

**National Organic Program Response to the
American National Standards Institute Peer Evaluation Report on
NOP Certifier Accreditation Operations**

December 8, 2004

Introduction:

The Agricultural Marketing Service (AMS), National Organic Program (NOP), contracted with the American National Standards Institute (ANSI) to conduct a series of peer review audits of NOP certifier accreditation operations. The purpose of the audits was to provide NOP managers with information necessary to improve the quality of NOP services, support compliance with international accreditation protocols, and meet the requirement for peer review of the Organic Foods Production Act of 1990.

Background:

ANSI conducted the audits based on the International Organization for Standardization (ISO) International Electrotechnical Commission (IEC) Guide 61, *General Requirements for Assessment and Accreditation of Certification Bodies*. On November 15, 2004, the NOP received the final ANSI Peer Evaluation Report. On December 8, 2004, NOP received a revised final report from ANSI, and this is the document to which the NOP presents its response.

The NOP response addresses each instance where ANSI found that NOP does not have "documented policies and procedures in place" that would put them in conformance to ISO/IEC Guide 61, as reported in "VI. Findings" of the ANSI report.

The NOP response also addresses "Areas for Improvement" and other comments made in "VII. Results of the Evaluation to the ISO/IEC Guide 61 requirements" that were not noted in "VI. Findings," along with comments in the "Witness-Assessment Reports" that ANSI made while accompanying AMS audit teams on three site visits.

We have organized each finding in the ANSI Report and our response into two general categories:

- (1) Organizational Structure or Policy Changes
- (2) Procedural or Documentation Changes

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

Organizational Structure or Policy Changes

Organization

ANSI finding:

(2.1.2.k, 2.1.4) It is noted that the assessment activities by the ARC Branch [Audit, Review and Compliance Branch of AMS] 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 [Memorandum of Understanding] 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.

NOP response:

--Finalize documents clarifying delegations of authority between NOP, ARC, AMS Compliance, the Office of the Deputy Administrator, and the Office of the Administrator.

--Update the Memorandum of Understanding between the NOP and the ARC Branch, for the provision of auditor services.

ANSI finding:

(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.

NOP response:

Publish the process for developing guidance on the regulations and program requirements.

ANSI finding:

(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.)

NOP response:

Finalize a functional organizational chart for the accreditation body which more clearly describes the relative functions and responsibilities with regard to certifier accreditation.

ANSI finding:

(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.

NOP response:

Finalize policies to more clearly distinguish between accreditation activities and other activities performed by the offices and personnel performing duties for or on behalf of the NOP.

General Policies

ANSI finding:

(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.

NOP response:

Documents provided by certifying agents to secure and maintain accreditation are Federal records subject to the provisions of the Freedom of Information Act. NOP consults with its attorneys regarding the release of information provided by the certifying agents.

ANSI findings:

(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.

(2.2.1.3) 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).

NOP response:

Finalize policy document that more clearly identifies delegations of authority and personnel responsible for the activities below:

- a) Accreditation activities
- b) Formulation of policy matters relating to the operation of the accreditation body
- c) Supervision of implementation of NOP policies
- d) Decisions on accreditation and the criteria for those decisions
- e) Delegation of authority to committees
- f) Individuals or offices within AMS performing specific activities on behalf of the NOP
- g) Procedures for website maintenance

ANSI finding:

(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.

NOP response:

Finalize documentation procedures for the handling of application review, assessment, evaluation, and recommendation activities.

ANSI finding:

(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.

NOP response:

More fully document procedures for granting, maintaining, withdrawing, suspending, or denying accreditation and for extending or reducing the scope of accreditation.

Qualifications of Personnel

ANSI finding:

(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.

NOP response:

In order to qualify and be selected for a Federal job, an applicant must demonstrate knowledge, skills, and abilities specific to that job. Once placed in a job, the employee must maintain a fully successful level of performance, as measured and documented in an annual performance appraisal by the employee's direct and second-line supervisors. Employees must also prepare an Individual Development Plan each year, which details proposed and completed training. NOP may consider developing a separate document that restates these qualification requirements.

Procedural or Documentation Changes

Quality Management

ANSI finding:

(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.

NOP response:

--More clearly document the NOP quality management system. Consolidate information or references to information in a manner that will promote accessibility.

--Make certain all policies and procedures for the accreditation body are available to all staff performing activities for the accreditation body.

ANSI finding:

(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.

NOP response:

--Create public access to current copies of AMS policies and procedures. NOP will prepare a master list of documents to be referenced in the NOP accreditation program.

