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## **Procedure: Peer Review of National Organic Program (NOP) Accreditation**

### **1. Purpose and Scope**

The National Organic Program (NOP) is establishing a peer review process to implement the peer review section (7 CFR 205.509) of the USDA organic regulations. This instruction describes the procedures for a peer review process to evaluate the U.S. Department of Agriculture (USDA) accreditation program.

### **2. Background**

Section 205.509 of the USDA organic regulations requires the USDA Agricultural Marketing Service (AMS) Administrator to establish a panel pursuant to the Federal Advisory Committee Act (FACA) to conduct peer reviews of the NOP's accreditation process and decisions. To satisfy the requirements of § 205.509, the NOP has in the past contracted with third-party auditing organizations to conduct peer reviews. The NOP contracted with the American National Standards Institute (ANSI) in 2005 and 2014, and with the National Institute of Standards and Technology (NIST) in 2010. During the last few years, foreign governments have also conducted peer reviews of the NOP: the European Commission in 2010, the Canadian Food Inspection Agency in 2011 and 2013, and both South Korea and the European Commission in 2014.

A 2010 Office of the Inspector General (OIG) audit of the NOP found that using third-party review organizations to conduct peer reviews does not satisfy the requirement for a peer review panel described in § 205.509 of the regulations. The OIG recommended that the NOP either form a peer review panel in accordance with the regulations or change the regulations.

The NOP is establishing a peer review panel to satisfy OFPA requirements regarding peer review of certifying agents.

### **3. Policy and Procedures**

A peer review panel will be established to evaluate the NOP's policies, processes and procedures for conformance to ISO/IEC 17011:2001 Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies, which replaced ISO/IEC Guide 61, and the accreditation procedures in subpart F of the USDA organic regulations. The panel will report its findings in writing to the NOP Deputy Administrator and the National Organic Standards Board (NOSB). The findings will be considered part of the NOP quality management system, and the Deputy Administrator will make corrective actions to the NOP accreditation processes as necessary and appropriate. The panel's findings will neither bind the NOP to take any action nor affect the NOP's decisions. The findings will be published and presented at public meetings of the National Organic Standards Board.



## a) Peer Review Procedure

1. Contract with assessment body. AMS will contract with a peer assessment body to coordinate and manage the peer review panel.
2. Select peer review panel. The peer assessment body, in consultation with the NOP Deputy Administrator, will select the peer review panel for each peer review assessment effort.
  - a. The panel will include at least three individuals, at least two of which are not employees of the Department of Agriculture.
  - b. All members must have knowledge of or experience with ISO/IEC 17011 or conformity assessment activities.
  - c. All members of the panel must sign a confidentiality statement to not copy, disclose, or distribute any documents they review as part of their participation on the panel.
  - d. At least two members must have expertise in organic production and handling methods.
  - e. At the discretion of the NOP Deputy Administrator, a current or ex officio member of the NOSB may be selected to augment the panel in an ex officio capacity, if and when the member is free from conflicts of interest as defined by the Secretary, to function as a conduit to the NOSB about panel activities.
  - f. A staff member of the NOP Accreditation Division (AD) will provide support for the panel. This person will be responsible for selecting, redacting, copying, assembling, and distributing copies of documents for panel review.
3. Select a representative sample of accreditation decisions. The panel will select at least three, but not more than five, samples from final accreditation decisions rendered by the NOP.
  - a. The decisions subject to sampling will be those signed during the 12 months immediately preceding the date of the panel's first organizational meeting.
  - b. The date of the accreditation decisions to be considered for sampling will be the date on which the NOP Deputy Administrator signed the decision.
  - c. The samples may be selected randomly or as individual items of interest at the discretion of the peer review panel. If only three or fewer decisions were issued during the prior 12 months, then all the decisions will be selected for review.
  - d. If possible, panel members should select accreditation decisions for at least one large, one medium, and one small certifier for review. This is not, however, a mandatory requirement. The selection of sample decisions is at the panel's complete discretion.
  - e. In addition to the above files, select additional files will be reviewed if necessary to ensure that each of the following type of file is sampled (if such activities were conducted during the sampling period):
    - i. Initial accreditation of a certifier;
    - ii. Renewal of accreditation of a certifier;
    - iii. Surveillance (routine or directed) of a certifier;
    - iv. Suspension of accreditation of a certifier;



