Instruction
Responding to Noncompliances

1. Purpose

This instruction is intended to improve the quality of the corrective actions submitted by certifying agents.

2. Scope

This instruction affects accredited certifying agents who are responding to accreditation noncompliances relating to the NOP Regulations. However, certified operations and accreditation applicants may also find this instruction useful.

3. Background

During the accreditation process (documentation adequacy reviews (desk audits), onsite assessments, reviews, or complaint investigations), the NOP occasionally encounters certifying agents not complying with NOP requirements. When this occurs, the NOP issues a notice of noncompliance to the certifying agents. The certifying agents are required to respond to and correct the noncompliance(s) in a timely manner. The NOP often receives responses from certifying agents that are incomplete or missing information necessary to issue an accreditation decision. The NOP believes that by outlining expectations for addressing noncompliances, the following will occur: a reduction of multiple submissions relating to the same noncompliance, a reduction in noncompliance closeout time, and ultimately an improvement in consistency and efficiency of the accreditation process.

4. Policy

4.1.1 Certifying agents are required to submit corrective actions that adequately address noncompliances identified by the NOP and issued by the Accreditation Division. In general, certifying agents are cited noncompliances pursuant to Subparts E, F, and G of the NOP Regulation which correspond to accreditation requirements. As a basis for a citing a noncompliance of regulatory sections in these subparts, findings that demonstrate nonconformity may include citations of regulatory sections in other subparts of the NOP Regulation.

For example, a certifying agent may receive a noncompliance for the failure to adequately review an operation's certification application to determine compliance (§205.402 (a)(2)). As a basis for this noncompliance, a NOP auditor's finding revealed during a file review of a certified operation's Organic System Plan (OSP), a lack of evidence that the certified land had no prohibited substances applied to it for a period of 3 years. The operation is in violation of §205.202(b), Land Requirements.

5. Procedure

5.1 General Corrective Action Guidance

When responding to accreditation noncompliances, certifying agents are encouraged to:

5.1.1 Read the noncompliance carefully to understand the citation and the facts of the violation.

5.1.2 Communicate with the Accreditation Manager to clarify the details and intent of the noncompliance.

5.1.3 Understand that a corrective action consists of **five** components.

a. Correcting the cause of the noncompliance.
Describe the verifiable action that will bring the certifying agent into compliance.

b. Providing objective evidence supporting how the noncompliance was corrected.
Provide documented evidence to the NOP indicating that the noncompliance was corrected.

c. Preventing the reoccurrence of the noncompliance in the future.
Describe the verifiable action that will prevent a reoccurrence of the event.

d. Providing objective evidence supporting how the noncompliance will be prevented in the future.
Provide documented evidence to the NOP indicating the implemented actions are effective in preventing a reoccurrence.

e. Controlling noncompliant product, when appropriate.
Describe what verifiable actions have been taken to correct noncompliant product. Examples of this may be correcting product labels, removing product from distribution, etc.

5.1.4 Submit the corrective action proposal within the required timeframe as indicated in the original notice.

5.1.5 Organize the corrective action submission so that it can be readily understood and reviewed by the Accreditation Manager.

a. Identify what actions have been implemented to correct the noncompliance and prevent occurrence in the future.

b. Submit a plan of action (including a timeframe for completion) for corrective actions that have not been implemented, and

c. Submit objective evidence that supports the proposed corrective actions. Objective evidence is documented supporting existence that indicates current or future execution or implementation of corrective measures. Objective evidence must be provided for each noncompliance, showing how the noncompliance was corrected and will prevent noncompliance reoccurrence.

Examples of objective evidence

Training: Where training is indicated as a proposed corrective action response, a copy of the proposed training agenda, training materials to be used, an attendance list or sign in sheet, certifying agent policy memos and/or Quality Manual updates covered in the proposed training.

Organic System Plan (OSP) Updates: A copy of the updated OSP template and any related policy memo and/or Quality Manual updates made as a result to OSP modifications, along with details and documents supporting any proposed training.

Procedural Changes: A copy of the updated policy memo and/or Quality Manual update, standard operating procedure (SOP) update resulting from the proposed corrective action, along with details and documents supporting any training provided.

5.1.6 Submit the materials as one submission.

5.1.7 Be prepared to answer questions about the proposed corrective action submission and additional requests for information.

5.2 Review of Corrective Action Proposal

The Accreditation Manger reviews the certifying agent's proposed corrective actions. The review may prompt one or more of the following actions:

5.2.1 Requests for clarification and submission of additional material. Unless otherwise specified, the certifying agent must submit additional information within 10 days of the request.

5.2.2 Corrective action proposals associated with pre-decisional assessments and renewal assessments are sent to the Accreditation Committee for review and recommendations.

a. If the Accreditation Committee recommends approval of the corrective action proposal, then the Accreditation Manager will create a noncompliance correction/resolution notice and a *Corrective Action Review Report for final review and accreditation decision by the Deputy Administrator*.

b. In certain circumstances, the Accreditation Committee may recommend a compliance audit to verify that the corrective actions have been implemented prior to recommending resolution of the noncompliance.

c. If the Accreditation Committee recommends denial of the corrective action, the Accreditation Manager prepares a *Notice of Proposed Revocation or Suspension Notice* and a *Corrective Action Review Report* to the certifying agent for review and final accreditation decision by the Deputy Administrator.

5.2.3 Corrective action proposals associated with initial assessments, mid-term assessments or identified independently of an assessment are reviewed by the accreditation manager and a recommendation is directly forwarded to the Deputy Administrator for review and an accreditation decision.

a. If the Deputy Administrator approves the corrective action proposal, then the Accreditation Manager will issue a noncompliance correction/resolution notice to the certifying agent; a *Corrective Action Review Report* is also issued if the noncompliance is a result of an assessment.

b. If the Deputy Administrator denies the corrective action, then the Accreditation Manager will issue a *Notice of Proposed Revocation or Suspension* to the certifying agent.

NOTE 1: The NOP recognizes that there are numerous corrective action measures and corresponding objective evidence possibilities to address a noncompliance depending on the circumstances of the occurrence. The selection of the appropriate corrective action and objective evidence is determined by the certifying agent. The NOP will determine if the submitted materials adequately address the noncompliance.

NOTE 2: Once a corrective action is approved, the noncompliance is considered "Submitted and Accepted," but not "Cleared." A noncompliance is considered cleared when verified by the NOP or their agent. Depending upon the nature of the noncompliance, verification of the corrective action's effectiveness is normally conducted during the next scheduled onsite assessment; however, an earlier or unscheduled onsite could occur.

6. Records

According to § 205.510(b)(3) records created or received by the certifying agent pursuant to the accreditation requirements of this subpart F, excluding any records covered by § 205.510(b)(2), must be maintained for not less than 5 years beyond their creation or receipt.

7. References

NOP 2000 General Accreditation Policies and Procedures
NOP 2024 National Organic Program Annual Report Procedures

Document Control This document is a new document.

Approval

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