National Organic Standards Board Statement on the
National Organic Program Response to the
American National Standards Institute Peer Evaluation Report on
NOP Certifier Accreditation Operations
Approved by the
NOSB Certification, Accreditation and Compliance Committee
Draft 4 - July 12, 2005

Introduction:

The USDA National Organic Program (NOP) and the National Organic Standards Board (NOSB) are implementing procedures for ongoing peer review of the NOP accreditation program. Under the procedures, the NOP accreditation program will be audited by an independent peer auditing/review organization at least once every three years. Once the audit is completed, the NOP will draft a detailed response to the audit report. Both the audit report and the NOP response will be provided to the NOSB for review. The NOSB, on behalf of the organic community, will evaluate the audit report and NOP response and work with the NOP to provide a sufficiency assessment to the Secretary in order to implement the audit findings, enhance implementation of the NOP accreditation program, and facilitate constructive dialog between the NOP and NOSB. It is the goal of this process to provide input to the Secretary within one year after each audit report is submitted to the NOP.

Background:

In 2003, the NOP contracted with the American National Standards Institute (ANSI) to conduct a peer review audit of NOP certifier accreditation operations. The purpose of the audit 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.[1]

ANSI conducted the audit 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. The NOP issued a written response to the ANSI report, also dated December 8, 2004.

The NOSB has been asked by NOP to evaluate the audit report and NOP response and provide a sufficiency assessment to the Secretary to assist in implementation of the audit findings. The NOSB's comments and recommendations are contained in this document.

NOSB Statement:

The NOSB has reviewed the ANSI report and the NOP's response. The NOSB commends the NOP for contracting with ANSI to conduct the review, and for providing thoughtful responses to the findings in the ANSI report. As noted in the ANSI audit report, many NOP accreditation activities, especially those conducted by the Audit Review and Compliance division, are functioning well, while others need improvement. The NOSB further acknowledges that the NOP is actively addressing deficiencies noted in the ANSI audit report.

The ANSI review of NOP is considered by the NOSB to be a comprehensive, professional, and independent peer review of the NOP accreditation program for adherence to accreditation

[1] National Organic Program Response to the American National Standards Institute Peer Evaluation Report on NOP Certifier Accreditation Operations, December 8, 2004.

procedures of ISO/IEC Guide 61[2]. Other than the items discussed below, the NOSB accepts and supports the NOP's responses to the ANSI findings with no comment.

Recommendations:

On behalf of the organic community, the NOSB offers the following recommendations to assist the NOP in the improvement of the accreditation program and compliance with the requirements of §205.509 and ISO Guide 61:

1. Scope of audit – According to the ANSI audit report, the scope of the audit was ISO Guide 61. While not overtly stated in the report, in order to have context for conducting the audit, ANSI assessed the NOP's adherence to the accreditation procedures in subpart F of the Final Rule, as required by section 205.509 of the Final Rule.

Recommendation # 1 – The next audit report should explicitly verify assessment of the NOP's adherence to the accreditation procedures in subpart F of the Final Rule and evaluate the NOP's accreditation decisions, in addition to adherence to ISO/IEC Guide 61, in order to demonstrate that the audit meets the requirements of §205.509.

2. ANSI findings 2.1.2.k and 2.1.4 – ANSI noted that the overall quality system for accreditation is not documented in a quality manual. While the NOP response mentions the need to "finalize documents," it does not address the absence of a quality manual.

Recommendation # 2 – The NOP should address the need for a quality manual and follow a quality system that fully documents all accreditation functions, policies, and procedures. This information may be in a quality manual or the quality manual may reference information contained in separate procedure, policy, and standards manuals.

3. ANSI finding 2.1.1.3 – ANSI noted that NOP does not define the process for developing explanations of the regulations and program requirements by "impartial committees or persons possessing the necessary technical competence." In response, NOP referenced the Good Guidance document, but did not address the need for impartial committees or persons with technical competence.

Recommendation # 3 – NOP should document that explanations of the regulations are developed by impartial persons or committees who possess the necessary technical competence in the requisite subject matter.

4. ANSI finding 2.1.2.l – ANSI found that the NOP does not have policies and procedures to distinguish between accreditation activities and other activities performed. The NOP response did not demonstrate how it separates its accreditation functions from other activities related to certification, such as the handling of suspensions, revocations, complaints, appeals, and enforcement actions.

Recommendation # 4 – The NOP should demonstrate how it has established a clear wall, described in the NOP Quality Manual, between its accreditation activities and other certification-related functions specified in the Final Rule, including how it handles suspensions, revocations, complaints, appeals, and enforcement actions.

5. ANSI findings 2.1.2.c and 2.2.1.3 – In response to these findings, NOP states that it will, "Finalize policy document that more clearly identifies delegations of authority and personnel responsible for the activities below:

a) Accreditation activities

[2] Since the Final Rule was published, ISO Guide 61 has been updated and renamed to ISO 17011.

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."

Recommendation # 5 – NOSB endorses the NOP's response and encourages the Secretary to provide adequate support to accomplish the tasks listed above in a timely manner.

6. ANSI finding 2.2.1.2 – ANSI found that the NOP does not define the minimum criteria for competence for auditors and technical experts. Finding 2.2.2 states, "Auditors who serve as technical experts have not received training on verification methods employed in the organic certification sector." The NOP response describes Federal job procedures, but does not directly address the finding.

Recommendation # 6 – NOP should establish or clearly demonstrate the existence of job descriptions with minimum qualification requirements for auditors and technical experts who provide advice on or verify compliance with organic regulations.

7. ANSI finding 2.1.7.2 – ANSI stated, "The accreditation body does not have procedures for controlling all documents and data related to accreditation functions." NOP responded by stating that it is "in the process of incorporating itself into the records management system established by AMS." There is no further discussion or description of the proposed AMS records management system, or if it complies with ISO requirements for document and data control.

Recommendation # 7 – In preparation for the next audit, the NOP should demonstrate that the document and data management system being implemented fully complies with the requirements of ISO/IEC Guide 61.

8. ANSI finding 3.1.1.2.a – ANSI found that NOP does not require that certifying agents comply with the relevant provisions of ISO/IEC Guide 65. The NOP response discusses "annual updates," but does not address the fact that NOP-accredited certifying agents are not required to comply with ISO Guide 65. The USDA offers ISO Guide 65 accreditation to organic certifying agents as a separate fee-for-service program. This leads to increased expenses and bureaucracy for certifying agents who choose to participate, and constitutes a barrier to trade for producers and handlers certified by agents who are not ISO 65 accredited.

Recommendation # 8 – The NOSB acknowledges that NOP and ISO Guide 65 requirements are not identical, which restricts access to international markets and results in increased costs and bureaucracy for certified operators and certifying agents.

Conclusion:

As stated, the NOSB commends the NOP for contracting with ANSI to conduct the review, and for providing thoughtful responses to the findings in the ANSI report.

The NOSB understands that creation and operation of the NOP accreditation program are huge undertakings. The NOSB stands ready to assist the NOP in developing and implementing work plans, policies, and procedures to provide for continuous improvement of the program.

Committee vote:
Yes – 4; No – 0; Absent - 1