

Corrective Actions

This section covers how to perform your HACCP duties using the HACCP 01 and 02 procedures to verify compliance with the corrective action requirements.

The thought process the CSI should use when verifying regulatory requirements should include:

- **G**athering information by asking questions;
- **A**ssessing the information; and
- **D**etermining regulatory compliance.

Gather Information by Asking Questions

When there is a deviation from a critical limit, the CSI verifies that the requirements of 9 CFR §417.3(a) are met by comparing the corrective actions taken by the establishment to the requirements of the regulation. The CSI should verify the corrective action requirements as part of the HACCP 01 and 02 procedures. The CSI can verify these requirements by using the recordkeeping component or the review and observation component of the procedures. The corrective action requirements should be verified every time a deviation occurs.

To verify compliance with the corrective action requirements, the CSI seeks answers to the following questions:

1. Did the establishment identify and eliminate the cause of the deviation?
2. Did the corrective actions ensure that the CCP is brought under control?
3. Were measures implemented to prevent recurrence of the deviation?
4. Did the actions ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce?

Assessing Information

When assessing the information gathered, the CSI should do the following:

- Review the corrective action records associated with the deviation from the critical limit and observe the establishment executing the corrective actions.
- Compare the establishment's recorded corrective actions to the regulatory requirements listed in 9 CFR §417.3(a) to determine whether the

corrective actions taken in response to the deviation from the critical limit meets all of these requirements.

- Observe the establishment executing the corrective actions to verify that the establishment has identified the appropriate affected product.
- Observe the establishment executing the corrective actions to verify that the establishment has identified and eliminated the cause of the deviation.
- Observe the establishment executing the corrective actions to determine if the CCP is under control after the actions were taken.
- Observe the establishment executing the corrective action to verify that preventive measures are established.
- Observe the establishment executing the corrective actions to verify that the establishment prevents product that is injurious to health or otherwise adulterated as a result of this deviation, from entering commerce.

Determine Compliance

After the CSI has gathered and assessed all available information pertaining to the corrective action requirement, he/she must determine regulatory compliance. If the CSI finds that the establishment has met all these regulatory requirements, there is no noncompliance. If the CSI finds that the establishment has not met all these regulatory requirements, there is noncompliance.

Some examples of noncompliance are as follows:

1. The establishment did not identify the cause of the deviation from a critical limit.
2. The establishment identified the cause of the deviation from the critical limit, but did not take appropriate actions to eliminate that cause.
3. The establishment did not implement appropriate measures to ensure that the CCP is under control after the actions were taken.
4. The establishment did not implement measures to prevent the recurrence of the deviation.
5. The establishment did not take appropriate measures to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce.

The CSI will document any noncompliance using the corrective action trend indicator. The CSI may need to discuss concerns with the establishment and issue a 30-day reassessment letter.

Note: This requirement cannot be randomly verified because corrective action occurs when it is triggered by a deviation from a critical limit or an unforeseen hazard occurs. Anytime there is a deviation from a critical limit the CSI will verify that the corrective actions taken by the establishment meet the requirements of the regulation.

Example Part 1: The CSI arrives at an establishment which produces roast beef and is notified that a deviation of the cooling CCP has occurred. The CSI begins the corrective action verification by reviewing the HACCP plan.

CCP	Critical Limit	Monitoring	Verification	Records	Corrective Action
CCP 3 Cooling	Product temperature reduced from 130°F to 80°F in less than 1.5 hours and from 80°F to 40°F in less than 5 hours.	Product temperature will be monitored continuously throughout process using internal temperature probe. The two pieces will be visually selected by QC to represent largest pieces in the lot.	Daily, QC Supervisor will review cooling temp. chart	Cooling temperature chart Calibration log Corrective action log	All parts of 417.3 will be met

Next the CSI reviews the cooling temperature chart. The first part of the critical limit was met, but the product took 6 hours to reduce from 80°F to 40°F. The CSI observes that the product has been moved to the storage cooler, and is held and segregated by QC.

Example Part 2: Verifying §417.3(a)(1): Continuing, the CSI observes that maintenance employees are working on the cooling unit. The maintenance supervisor reports that one of the motors burned out, and is being replaced. The CSI determines that the establishment has identified and eliminated the cause of the deviation.

Example Part 3: Verifying §417.3(a)(2): Continuing, the CSI observes that the cooler unit is returned to production. The supervisor reports QC will observe the cooler temperature every hour through a complete cooling cycle, in addition to product temperature. The CSI determines that the CCP is under control.

Example Part 4: Verifying §417.3(a)(3): Continuing, the QC Supervisor reports that the HACCP plan is being modified to include a verification procedure for checking the cooler temperatures. The CSI reviews the HACCP plan. Verification has been modified to include: "Once per cooling cycle, QC will check cooler temperature." QC Supervisor informs the CSI that a new maintenance SOP has been established, to check cooler unit operation monthly. CSI determines that the establishment has established preventive measures.

