

ANSI Peer Evaluation Report

USDA – Agricultural Marketing Service

Accreditation of Certifying Agents under the National Organic Program

PROPRIETARY

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I. Executive Summary

The Organic Foods Product Act of 1990, as amended (reference 7 U.S.C. 6516), hereinafter referred to as the “Act,” authorizes the Department of Agriculture (USDA) to establish a peer review panel to evaluate the accreditation activities of its National Organic Program (NOP). The scope of the USDA NOP activity is the accreditation of certifying agents meeting the regulatory requirements identified in 7 CFR Part 205.500. Since October 2002, producers and food handlers have been required to be certified by a USDA NOP-accredited certifying agent in order to market their products as organic.

Under the Act’s implementing regulations (reference 7 CFR 205.509), a peer review panel is to be comprised of not less than three members who shall evaluate the NOP’s adherence to (a) the accreditation procedures in subpart F of the regulations, (b) the NOP’s accreditation decisions, and (c) ISO/IEC Guide 61, the International Organization for Standardization (ISO) / International Electro technical Commission (IEC) *General Requirements for Assessment and Accreditation of Certification/Registration Bodies*.

The American National Standards Institute (ANSI), a private, non-profit organization (501(c)3) that administers and coordinates the U.S. voluntary standardization and conformity assessment system, and who serves as the U.S. member of ISO and IEC, was contracted by USDA to conduct a peer evaluation of the NOP accreditation system. According to the USDA-authored *Federal Register* Notice, “ANSI was selected by the NOP to perform this peer evaluation because of its world-wide credibility, knowledgeable and professional staff, and performance of accreditation activities similar in size and scope to those undertaken by the NOP.”

An ANSI evaluation team launched the first phase of the peer assessment of the organization, accreditation system, staffing, and assessment procedures and practices of the USDA’s National Organic Program by conducting an opening meeting on October 1-2, 2003. [The identification of USDA personnel attending this, and other related peer evaluation meetings, is detailed under Section V: Review of Accreditation Program Operations].

It was confirmed at this meeting that the following documents would serve as the basis for criteria to verify the expertise of the USDA in the management and coordination implementation of its NOP accreditation program:

- the USDA NOP procedures, as defined in the relevant regulations,
- ISO/IEC Guide 61, *General Requirements for Assessment and Accreditation of Certification/Registration Bodies*, and
- the International Accreditation Forum (IAF) *Policies and Procedures for a Multilateral Recognition Arrangement of the Levels of Accreditation Bodies and on the Level of Regional Groups* (IAF-PL-03-001 – Issue 3, Version 4, February 1, 2003).

A follow-up site visit was held on December 18, 2003.

As an additional component of the peer assessment, the ANSI evaluation team was scheduled to conduct three witness assessments by observing three USDA NOP audits of accredited organic certification agencies. Specifically:

- an ANSI assessor witnessed the audit by the USDA Audit, Review and Compliance (ARC) Branch to evaluate the audit process of a certifying agent in the Idaho State Department of Agriculture (October 7-8, 2003)
- an ANSI assessor/technical expert witnessed the audit process of a certifying agent in the Indiana Certified Organic Program (January 13-14, 2004)
- two ANSI assessors performed the last witness assessment during a USDA audit at the Oklahoma Department of Agriculture (May 10-12, 2004)

As of December 2003, approximately ninety (90) accreditations have been issued by the USDA NOP. The number of applications pending review and accreditation is approximately forty (40). The process for decision-making is defined by NOP regulations.

Direct support of the accreditation body functions is provided by compliance staff in the Agricultural Marketing Service of the USDA's NOP Office. The total number of staff in the National Organic Program (NOP) Office is approximately ten (10); four (4) persons are directly involved in the accreditation program.

Assessment services are provided by personnel in the ARC Branch. Approximately fifteen (15) staff support this effort – ten (10) field auditors and five (5) administration personnel. Each of these staff has other duties and responsibilities outside of the NOP accreditation program.

The decision for accreditation is made by the Agricultural Marketing Service Administrator.

The overall process of peer evaluation is conducted in accordance with IAF-PL-03-001 which requires the peer evaluation team to identify and document significant differences in approach (reference Section 3.3.1.4). During the October 2003 opening meeting the evaluation team noted that the NOP accreditation body does not have a number of documented policies and procedures in place, as required by ISO/IEC Guide 61 (pp. 8-10). Current NOP regulations do not reflect conformance to ISO/IEC Guides 61 and 65 requirements. As a result, a majority of the discrepancies identified are due to the absence of complete and consistent requirements as defined in the regulations.

Qualified auditors conduct the application review, assessment, and evaluation of all information for the elements required in ISO/IEC Guide 61. The ARC Branch is working to document, adopt and implement the necessary improvements to the procedures governing its assessment activities.

In order for the USDA NOP Office to be in conformance to ISO/IEC Guide 61, it must have a defined quality system that is documented in a quality manual (and appropriate related documentation) and that describes the procedures and processes in place for its accreditation of certifying agents. These quality system documents shall also define the interrelationship between personnel and offices for performing various aspects of the accreditation function.

Following the October meeting, the NOP Office developed a work plan to draft procedures to govern, within the purview of the NOP regulations, several functions of the accreditation body. The initial draft of the new procedural document was presented during the December 18, 2003 site visit. Attempts have been made to incorporate within this report many of the issues that were identified as needs.

The peer evaluation team also noted for the USDA NOP representatives that, while suspension and revocation constitute parts of the legal process defined by the law, these points are not consistent with the requirements document in ISO/IEC Guide 61. Any inconsistencies should be addressed in the quality documentation being developed.

Finally, the ANSI team emphasized that the impartiality of the accreditation body must be preserved. Because the ARC Branch also performs certification activity for other regulatory programs, the USDA NOP must ensure impartiality of the accreditation body during development of the organizational structure and the interface between the NOP and the ARC Branch. In accordance with ISO/IEC Guide 61, the accreditation and the certification functions must not be performed by the same bodies; the accreditation body must clearly distinguish between accreditation and other activities in which the entities are engaged.

This report for the peer evaluation site visit on the USDA-AMS accreditation program is being submitted to the accreditation body's representative, AMS Administrator, A.J. Yates, with copies to supporting managers.

II. General Information

Accreditation Body:	United States Department of Agriculture (USDA) - Agricultural Marketing Service (AMS)
Witness Assessments:	Three witness assessments ▪ October 7-8, 2003: Idaho Certification Program ▪ January 13-14, 2004: Indiana Certification Program ▪ May 10-12, 2004: Oklahoma Department of Agriculture
Evaluation Dates	
USDA Headquarters:	October 1-2, 2003 December 18, 2003
Evaluation Standards:	ISO/IEC Guide 61:1996, <i>General Requirements for Assessment and Accreditation of Certification/Registration Bodies</i> ISO/IEC Guide 65:1996, <i>General Requirements for Bodies Operating Product Certification Systems</i> 7 CFR Part 205, <i>USDA – National Organic Program</i>
Process Criteria:	IAF-PL-03-001, Issue 3, Version 4, <i>Policies and Procedures for a Multilateral Recognition Arrangement of the Levels of Accreditation Bodies and on the Level of Regional Groups</i> ISO 19011:2002, <i>Guidelines for Quality System and/or Environmental Management Systems Auditing</i>
ANSI Evaluation Conducted by:	Marlene Moore, Lead Assessor Reinaldo Figueiredo, Assessor Ken Commins, Assessor/Technical Expert
Evaluation Report Prepared by:	Marlene Moore, Lead Assessor with inputs from other Assessors
Date of Report:	Revision 2 - November 15, 2004 Revision 3 – December 8, 2004

III. Introduction

The purpose of the ANSI visit was to perform a peer evaluation of the USDA-AMS accreditation program for the National Organic Program, and to review NOP conformance to requirements under ISO/IEC Guide 61:1996, *General Requirements for Assessment and Accreditation of Certification/Registration Bodies*, and the USDA National Organic Program.