--Document specific responsibilities within NOP for preparing, amending, or updating instructions and policies.

ANSI finding:

(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.

(2.6.1) The accreditation body does not have procedures in place for appeals, complaints, and disputes received from applicants, certifying agents and others.

NOP response:

The NOP regulation (7 CFR 205) provides the procedures for the resolution of complaints, appeals, and disputes received from bodies or other parties about the handling of accreditation matters. NOP also has posted on its website fact sheets on complaint and appeal procedures. NOP may consider providing additional information in this area.

ANSI finding:

(2.1.6) The accreditation body does not conduct an internal audit and management review of all accreditation body activities.

NOP response:

As a program of the Federal government, the NOP is subject to internal audits conducted by the Office of the Inspector General (OIG). The OIG conducts scheduled and unscheduled audits of all USDA programs. The NOP is currently undergoing a routine OIG audit due to the fact that it is a new program. Further, the NOP plans to routinely contract for the audit and review of its accreditation program. Finally, NOP has hired an accreditation manager with responsibility for

periodically evaluating the effectiveness of management controls over the accreditation program.

ANSI finding:

(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.

NOP response:

Each agency of the Federal government must follow specific records management procedures relating to the creation, use, maintenance, security, and disposition of records. NOP is in the process of incorporating itself into the records management system established by AMS. Procedures will include posting of information on the NOP website.

Accreditation and Auditing Activities

ANSI finding:

(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.

NOP response:

Ensure that all auditor training records are complete and kept updated.

ANSI finding:

(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.

NOP response:

Finalize policies and procedures to ensure all certifying agents make available to the NOP records of complaints, appeals, disputes, and subsequent actions.

ANSI finding:

(3.1.1.2.a) The accreditation body does not require that certifying agents comply with the relevant provisions of ISO/IEC Guide 65.

NOP response:

This ANSI finding refers to the fact that the NOP regulations, section 205.510, require an annual update of changes in certifying body procedures, while ISO/IEC Guide 61, Section 3.5.3, requires the certifying body to inform the accreditation body of changes without delay. ANSI contends that a number of accreditation bodies require notification within 30 to 60 days. NOP plans no change, at this time, to section 205.510. However, this finding may be reviewed again at a later date when changes in individual certifying agent procedures become more substantive, rather than a refinement of understood processes.

ANSI finding:

(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.

NOP response:

Prepare and implement a procedure that informs the applicant of the members of the audit team and allows them the chance to appeal the use of any particular auditors or experts.

ANSI finding:

(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.

NOP response:

The NOP regulations provide for assessment of the applicant's qualifications and capabilities through a rigorous review of the application and supporting documentation. Following this review, an initial site evaluation shall be conducted before or within a reasonable period of time after issuance of the applicant's "notification of accreditation." In cases where the document review raises concerns regarding the applicant's qualifications and capabilities and the Administrator deems it necessary, a pre-approval site evaluation will be conducted. We have further provided that a site evaluation shall be conducted after application for renewal of accreditation but prior to renewal of accreditation.

Our purpose in allowing for initial accreditation prior to a site evaluation was to facilitate implementation of the NOP and to provide a means for newly established certifying agents to obtain a client base to demonstrate that they can meet the requirements of the NOP regulations. It should be noted that certifying agents must be accredited in compliance with section 205.500 of the NOP regulations to perform certification services to the NOP.

We believe our position is consistent with the intent of ISO/IEC Guide 61, section 2.3.1, and fits within its "and any other relevant information" provision. Accordingly, we restate our position that accreditation approval without a site evaluation is appropriate, necessary in the case of established certifying agents that may need to make adjustments in their operations to comply with the NOP regulations, and necessary in the case of newly established certifying agents who will have to obtain a client base to demonstrate beyond the paperwork that they can meet the requirements of the NOP regulations.

ANSI finding:

(3.4.1.d) The accreditation body does not invite the certifying agent to comment on the report.

NOP response:

Revise desk and onsite audit protocols to include a provision to allow the applicant to comment on the audit report.

NOP Response to ANSI Suggestions for Improvement

ANSI found many areas in which the NOP is in conformance with ISO Guide 61 requirements, especially in the performance of site audits of accreditation applicants. ANSI strongly commended audit teams, noting for example that,

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

ANSI did note “areas of improvement” in the “Witness-Assessment Reports” and section “VII. Results of the Evaluation to ISO/IEC Guide 61 requirements,” which were not significant enough to be included in section “V. Findings.” NOP has carefully reviewed these suggestions and will address them in their work plan for the coming year.