



NATIONAL ORGANIC PROGRAM ACCREDITATION FOR ORGANIC CERTIFICATION ORGANIZATIONS

Scope

The policies and procedures in this document apply when providing auditing and accreditation service to domestic and foreign organic product certification organizations that request assessment to the National Organic Program Regulations. All agricultural products that are sold, labeled or represented, as "organic" in the United States must be certified by an agent accredited by USDA or by an agent in a country that has been accepted by USDA.

Accreditation and Verification

Livestock and Seed Program, Audit, Review and Compliance (ARC) Branch, Quality Systems Verification Program (QSVP) will conduct verification and monitoring services for the National Organic Program. All services are provided on a cost-recovery basis with fees as nearly equal as possible to the actual cost of providing the service. Fees for service, the hourly fee charged by auditors, will be waived until the NOP Program is fully implemented on or about October 21, 2002.

Reference Documents

The following documents are incorporated by reference throughout the instruction:

- 7 CFR Part 205, National Organic Program Regulation
- ISO 10011-1:1990, Guidelines for auditing quality systems-Part 1-Auditing

Policy

The Transportation and Marketing Program, National Organic Program (NOP), provides accreditation services under 7 CFR Part 205 to domestic and foreign organic certification organizations to meet the purposes of the Organic Foods Production Act of 1990. The purposes are: 1) to establish national standards governing the marketing of certain agricultural products as organically produced products; 2) to assure consumers that organically produced products meet a consistent standard; and 3) to facilitate interstate commerce in fresh and processed food that is organically produced.

Availability of Service

NOP services are available to both U.S. and foreign organic certification organizations that wish to certify organic agricultural production and handling operations. The service is extended to private businesses and State governments. The scope of accreditation includes crops, livestock, wild crop harvesting, and handling.

Authority for Providing Service

NOP accreditation is authorized by the Organic Food Production Act of 1990 and 7 CFR Part 205.



Application for Service

Persons interested in accreditation services under the NOP may contact the NOP in Washington, DC, on (202) 720-3252. The NOP staff will provide a copy of ARC Instruction 1019, National Organic Program Accreditation for Organic Certification Organizations; 7 CFR Part 205; and a copy of Form TM-10CG, Application for Accreditation. Documents can also be found on the internet at:

<http://www.ams.usda.gov/nop/> Applicants must complete the Form TM-10CG as described on the form and submit it to the NOP along with the attachments listed under the signature block in the section entitled, PLEASE ATTACH.

Upon receiving the application, an NOP representative will contact the applicant to request additional information if needed. When the application is complete it will be passed to an ARC Branch auditor who will arrange to provide services requested and will supply the following information to the applicant:

1. Estimated duration and cost of the document review, if applicable.
2. Estimated duration of the initial compliance audit and number of locations to be reviewed.
3. Frequency and duration of surveillance audits and number of locations to be reviewed.
4. Estimated travel and per diem expenses associated with the audits.
5. Total estimated annual costs of providing service.

Assessments

NOP accreditation assessments are conducted in accordance with ISO 10011-1:1990, Guidelines for auditing quality systems-Part 1-Auditing.

Document reviews. The ARC Branch will evaluate the initial application, including the attached documents, with the assistance of a subject matter expert, as necessary. The initial review will include a detailed analysis of all applicable program requirements according to 7 CFR Part 205.

Upon successful completion of the initial review, the ARC Branch Quality Manager will assign the lead auditor who will be responsible for the program document review and site evaluation audits as necessary.

Site evaluation audits. Qualified lead auditors supervised by the ARC Branch will conduct a detailed audit of certification program activities at the applicant's place of business. The purpose of the site evaluation audit is to validate policies and procedures described in the application. Site evaluation audits will be of sufficient duration and detail to provide auditors with reasonable assurance that the policies and procedures stated in the application have been fully implemented and achieve the desired program objectives. Compliance audits will include a review of inspection activities at one or more producers and one or more processors under contract with the certifier. At the conclusion of the audit, the lead auditor will discuss the audit findings at a closing meeting and forward the findings to

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the Review and Approval Committee that operates under the authority of the AMS Administrator for final disposition.

Auditors

Auditors assigned to provide program document reviews and site evaluations must meet all qualifications for ARC Branch lead auditors as described in ARC Instruction 1030, Training and Experience Requirements for Quality Systems and Compliance Audits. Auditors must have signed conflict of interest statements and appropriate disclosure agreements on file with the Branch prior to assignment to provide service to a specific applicant.