The scope of activity was the accreditation of certifying agents who were evaluated on meeting regulatory requirements contained in 7 CFR Part 205.500 for the National Organic Program.

The peer evaluation was performed in accordance with IAF-PL-03-001 (February 1, 2003), Issue 3, Version 4, *Policies and Procedures for a Multilateral Recognition Arrangement of the Levels of Accreditation Bodies and on the Level of Regional Groups*.

The visits included examination of program activities of USDA-AMS operational units located in Washington, DC. As indicated in the USDA statement of work, "ANSI is tasked with performing an assessment using ISO/IEC Guide 61, *General Requirements For Assessment And Accreditation Of Certification/Registration Bodies*, and ISO/IEC Guide 65, *General Requirements For Bodies Operating Product Certification Systems*, to satisfy the requirements of 7 U.S.C. 6516 and its implementing regulations (7 C.F.R. §205.509)."

The regulations that established the National Organic Program Office were adopted in December 2000. The establishment of quality system documentation and process has been underway within the USDA-AMS offices. This is the first peer evaluation of USDA NOP program activities and operations for conformance to the above requirements.

Personnel in the National Organic Program (NOP) Office, AMS Compliance staff and the Audit, Review and Compliance (ARC) Branch support the accreditation body. The number of staff in the National Organic Program (NOP) office is approximately ten, with four personnel involved in the accreditation program. The ARC Branch support staff of 15 (10 field auditors and five administration personnel) provides assessment services to the accreditation body. All personnel have other duties and responsibilities outside the NOP accreditation program.

The process for decision-making is defined by Federal Register and USDA implementing regulations. Based on personnel interviews, it was determined that the AMS Administrator makes the decisions on accreditation. Approximately ninety (90) accreditations have been issued as of December 2003. The number of applications pending review and accreditation is approximately forty (40).

The organizational structure of the accreditation program is not documented and information on the organizational structure presented in this report is based on the regulations, ARC Branch procedures, and personnel interviews. The initial draft document to meet these requirement was reviewed by the ANSI team during the December 18, 2003 visit.

The auditors for the accreditation program are employees of the United States Department of Agriculture (USDA), a U.S. cabinet-level government agency that administers the accreditation program.

Accreditation procedures are defined in the laws and regulations of the US government.

IV. Review of Documentation

ANSI requested that the USDA NOP submit the following information:

- 1 USDA legal status/relationship to government;
- 2 Description of any separate functions or affiliations of USDA to activities other than accreditation of certification bodies;
- 3 US government organic regulations related to accreditation in the NOP program;
- 4 Copy of the USDA Directory or other listings, which provide the name and scope of accreditation for each body accredited by USDA (including bodies that had already received on-site visits);
- 5 Number of assessments and surveillance/reassessment visits performed to date;
- 6 Contract or agreement that USDA has with accredited certification bodies;
- 7 2003 Assessment schedule;
- 8 List of assessors and technical experts including subcontractors, if applicable;
- 9 USDA accreditation program quality manual in which the policies and procedures and the responsibility for implementation of the quality system are clearly designated. Full details of staffing, including numbers and functions of its operational staff as well as their backgrounds and length of experience in assessment and accreditation of organic certification bodies;
 - a. All accreditation criteria and associated generally applicable criteria that USDA publishes;
 - b. All other published criteria, including formal rules or regulations that apply to USDA operation and the responsibility and obligations of USDA accredited bodies;
 - c. Any other documentation that describes the mechanics of operation of the USDA NOP accreditation system, including annual reports, questionnaires, newsletters, guidance documents, etc;
 - d. List of all documents, forms, checklists, etc. used by USDA

- 10 Cross-reference table between each clause, sub-clause or specific requirements of ISO/IEC Guide 61 and USDA accreditation documents;
- 11 Details of any formal agreement or recognition scheme to which USDA is a domestic or international party
- 12 Policy on the surveillance and reassessment of accredited organic certifying agents;
- 13 Latest internal audit report; and
- 14 Latest management review report.

The Accreditation Body submitted quality program documentation as part of the evaluation process, and assessors reviewed it prior to the on-site assessment. In addition, the following USDA documentation was reviewed prior to, and during, the peer evaluation.

- ARC 1025 Procedure (June 3, 2003) [replaces ARC procedure 1019, November 1, 2001]: National Organic Program (NOP) Accreditation for Organic Certification Organizations,
- USDA Website Subpart E and Subpart F, 205.400, 205.500: Certification Regulatory Text
- USDA document response to ANSI prior to peer evaluation
- USDA ISO/IEC Guide 61 Audit Response
- ARC 1000 Instruction, December 26, 2001: Quality Systems Verification Program (QSVP) General Policies and Procedures
- QSVP Quality Manual, Revision 2 (January 20, 2002)
- ARC Procedure 1006, (January 1, 2003): Selection of Audit Team Members for Quality Systems Verification Program audits (QSVP),
- ARC 1115 Procedure (June 3, 2003): Program Review Committee Procedures
- ARC 1410A List (August 15, 2003): Program Identifiers
- ARC 1025C Checklist (March 20, 2003): Annual Update of NOP Accredited Certifying Agents Checklist
- ARC Instruction 1030 (December 26, 2001): Training and Experience Requirements of Quality Systems Verification and Compliance Audits
- ARC Instruction 1100 (January 7, 2002): Management Review of ARC Branch Quality System
- ARC Form 1110 (August 1, 2003): Quality System Audit Report

- ARC Instruction 1120 (November 16, 2001): Internal Quality Audits of ARC Branch Quality system
- Quality System Audit Report (QSSS-AREP) 3/00 (December 10, 2002)
- ARC 1410 Procedures (June 24, 2003): Naming Protocol for Audits, Audit Documents and Client Documents
- ARC 1415 Procedure (June 24, 2003): Completing an Audit Plan
- ARC Instruction 1020 (August 23, 1999) for ISO/IEC Guide 65 Accreditation for Organic Certifying Agents
- Agricultural Marketing Service, Transportation and Marketing Programs and Livestock and Seed Program: Memorandum of Understanding (February 21, 2001; expired on February 23, 2003)
- ARC Branch: draft document control procedure
- USDA, NOP website: Listing of Accredited Certifying Agents from the
- TM-10CG (August 8, 2001): Application Form
- During the peer evaluation site visit of October 1-2, 2003, the number of applications reviewed was two. The number of complete evaluation packages reviewed for all visits was five. The number of decision packages reviewed for all visits was three. Withdrawal packages (three available) were not reviewed and these should be part of any future evaluation after the revised quality program system and documentation are more clearly delineated by NOP.

