

## Corrective Actions

Before we elaborate on the corrective action requirements, let's review the difference between a *deviation from a critical limit* and a *HACCP noncompliance*.

A ***deviation from a critical limit*** is the failure to meet the applicable value determined by the establishment for a CCP. If a deviation from a critical limit occurs, an establishment is required to take corrective actions in accordance with 9 CFR 417.3.

A ***HACCP noncompliance*** is the failure to meet any of the regulatory requirements of 9 CFR part 417: monitoring, verification, recordkeeping, reassessment, and corrective action. If a HACCP noncompliance occurs, an establishment is expected to take immediate and further planned actions to correct the noncompliance.

NOTE: In every situation where there is a deviation from a critical limit, it is necessary for an establishment to take actions that meet the requirements of 9 CFR 417.3 and it is necessary for the CSI to verify that these requirements are met. CSIs are to verify that the required actions are taken by comparing the corrective actions taken by the establishment to the requirements of the regulation.

### A. Corrective Actions in Response to a Deviation from a Critical Limit

The regulation that applies to corrective actions taken in response to a deviation from a critical limit is:

**9 CFR Part 417.3(a)**—The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure: (1) The cause of the deviation is identified and eliminated; (2) The CCP will be under control after the corrective action is taken; (3) Measures to prevent recurrence are established; and (4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

This requirement cannot be randomly verified because corrective action occurs when something triggers it (a deviation from a critical limit). **Anytime** there is a deviation from a critical limit you will **always** verify that the corrective actions taken by the establishment meet the requirements of the regulation. This will be done as part of the 01 or 02 procedure. The recordkeeping component or the review and observation component can be used to verify these requirements.

The thought process you should use when verifying regulatory requirements includes:

**Gathering information by asking questions;**  
**Assessing the information; and**  
**Determining regulatory compliance.**

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

### **Gather information by asking questions**

To verify compliance with the corrective action regulatory requirements, you will seek 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?

### **Assess the information**

When seeking answers to these questions, you should:

- Observe the establishment executing the corrective actions.
- Review the corrective action records associated with the deviation from the critical limit.
- 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.

Now let's have a look at each of these in more detail.

### **Observing the Establishment Execute Corrective Actions**

In observing the establishment executing corrective actions, you should verify that the appropriate affected product has been identified.

#### ***Corrective Action Example 1, part 1:***

*Upon arrival at a raw ground beef patty operation establishment on your patrol assignment at 10:30 am, you are notified by the plant management that there has been a deviation of the metal detection critical limit. You thank the plant manager for voluntarily notifying you about this situation. You know that you must verify that the corrective action requirements are met, and realize you could do this by performing the review and observation component. You review the*

*establishment's HACCP plan and find that the monitoring procedure is that the packaging line supervisor will check the metal detector using a seeded sample every two hours to determine that the metal detector is functioning, that results are recorded on the metal detection control log, and that corrective actions are recorded on the corrective action log. You find that the corrective actions are "all parts of 417.3 will be met." You proceed to the production area and review the metal detection control log, and find the deviation noted at the 10:04 am monitoring check.*

*The form notes that the equipment failed to detect the seeded sample. You note that the form states that at the 8:00 check the equipment was operating properly. You observe that the establishment has product identified and segregated. You inspect the amount and the codes of segregated product and compare them to the codes on the monitoring record. You ask the packaging line supervisor about the segregation of product and are informed that all product produced after the 8:00 am check has been identified and segregated. You determine that the plant has segregated the appropriate affected product.*

## **Determine Compliance**

After you have gathered and assessed all available information pertaining to the records retention and availability requirement, you must determine regulatory compliance. If you find that the establishment has met all regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met all regulatory requirements, there is noncompliance. You will receive more information about making compliance determinations in a later section.

## **Noncompliance with Records Retention and Availability**

The following are examples of noncompliance with 417.5(e)(1)(2):

- 1. In October, you ask the establishment to provide a sample of the fecal CCP monitoring log records from last January. They give you a folder that contains February's records. You ask the establishment about January's records and they tell you they had to clean out the files because they were getting too full. The establishment cannot produce January's records. **The establishment is not maintaining records for the required length of time.***
- 2. In October, you are reviewing the establishment HACCP records for the sampling component of the steam pasteurization CCP in a large beef plant. You suspect the establishment is not maintaining records on site. You discuss this with your frontline supervisor and then you ask the establishment for the records from May. They tell you that they can give you the records for the past month but they will have to retrieve any*

*other month's records from the corporate headquarters 500 miles away. **The records are not being maintained on-site for 6 months.***

- 3. You are new to this assignment at a large poultry plant and are performing records maintenance verification as part of 03J01. You wonder about whether the establishment is able to retrieve records stored offsite and discuss this with your supervisor. You decide to ask the establishment to provide a sample of records from 7 months in the past. They tell you that after 6 months they store them at corporate headquarters. You request they retrieve the records from corporate headquarters. You receive the records 5 days later. **The establishment cannot retrieve the records within 24 hours when stored off-site.***

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

### **Regulatory noncompliance**

If you find that the establishment has not met all regulatory requirements, there is noncompliance. You will receive more information about making compliance determinations in a later section.