Example Part 5: Verifying §417.3(a)(4): Continuing, the plant has held and segregated the affected product, and provided a processing authority with its cooling data points (time/temperature combinations) for the deviation. The processing authority has plotted the data into a pathogen modeling program and used other scientific literature to determine that there would be no outgrowth of *Clostridium botulinum* and no more than one log increase in *Clostridium perfringens*, based on the cooling curve that the product experienced. The report from the processing authority which indicates that the product is safe for distribution is attached to the corrective action log. The CSI determines that the establishment has prevented product that is injurious to health or otherwise adulterated, as a result of this deviation, from entering commerce. The CSI determines that the requirements for 417.3(a) have been met, and records 03G01 as an unscheduled procedure, marking it "a" performed.

Unforeseen Hazard

The thought process the CSI should use when verifying regulatory requirements should include:

- **G**athering information by asking questions;
- **A**ssessing the information; and
- **D**etermining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements.

Gather Information by Asking Questions

CFR §417.3(b) are met by comparing the corrective actions taken by the establishment with the regulatory requirements in 9 CFR §417.3(b). The CSI should verify that these requirements are met each time there is a deviation not covered by specific corrective actions, or an unforeseen hazard occurs. These requirements should be verified as part of the HACCP 01 or 02 procedures.

The CSI should ask the following questions to determine whether the corrective action requirements have been met:

1. Did the establishment segregate and hold all affected product?
2. Did the establishment perform a review to determine the acceptability of the affected product for distribution?
3. Did the establishment take necessary action with respect to the affected product to ensure that no product that is injurious to health, or otherwise adulterated as a result of the deviation, enters commerce?
4. Was a reassessment conducted to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan?

Assessing Information

When assessing the information gathered, the CSI should do the following:

- Review the corrective action records associated with the deviation or unforeseen hazard and observe the establishment executing corrective actions.
- Compare the establishment's recorded corrective actions to the regulatory requirements listed in 9 CFR §417.3(b)(1)(2)(3)(4) to determine whether the corrective actions taken meet all of these requirements.
- Observe the establishment segregating and holding all of the affected product to verify that the establishment segregated and held all affected product.
- Observe the establishment evaluating the affected product so that only acceptable product is released.

Determine Compliance

Sometimes a hazard may occur that the establishment had not anticipated in its hazard analysis, or if it did, it did not determine that the hazard was reasonably likely to occur. For example, the establishment did not identify *Listeria monocytogenes* as a hazard. An FSIS sample of the establishment's chicken salad (intact sample) had a positive result for *Listeria monocytogenes*. The establishment may not have considered this situation, but it is required to take corrective action to ensure food safety.

If an unforeseen hazard occurs, the CSI should verify that the establishment meets the regulatory requirements (§417.3(b)). The CSI must verify that the corrective actions the establishment implements meet all required parts of the corrective action regulation. Verify that these requirements are met **each time** there is a deviation not covered by specific corrective action or an unforeseen hazard by performing the HACCP 01 or 02 procedures.

After the CSI has gathered and assessed all available information pertaining to the corrective action requirement, he/she must determine regulatory compliance. If the CSI finds that the establishment has met all these regulatory requirements, there is no noncompliance. If the CSI finds that the establishment has not met all these regulatory requirements, there is noncompliance.

Some examples of noncompliance include the following:

1. The establishment did not hold all affected product.
2. The establishment held product, but it was not the product that was affected.
3. The establishment did not evaluate the product to determine whether it was acceptable for distribution.
4. The establishment evaluated the product and found it to be unacceptable for distribution, but did not take the necessary action to ensure that no product injurious to health or otherwise adulterated, as a result of this deviation or unforeseen hazard enters commerce.
5. A reassessment was not conducted to determine whether the newly identified deviation or unforeseen hazard should be incorporated into the HACCP plan.

Example (Part 1): The CSI is performing the 03G02 procedure in a poultry parts cooking operation to follow-up on an event that occurred earlier in the shift in which the establishment monitoring personnel found metal shavings on the parts after the batter and breading operation. The establishment decided that the metal would constitute a food safety hazard. The establishment has no CCP for metal contaminants.

The CSI reviews the corrective action log dated 5-4-2003 and finds the following entry for this incident:

All parts exiting the batter and breading system held by QA on trays and placed in the cooler. Parts were visually examined by production personnel for the presence of metal. Pieces with metal shavings were placed in inedible containers.

After deciding that too much product was affected, all parts on the trays and all parts in the batter and breading system were condemned. All products from the shift (exiting the blast freezer) will be held and run through a metal detector on 5-5-03. Such product will be held in freezer under QA tag. HACCP plan will be reassessed by 5-5-03.

Based upon the CSI's review of the records, the CSI determines that the recorded actions meet the requirements of §417.3(b).

The CSI observes the establishment executing corrective actions to verify that all affected product is segregated and held.

Example (Part 2): Continuing from the previous example, the CSI verifies that the establishment segregates and holds the affected product by going to the batter and breading system. The CSI finds no product exiting the system. The CSI finds no product on any trays in the cooler, but the CSI does see an inedible barrel over half filled with various denatured battered and breaded chicken parts. The CSI goes to the freezer and sees 5 skids of boxed product under a QA tag stating the product was to be run through a metal detector. Based upon the CSI's observations, the CSI determines that the establishment has adequately held and segregated affected product.