V. Review of Accreditation Program Operations

The assessment plan was submitted by facsimile on September 30, 2003 for the initial visit and on December 16, 2003 for the final USDA Washington office visit. The assessment plans are based on the evaluation elements from ISO/IEC Guide 61.

An opening meeting was held at the USDA-AMS Washington, DC office on the mornings of October 1, 2003 and December 18, 2003 with ARC and NOP personnel. Personnel attending the opening meeting on October 1, 2003 were: James Riva, ARC Branch Chief, Beth Hayden, ARC Branch Accreditation Manager, Keith Jones, NOP Director, Program Development and the ANSI assessors. Personnel attending the opening meeting on December 18, 2003 were Beth Hayden, ARC Branch Accreditation Manager, and Keith Jones, NOP Director Program Development. At the opening meeting participants reviewed the assessment process, scope of the peer assessment, and the other items listed in the Assessment Plan agenda.

Following the opening meeting on October 1, 2003, the assessors toured the ARC offices, and attended a process review meeting with ARC Branch personnel. Assessment records, process and procedures were presented. The document control process and training records were reviewed with the ARC Quality Manager and ARC Branch Chief.

On the afternoon of October 1, 2003, the assessors met with NOP program personnel in order to evaluate the final processing of the accreditation documentation. At the end of the first day, a summary of assessment findings, progress of the review, and plans for the second day were reviewed with NOP and ARC management personnel.

On the second day (October 2), assessors completed a review of ISO/IEC Guide 61 and clarified the remaining open items. During the morning, the activities of the ARC Branch were reviewed and in the afternoon, the activities of the NOP office were discussed. A brief exit meeting was convened to review findings, next steps, and the process for reporting.

The visit on December 18, 2003 clarified the open items from the October 1-2, 2003 visit and allowed the ANSI Assessor/Technical Expert to review ARC Branch files for the accreditations within the NOP program and review the qualifications of ARC Branch auditors and reviewers.

The closing meeting for the peer evaluation of October 1-2, 2003 was held at the end of the evaluation on December 18, 2003.

Documentation of observations and objective evidence reviewed during the evaluation are presented in this assessment report. This report was submitted to USDA representatives for comment.

VI. Findings

As indicated in IAF-PL-03-001, Section 3.3.1.4, significant differences in approach are to be identified and documented by the peer evaluation team. The following presents the significant differences in approach for ensuring conformance with ISO/IEC guides and standards. These items should be harmonized with other accreditation bodies, wherever possible.

The accreditation body, Agricultural Marketing Services (AMS), does not have the following documented policies and procedures in place, as required by ISO/IEC Guide 61. It is noted that NOP regulations do not adhere to all elements found in ISO/IEC Guide 61, and in some cases, contradict ISO/IEC Guide 61 requirements.

The numbers in parentheses denote the clauses from ISO/IEC Guide 61.

- (2.1.1.3) The accreditation body does not define the process for developing explanations of the regulations and program requirements by impartial

committees or persons possessing the necessary technical competence and how the accreditation body publishes this information.

- (2.1.2.c) The accreditation body has not identified the management (organization personnel) with responsibility for accreditation activities, formulation of policy matters relating to the operation of the accreditation body, supervision of the implementation of its policies, decision on accreditation, delegation of authority to committees, and individuals or offices within AMS for performing specific activities on behalf of the accreditation body.
- (2.1.2.e) The accreditation body does not have a documented structure of the organization. (This was being drafted and was presented in preliminary form during the ANSI visit of December 18, 2003.)
- (2.1.2.k, 2.1.4) The accreditation body does not have a documented quality system as outlined in section 2.1.4. The policies and procedures for the accreditation body are not available to all staff performing activities for the accreditation body. It is noted that the assessment activities by the ARC Branch are documented, but the overall quality system for accreditation activities is not documented in a quality manual and related documentation. Activities include: structure of accreditation process; AMS administrator responsibility, NOP personnel responsibilities and ARC branch responsibilities; website update; review of documents by NOP personnel; internal audits; management review of all accreditation activities; organizational chart for accreditation body; and qualification requirements for all accreditation body personnel. It is noted that an MOU between the NOP office and the ARC Branch office has expired and indicates that ARC Branch is to provide audit reports for NOP. The ARC Branch currently performs application review, assessment, evaluation, and recommendation activities for the accreditation body. The NOP office provides review of documentation from ARC personnel prior to the Administrator making the decision on accreditation. These activities are not documented as to the specific process followed.
- (2.1.2.l) The accreditation body does not have policies and procedures to distinguish between accreditation activities and other activities performed by the offices and personnel performing duties of the accreditation body.
- (2.1.2.p) The accreditation body does not have policies and procedures for resolution of complaints, appeals and disputes received from bodies or other parties about the handling of accreditation matters.
- (2.1.4.3.g) The accreditation body does not have procedures to assure that current copies of all reference documents, as defined in ISO/IEC Guide 61, are maintained on file and available to all of its applicants and participants. The ARC Branch is developing a master document list of internal and external documents. This is the document control process for ARC Branch Activities and does not include all accreditation body personnel and activities. It is unclear if separate

procedures are required to assure that NOP personnel and other accreditation body personnel have these documents available.

- (2.1.5.2) The accreditation body does not have procedures for granting, maintaining, withdrawing, suspending or denying accreditation and for extending or reducing the scope of accreditation. The ARC 1025 procedure has defined instructions. However, the personnel identified as responsible for these activities do not authorize these instructions. For example, the NOP Program Manager is responsible for denial of accreditation and the AMS Administrator for granting, maintaining, extending, withdrawing, suspending accreditation. The ARC Branch Chief authorizes the ARC 1025 procedure. Due to the lack of documented structure or documentation of delegation of authority, it is not clear if the appropriate person within the accreditation body authorizes this instruction.
- (2.1.6) The accreditation body does not conduct an internal audit and management review of all accreditation body activities.
- (2.1.7.2) The accreditation body does not have procedures for controlling all documents and data related to the accreditation functions. It is not clear who is authorized to review and approve documents posted to the website, used internally and authorized to amend documents. The accreditation body does not define the control of documents and records. Note: The ARC branch is in process of implementing ISO 9000/2000 standard.
- (2.1.8) The accreditation body does not maintain a system for all records, such as the records of review by NOP and quality records, such as internal audits, management review records and complaint records.
- (2.1.9.2) The accreditation body does not obtain written consent from the certifying agent for disclosure of information. This may be part of the Freedom of Information Act (FOIA) requirements for federal and state agencies. The need for this consent requires additional review.
- (2.2.1.2) The accreditation body does not define the minimum criteria for competence for auditors and technical experts providing advice on the regulations.
- (2.2.1.3) The accreditation body does not have clearly documented instructions describing the duties and responsibilities for the accreditation activities performed by the NOP personnel, administrator, and other parties (e.g. website updates).
- (2.2.5.1.e) The auditor training records (ARC Branch) do not always include the date of the most recent update of records. Some records were incomplete in the database and paper records were not always complete. It is noted that information was found during the evaluation and that an internal audit of this area is scheduled for December 2003.

