

Corrective Actions

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

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. In addition, if the establishment uses the canning regulations in lieu of addressing microbiological contamination in a HACCP plan, failing to meet any thermal processing regulatory requirements (§318/381.300-318/381.311) is also noncompliance with §417.5(a)(1).

A ***process deviation*** is another term that is commonly used in canning establishments. The term ***deviation in processing***, or process deviation, is used whenever the actual process is less than the process schedule or when any critical factor does not comply with the requirements for that factor as specified in the process schedule. If a process deviation occurs, the establishment is expected to follow the canning regulations, 318.308/381.308.

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 this 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 corrective action 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 fermented dry sausage establishment at 0800, you are notified by the plant management that there has been a deviation from the minimum pH that must be achieved during fermentation for a lot of pepperoni. You thank the plant manager for voluntarily notifying you about this situation. You realize that you must verify that the corrective action requirements are met, and that 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 QA technician or designee will measure the pH of 3 individual samples from each lot at the completion of the fermentation cycle. Before product enters the heat cycle, the QA technician or designee will verify that a pH of 5.2 or less has been achieved at a

fermentation chamber temperature of 105°F in 14 hours or less. The pH results are recorded on the fermentation control log. You proceed to the QA lab and review the fermentation control log, and find the deviation noted at the 0600 monitoring check. The results are pH readings of 5.12, 5.28 and 5.26, after the 14 hours had elapsed. You review the corrective action log. It states that a processing authority at a university has been contacted and is in the process of reviewing the deviation, and that the product was moved to the cooler and placed on QA hold. It also indicates that the temperature of the starter culture freezer was 42°F instead of below freezing, which affected the viability of the starter culture. You observe the QA hold tags on the lot of pepperoni and verify that the lot number and the amount of product matches the monitoring record. You determine that the plant has segregated the appropriate affected product.

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 go to the room where the starter cultures are kept and observe maintenance employees working on the freezer. The maintenance supervisor reports that the cooling coils are worn out, and are being replaced. The plant manager is there and informs you that a new SOP for handling starter cultures, including the daily monitoring of the freezer temperature and a quarterly examination of the cooling parts, will be established. 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, later in the morning you return to the room where the starter cultures are kept and see that the work is done on the freezer and it is up and running. You notice several starter culture containers in the trash. The maintenance supervisor notifies you that they will monitor the freezer temperature 3 times a day for the next two days, and record the results on the record developed for the new SOP. Based on these observations, you determine that the establishment has the CCP under control. You will need to verify that the establishment does monitor the freezer temperatures as the maintenance supervisor stated and that what he said is documented as part of the corrective actions.

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 and see that an employee is loading racks of pepperoni sticks into the oven. You go to the QA office and question the QA technician about the plant's release of the lot of pepperoni. The QA technician tells you that the processing authority determined that the fermentation process was acceptable even though the critical limit was not met, because the rate of pH drop to 5.3 or below was within the "degree-hour" limit to prevent growth and enterotoxin production by *S. aureus*. You observe the corrective action log and find an attached e-mail from the processing authority with the degree-hours calculation and the website for American Meat Institute's Good Manufacturing Practices for fermented Dry and Semi-dry Sausage Products. The plant

has attached information from that website that supports the determination made by the processing authority. Based on these observations, you determine that the establishment has prevented product that would be 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 one week since the deviation. You review the establishment's SOP and find that it has instructions for the proper handling of starter cultures, including a procedure for monitoring the freezer temperature and maintaining the freezer in good repair. You review the SOP records and observe that maintenance personnel observed the freezer temperature 3 times for the first two days and once a day since then, as proposed. 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 determine that this requirement is met, and you record 03E01 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 the corrective action regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met the corrective action 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 fermentation step in a semi-dry sausage establishment and you find a pH of 5.3 or less was not achieved in the maximum hours, i.e., the degree-hour critical limit was not met, for a lot of summer sausage. A pH of 5.38 was achieved for the summer sausage. You*

proceed to verify that corrective actions were taken as required in §417.3(a) by reviewing the entries on the corrective action log, which reads as follows:

“The supplier of our meat starter cultures sent us cultures with the same organism but the culture was developed and prepared by a different manufacturer. We disposed of the remaining shipment of the cultures from that manufacturer and contacted the supplier and informed them of their error. When the next shipment of starter cultures from our supplier arrives, the manufacturer’s name on the container of the starter cultures will be verified before it is received. The lot of summer sausage was moved to the cooler and placed on QA hold. Fifteen 25g samples from the outer 1/8 inch of the sausage were selected from the lot and sent to an accredited lab for staphylococci testing. The results of the samples did not indicate high levels of staphylococci thus thermonuclease (enterotoxin) testing was not necessary (see the attached lab results). The lot was released and cooked. pH measurements from the finished lot of summer sausage were 5.18 and 5.20”.

