Guidance documents lack the force and effect of law, unless expressly authorized by statute or incorporated into a contract. USDA may not cite, use, or rely on any guidance that is not available through their guidance portal, except to establish historical facts.

Instruction
Internal Program Review

1. Purpose and Scope

This instruction clarifies and standardizes procedures to be followed by certifying agents accredited by the U.S. Department of Agriculture (USDA) National Organic Program (NOP) when conducting internal program reviews. This instruction is directed at certifying agents, who must satisfy additional USDA requirements as part of their accreditation. (See § 205.501(a)(21).)

2. Background

Section 205.501(a)(7) of the USDA organic regulations requires that certifying agents conduct an annual program review of their certification activities. The internal program review, also referred to as an internal audit, evaluates a certifying agent's certification system and procedures for the purposes of continuous improvement, by identifying issues prior to external audits as well as areas of strength and those needing improvement. This instruction establishes the minimum requirements for conducting internal program reviews.

3. Policy and Procedure

A certifying agent must conduct an annual program review of its certification activities. (See § 205.501(a)(7).) The results of the program review, as well as any adjustments made in response to the review, must be reported to the NOP annually. (See § 205.510(a)(4).)

3.1 Program Reviewer

The internal program review must be conducted by one or more of the following:

a. Certifying agent's staff
b. Outside auditor
c. Consultant

Qualified program reviewers must have the expertise to conduct such reviews, including knowledge of certification, auditing, and the USDA organic regulations as directed by § 205.501(a)(4). Internal program reviews are conducted by personnel different from those who performed the certification activity being audited.

3.2 Summary of Findings

The annual internal program review of all certification activities ensures adherence to the regulations. The review must be conducted in a planned and systematic manner and the results must be documented in a report, which must:

Guidance documents lack the force and effect of law, unless expressly authorized by statute or incorporated into a contract. USDA may not cite, use, or rely on any guidance that is not available through their guidance portal, except to establish historical facts.

a. Identify the dates on which the review was conducted;
b. Identify any findings;
c. Identify how any proposed corrective actions will be addressed in a timely and appropriate manner; and
d. Assess prior findings and implemented corrective actions of prior program reviews.

Personnel responsible for certification activities must be informed of the findings. Certifying agents must annually report to the NOP the program review results and any adjustments made in response thereto. Certifying agents must also maintain records of the internal program review.

4. References

USDA Organic Regulations (7 CFR Part 205)

§ 205.501 General requirements for accreditation.

(a) A private or governmental entity accredited as a certifying agent under this subpart must:

…

(4) Continuously use a sufficient number of qualified and adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the USDA organic standards.

…

(7) Have an annual program review of its certification activities conducted by the certifying agent's staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part that are identified in the evaluation;

§ 205.510 Annual report, recordkeeping, and renewal of accreditation.

(a) *Annual report and fees.* An accredited certifying agent must submit annually to the Administrator, on or before the anniversary date of the issuance of the notification of accreditation…

(4) The results of the most recent…annual program review and a description of adjustments to the certifying agent's operation and procedures implemented or to be implemented in response to the…program review.

Original Issue Date: August 2, 2013