- (2.6.1) The accreditation body does not have procedures in place for appeals, complaints, and disputes received from applicants, certifying agents and others.
- (2.7) The accreditation body does not require its certifying agents to make available to it the records of all complaints, appeals, disputes, and subsequent actions.
- (3.1.1.1) The accreditation body does not have a detailed description of the completion of the accreditation process. No procedure is available for the operations that occur after the completion of the documentation by the ARC Branch and transmittal to the NOP office.
- (3.1.1.2.a) The accreditation body does not require that certifying agents comply with the relevant provisions of ISO/IEC Guide 65.
- (3.2.4) The accreditation body does not inform the applicant of the names of the auditor to carry out the assessment with sufficient notice to appeal against the appointment of any particular experts or auditors.
- (3.3.2) The accreditation body does not witness fully the on-site activities of one or more assessments or audits conducted by the applicant prior to initial accreditation. It is noted that the regulation allows accreditation prior to the on-site visit and that this visit may not occur for five years from the date of renewal.
- (3.4.1.d) The accreditation body does not invite the certifying agent to comment on the report.

VII. Results of the Evaluation to the ISO/IEC Guide 61 requirements

2.1 Accreditation Body

The accreditation body is identified as the United States Department of Agriculture-Agricultural Marketing Service (USDA-AMS).

2.1.1 General Provisions

USDA-AMS operates the accreditation program for the National Organic Program, as required by 7 CFR Part 205, Organic Foods Production Act of 1990 (7U.S.C. 6501-6522). The certification bodies are referred to as certifying agents within these regulations.

The regulation does not impede or inhibit access by applicant bodies and is open to participation. The regulation provides for exclusions such as an entity with the revenue of less than \$5000. Although the regulation does not require certification, it does not deny certification for small organizations wishing to be a certifying agent or certified for the National Organic Program. In § 205.640, NOP provided the first round of accreditation services to any qualified applicant for only the cost of the on-site travel and per diem. This resulted in a significant number of applications being submitted for the initial accreditation. Some

consolidation is being observed as a result of the annual fee charges currently being assessed. After October 21, 2002, fees collected from certifying agents are expected to support the cost of the NOP accreditation function.

The ARC Branch has been verifying open applications to determine interest. The process is to notify certifying agents, and to follow up by email. If there continues to be no response, the application is being removed. Thirty applications, with no activity, are being verified.

As stated in Subpart F of the regulations, the National Organic Program (NOP) accreditation process will facilitate national and international acceptance of U.S. organically produced agricultural commodities. A statement of work was issued to ANSI to review the operations of USDA-AMS for conformance to the relevant ISO/IEC Guides and Standards. This evaluation does not cover the adequacy of the content of the regulations, but addresses the implementation and support of the NOP for meeting internationally defined standards.

ISO/IEC Guide 61 and ISO/IEC Guide 65 were the standards identified as relevant for the accreditation of certifying agents. Although these standards are not cited in the regulation, they are used for this peer review process to determine consistency with these international guides. As presented in this report, significant differences in the regulatory requirements and ISO/IEC Guide 61 were identified.

The USDA-AMS restricts accreditation requirements, assessment, and decisions to those matters related to the National Organic Program. The USDA-AMS provides other services and operations that are not within the scope of the National Organic Program and are excluded from this peer evaluation.

2.1.2 Organization

The USDA-AMS is impartial and the administrator is responsible for the decision of accreditation as stated in § 205.506. USDA-AMS is part of the government agency cabinet-level United States Department of Agriculture (USDA). The structure and organization of the USDA are documented on the USDA website.

The United States Department of Agriculture (USDA) is charged with executing laws related to agriculture. The Audit, Review and Compliance (ARC) Branch operates under 7 CFR Part 54 (August 14, 1946, ch. 966, 60 Stat. 1087, 7 U.S.C. 1621 et seq.) and the National Organic Program (NOP) operates under 7 CFR Part 205, Organic Foods Production Act (7 U.S.C 6501 – 6522). The ARC Branch and NOP operate within the Agricultural Marketing Services (AMS) Office.

The USDA Secretary and the AMS Administrator, operating through the chain of command, delegates authority to the NOP Program Manager and the ARC Branch Manager to manage frontline accreditation activities. The AMS Administrator, the Deputy Administrator for Transportation and Marketing Program and the NOP Program Manager formulate policy for implementing

various aspects of the NOP regulations, as indicated in the response to the ISO/IEC Guide 61 response received from the ARC Branch Accreditations Manager.

The structure and management for accreditation body operations are not documented, as required in ISO/IEC Guide 61 2.1.2.c, n. The documented structure must present information to ensure impartiality of the operations.

For example, in addition to accreditation activities, the ARC Branch also performs certification activity for other regulatory programs. The operations of an accreditation body and certification body must be kept separate, because these two activities must not be performed by the same organization, as defined by international agreements. Personnel also performing duties for certifying organizations may not be impartial during the accreditation of the same or related organizations.

The accreditation body must clearly distinguish between accreditation and other activities in which the entities are engaged. The Organic Foods Production Act (OFPA) is the legislative basis for NOP regulation of production, processing, and labeling of organic food, certification of production and handling operations, and accreditation of certifying agents. The OFPA does not provide for other types of accreditation. Other Acts implemented by USDA may require certification activities, which must be distinguished from the accreditation activities required by the OFPA. Based upon interviews and documentation presented, it was concluded that the ARC Branch does not make decisions on certification or accreditation.

The operations of the USDA-AMS are primarily performed within two units of USDA-AMS: (1) National Organic Program (NOP) Office; and (2) Audit Review and Compliance (ARC) Branch. It was noted during the evaluation that the AMS Compliance staff also supports the NOP office in the review of complaints and disputes. The NOP Office updates the website, interprets regulations, and handles suspension, revocation, withdrawal, denial and appeals for the accreditation body. The ARC Branch performs application review, assessment, and provides a recommendation for accreditation. The AMS Administrator makes the decision on accreditation of certifying agents.

USDA-AMS has adequate arrangements in place to cover liabilities arising from operations and has the financial stability as a U.S. government agency department. The resources provided to the program include approximately 30 personnel for the accreditation of 130 applicants as of December 2003. Additional personnel within the USDA-AMS are available for support in the administration of the program. All personnel are free of commercial, financial, and other pressures, which might influence accreditation. All federal employees must disclose financial and other information to ensure no conflict of interest exists.

The USDA NOP quality system has not been documented and defined for the accreditation body, as required by ISO/IEC Guide 61 2.1.2k and 2.1.4. The lack of documentation on the structure and operations of the accreditation body does not foster confidence in the ability of the accreditation body. Interviews with personnel found that the organizational structure is being developed and that this new program requires time to mature through development of documentation. From interviews, it was observed that some personnel are familiar with the requirements for ISO/IEC Guide 61 and quality system management.

The responsibility for granting maintaining, extending, reducing, suspending and withdrawing accreditation for the NOP program is defined in §§ 205.506, 205.510 and 205.665(e), and 205.665(f).

The accreditation body currently operates two committees; (1) National Organic Standards Board (NOSB), which is a Federal Advisory Committee formed under the rules and structure of the Federal Advisory Committee Act (FACA). The FACA process ensures a diverse committee structure, with a cross section of regulated and community members. The terms of appointment for members are for five years and the committee purpose and mission is promulgated every two years. Historically, the NOP has depended upon its advisory board, the National Organic Standards Board (NOSB), for advice concerning the development and implementation of the NOP regulations. Since the finalization of the regulations, the mission of the Board has been revised to provide input on materials and other matters related to implementation of the NOP regulations. The NOSB is composed of 15 individuals who represent the spectrum of the organic industry.

