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National Organic Program (NOP) Accreditation for Organic Certification Organizations

1 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 recognized by USDA. Organic products from countries with whom the United States had entered into an equivalency agreement also may be sold in the U.S.

2 Accreditation and Verification

Livestock and Seed Program, Audit, Review and Compliance (ARC) Branch will conduct verification and monitoring services for the Transportation and Marketing Program, National Organic Program (NOP). 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, were waived prior to the Program's full implementation on October 21, 2002.

3 Reference Documents

The following documents are incorporated by reference throughout this Procedure:

- 7 CFR Part 205, National Organic Program Regulation;
- Organic Foods Production Act of 1990;
- ARC Instruction 1000, Quality Systems Verification Program General Policies and Procedures; and
- ISO 19011:2002, Guidelines for quality and/or environmental management systems auditing.

4 Policy

The NOP provides accreditation services under 7 CFR Part 205 to both U.S. 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.

5 Availability of Service

NOP services are available to both U.S. and foreign organic certification organizations (certifying agents) 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.

6 Authority for Providing Service

NOP accreditation is authorized by the *Organic Food Production Act of 1990* and 7 CFR Part 205. The ARC Branch is authorized by the *Agricultural Marketing Act of 1946* and 7 CFR Part 54.

"The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, sexual orientation, marital or family status, political beliefs, parental status, or protected genetic information. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at 202-720-2600 (voice and TDD). To file a complaint of discrimination, write USDA, Director, Office of Civil Rights, Room 326-W, Whitten Building, 14th and Independence Avenue, SW., Washington, DC 20250-9410 or call 202-720-5964 (voice and TDD). USDA is an equal opportunity provider and employer."



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7 Application for Service

Certifying agents interested in accreditation services under the NOP regulations may contact the NOP in Washington, DC, on (202) 720-3252. The NOP will provide a copy of 7 CFR Part 205 and a copy of Form TM-10CG, Application for Accreditation. These documents can also be found on the NOP website at http://www.ams.usda.gov/nop/. Certifying agents 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".

The ARC Branch will supply a copy of *ARC 1025 Procedure, National Organic Program Accreditation for Organic Certification Organizations* and a copy of the NOP Accreditation Audit Checklist to interested parties. These documents are available by calling the ARC Branch Accreditation Manager at (202) 720-2647 or on the ARC Branch website at www.ams.usda.gov/lsg/arc/audit.htm.

Upon receiving the application, the ARC Branch Accreditation Manager will contact the certifying agent 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 the services requested.

8 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 on file with the ARC Branch prior to assignment to provide service to a specific applicant.

9 Program Review Committee

The Program Review Committee operates under the authority of the AMS Administrator to review audit reports and make recommendations to grant or deny accreditation. The ARC Branch Quality Manager will appoint the Program Review Committee in accordance with the *ARC 1115 Procedure, Program Review Committee Procedures*. It will include independent third party representation from the NOP and the ARC Branch. The committee also may include qualified representatives from the Livestock and Seed Program. At no time will the auditor of record be a member of the committee. Committee minutes will be recorded on *ARC 1025 Form, NOP Committee Meeting Minutes*.

10 Assessments

NOP accreditation assessments are conducted in accordance with ARC Instruction 1000, Quality Systems Verification Program General Policies and Procedures and ISO 19011:2002, Guidelines for quality and/or environmental management systems auditing

<u>Document Reviews</u>. Upon successful completion of the initial review, the ARC Branch Accreditation Manager will assign a qualified ARC Branch auditor who will be responsible for the program document review and site evaluation audits as necessary. The auditor will evaluate the application with the assistance of a subject matter expert, as necessary. The review will include a detailed analysis of all applicable program requirements according to 7 *CFR Part 205* using the NOP Accreditation Audit Checklist.

Site Evaluation Audits. Qualified ARC Branch auditors will conduct a detailed audit of certification program activities at the certifying agent's place of business. The purpose of the site evaluation audit is to verify 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 producer or processor certified by the agent. At the conclusion of the audit, the auditor will discuss the audit findings at a closing meeting and forward the findings to the ARC Branch Accreditation Manager. When the ARC Branch Accreditation Manager is the audit findings for review.

Prior to the site evaluation, the auditor will contact the certifying agent and will supply the following information:

- 1. Estimated duration of the on-site evaluation and number of locations to be reviewed.
- 2. Estimated fee for service, travel and per diem expenses associated with the audits.