### **Noncompliance with the Computerized HACCP Records Requirement**

The following are examples of noncompliance with 417.5(d):

- 1. The establishment uses a computer-based system to monitor and record the temperatures in all processing rooms, coolers, and chillers. You request information about controls to ensure the integrity of the records, which the establishment is not able to provide. **The establishment does not have controls in place to ensure the integrity of the electronic records.***
- 2. The establishment uses a computer-based system to monitor and record the temperatures in all processing rooms, coolers, and chillers. You observe that on a warm day a processing room employee adjusts the computer settings so that the alarm will not keep going off. You observe that the passwords are prominently posted near the computer station. **The establishment has controls to ensure the integrity of the electronic records but is not following those controls. The passwords are not kept secure.***

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

You would observe the execution of corrective actions to verify that the cause of the deviation has been identified and eliminated.

**Corrective Action Example 1, part 2:** *Continuing with the above example, you continue to observe the establishment's actions in the production area. You observe that production has stopped. Maintenance employees are working on the metal detector, which is then removed from the area. The packaging line supervisor reports to you that the unit is malfunctioning, and that it will not be used until it is repaired. Later, the establishment informs you that the cause of the deviation was that water got into the machine during cleanup. They establish a new SOP for removing the machine from the area during wet cleanup. Based on these observations, you determine that the establishment has identified and eliminated the cause of the deviation.*

You would observe the execution of corrective actions to verify that the CCP is under control upon completion.

**Corrective Action Example 1, part 3:** *Continuing with the above example, you continue to observe the establishment's actions in the production area. The establishment brings in a replacement unit for the metal detector. The packaging line supervisor checks the replacement unit with the seeded sample, and the equipment responds appropriately. You observe production resume. The packaging line supervisor notifies you that they will perform the monitoring checks at an increased frequency of once per hour for one week. Based on these observations, you determine that the establishment has the CCP under control.*

You would observe the execution of 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.

**Corrective Action Example 1, part 4:** *Continuing with the above example, you return to the production area. You observe a monitoring check on the metal detector. Next you observe as the establishment begins to run the segregated product through the metal detector. No metal is detected, and the packaging line supervisor releases the segregated product. Based on these observations, you determine that the establishment has prevented product that is injurious to health or otherwise adulterated, as a result of this deviation, from entering commerce. You would observe the execution of corrective actions to verify that preventive measures are established.*

**Corrective Action Example 1, part 5:** *Continuing with the above example, it is now about two weeks since the deviation. You review the establishment's HACCP plan and find that a verification procedure has been added, to observe that the machine is placed in a dry room during cleanup. You go to the production area. You notice that the original metal detector, the one that malfunctioned, is back in place. You observe that the metal detector appears to be working. You review the monitoring records and observe that the monitoring*

*had been done at the increased frequency for one week, as proposed. Later, you observe that the machine is removed to a dry room during cleanup. Based on these observations, you determine that the establishment has established preventive measures.*

## **Reviewing the Corrective Action Records**

In reviewing the corrective action records, you should compare the establishment's recorded corrective actions with the requirements of 417.3(a).

***Corrective Action Example 1, part 6:*** *Continuing with the above example, you review the establishment's corrective action log for this deviation. You compare the recorded corrective actions with what you have observed, and with the requirements of 417.3(a), and find that all requirements were met. The establishment identified and eliminated the cause of the deviation, the CCP was under control after the corrective action was taken, measures to prevent recurrence were established, and no product that is injurious to health or otherwise adulterated, as a result of the deviation, entered commerce. You observe the record that shows the proposed maintenance repairs were performed. You determine that this requirement is met, and you record 03B01 as an unscheduled procedure, and mark it as (a) performed.*

## **Determine Compliance**

After you have gathered and assessed all available information pertaining to the corrective action requirement, you must determine regulatory compliance. If you find that the establishment has met all regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met all regulatory requirements, there is noncompliance. You will receive more information about making compliance determinations in a later section.