The Program Review Committee reviews the application and certifying agent submittal (i.e., report), the USDA NOP auditor's report of review of these submittals, and then evaluates all this information to provide a recommendation on the accreditation of the certifying agent. The committee is comprised of the ARC Branch Chief, the ARC Branch Accreditation Manager (an employee of NOP who is on detail to ARC Branch), and an auditor not involved in the assessment. The Program Review Committee structure and operation is documented in the ARC Branch procedures.

The accreditation body does not provide consulting or other services that would affect the impartiality, objectivity and confidentiality of the accreditation. All employees are federal workers and therefore must abide by the federal rules and directives relating to these matters.

The accreditation body does not have detailed procedures in place for resolution of complaints, appeals and disputes received from bodies to other parties about the handling of accreditation related matters. There are processes in place within the ARC Branch and NOP office to handle and document these activities, but the process and records for the accreditation activity were unclear at the time of evaluation. The accreditation body does not define the responsibilities for these activities nor does it specify whether one or multiple complaint processes are to be followed.

Additional review by the technical expert is required to evaluate the personnel education, training, and technical knowledge for the work performed by the accreditation body.

2.1.3 Subcontracting

The USDA-AMS does not subcontract any activities associated with the accreditation process. USDA employees conduct all activities related to the accreditation of certifying agents.

2.1.4 Quality System

The quality system for the USDA-AMS accreditation program is not documented in a quality manual or related procedures. The NOP office and ARC Branch have developed procedures for operations within each group. The NOP has draft procedures, which have not been distributed or finalized for implementation. The ARC Branch procedures have been implemented and revised over the last year. Records are available in the ARC Branch to support the procedures developed and training is documented in the applicable procedures for the NOP activities.

An MOU between the NOP and ARC Branch offices that stipulates the ARC Branch is to provide “audit reports for NOP” has expired. The ARC Branch currently performs application review as well as plans and conducts assessments, evaluation and recommendation activities for the accreditation body. The NOP office provides review of documentation from ARC personnel prior to Administrator decision on accreditation. These activities are not documented in regard to the specific process followed.

The accreditation body has not documented the policy for quality including objectives and commitment for quality as required by ISO/IEC Guide 61 Section 2.1.4. Reports on the accreditation body quality system were not available, as required in ISO/IEC Guide 61, Section 2.1.4.2.b. The quality system elements required by ISO/IEC Guide 61, Section 2.1.4.3(a to n) are not identified or referenced in a quality manual issued by the management of the accreditation body.

2.1.5 Conditions for Granting, Maintaining, Extending, Reducing, Suspending and Withdrawing Accreditation

Regulations § 205.506, 205.507, 205.665 and ARC Procedure 1025 define the conditions for granting, maintaining, extending, reducing, suspending and withdrawing accreditation.

The specific implementation procedures are not documented for the accreditation process. As explained during interviews with the NOP staff, the USDA-AMS compliance staff performs the investigation of use of the USDA organic mark and other matters assigned by the NOP office. A report of the investigation is reviewed and acted upon by the NOP office. Currently, the program has not denied, suspended or reduced accreditation schemes. Three withdrawals have been processed since the start of the program.

2.1.6 Internal Audits and Management Review

The accreditation body has not performed an internal audit or management review of the accreditation body activities. Internal audit and management reviews within the ARC Branch were presented. This information relates only to the activities of the ARC Branch and not to the audit nor review of the quality system of the accreditation body.

2.1.7 Documentation

The ARC and NOP office are in the process of developing and updating a document control system within each operation. The ARC Branch has copies of ISO/IEC Guide 2, 61, 65, and ISO 19011. The NOP branch has copies of ISO/IEC Guide 61. A master list of documents is being prepared within each office along with the procedure for document control. The accreditation body does not have a master list of internal and external documents. The accreditation body has not identified the documents required and had not defined the process for using the documents developed within each operation (i.e., NOP Office or ARC Branch).

The authority of the NOP program is based on federal law. The requirements of the accreditation program are available to all parties on the USDA website for the National Organics Program. Any changes regarding the authority under which the accreditation body operates occurs either through changes in regulations which would be open for public comment and then published in the Federal Register or through policies which would be posted on the NOP website.

The process for updating information on the NOP website is not documented. The responsibility of updating and approving website information related to the application, assessment, reporting, standards interpretation, and listings are not identified.

It is noted by the ANSI technical expert that some documents supplied for the witness assessment were not consistent with the documents used by the NOP auditors. Procedural Form ARC 1000 supplied to the ANSI assessor relates to certification procedures and not to accreditation procedures. Auditors stated that in reality ISO19011 procedures are being followed.

2.1.8 Records

NOP regulations set requirements for record keeping by certifying agents under §205.510 (b) and for certified operations under §205.103.

Federal regulations define the requirements for record retention by the accreditation body. The timeframe for maintaining records, security, and location of the records is not documented by the accreditation body. The location of assessment records is defined within ARC Branch procedures. The specification to transfer records to the NOP office for review and final decision-making is not documented. The location of the records of signatures of review by NOP office personnel and the final signature by the ASM administrator are not specified.

It is noted that the records of the accreditation body may not be located at the Washington, DC office, and may reside at remote sites. Electronic copies of the initial audit checklist and application are made prior to transmitting them to the auditor. The records are maintained in a database. The records are returned after the final report has been issued and reviewed by the internal committee. The committee documentation of review is scanned and made available electronically. The form "Decision on Accreditation" that documents the outcome of the committee review is also scanned. The form and other documents are submitted to the NOP office for review and then forwarded to the AMS Administrator for signature. The accreditation body does not define the specifications for the information to be transferred to each party.

It is noted that the form, "Decision on Accreditation," is completed only by the Accreditation Manager and serves as a recommendation for accreditation. The AMS Administrator makes the decision on accreditation following review by the NOP Program Manager. The form contains the presentation of the recommendation on accreditation by the Program Review Committee.

A staff member of NOP performs compliance tracking of corrective actions from certifying agents. These corrective actions are to be used for review by the NOP auditor during visits. The process for transferring this information was not documented during the visit. AMS compliance personnel handle all complaints related to the program. If the agent does not agree with the complaint interpretation, then the agent has the right to appear (due process per federal government activity). Compliance may be handled through letters that are outside the appeals process (legal action). Related bodies often present these compliance issues, and letters address the concern.

2.1.9 Confidentiality

Federal employees are required under 2635.703 of the Federal Code to keep information confidential.

USDA must comply with all laws regarding the Freedom of Information Act 5 USC §552 (FOIA). This act defines the requirements for obtaining information from the government. When FOIA material is provided to a third party, the certifying agent must be informed, as required under Guide 61, Section 2.1.9.2. This procedure is not currently performed by the accreditation body.

It was noted by the lead assessor that the accreditation body may want to inform certifying agents of the process for obtaining confidential business information. Other federal agencies (e.g., EPA) have defined processes for handling confidential information (40CFR Part 2 Subpart B). Certifying agents and their listing organizations associated with the USDA NOP program may not be familiar with this process, if available at USDA.

2.2 Accreditation Body Personnel

2.2.1 General

Personnel interviewed were found to be knowledgeable in the regulations and operations of government activities and procedures. Personnel interviewed all have experience in agricultural activities and have worked within various offices of the USDA. In addition, personnel in the ARC Branch have documented training in quality system management and activities.