You find no documentation and observe no evidence that the establishment **established measures to prevent the deviation from the critical limit from recurring.**

2. You are reviewing monitoring records for the cooking (lethality) step in a jerky establishment and find the critical limit of 90% or higher relative humidity was not maintained during the 2 hour cook cycle. Relative humidity is monitored every 30 minutes by comparing the wet bulb temperature reading to the dry bulb temperature reading. The wet bulb reading was not within 4.5°F of the dry bulb reading for the third and fourth monitoring checks. You proceed to verify that corrective actions by reviewing the corrective action log, which reads as follows:

“The oven operator failed to replenish the water in the wet-bulb thermometer well. The well was re-filled. The operator was counseled regarding the importance of filling the water well to the required level before the next cook cycle is started. The HACCP plan is being modified to include a procedure for verifying that the wet-bulb water wick well contains the appropriate amount of water prior to startup and once during the shift. The relative humidity will be monitored every 15 minutes on the average for the next four cook cycles”.

You review the HACCP plan and find that the verification column has been modified to include the new verification procedure. You find no documentation and observe no evidence that **the establishment took measures to ensure that no product injurious to health or otherwise adulterated entered commerce.**

3. You are reviewing the metal detection log in a snack stick establishment and find a deviation recorded at the 10:04 am monitoring check. The documentation on the log states that the machine failed to detect the metal in the seeded sample. The machine was operating properly at the last monitoring check that occurred at 7:58 a.m. You verify corrective actions by reviewing the corrective action log, which reads as follows:

“Production was stopped. All product produced after the 7:58 a.m. check was identified, segregated and run through a functional metal detector. No metal was detected, and the packaging supervisor released the segregated product. Maintenance personnel removed the nonfunctioning metal detector and replaced it with another functioning metal detector. The packaging supervisor checked the replacement unit with a seeded sample and it responded appropriately. Production resumed at 1:10 p.m. The packaging supervisor will perform monitoring checks at an increased frequency of every half hour for the rest of the day”.

*You find no documentation and observe no evidence that **the establishment identified and eliminated the cause of the deviation or established measures to prevent the deviation from the critical limit from recurring.***

4. *You are reviewing the product temperature log for the raw product storage CCP in a large fermented, non heat-treated, dry sausage establishment and find that one of the internal product temperatures recorded for the afternoon monitoring check in cooler 2 was 42°F, which exceeded the critical limit of 40°F. The recorded internal product temperatures for the morning monitoring check were lower than the critical limit. You proceed to verify that corrective actions were taken as required in §417.3(a) by reviewing the entries on the corrective action log, which read as follows:*

The internal temperatures of beef chucks in 3 combo bins along the north wall was 41°F, 42°F and 42°F. These combo bins were segregated and placed on QC hold in cooler 1. Combo bins with beef chucks with internal temperatures 40°F or below were moved to coolers 1 and 3. Maintenance personnel determined that the motor for one of the circulating fans in the refrigeration unit against the north wall had had a short. The motor was replaced. The time interval between the last acceptable monitoring check and the internal temperatures were plugged into a pathogen modeling program. Resulting growth curve indicated that the pathogens of concern would still be in the lag phase, thus no significant increase in the number of pathogens would occur. We found two scientific articles that support that it would take several hours at 42°F to get logarithmic increase in microorganisms and have included them in our supporting documentation file. An SOP has been established for the quarterly maintenance of the refrigeration units and the daily monitoring of a thermometer attached to the wall under each refrigeration units in the coolers. The 3 combo bins were released into production.

*You find no documentation and observe no evidence that **the establishment took appropriate measures to ensure the CCP was under control after the actions were taken.***

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:

- 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

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) and (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 03E02 procedure in a fermented dry sausage establishment in response to a positive Listeria monocytogenes result, which the establishment received in a sliced pepperoni sample it sent for laboratory analysis as a quarterly verification of the HACCP system. The establishment has a CCP in the HACCP plan, at receiving, for confirming that suppliers certify that they apply a validated antimicrobial intervention and conduct E. coli O157:H7 testing. The establishment has controls for raw material storage temperature in a prerequisite program. It also has CCPs for fermentation and drying (the products don't receive a heat treatment). At the slicing and packaging steps, the plant concluded that Lm was not a hazard likely to occur because of the interventions that occur in previous steps. The plant has supporting documentation on file that the final product pH and water activity reduces the numbers of E. coli O157:H7, Salmonella and Lm and inhibits their growth and the growth of sporeforming bacteria in the products. Therefore, the antimicrobial process is both a post-lethality treatment and growth inhibitor for Lm; and the plant has*

selected Alternative 1. You review the corrective action log dated 4-1-2005 and find the following entry for this incident:

“All affected product (pack codes 032605A and 032605B) was identified, segregated, and placed on QA hold in the finished product warehouse the day we submitted the sample to the laboratory. Since we don’t have a lethality step (cooking) in our process sufficient to destroy Lm, the affected product lots will be moved off-site on the morning of 4-3-05, under appropriate company control including the use of company seals, to our sister establishment, 38A, for proper disposition. Establishment 38A has both a cooking step and validated steam pasteurization post lethality treatment in the HACCP plan that would render our product free of Lm. The HACCP plan will be reassessed by 4-3-2005”.