## **Noncompliance with the Corrective Action Requirements**

The following are examples of noncompliance with 417.3(a):

- 1. You are reviewing monitoring records for the TSP CCP in a poultry slaughter operation and you find that at 0800 the recorded TSP concentration was below the critical limit of 8%. You proceed to verify that corrective actions were taken as required in 417.3(a) by reviewing an excerpt from the entries in the corrective action log, which reads as follows:*

*“TSP concentration control dial was increased to 9% at 0805. Chlorine in the chiller was increased from 20 to 50 ppm and the post-chill chlorinated rinse cabinets were turned on at 0810.”*

*These actions are consistent with the corrective actions in the HACCP plan but you find no documentation and observe no evidence that the establishment attempted to **identify the cause of the deviation from the critical limit.***

2. Continuing from the example above, the establishment later documents that the deviation from the critical limit was due to a defect in the electronic apparatus that controls the TSP concentration. You find no record and no evidence that the establishment took any actions to repair or replace the electronic device. **The establishment identified the cause of the deviation from the critical limit but did not take appropriate actions to eliminate the cause.**

**Recordkeeping Example 8:** *You are performing the 03C01 procedure in a poultry cut-up operation and have randomly selected to verify the establishment recordkeeping requirements for the product storage CCP. You review the establishment's HACCP plan and find that the verification procedure is that QC personnel will check the product storage area temperature recording device (continuous process monitoring instrument) every two hours, and record the results on the chart. You review the chart and observe that the QC personnel have recorded actual time and temperature results for each entry, and initialed each entry, and that the date is recorded at the top of the form.*

*You notice that it is almost time for the next check and so you remain in the area and observe that the QC employee performs the check and records the results at the time of the check. You determine that this part of the recordkeeping requirement is in compliance because the entries are made at the time the event occurs, each entry includes the time, the form includes the date, and each entry is initialed.*

## **Determine Compliance**

After you have gathered and assessed all available information pertaining to the HACCP record authenticity requirement, you must determine regulatory compliance. If you find that the establishment has met all regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met all regulatory requirements, there is noncompliance. You will receive more information about making compliance determinations in a later section.

## **Noncompliance with HACCP Record Authenticity**

The following is an example of noncompliance with 417.5(b):

The HACCP plan has a monitoring procedure for checking temperature of incoming trimmings by checking 2 combos from each truck with a long-stem thermometer. You observe this record:

You observe the next truck unloaded. The plant employee “GM” performs the monitoring procedure on the combo bins, and does not enter the results on the form until much later in the day. You determine that there is a recordkeeping noncompliance. **One entry on the record does not contain the time the event occurred or the temperature. The records do not include the signature or initials of the person performing the activity. Results are not being recorded when the events occur.**

3. Continuing the example above, you review the corrective action records again and find that there was no follow-up measurement to verify that the TSP concentration was above the critical limit of 8% after the electronic control was turned up to 9%. **The establishment did not implement appropriate measures to ensure the CCP was under control after the actions were taken.**
4. Continuing the example above, if the establishment had not implemented the measures of increasing the chiller chlorination and turning on the chlorinated rinse cabinets, it could be assumed that **the establishment did not take measures to ensure that no product injurious to health or otherwise adulterated enters commerce.**

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

## **B. Corrective Actions in Response to a Deviation Not Covered by a Specific Corrective Action, or an Unforeseen Hazard**

The regulation that applies when a deviation not covered by a specific corrective action or an unforeseen hazard occurs is:

**9 CFR 417.3(b)**—*If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall: (1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met; (2) Perform a review to determine the acceptability of the affected product for distribution; (3) Take action, when necessary, 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) Perform or obtain reassessment by an individual trained in accordance with §417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.*

This requirement cannot be randomly verified because corrective action occurs when something triggers it (i.e., an unforeseen hazard or a deviation not covered by a corrective action. If an unforeseen hazard or a deviation not covered by a critical limit occurs, **always** verify that the regulatory requirements are met by comparing the corrective actions taken by the establishment with the regulatory requirements in 9 CFR 417.3(b).

These requirements should be verified as part of the HACCP 01 or HACCP 02 procedures.

The thought process you should use when verifying regulatory requirements includes:

- **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**

You should answer 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?

### **Assess the information**

When seeking answers to these questions, you should:

- Review the corrective action records associated with the deviation or unforeseen hazard 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(b)(1)(2)(3)(4) to

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

- Observe the establishment segregating and holding the affected product to verify that the establishment segregated and held **all** affected product.
- Observe the establishment evaluating the affected product to verify that only acceptable product is released.
- Review the corrective action records, determine if a reassessment was performed and, if so, verify that the establishment has supporting documentation for decisions made during the reassessment.

Now let's look at each of these in more detail.

### **Reviewing the Corrective Action Records**

In reviewing the corrective action records, you should compare the establishment's recorded corrective actions with the requirements of 417.3(b).