The accreditation body neither defines the qualification requirements nor provides detailed instruction regarding the duties and responsibilities for each member of the accreditation body involved in the accreditation process. ISO/IEC Guide 61, Section 2.2.1.3 requires that these instructions be up-to-date. It is not clear if the accreditation body requires the auditors to have specific industry knowledge to perform these assessments (e.g., horticulture, livestock, etc.)

2.2.2 Qualification Criteria

The ARC Branch Chief defines the qualification requirements for the ARC Branch. The NOP Program Manager defines the qualifications for the personnel in the NOP office. The qualifications of all accreditation body personnel are not defined for the job functions that relate to accreditation, although job qualifications for government service are defined. These qualifications do not always include specific knowledge in ISO/IEC Guide requirements (e.g., Guides 61, 62, and 65). Individual development plans for auditors in the ARC Branch have been updated to include knowledge in ISO 19011 requirements.

Procedures related to qualifications of personnel involved in assessment activities within the ARC Branch are available and clearly defined in ARC procedures 1030 and 1450. Not documented is the specific level required to be qualified as an auditor for the NOP program. The ARC Branch Chief indicated that a Level II qualification was required in order to work as an auditor for NOP.

The auditors must meet the requirements of ISO 19011:2002, *Guidelines for Quality and/or Environmental Management Systems Auditing*. Auditors are trained in ISO 19011, 9000, 14000 and the NOP regulations. Performance is monitored and recorded by a supervisor who has as a minimum the same level of documented training.

The technical expert for ANSI reviewed the qualifications and technical expertise of the NOP auditors. Records of training were not always complete. In particular, the training attendance sheet from the initial training given to personnel of the Audit Review and Compliance Branch (ARC) was missing. It is noted that the ARC Branch has been improving the training records to ensure that all records are available for review. Auditors who serve as technical experts have not received training on verification methods employed in the organic certification sector.

2.2.3 Selection Procedure

Federal employees must sign agreements and annual statements of conflict of interest. Consulting by federal employees is prohibited under Directive 365.1 –

Employee Responsibility and Conduct. The Program Review Committee documents as part of each review that no conflict of interest exists for the members of the committee conducting the specific review.

The selection of the auditor is defined in ARC 1102 Procedure. The technical expert for ANSI reviewed the selection criteria of the NOP auditors.

2.2.4 Contracting of assessment personnel

The USDA does not contract personnel for any activities performed in the accreditation program.

2.2.5 Assessment Personnel Records

The records for the ARC Branch were reviewed for at least three of the nine auditors to verify documentation of the qualification defined by the ARC Branch procedures. The records for the accreditation process are separated from other activities. A database of the information related to the status of the training for each auditor is available.

Some information in hard copy records and electronic records were missing. For example, ISO 9000 lead auditor training certificates for two of the three auditors were not in the records. One of these was misfiled and found before the end of the assessment. Database records did not always indicate the level the person had currently attained. At least one of the three auditors identified as qualified did not have a level designation in the database. While hard copy records provided information that the person was trained, the database record was not up-to-date. The ARC Branch Chief indicated that a complete quality system internal audit was scheduled for December 2003. This would be the first audit of these records and systems, which had been implemented within the last year.

In addition, the records do not always include the date of the most recent update of the records, as required by ISO/IEC Guide 61, section 2.2.5.1.e. All other information from section 2.2.5.1 was available, either in hard or in electronic copy for the three auditor files reviewed.

2.2.6 Procedures for Assessment Teams

The assessment team was provided with up-to-date instructions (checklist) with each application package. Updates to the instructions are transmitted to auditors via electronic mail notifications. An ARC intranet site is available to the auditors for downloading and review of the most recent procedures for conducting assessments.

2.3 Decision on Accreditation

A letter from the Administrator documents the decision on accreditation made by the AMS Administrator. NOP regulation § 205.506 defines the AMS Administrator as the officer responsible for granting accreditation. The letter includes the information found in ISO/IEC Guide 61, Section 2.3.3. The decision

is not delegated. Amendments to the scope of accreditation are defined in regulations §§ 205.510(f).

2.4 References to Accredited Status

OFPA and NOP regulations designate the Administrator with the responsibility of the program. These regulations do not provide legal authority for NOP to provide certification services. OFPA and NOP regulations § 205.303 state that the USDA seal may be used only on products labeled "100 percent organic" and "organic" that have been produced and handled in accordance with standards set out in the regulations and certified by an accredited agent.

2.5 Change in the Accreditation Requirements

Under the Administrative Procedures Act, NOP is required to publish in the Federal Register proposed amendments to the requirements for accreditation. The public, including certifying agents accredited by NOP, may comment on the proposed amendments. Changes are made based on public comment and the NOP Organic Foods Production Act.

Any changes regarding the accreditation program are made either through changes in regulations or through policies which would be posted on the NOP website. The NOP program is currently proposing, through a Federal Register Notice, a formal process for providing interpretations on the regulations. The proposal is modeled after the FDA program for using Level 1 and Level 2 guidelines for documenting changes and obtaining public comment. These guidelines will be posted on the website as they are developed and updated.

2.6 Appeals, Complaints and Disputes

NOP regulation § 205.580 provides the procedure for appeals, which includes record keeping. No appeals have been made, as of December 2003.

The accreditation body does not currently have procedures in place for complaints and disputes brought before the accreditation body. The NOP office and ARC Branch follow procedures defined by each operation, but the procedure for the accreditation body is not documented. For example, each operation receives complaints, and processes the complaint, as it relates to the specific office. If the complaint is not within the scope of the office (e.g., ARC Branch), it is forwarded to the appropriate office. Documentation of the complaint and the follow-up associated with the complaint are not always available and traceable. It was not possible as part of this evaluation to determine whether the accreditation body takes appropriate corrective and preventive actions and assesses the effectiveness of these actions.

2.7 Access to Records of Appeals, Complaints and Disputes

NOP regulation § 205.501(a)(7) requires an annual program review by the certifying agent to correct any noncompliance with the Act and regulations. The ARC Branch indicated that this review includes addressing of complaints and disputes and recording of them. The checklist and Act do not clearly indicate that the certifying agent must maintain records of all complaints and disputes and

that these must be reviewed during on-site assessment or submitted as part of the annual surveillance. ISO/IEC Guide 61 requires the certifying agents to retain documents and have available to the accreditation body on request, all complaints, appeals, disputes and subsequent actions. NOP regulation § 205.665 requires that the certifying agent notify the AMS Administrator of any appeals related to certification. However, the regulations do not specifically address complaints or disputes.

3.1 Application for Accreditation

3.1.1 Information on the Procedure

The NOP regulation provides a system whereby the certifying agent certifies producers and handlers of organic agricultural products. Certification and accreditation are clearly separated both by the regulation and also by rights and responsibilities.

Certifying agents must comply with NOP regulations in order to provide services. Failure to comply could result in fines as specified in § 205.100 (c).

The accreditation body does not have detailed documents that have been authorized by the AMS Administrator on the requirements for accreditation, as required by ISO/IEC Guide 61, Section 3.1.1.1.