*Based upon your review of the records, you determine that the recorded actions meet the requirements of §417.3(b). **You notify the DO via e-mail that the establishment intends to move product that tested positive for Lm off-site for proper disposition and provide the name and number of the establishment that will receive the product.***

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, you verify that the establishment has segregated and held the affected product by going to the finished product warehouse to observe the product. In the warehouse, you find 15 pallets of boxed product segregated and on hold with QA control tags. You have the packaging supervisor open a few boxes and find immediate containers with the correct lot codes on them. You examine production records and determine that the two lots of sliced pepperoni were the only products produced on that day. Based upon your observations, you determine that the establishment has adequately held and segregated affected product.*

You would observe the procedures the establishment implements to maintain control of adulterated product while in transit to the official establishment for proper disposition.

Corrective Action Example 2, part 3: *Continuing from the previous example, it is now the morning of 4-3-05 and you observe a forklift loading the affected product onto a truck trailer in the shipping bay. You go into the shipping office and ask the shipping supervisor how the establishment intends to maintain control of the product while in transit to ensure that it is received by establishment 38A. The supervisor shows you a record that has establishment 38A identified as the receiving plant and the numbers of the seals that are to be affixed to the trailer, the total number of pallets of product, total number of boxes, etc. He tells you that a copy of this record will be attached to the first pallet inside the door of the trailer and establishment 38A will fax a record confirming receipt of the product that will be attached to the shipping record. Based upon your observations, the establishment took necessary measures to ensure that it maintained control of the adulterated product during transit.*

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 2, part 4: *Continuing from the previous example, it is now 4-4-05 and you determine if the plant reassessed the HACCP plan by the date documented on the corrective action log. You review the corrective action log dated 4-1-2005 and find the following entry*

"...The HACCP plan will be reassessed by 4-3-2005. The HACCP plan was reassessed on 4-2-05 and modifications were made. SSOP was also modified".

Because the plant must reassess the HACCP plan as a result of the unforeseen hazard, you request the record documenting the decisions the plant made during the reassessment and observe the following:

"After evaluating the supporting data for the log reduction of Lm achieved by the fermentation and drying processes, we concluded that the positive Lm result was most likely due to Lm contamination during slicing and packaging. The positive Lm result suggests that the post-lethality treatment may have been challenged by the sanitation conditions in the environment. Since this is our first positive result for Lm, we still believe that Lm is not likely to occur in our process, but we are incorporating new sanitation measures to prevent Lm in the processing environment, and food contact surface testing for Listeria spp. to evaluate the effectiveness of such measures, into our SSOP. As a precaution, we are modifying the HACCP plan to include a new intermediate heat treatment CCP after the fermentation step prior to the drying step. The critical limit is an internal product temperature of 128°F or above for 1 hour or more".

You decide to investigate further and ask for supporting documentation from plant management for the critical limit at the new CCP and review the changes in the SSOP.

You are shown two scientific studies that applied this intermediate heat treatment to pepperoni which resulted in a 2-log lethality treatment for vegetative pathogens. The SSOP was modified to include the proposed changes. 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.

Verify that the establishment maintains records that show that the Lm positive product received the proper disposition.

Corrective Action Example 2, part 5: *Continuing from the previous example, it now two weeks from when the plant shipped the pepperoni that tested positive for Lm to establishment 38A for cooking. You ask the plant to provide documentation that the adulterated product was given a lethality treatment sufficient to destroy Lm. Copies of establishment 38A's HACCP records that show that the product received a heat process sufficient to destroy Lm, supporting documentation for the heat cycle parameters (time and temperature), and an original letter certifying that the product received the heat*

treatment are attached to the corrective action log. While reviewing the records, you notice that the plant has signed and dated the pre-shipment review. You determine that the establishment is in compliance with §417.3(b) and all other regulatory requirements for that specific production,, you record 03E02 as an unscheduled procedure, and mark it as "A" for 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 the corrective action regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met the corrective action 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 a RTE product sample submitted by the establishment tested positive for Lm, if you found evidence that product in addition to the two lots of pepperoni was produced on the same day and the establishment had not documented that contamination would be limited to an individual production line or individual products, you could conclude **that all of the affected product was not held.***
- 2. If the establishment **did not perform a HACCP plan reassessment** after receiving the positive sample result for Lm in a RTE product (the pepperoni), it would not be in compliance with §417.3(b).*
- 3. If the plant did not maintain appropriate control of the adulterated pepperoni while in transit (e.g., through company seals) to the official establishment (38A) for proper disposition, **the establishment did not take necessary action to ensure that no product injurious to health enters commerce.***
- 4. If the establishment did not receive documentation that provided evidence that the adulterated pepperoni had received a lethality treatment sufficient to destroy Lm from the official establishment (38A) where final disposition of the product occurred, **the establishment did not take necessary action to ensure that no product injurious to health enters commerce.***