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- v. Revocation (withdrawal) of accreditation of a certifier;
      - vi. Amendment of scope of accreditation of a certifier;
      - vii. Appeal of proposed adverse action(s) against a certifier; and
      - viii. Audits and resulting decisions in response to formal complaints filed against a certifier.
    - f. Files with allegations of wrongdoing by a certifier that may be the subject of investigations beyond the scope of the NOP accreditation process should not be selected.
  4. Prepare NOP accreditation process documents for review by the panel. A staff member of the AD will assemble all relevant NOP AD procedural documents for review by the panel, including findings and corrective actions from past peer reviews. These may be saved as files, or as links to public documents that are already available on the NOP Web site, as applicable.
  5. Prepare certifier documents for review. The staff member of the AD will provide the following documents for each certifier selected for review:
    - a. Application for accreditation or renewal, including all attachments;
    - b. AD document review summary sheet;
    - c. NOP audit plan;
    - d. NOP audit report;
    - e. Letters and any Notices sent to the certifier;
    - f. Proposed corrective action from the applicant;
    - g. Notes and decision summary from accreditation committee meeting;
    - h. Signed Terms of Accreditation from the certifier, if applicable;
    - i. Decision letter from the Deputy Administrator; and
    - j. Certificate of accreditation, if applicable
  6. Review accreditation procedures. Each member of the review panel will review the NOP accreditation procedural documents for the following criteria:
    - a. Compliance with the accreditation procedures in Subpart F of the USDA organic regulations (7 CFR 205.500 - 205.510); and
    - b. Compliance with ISO/IEC 17011.
  7. Review accreditation decision documents in preparation for meeting. Each member of the peer review panel will review the accreditation decision documents provided. Panel members should consider whether the NOP and/or AD followed established NOP procedures for accrediting certifiers, renewing their accreditations, and conducting other review types.
  8. Prepare individual opinions. Each member of the panel will complete a peer review report form for the review of the accreditation procedures and for each of the decision files. Reports will identify:
    - a. Any elements of the NOP accreditation procedures that are not aligned with Subpart F of the regulations or ISO/IEC 17011;
    - b. Any instances where records indicate AMS personnel or committees did not adhere to established NOP procedures for accrediting, renewing, or otherwise reviewing certifiers; and
    - c. Completeness and effectiveness of corrective actions from past reviews.



9. Prepare draft consensus report. The peer review assessment body will consolidate the reports into a single narrative summary report. The draft report, along with copies of individual reports, will be circulated to the peer review panel.
10. Peer review panel meeting. After reviewing the report, the peer review panel will meet by conference call to discuss their findings and the draft report. The panel will provide comments to the peer review assessment body and agree on language for the final report.
11. Peer review panel report. The peer review assessment body will consider the comments and prepare a final report. The final report will be sent to the NOP Deputy Administrator with copies to the peer review panel.
12. Presentation. The peer review panel report, along with any NOP response, will be presented at the next NOSB public meeting.
13. Publication. After the public meeting, the NOP will post a copy of the peer review panel report and the NOP response, on the NOP Web site. A USDA Organic Insider notice will announce the availability of the report.

#### 4. Records

The Office of the NOP Deputy Administrator will maintain copies of all peer review panel documents as electronic files on the NOP internal server for five years beyond their creation. As noted above, all final peer review panel reports will be posted on the NOP website; these final reports will be considered permanent records.

#### 5. References

##### **Organic Foods Production Act of 1990, as amended**

7 U.S.C. 6516 Peer review of certifying agents.

##### **USDA Organic Regulations ([7 CFR Part 205](#))**

7 CFR 205.2 Terms Defined.

*Peer review panel.* A panel of individuals who have expertise in organic production and handling methods and certification procedures and who are appointed by the Administrator to assist in evaluating applicants for accreditation as certifying agents.

7 CFR 205.509 Peer review panel.

##### **Other Resources**

ISO/IEC 17011:2004 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.