***Corrective Action Example 2, part 1:*** You are performing the 03J02 procedure in a poultry slaughter establishment to follow-up on an event that occurred earlier in the shift in which the establishment monitoring personnel found metal shavings on the carcasses exiting from the chill system. The establishment decided that the metal would constitute a food safety hazard. The establishment has no CCP for metal contaminants in the chill system. You review the corrective action log dated 2-1-2003 and find the following entry for this incident:

*All carcasses exiting the chill system held by QA in vats and placed in the cooler. Carcasses were visually examined by production personnel for the presence of metal. Metal shavings were removed from affected carcasses. All carcasses will be deboned and resulting product run through a metal detector system. HACCP plan will be reassessed by 2-3-2003.*

*Based upon your review of the records, you determine that the recorded actions meet the requirements of 417.3(b).*

### **Observing the Establishment Execute Corrective Actions**

You would observe the establishment executing corrective actions to verify that all affected product is segregated and held.

***Corrective Action Example 2, part 2:*** Continuing from the previous example in which there were metal shavings on the product, you verify that the establishment segregates and holds the affected product by going to the chiller and the cooler to observe the product. At the chiller, you find no product exiting the chiller since operations ceased an hour earlier. You find the affected product held by a QA tag and segregated in the cooler. Based upon your observations,

*you determine that the establishment has adequately held and segregated affected product.*

You would observe the establishment evaluating the affected product to verify that only acceptable product is released.

**Corrective Action Example 2, part 3:** *Continuing from the previous example in which there were metal shavings on the product, you observe the establishment examine and remove the metal contaminants, debone the carcasses, and run the boneless product through a metal detector. Upon completion of the establishment's corrective actions, you inspect several samples of boneless product and find no trace of metal contamination. Based upon your observations the establishment took necessary measures to ensure that only acceptable product was released.*

### **Determine if a reassessment was performed**

Verify that the establishment performed the reassessment and has supporting documentation for decisions made during the reassessment.

**Corrective Action Example 3:** *During a routine review of an establishment's HACCP plan for raw ground beef, you observe a notation that the HACCP plan has been reassessed, and updates made. You further observe that the establishment has added a CCP for receiving that reads "E. coli O157:H7 in raw beef trimmings" The critical limit is that suppliers must provide certification that products have been subjected to a validated antimicrobial carcass treatment. You decide to investigate further and ask for more information, and any supporting documentation, from plant management.*

*You learn that this reassessment was conducted as a result of an unforeseen hazard. You are shown a laboratory test result that the establishment conducted on finished product, which came back positive for E. coli O157:H7. This is the first positive result for this organism. The corrective action log shows that all corrective actions were met, and product was diverted for cooking. You are shown a record documenting the reassessment, which states that because of the positive result the establishment determined that E. coli O157:H7 was now considered "reasonably likely to occur" and therefore this update was made to the hazard analysis and HACCP plan. You are shown documentation the plant received from its supplier stating which antimicrobial treatment products received, and the specified reduction in the number of pathogens achieved. You determine that the establishment has met its requirement to perform reassessment when an unforeseen hazard arises, and to determine whether the unforeseen hazard should be incorporated into the HACCP plan. You determine that the establishment is in compliance, and you record 03B01 as an unscheduled procedure, and mark it as (a) performed.*

## Determine Compliance

After you have gathered and assessed all available information pertaining to the corrective action requirement, you must determine regulatory compliance. If you find that the establishment has met all regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met all regulatory requirements, there is noncompliance. You will receive more information about making compliance determinations in a later section.

## Noncompliance with the Corrective Action Requirements

The following are examples of noncompliance with 417.3(b):

- 1. Continuing from our above example in which metal shavings were found on carcasses coming out of the poultry chiller, if you found product in the cooler with metal shavings that the establishment had not held, you could conclude **that all affected product was not held.***
- 2. If the personnel collecting the birds coming out of the chill system had misunderstood which chiller was affected and held product from the wrong chill system, the establishment would have **held product but it would not be the affected product.***
- 3. If the plant did not thoroughly examine the product and pass the deboned product through a metal detector, the establishment **did not evaluate the product to determine whether it was acceptable for distribution.***
- 4. If the establishment found metal in the product after corrective actions were completed and did not hold the product, **the establishment did not take necessary action to ensure that no product injurious to health enters commerce.***
- 5. If the establishment **did not perform a HACCP plan reassessment** after the unforeseen hazard event, it would not be in compliance with 417.3(b).*
- 6. You are performing the 03B01 procedure in a small beef grinding operation and have randomly selected to verify the establishment recordkeeping requirements for all CCPs. You review a recent corrective action log that documents a large fecal smear observed on the boneless bull meat chucks as they were being prepared for grinding. Currently, the plant does not have a CCP for visual observation of raw materials. Under preventive measures on the corrective action log, "none needed" is recorded. You ask whether they considered this an unforeseen hazard, and whether they performed a*

*reassessment of the hazard analysis and HACCP plan. The QC manager replies “No, because this was the only time we’ve observed this.”* **A deviation not covered by a specific corrective action or an unforeseen hazard occurred, and a reassessment was not conducted.** You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.