Responding to Noncompliances

1. Purpose

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

2. OCal ~~r~~Regulations,~~r~~ Title 3 California Code of Regulations (3 CCR)~~r~~

3 CCR § 10000. Definitions.

3 CCR § 10202. Land Requirements.

3 CCR § 10401. Requirements for accreditation.

3 CCR § 10502. Review of certification application.

3. Policy

Corrective actions must adequately address noncompliances identified by the department. While certifying agents are generally cited for noncompliance with regulations associated with accreditation and registration, they may be cited noncompliant with any section of the regulations, as appropriate.

For example, a certifying agent may receive a noncompliance for the failure to adequately review an operation's certification application to determine compliance (§ 10502(a)(2)). The basis for this noncompliance may be: "A department auditor's finding revealed during a file review of a certified operation's OCal 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 § 10202(b), Land Requirements."

4. Procedure

4.1. General ~~c~~Corrective ~~a~~Action ~~g~~Guidance

When responding to accreditation noncompliances, registered certifying agents should:

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

b. Communicate with the department to clarify the details and intent of the noncompliance.

c. Address the following five components in the proposed corrective action:
   1. Correcting the cause of the noncompliance. Describe the verifiable action that will bring the certifying agent into compliance.
   2. Providing documentary evidence supporting how the noncompliance was corrected. Provide documentary evidence indicating that the noncompliance was corrected.
   3. Preventing reoccurrence of the noncompliance. Describe the verifiable action that will prevent a reoccurrence of the noncompliance.
   4. Providing evidence supporting prevention of reoccurrence of the noncompliance. Provide verifiable evidence that implemented actions are effective in preventing a reoccurrence.
   5. 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.

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

e. Organize the corrective action submission so that it can be readily understood and reviewed by the Department.
   1. Identify what actions have been implemented to correct the noncompliance and prevent reoccurrence.
   2. Submit a plan of action (including a timeframe for completion) for corrective actions that have not been implemented.
   3. Submit documentary and other evidence of implementation of corrective action and prevention of reoccurrence.

Examples of documentary evidence

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

OCal System Plan (OSP) Updates: A copy of the updated OSP template and any related policy memo and/or Quality Manual updates, along with documents supporting any proposed or implemented training.

Procedural Changes: A copy of the updated policy memo and/or Quality Manual update, standard operating procedure update resulting from the proposed or implemented corrective action, and documents supporting any proposed or implemented training.

f. Submit the materials as one submission.

g. Be prepared to answer questions about the submission.

4.2. Review of ~~c~~**C**orrective ~~a~~**A**ction ~~p~~**P**roposal

The department may respond to review of the certifying agent's proposed corrective actions as follows:

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

b. Approval of the corrective action and issuance of a noncompliance correction/resolution notice to the certifying agent. The noncompliance is considered "submitted and accepted."

c. A compliance audit to verify that the corrective actions have been implemented. A noncompliance is considered "cleared" when verified by the department. Depending upon the nature of the noncompliance, verification may be conducted during the next scheduled onsite assessment or during an earlier onsite audit.

d. Denial of the corrective action and issuance of a Notice of Proposed Revocation or Suspension to the certifying agent.

5. Determining ~~c~~Corrective ~~a~~Actions and ~~e~~Evidence

The certifying agent shall determine the corrective action and supporting evidence. The department will assess whether the corrective action and evidence adequately address the noncompliance.

6. Records

6.1. Records obtained from applicants for certification and certified operations shall be maintained for not less than 5 years beyond their receipt.

6.2. Records created by the certifying agent regarding applicants for certification and certified operations shall be maintained for not less than 10 years beyond their creation.

6.3. Records created or received by a certifying agent pursuant to the accreditation requirements of the OCal Program or the National Organic Program (NOP), excluding any records covered by 6.2 above, shall be maintained for not less than 5 years beyond their creation or receipt.

7. References

National Organic Program ~~Regulations~~, Title 7, Code of Federal Regulations (7 CFR part 205)

7 CFR § 205.501. General ~~r~~**R**equirements for ~~a~~**A**ccreditation.