commitment for implementation requires further clarity as to the nature and extent of the application of ISO/IEC 17011.

The USDA/AMS/NOP provided all requested documentation for review in a timely and expeditious manner. The timeliness of the information allowed for an efficient and thorough document review.

III. BACKGROUND

A Memorandum of Understanding (MOU) between the ***USDA/AMS/NOP*** and ***NIST***, U.S. Department of Commerce (DOC) was signed in January 2011. The MOU is for NIST to coordinate an assessment of the organic certifier accreditation system to determine compliance of the direct accreditation program of organic certifiers (as assessed by USDA Audit, Review and Compliance (ARC) and accredited by the National Organic Program) to the following standards:

(a) ISO/IEC 17011 (ISO/IEC Guide 61 is called out in the regulations).
(b) The Organic Foods Production Act of 1990 (as amended - 7 U.S.C. 6516) and the implementing regulations of 7 CFR 205.509

The assessment activities are divided into specific stages and conducted against estimated timelines, as mutually agreed upon by NIST and NOP. The following are the activities completed to date:

- NOP submitted documentation for Stage 1a in August 2010, April 2011 and July 2011.
- NOP and NIST Teleconference July 1, 2011: Attendees: Dana Stahl and Miles McEvoy - NOP; Ramona Saar and David Alderman - NIST, Marlene Moore and Krista Wanser – NIST contracted assessors
- The contracted assessors completed Stage 1b, NIST Desk Audit in June and July 2011. This report presents the outcome of the Initial Desk Audit on the conformance of the NOP Quality Management System to ISO/IEC 17011 and 7 CFR Part 205.
- The NIST Closing Meeting, Stage 1c is scheduled for July 11, 2011. This will be a teleconference between NIST, NOP and NIST contracted assessors to review and discuss the draft report.

The listing of current documents is found in the NOP Document Control Master List dated May 26, 2011. The latest versions of the documents presented on the NOP checklist were reviewed as part of the document review.

IV. DOCUMENT REVIEW OUTCOME

Dates of Document Review:	June 17, 2011 and July 5 to 8, 2011
NIST Assessors:	1. Marlene Moore, Lead Assessor (contracted by NIST) 2. Krista Wanser, Assessor/Technical Expert (contracted by NIST)
USDA-NOP Personnel:	1. Dana K. Stahl, Quality Manager, NOP 2. Miles V. McEvoy, Deputy Administrator NOP
NIST Secondary Technical POC:	1. Ramona Saar
Location:	Desk Audit - Remote
Scope of Audit:	1. USDA-NOP for compliance with ISO/IEC 17011 standard as an accreditation body of certification bodies for the National Organic Program. 2. USDA-NOP's ability to accredit certification bodies for conformance with 7 CFR Part 205, NOP Program Handbook and procedures.

i. General Statement of Conformance

As a result of the document review, it was confirmed that the NOP has:

1. A documented process for meeting 7 CFR Part 205.
2. A documented process that is publicly available in the form of the NOP Handbook.
3. A documented process for input from all stakeholders related to technical standards.

ii. ACCREDITATION BODY

The accreditation body is USDA/AMS/NOP. The body is to be reviewed to determine if it operates in conformance with ISO/IEC 17011. However, the operations of the NOP are designed and developed to meet the requirements of 7 CFR Part 205. These regulations do not address all the ISO/IEC 17011 requirements. As presented in the Issues of Concerns section of this report, in order for the NOP to operate in accordance with ISO/IEC 17011, any additional policies and procedures that are beyond the regulations must be required in the same fashion as the regulations.