The accreditation body does not define if the ARC Branch Chief is authorized to approve the accreditation process procedure. The ARC 1025 procedure includes elements of accreditation such as appeals, decision and other elements that do not appear to be within the scope of the work performed within the ARC Branch.

3.1.2 The application

NOP regulation §205.503 defines the application information which meets the requirements of ISO/IEC Guide 61, Section 3.1.2. The application for accreditation also serves as the contract by which the certifying agent agrees to perform certification in accordance with the requirement of the National Organic Program cited in 7 CFR Part 205. The application form is TM-10CG or OMB Form 0581-0191 and includes the information required in §205.505 of the NOP regulation. All applications must be in English as stated in the regulations.

NOP regulation § 205.505 (a)(2) defines the agreement made by the certifying agents to ensure proper use of the accreditation status and other requirements of the regulations.

As required in ISO/IEC Guide 61, Section 3.1.1.2.a, the accreditation body does not require that a certifying agent comply with all the applicable provisions of ISO/IEC Guide 61. The regulations do not include neither this requirements nor all applicable requirements. For example, ISO/IEC Guide 61 requires the issuance of the accreditation after the initial assessment (see ISO/IEC Guide 61), Section 3.3.2). An interim accreditation status is allowed prior to the site visit.

The technical expert reviewed the following files: (1) Stellar Certification Services (private domestic certifier); (2) Idaho State Department of Agriculture (state program); and (3) DIO (private foreign certifier).

3.2 *Preparation for assessment*

NOP audits are performed in conformance with ISO 19011:2002. The ANSI witness assessments found that the requirements of ISO 19011:2002 have been satisfied during NOP site audits. It is noted by ARC Branch personnel that current audits for the NOP are not in complete conformance to ISO/IEC Guide 65. The ARC Branch implements a separate certification program for meeting ISO/IEC Guide 65, when required for specific regulatory programs where export requirements mandate the use of ISO/IEC Guide 65.

The ARC 1025 procedure includes an initial review to ensure that the application is complete. The Accreditation Manager completes a checklist of the initial review that documents the information received from the applicant. If information is not complete, a request is made to obtain the information prior to further processing.

ARC Branch Procedure 1030 describes the procedure for qualification of auditors that complies with ISO 19011:2002, *Guidelines for Quality and/or Environmental Management Systems Auditing*. The ARC quality system requires that an audit plan (as recorded within ARC Form 1415) be filed and signed by the audited body.

When the application is complete the file is forwarded to an auditor who performs a detailed desk audit using the NOP Audit Checklist. In most cases the auditor requests more information and writes an initial report. Auditors also conduct exchanges with the applicant by e-mail and telephone to clarify specific checklist items.

Following technical expert review of three files, it was determined that the paper review should include check (i.e. review) on the implementation of documentation (forms etc.) used by the certification body. The files under review revealed that the desk audit consisted of verifying that the certification body's rules and procedures contained all elements of the USDA NOP Rule and did not contain any additional requirements.

These checks were carried out in a complete and thorough manner. No evidence was found that the methods for implementing these policies and procedures (forms, work instructions, etc.) were reviewed as part of the desk audit, but rather during the onsite visit. As long as accreditation may be issued before the on-site visit, consideration should be given to include a review of the implementation of documentation as part of the desk audit.

The current ARC procedures do not include the requirement to transmit the names of auditors to the certifying body prior to assignment and to allow the

certifying agent to appeal the selection of the auditor, as required by ISO/IEC Guide 61, Section 3.2.4.

3.3 Assessment

ARC Branch auditors conduct assessments in accordance with ISO 19011:2002, *Guidelines for Quality and/or Environmental Management Systems Auditing*. Certifying agents [(Section § 205.501 (a)(9))] and their clients [Section§ 205.103(c)] are required under NOP regulations to allow access to all records.

ARC Branch auditors use ARC Form 1110, *Quality System Audit Report*, to record findings. ARC Work Instruction 1110, *Quality System Audit Report*, directs the auditors to supply the above information. A recently adopted new procedure (ARC 1415) requires documentation of an audit plan. During the peer evaluation, a completed audit plan was observed. However, it was not clear if this audit plan should be submitted as part of the audit file for the certifying agent. The auditor may retain these records, and not submit this form. As indicated in Section 2.1.8 of this report, the accreditation body does not define the records to be retained or their location.

Accreditation is granted after document review has been conducted and information has been found to be complete and in compliance with the regulations. As stated in the regulation §205.507(d), accreditation may be granted without an initial site visit. The site visit must be conducted prior to renewal of accreditation within five years. As required by ISO/IEC Guide 61, Section 3.3.2, the accreditation is not to be granted unless an assessment of all activities is performed including audits.

Different systems for review of the certification files were identified during the file checks on December 18, 2003, including different methods for recording paper review and also inconsistent sampling sizes for on-site certification body file checks. Two separate certifying agent files reviewed were of similar size. However, in one, 12 files had been reviewed, while in the other, only four files had been selected. This observation was further verified by interview with auditors during the witness audit of January 13-14, 2004. It was confirmed that the auditor has the prerogative to decide the nature and size of the sample without reference to guidelines relating to the sampling process.

3.4 Assessment Report

The checklist, which recently has been incorporated into the audit report, represents a summary of applicable regulatory requirements and guidance information for the NOP. The auditor completes the checklist by identifying the objective evidence of conformance to the regulation on the checklist. The checklist was found to be complete and the information in the files will be further reviewed for technical completeness during the witness assessment and technical evaluation. A file for an accredited certifying agent was reviewed during the visit, and it was found that all information was complete, non-conformances identified and follow-up activities of the response to the non-

conformances monitored. The notations in the records were not always dated and initialed by the person supplying the information on the checklist. In some cases, two auditors may review the file at different times, and information is recorded (handwritten) without the identity of the person.

The Accreditation Manager sends audit reports, when finalized, to clients. The current ARC Procedure does not include the ISO/IEC Guide 61, Section 3.4.1.d requirement that allows the certifying agent to comment on the report.

The technical expert indicated that witness audit reports should analyze the effectiveness of inspection (thoroughness of verification of NOP requirements, suitability of verification methods employed). In files reviewed, the witness audit report contained comment only on whether procedures were followed.

3.5 Surveillance and Re-assessment Procedures

The accreditation body performs reassessment once every five years, as required by the regulations. The ARC Branch uses the same procedures for reassessment as the initial assessment. Accredited certifying agents are subject to on-site assessment at any time the Administrator believes it is necessary to verify compliance, as stated in §205.508.

As required by NOP regulations §205.510.f, each year the certifying agent must submit information on any changes in the program (including personnel, location, and other key functions). Changes requiring notification are consistent with requirements found in ISO/IEC Guide 61, Section 3.5.3 (a to e). The accreditation body requires an annual update, a practice that is not consistent with the ISO/IEC Guide 61, Section 3.5.3 requirement for informing the accreditation body without delay of changes. In fact, a number of accreditation bodies require notification within 30 to 60 days. The annual update specification is cited in NOP regulations and the accreditation body was receiving updates for certifying agents accredited within the last year.

NOP regulation § 205.510 (f) allows amendment to the scope of accreditation. One file related to a change in scope was requested for review during the evaluation. Because the file had been sent to the ARC Branch auditor, only available electronic information was reviewed at the time of the initial evaluation.

