Corrective Actions Job Aid

Instructions: Review this Job Aid and policy documents, regulations, and inspection methodologies with a mentor.

Acronyms/Definitions

- Sanitation SOP – Sanitation Standard Operating Procedures
- HACCP – Hazard Analysis and Critical Control Point
- HACCP Noncompliance – The failure to meet any of the regulatory requirements of 9 CFR Part 417.
- Food Contact Surface (FCS) – Any surface that may come in direct contact with exposed meat or poultry product (e.g., conveyor belts, tabletops, viscera table, knives, saw blades, stuffers).
- Regulatory Control Action (RCA) – A regulatory action commonly taken by IPP to address specific problems described in 9 CFR 500.2 that IPP come upon when performing inspection (i.e., retaining product).
- Corrective Actions – Actions the establishment is required to take in accordance with the regulatory requirements.

Overview

- The establishment is required to take **Sanitation SOP corrective actions** when the Sanitation SOPs may have failed to prevent direct contamination or adulteration of products (9 CFR 416.15) and maintain records documenting the corrective actions taken (9 CFR 416.16(a)) (FSIS Directive 5000.1, Ch. II, Pt. III, Sec. VII.).
- The establishment is required to take **HACCP corrective actions** whenever there is a deviation from a critical limit or unforeseen hazard (9 CFR 417.3) and document a record of all corrective actions taken (9 CFR 417.3(c)) (FSIS Directive 5000.1, Ch. III., Pt. II., Sec. III., B.7.).
- If a HACCP noncompliance occurs, the establishment is expected to take immediate and further planned actions to correct the noncompliance and ensure any adulterated product is not shipped into commerce.
- There is no regulatory requirement for SPS corrective actions. If an SPS noncompliance occurs, the establishment is required to take actions to restore sanitary conditions in order to return to compliance with regulatory requirements.
- **Note:** While the establishment is required to maintain records documenting the corrective actions, there is no requirement that the establishment provide corrective actions in writing in response to a NR.

Basic Procedure

- Review the establishment's written programs and observe conditions in the establishment. When conditions support a determination of noncompliance, verify the establishment takes necessary actions to return to compliance.
    - **Note:** Not all failures require regulatory "corrective actions." However, the establishment is expected to return to compliance.

- When the regulations require specific corrective actions, verify that the establishment meets and documents those specific regulatory requirements:
    - Sanitation SOP (FSIS Directive 5000.1, Ch. V., Sec. IV)
        - When the establishment's **Sanitation SOPs may have failed to prevent direct contamination of products** (i.e., product has become contaminated or FCSs have become contaminated), verify that the establishment meets all requirements of 9 CFR 416.15 by reviewing Sanitation SOP records and, when possible, observing the establishment implement the following corrective actions:
            - Ensure appropriate disposition of affected product;
            - Restore sanitary conditions; and
            - Prevent recurrence of direct contamination or adulteration of products.
        - **Note:** When IPP or the establishment observe **contaminated FCSs before operations begin (pre-op) and there is no product present**, the establishment is only required to **restore sanitary conditions**.
        - Take a RCA by retaining the affected product or rejecting the affected equipment with U.S. Rejected/Retained tag(s); do not remove RCA until after the establishment has proposed corrective actions that restore sanitary conditions, and when appropriate, ensure the proper product disposition, and prevent recurrence of direct contamination or adulteration of products.
        - Document noncompliance when the establishment fails to meet the requirements of 9 CFR 416.15 using the appropriate Sanitation SOP verification task.
    - HACCP (FSIS Directive 5000.1, Ch. V., Sec. V)
        - When a **deviation from a critical limit** occurs, verify that the establishment meets all requirements of 9 CFR 417.3(a) by reviewing the corrective action records associated with the deviation and observing the establishment execute the following corrective actions:
            - Identify and eliminate the cause of the deviation;
            - Reestablish control of the CCP;
            - Prevent recurrence of the deviation; and
            - Ensure that no adulterated product enters commerce.
        - When an **unforeseen hazard** occurs, verify that the establishment meets all requirements of 9 CFR 417.3(b) by reviewing the corrective action records associated with the unforeseen hazard and observing the establishment execute the following corrective actions:
            - Segregate and hold the affected product;
            - Perform a review to determine the acceptability of the affected product;
            - Ensure that no adulterated product enters commerce; and
            - **Reassess the HACCP plan**.

        - Take a RCA by retaining the affected product when it becomes apparent the establishment intends to release product but cannot demonstrate that it is not adulterated (e.g., establishment signs pre-shipment review before performing necessary corrective actions).
        - **Note:** Verify the establishment applies corrective actions to **all product affected by the deviation or unforeseen hazard**. Consider:
            - How the establishment supports how they identified the affected product.
            - Information about the process that could indicate whether additional product was affected (i.e., HACCP records, Sanitation SOP records, establishment testing results, prerequisite program records, carrying rework over from one production to another).
        - Document noncompliance when the establishment fails to meet the requirements of 9 CFR 417.3.
- Assess the establishment's corrective actions, both Sanitation SOP and HACCP, in the context of the food safety system to identify trends and determine whether findings indicate a systemic problem.
    - Are the same or similar problems occurring repeatedly?
    - Is the establishment responding effectively to problems that arise?
    - Are the establishment's corrective actions effective in reducing the frequency of similar noncompliances or other findings?
    - **Note:** Whether FSIS or the establishment identifies the problem, IPP are to assess the establishment's corrective actions.

Discussion Points

- Review corrective action records documented by the establishment for a Sanitation SOP failure and a HACCP failure (deviation from a critical limit or an unforeseen hazard).
- Discuss the different aspects of corrective actions required by 9 CFR 416.15 and 9 CFR 417.3, respectively.
- Discuss how to verify the establishment's decision about which corrective actions apply.

Knowledge Check

- What type of HACCP failure requires the establishment to perform a reassessment of the HACCP plan as part of their corrective actions?
- Which corrective action requirements of 9 CFR 416.15 do not apply when IPP observe contaminated FCSs are observed before operations begin and **no product is involved**?

Resources

- FSIS Directive 5000.1 – *Verifying an Establishment's Food Safety System*
- FSIS Directive 5000.4 – *Performing the Pre-Operational Sanitation SOP Verification Task*
- IM Workbook – Sanitation Standard Operating Procedures (SSOP) and HACCP Verification Task