Program Review and Approval Committee

The ARC Branch Quality Manager will appoint the Program Review and Approval Committee. It will include representation from NOP, ARC and an independent third party. The Committee also may include qualified representatives from the Livestock and Seed Program.

Decisions on Accreditation

All decisions on accreditation will be based on recommendations of the Review and Approval Committee to the NOP Program Manager, who issues the final approval on behalf of the Administrator.

Basis for evaluation. The Review and Approval Committee will review certification programs and base their recommendations on the following criteria. To recommend approval, committee members must find that programs:

1. Appropriately address all applicable elements of 7 CFR Part 205.
2. Clearly define the scope of the certification services provided.
3. Have demonstrated an effective and credible certification program.
4. Have necessary financial resources to pay for NOP/ARC services.

Granting accreditation. The NOP Program Manager, acting under the authority of the Administrator, may grant accreditation to applicants upon successful completion of the document review and a recommendation of the Review and Approval Committee. If accreditation is granted prior to the site evaluation, it must be performed as soon as it is feasible. For example, when a new certifying agent is accredited, the site evaluation should be performed when the agent has established a record of certification activities.

Denying accreditation. Committee members may elect to deny initial accreditation to an applicant for any of the following reasons:

1. Failure by an applicant to submit documentation that demonstrates compliance with all applicable provisions of 7 CFR Part 205.



2. Failure to provide objective evidence of complete program implementation during the course of the initial site evaluation audit.
3. Failure to submit the necessary fees.
4. Failure to provide unlimited access to applicants' records within the scope of the accreditation.
5. Presenting false or misleading information to any NOP Program official, applicable State official or delegate of the NOP at any point in the accreditation process.

Duration of accreditation. The period of accreditation is 5 years, at which time applicants may renew accreditation. Renewal requires submission of an application and completion of a document review and site evaluation.

Maintaining accreditation. Applicants are required to maintain program documentation and systems as described in the material submitted with the application and any changes the Administrator requires as a condition of accreditation. Accredited certifying agents must submit updated information annually. NOP will review updated information and perform at least yearly surveillance audits or as deemed necessary to maintain confidence in the ability and expertise of the certifying agent to perform certifications in compliance with 7 CFR Part 205.

Amendments to Scope of Accreditation

Any changes to the scope of the accreditation or certification procedures must be submitted in writing to the NOP Manager for consideration at least 30 days prior to the proposed effective date of the changes. Requests for amendments or procedures must include a clear description of the proposed changes. Substantive changes may require additional document and site evaluation audits as determined by the Review and Approval Committee.

Suspending Accreditation

Suspension. Under section 205.665 of 7 CFR Part 205, the NOP may temporarily suspend accreditation of programs for any of the following reasons:

1. Failure by the accredited program to take required corrective/preventive action to a previously documented nonconformance.
2. Implementing substantive changes in the accredited program without prior written approval.
3. Misuse or misrepresentation of official certificates or accreditation status and failure to take effective corrective/preventive action within time period designated in the notification.
4. Failure to pay ARC fees within 60 days of original billing date.

Notification of suspension. The NOP Program Manager will arrange to notify the certifying agent in writing of any decision to suspend accreditation within 5 working days of the Committee's

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recommendation. Notification will include details of nonconformances, conditions for reinstatement of accreditation, and timeframes for completion.

Revocation of Accreditation

Revocation. The NOP may withdraw accreditation of a certification body for any of the following reasons:

1. Repeated failure to maintain it's system in compliance with referenced standards and approved procedures.
2. Failure of suspended programs to meet conditions for reinstatement within required timeframes.

Removal from lists of accredited certification bodies. An accredited certifying agent that has had its accreditation suspended or withdrawn will have its name and program information removed from all official lists of accredited programs in accordance with **Publication of Accreditation Status**.

Surrender of certificates. Revocation of accreditation will result in cancellation and recall of the certifying agent's accreditation certificate. If an agent whose accreditation is suspended or revoked does not appeal the decisions, its certificate of accreditation must be surrendered upon notice of suspension or revocation. A certifying agent that receives an unfavorable decision resulting from a formal administrative proceeding to suspend or revoke accreditation must surrender its certificate when notified of the decision.