The ANSI assessor witnessed an assessment by the USDA ARC Branch to evaluate the quality system implementation of the surveillance activities. The witness assessment was performed on October 7-8, 2003. The NOP auditors were Steve Ross (lead auditor) and Phil Fredericks (auditor). The scope of the audit was accreditation under NOP Organic Rule Subpart F of the Idaho State Department of Agriculture. The ANSI assessor observed that during the formal opening meeting with Idaho State Department of Agriculture officials, the lead auditor demonstrated thorough knowledge of content, objectives of the audit, and policies and procedures.

Overall, the audit team performed its duties in a commendable manner. They consistently obtained evidence to document how the certification agency implements USDA NOP requirements and complies with USDA-NOP program accreditation and certification criteria. Questions regarding interpretation and implementation of NOP criteria were answered professionally and thoroughly.

One suggestion from the ANSI assessor would be to include a larger degree of participation by the auditee during the client's file review in order to explain the process to the audit team. Also to be considered could be inclusion of the following items in the audit plan: (a) type of audit (i.e., initial, surveillance, follow-up or re-audit); detailed activities to be covered in an item-by-item format keyed to USDA NOP regulations; and (c) allocation of tasks among audit team members.

The ANSI technical expert witnessed the assessment by the USDA ARC Branch to evaluate the assessment process and technical application of the NOP requirements of a certifying agent. The on-site witness audit was performed on January 13-14, 2004 by technical expert, Mr. K. Commins. The NOP auditors were Miguel A. Caceres (lead auditor) and Darrell B. Wilson (auditor). The scope of the audit was accreditation under NOP Organic Rule Subpart F, Identification NP4013 MA, of the Indiana Certified Organic Program.

The NOP auditors carried out a highly professional audit under the NOP program. Their knowledge of the NOP requirements was complete. Procedures were carried out in accordance with ISO19011 requirements. The opening and exit interviews were handled with great skill and sensitivity, as was the whole audit. Assessment methods were thorough. Their extensive knowledge of the National Organic Program enabled these auditors to identify areas of concern quickly and efficiently.

Three items observed by the ANSI technical expert during the witness assessment were not considered by the NOP auditors as non-conformances. It is noted that this may have resulted from different interpretations of NOP rule requirements among experts and may possibly point to some inconsistencies in implementation of the rule among certifiers and auditors. These items are presented for review by NOP and are NOT considered by ANSI to be non-conformances.

NOP 205.504(b)(6): The certifying agent failed to produce a written procedure for sampling and testing, as required by this clause of the rule. This finding was omitted from the list of non-compliances presented during the exit interview.

NOP 205.403(a)(2)(iii): in regard to the NOP on-site audit checklist verification of the procedure for performing and verifying additional/unannounced inspections, the certifying agent had no written procedure in place on how to conduct such visits. This finding was not included in the list of non-compliances presented to the certifying agent

at the exit interview. (Note: The auditors did not accept this finding on the basis that the NOP rule states that certifying agents "may" conduct such visits and that in this case the certifying agent had chosen not to do so.)

NOP 205.403 (c): The inspector conducting the witness inspection failed to conduct an input-output (purchases/sales) reconciliation. The auditors did not consider this a noncompliance, as the NOP does not specifically require this verification audit. It is unclear whether inspectors, in cases of mixed operation in processing plants, can adequately fulfill the requirements of 205.403 without this type of audit which is standard procedure for inspections in the organic industry. The NOP auditors confirmed that in all other witness audits that they had conducted, this procedure had been carried out. Consideration should be given either to instructing auditors to use this standard procedure under mixed-operation circumstances for verification or, if considered necessary, to amend the rule to require specifically such a reconciliation.

It is noted that a system should be put in place to ensure that implementation of corrective actions are reviewed at the next on-site visit. This follow-up is particularly relevant given the lengthy time period between visits.

The ANSI technical expert and the assessor witnessed the audit conducted by the USDA ARC Branch to evaluate the audit process and technical application of the NOP requirements of a certifying agent. The third on-site witness assessment was performed on May 10-12, 2004 by Mr. K. Commins (technical expert) and Mr. Figueiredo (assessor). Representing the NOP were Mr. Martin Friesenhan (lead auditor) and Ms. Lauren Kavanaugh (auditor).

The purpose of the USDA NOP audit was to evaluate the implementation of requirements defined under the NOP Organic Rule by the Oklahoma Department of Agriculture. The USDA NOP representative performed a thorough audit of the product certification agency to determine their competence to certify organic products in accordance with USDA regulations.

Mr. Martin and Ms. Lauren performed this audit in accordance with principles established in ISO 19011 as well as NOP internal procedures. It was observed that they were very diligent in their auditing efforts. The lead assessor conducted both an opening and closing meeting with Oklahoma Department of Agriculture representatives, reviewed the audit plan, and informed them of the USDA methodology to be used during the audit.

Especially effective was the audit team's approach in identifying areas to assess and following up with relevant specific questions to determine the degree of knowledge of certification agency personnel. This method helped technical personnel to develop clear understanding of the USDA NOP regulations. The audit team efficiently obtained the evidence to document how the certification

agency implemented USDA NOP requirements and complied with USDA accreditation and certification criteria.

Areas for Improvement:

- USDA NOP program must update changes in procedures for its clients (similar to the example when lead assessor informed the Oklahoma Department of Agriculture about the new classification of non-conformities into to major and minor subcategories);
- In the audit plan sent to the certification agency, there is no indication of audit type (initial, surveillance or re-assessment). In the supplement to the audit plan, the generic points indicated must provide a delineation of topics related to USDA NOP regulations ;
- Audit plan or supplement to the audit plan should define who (team leader or auditor) will be responsible for specific topics.);
- ANSI assessment team would like to suggest that USDA NOP develop guidance to be used by the accredited certification agencies for the following:
 - Use of USDA logo by the clients of certification agencies.

Instructions for the certification agencies to address a situation where a certified company requests a certification agency (A) to list the name of that company in the list of companies certified by this certification agency; and (B) this company is certified by another USDA-accredited certification agency .

VIII. Results of any differences in reporting

A closing meeting was conducted on December 18, 2003 in Washington, DC, following the technical evaluation and one witness assessment.

All information related to the site evaluation was conveyed to accreditation program personnel present throughout the assessment. No differences were found between the report presented during the witness assessment and the final report.

IX. Summary

This document completes the report for the peer evaluation site visit for the USDA-AMS accreditation program that started in 2003 and was completed in 2004.

The final evaluation report is submitted to the accreditation body's representative, A.J. Yates, AMS Administrator, with copies to Mr. Barry Carpenter, Livestock and Seed Programs and Barbara Robinson, Transportation and Marketing Programs. The Summary Report was presented to Mr. Richard Mathews, NOP Program Director, Mr. Keith Jones, Director, Program Development, Mr. James Riva, ARC Branch Chief, and

Ms. M. Hayden, ARC Accreditations Manager. The final evaluation report was sent for comment to the USDA NOP program director and ARC Branch Chief.

X. Additional Information

Assessment Plans (October 1-2, 2003 and December 18, 2003)

Evaluation Summary Reports

USDA_Summary Report_100203.doc

USDA_Summary Reprot_12803.doc

FR-019-Rpt Witness Oct 2003.doc

FR-019-Rpt Witness Jan 2004 .doc

FR-019-Rpt Witness May 2004.doc