11 Decisions on Accreditation

All decisions on accreditation will be based on recommendations of the Program Review Committee to the AMS Administrator. The Program Review Committee will review the certifying agent's program and base the recommendation on the following criteria.

<u>Recommending Approval of Accreditation</u>. To recommend approval, committee members must find that the certifying agent's program meets the following criteria:

- 1. Complies with or has the ability to comply with all applicable elements of 7 CFR Part 205.
- 2. Clearly defines the scope of the certification services provided.
- 3. Has demonstrated an effective and credible certification program or has the ability to sustain such a program.

<u>Recommending Denial of Accreditation</u>. Committee members may elect to recommend denial of initial accreditation to a certifying agent for any of the following reasons:

- 1. Failure by a certifying agent to submit documentation that demonstrates compliance or the ability to comply 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 the certifying agent's records within the scope of the accreditation.

5. Presenting false or misleading information to any NOP official, applicable State official, or delegate of the NOP at any point in the accreditation process.

If the NOP Program Manager agrees to deny accreditation, then the NOP Program Manager will provide notification in compliance with *section 205.507 of 7 CFR Part 205*.

<u>Granting Accreditation</u>. The AMS Administrator may grant accreditation to applicants upon successful completion of the document review and a recommendation of the Program Review Committee. If accreditation is granted prior to the site evaluation, then the site evaluation 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 certifying agent has established a record of certification activities.

<u>Duration of Accreditation</u>. The period of accreditation is 5 years, at which time certifying agents may renew accreditation. Renewal requires submission of an application and completion of a document review and site evaluation.

<u>Maintaining Accreditation</u>. Certifying agents 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. Qualified ARC Branch auditors will review updated information and perform surveillance audits 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.

12 Amendments to Scope of Accreditation

Any changes to the scope of the accreditation or certification procedures must be submitted in writing for approval by the AMS Administrator. Requests for amendments or procedures must include a clear description of the proposed changes and supporting documentation to demonstrate compliance or the ability to comply with the NOP regulation. Substantive changes may require additional document and site evaluation audits.

13 Suspending Accreditation

<u>Suspension</u>. Under *section 205.665 of 7 CFR Part 205*, the NOP may temporarily suspend accreditation of programs. Reasons for suspension include, but are not limited to the following:

- 1. Failure by the accredited program to take required corrective and preventive actions to a previously documented nonconformance.
- 2. Implementing substantive changes to the scope of the accredited program without prior written approval.
- 3. Misuse or misrepresentation of accreditation status and failure to take effective corrective and preventive actions within time period designated in the notification.
- 4. Failure to pay the necessary fees.

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13 Revocation of Accreditation

<u>Revocation</u>. The NOP may withdraw accreditation of a certification agent for any of the following reasons:

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

<u>Notification of Suspension or Revocation</u>. The NOP Program Manager will arrange to notify the certifying agent in writing of any decision to suspend or revoke accreditation. Notification will include details of non-compliances, conditions for reinstatement of accreditation, and timeframes for completion. The procedure will follow *section 205.665 of 7 CFR Part 205*.

<u>Removal from Lists of Accredited Certification Bodies</u>. 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**.

14 Appeals

Certifying agents have the right to appeal the findings of any audit or decision based on those findings. Appeals regarding an certifying agent's accreditation or any audit findings must be submitted in writing within the time period provided in the letter of notification to the AMS Administrator.

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 CFR Part 1 Subpart H.

15 Fees for Service

The ARC Branch will provide auditing services in the most efficient, cost-effective manner possible with consideration to the needs of the certifying agent, the capabilities and needs of the Program, and sound management practices. When assigning auditors to perform specific audits, the ARC Branch Accreditation 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 Branch Accreditation Manager to staff audits in the most cost-effective manner possible while ensuring uniform, high-quality service.

<u>Fee Rate</u>. 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.



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16 Audit preparation

Certifying agents will be billed for official time required in preparing for NOP 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 non-compliances and corrective actions from previous audits.

17 Travel

Certifying agents 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 certifying agents, charges will be pro-rated between the applicants.

Recording hours charged. Hours of service to be charged to the certifying agent 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 in Golden, Colorado, for billing. Copies of the charge certificate will be maintained with the audit working papers.

18 Publication of Accreditation Status

Upon successful completion of the assessment process, the NOP Program Manager will arrange to post the certifying agent's accreditation status on the NOP website www.ams.usda.gov/nop. 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.

19 Removal from lists of accredited programs

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

20 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 certifying agents 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. The NOP Program Manager will make appropriate provisions to protect proprietary information from disclosure to the extent possible under existing Federal laws.