If a certificate is cancelled, the certifying agent must immediately discontinue use, reference to, or distribution of materials that make reference to USDA's NOP accreditation. Applicants must effectively recall or arrange for discontinuation of distribution all point-of-purchase materials referencing or implying accreditation by NOP within 10 working days of written notification by NOP.

Appeals

Applicants have the right to appeal the findings of any audit or decision based on those findings. Appeals regarding an applicant's accreditation or any audit findings must be submitted in writing to the NOP Program Manager.

Requests for appeal must include:

1. The basis for the appeal.
2. The requested alternative decision or actions.
3. Any other information requested by the NOP Program Manager.



If the Administrator denies an appeal, a formal administrative proceeding to deny, suspend or revoke the accreditation will be initiated and conducted pursuant to the USDA Uniform Rules of Practice, 7 CFT Part 1 Subpart H.

Reasonable Security

All accredited certifying agents must furnish reasonable security, in an amount and according to the terms of 7 CFR Part 205, for the purpose of protecting the rights of the operations they certify.

Fees for Service

NOP will provide auditing services in the most efficient, cost-effective manner possible with consideration to the needs of the applicant, the capabilities and needs of the Program, and sound management practices. When assigning auditors to perform specific audits, the ARC Branch Quality Manager will give consideration to providing service using the auditor who would incur the least travel cost. However, auditor assignments will also include considerations such as ensuring uniformity of service, specialized training, personnel staffing issues, and specific program needs. It will be the responsibility of the ARC Quality Manager to staff audits in the most cost-effective manner possible while ensuring uniform, high-quality service.

Fee Rate. Fees charged for service will be charged according to the approved hourly rate published in the Federal Register. Hourly fees will be assessed for official time required to prepare for, conduct, and report the results of assessments and time required to complete all related travel.

Audit preparation

Applicants will be billed for official time required preparing for quality system audits performed on their behalf. Official preparation time will include review of applications and attached documents, records from previous audits, and preparation of checklists. The amount of preparation time necessary to prepare for an audit will depend upon the complexity of the system to be audited, the volume of documentation, and the number of nonconformances and corrective actions from previous audits.

Travel

Applicants will be charged for travel time to and from the assigned auditors' official duty location and between audit sites. When traveling to provide service to multiple applicants, charges will be prorated between the applicants.

Recording hours charged. Hours of service to be charged to the applicant will be documented on LS Form 5-3 (1-93), Agricultural Products Certificate and submitted to the Meat Grading and Certification Branch Office of Field Operations, Denver, Colorado, for billing. Copies of the charge certificate will be maintained with the audit working papers.

The hourly fee will be suspended until the NOP is fully implemented, on or about October 21, 2002.



Certificates of Accreditation

Upon recommendation of the Review and Approval Committee, the NOP Program Manager will issue an official certificate of accreditation to the certification organization, stating the scope of the accreditation, the location of the program evaluated, and the effective dates of the certificate. Certificates will be valid for the 5-year duration of accreditation unless they are formally surrendered because of suspension or revocation.

Publication of Accreditation Status

Upon successful completion of the assessment process, the NOP Program Manager will arrange to post the applicant's accreditation status on the NOP web site. The posting will include the terms, scope, and limitations of the accreditation. The NOP Program Manager also may post information regarding applications in various stages of approval when it is reasonable to expect that the applicant will successfully complete the accreditation process within a reasonable time period.

Removal from lists of accredited programs

A program whose accreditation has expired or has been suspended or revoked will immediately be removed from all official lists of accredited programs.

Confidentiality

Accreditation services are designed to provide confidence in the ability of the agent to certify that organic agricultural products have been produced and handled in compliance with 7 CFR Part 205. All materials submitted by applicants and maintained by the NOP or ARC Branch are available for public inspection and are subject to complete disclosure under the Freedom of Information Act. Any portion of the program documentation that the applicant considers proprietary must be identified at the time the information is submitted along with written justification why said documents should not be released to or reviewed by the public.

If, upon review of the information, the Review and Approval Committee agrees that the identified information is indeed proprietary and that protecting the information from public review will not hinder public confidence in the system, the NOP Program Manager will make appropriate provisions to protect the information from disclosure to the extent possible under existing Federal laws.

/s/ Larry R. Meadows

Larry R. Meadows, Acting Chief
Audit, Review, and Compliance Branch
Livestock and Seed Program