The accreditation body must more clearly define the operations (State Organic Program, International Agreements, certificates exemptions, etc.) that are included in the activities

of accreditation. This includes defining the structure of the organization and the related bodies.

iii. MANAGEMENT

The direct line managers of the National Organic Program (NOP) are clearly presented in the documents and procedures. The related bodies or associated divisions performing some of the functions for NOP (e.g. C&A and CE) are not as clearly presented. As presented in the Issues of Concern and the Opportunities for Improvement, the AMS Administrator makes the decisions on appeals and accreditation but is not included in the top management. There is no documented evidence to demonstrate that the AMS administrator is committed to operating the NOP program in accordance to ISO/IEC 17011.

iv. HUMAN RESOURCES

The AB has documented procedures and policies for ensuring the competency of its auditors and accreditation review committee. It is not clear from the procedures if the same details are available for all staff and if the NOP and ARC Branch auditor's competency records are formally approved by NOP personnel. As presented in the Issues of Concern, some elements of ISO/IEC 17011 do not appear to be addressed. In several procedures the processes are not sufficiently detailed to determine the extent of implementation. These items are presented as Opportunity for Improvements.

v. ASSESSMENT PROCESS

The assessment process meets the requirements of 7 CFR Part 205 but does not meet all the process requirements defined by ISO/IEC 17011. In the current program, a document review is performed prior to initial assessments and reassessments. A report on the outcome of a site visit is documented on checklists and reports to present objective evidence of conformance to the 7 CFR Part 205 requirements and the related technical requirements defined in the NOP handbook. The Accreditation Committee reviews the report of the assessment process and prepares the recommendation for accreditation. The recommendation is presented to the AMS Administrator for a decision on accreditation. A certificate is issued for accreditation and posted on the USDA/AMS/NOP website. The overall scheme is consistent with ISO/IEC 17011, but the specific details are not thoroughly addressed as presented in the Issues of Concern.

vi. RESPONSIBILITIES OF THE ACCREDITATION BODY and the CAB

The obligations of the CB, AB and use of the USDA Organic Symbol are not clearly presented to meet the requirements of ISO/IEC 17011. Some elements are identified in the procedures. As presented in the Issues of Concern, it is not clear if these elements are required or recommended. It is not clear if suspension/revocation or other actions can be taken if the USDA seal is used in a manner that is not allowed in ISO/IEC 17011.

V. ISSUES OF CONCERN

Clause of ISO/IEC 17011 or other standard/ requirement (specify)	Type # Auditor	Issues of Concern (IC)
§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.
§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

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		clearly stated such as the issuing of export certificates, review of International Agreements, State 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.
§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.)
§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 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

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		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.
§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.
§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.)
§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.*

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		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.
§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
§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.
§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.
§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.*

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		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.
§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.
§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 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.
§7.1.2.e	IC-14	*The current status of the accredited CBs is not presented on the website as required in ISO/IEC 17011*

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	(MM)	*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)
§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)
§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 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.
§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:*

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		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.
§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 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.
§7.7.3	IC-20 (KW)	*The AB does not specify the number of witness assessments based on number of staff of the CB.*

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		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.
§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.
§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.
§7.10.2.a and d	IC-23 (MM)	*The AB does not ensure that all the 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

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		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.
§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 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.
§ 8.1.1	IC-26 (MM)	*The AB does not clearly specify the requirements to be performed by the CB.* *Evidence:*

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		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.
§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.

Clause of ISO/IEC 17011 or other standard/ requirement (specify)	Type # Auditor	Issues of Concern (IC)
§8.3	IC-28 (MM)	*The AB does not clearly define the policy and procedures for the use of the UDSA 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).

VI. OPPORTUNITIES FOR IMPROVEMENT

Clause of ISO/IEC 17011 or other standard/ requirement (specify)	Type # Auditor	Opportunities for Improvement
§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.
§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.
§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.

VII. NEXT STEPS

1. As per the NIST MOU NOP Quality Management System Review Timeline, Stage 1d is to allow NOP review and respond in writing to the Desk Audit findings within a defined agreed-upon time period.
2. NIST reviews the NOP response to determine the adequacy of the submitted corrective actions and provides a report to NOP on the outcome of this review (Stage 1 e).
3. The initiation of the Complete Peer Review for conformance to ISO/IEC 17011, Stage 2 Desk audit will start following the acceptable outcome of the initial desk audit.
4. Office visits and witness assessments (Stages 3, 4 and 5 – MOU Attachment 2) are scheduled to be completed in FY 2012. The date of termination of the MOU is currently September 30, 2012.