

Documentation: Completing a Noncompliance Record (NR) and Trend Indicators

When documenting noncompliance on a Noncompliance Record (NR), do the following.

- Identify each noncompliance.
- Be specific and thorough, including time and location.
- Explain that plant management has received notification.
- State any regulatory control actions you took.

If you need further information about completing the NR, please consult FSIS Directive 5400.5.

When you determine that a HACCP noncompliance has occurred, you will complete a Noncompliance Record (NR), which will include marking the appropriate trend indicator.

HACCP Trend Indicators

There are four trend indicators for HACCP noncompliance: **monitoring, verification, recordkeeping, and corrective action.**

1. Monitoring

You will use the monitoring trend indicator when there is noncompliance with the monitoring requirement. The monitoring trend indicator would be marked if:

- a. The establishment is not monitoring the critical limit at the frequency stated in the HACCP plan.
- b. The establishment is not monitoring the critical limit using the prescribed procedures in the HACCP plan.
- c. A deviation from a critical limit exists that the establishment has no way of detecting.

Monitoring Trend Example 1: *You are verifying monitoring at the establishment's fecal CCP in a poultry slaughter operation. The establishment has a CCP for feces in the reprocessing area and the carcasses are dumped directly into the chill system after leaving this area. Monitoring personnel have already completed their observation of the carcasses and found no deviations; however, in your reinspection you find a carcass with feces on the leg. The establishment would be notified and an NR would be completed using procedure code 03J01 and the monitoring trend indicator. You would also perform an 03J02 procedure on that specific production. This would be a deviation that the establishment has no way of detecting since the deviation has gone undetected by the establishment controls.*

Monitoring Trend Example 2: You are performing an 03J01 procedure at a beef slaughter operation and observe establishment personnel perform a monitoring procedure by observing two consecutive carcasses at the final rail station for contaminants. From your review of the HACCP plan, you know that the HACCP plan specifies that the monitoring procedure will consist of ten consecutive carcasses observed for contaminants. You check the records and find no explanation why only two carcasses are being observed. You would notify the establishment, complete an NR for 03J01, and mark the monitoring trend indicator. You would also perform an 03J02 procedure on that specific production. The establishment is not monitoring the critical limit using the prescribed procedures in the HACCP plan.

Monitoring Trend Example 3: You are performing an 03J01 procedure at a pork slaughter operation and have selected to verify the monitoring requirement. You review the HACCP monitoring records for the antimicrobial rinse CCP. It is four hours into the shift, and you note that QA personnel have not yet recorded a procedure for monitoring the pressure and concentration of the rinse. From reviewing the HACCP plan, you know it specifies that monitoring will be performed every two hours for pressure and concentration of the rinse at this CCP. You request any further information available about the apparent missed monitoring, which the establishment cannot provide. You would notify the establishment, write an NR for 03J01, and mark the monitoring trend indicator. You would also perform an 03J02 procedure on that specific production. The establishment is not monitoring the critical limit at the frequency stated in the HACCP plan.

2. Verification

The verification trend indicator should be used when:

1. The establishment is not conducting the verification activities as described in the HACCP plan.
2. The establishment is not conducting the verification activities at the frequencies prescribed in the HACCP plan.
3. The establishment has a positive FSIS *E. coli* O157:H7 sampling result.

Verification Trend Example 1: You are performing the 03C01 procedure in a multi-shift mechanically deboned chicken operation and have randomly selected to verify the establishment verification requirements. You review the establishment's HACCP plan and find one of the verification procedures specifies that the HACCP Coordinator will observe QC personnel perform the monitoring check for product exiting the deboning machine once per shift. You review several recent temperature logs and observe that the HACCP Coordinator has recorded results for the verification procedure for each day rather than each shift. You ask the HACCP Coordinator about the apparent missed verification procedures, but no further information can be provided by the establishment. You determine that this requirement is not in compliance because the verification procedures are not being performed at the frequency specified in the HACCP plan. You would document this finding on an NR and mark the verification trend indicator.

Verification Trend Example 2: Continuing with the above example, you decide to observe the next verification procedure and accompany the HACCP Coordinator to the deboning machine. You observe the HACCP Coordinator perform a temperature check of the product. The QC personnel are not present in the cooler. You observe the HACCP Coordinator record this on the temperature log as a direct observation verification procedure. You determine that this requirement is not in compliance because the verification procedure is not being conducted as described in the HACCP plan. You recall that a plant verifier conducting the same activity as the monitor does not meet the regulatory requirement for the direct observation verification activity described in 9 CFR 417.4(a)(ii). You would document this finding on an NR and mark the verification trend indicator.

3. Corrective Action

The corrective action trend indicator should be used when corrective actions taken by the establishment in response to a deviation from a critical limit, or unforeseen hazard, did not meet the requirements of 417.3 because they did not:

1. Adequately address identifying and eliminating the cause of the deviation.
2. Include measures to ensure that the CCP is under control.
3. Include measures to prevent the deviation or unforeseen hazard from recurring.
4. Include appropriate disposition of the product.
5. Conduct a reassessment, if an unforeseen hazard was identified.

Corrective Action Trend Example: You are performing the 03B01 procedure in a ground turkey operation. You realize that you should verify the corrective actions whenever a deviation occurs. You also realize that the plant does not have to notify you of the deviation when it occurs. Therefore, you regularly review the corrective action logs, and ask QC personnel about any current corrective actions that are taking place. When you arrived and walked through the plant today, you observed that the QC department has put a production hold on a particular lot of product and you decide to investigate. You observe that yesterday's monitoring log for chilling recorded a deviation; product was not within the critical limit for temperature. You review today's monitoring log, observe the chilling equipment, and take a measurement. You conclude that the equipment appears to be working properly. You review the corrective action log and find that it includes documentation of the deviation found at monitoring and the measures taken to ensure that the CCP is under control. You find a notation that the product is being held pending microbiological tests to be reviewed by a processing expert. You ask for further information but this is all that the establishment has available. You determine that there is a noncompliance; corrective actions did not include adequately identifying and eliminating the cause of the deviation, and there are no measures to prevent the deviation from recurring. You would document this finding on an NR and mark the corrective action trend indicator.

4. Recordkeeping

The recordkeeping trend indicator should be used when:

1. The monitoring records do not include the actual times, temperatures, or other quantifiable values, the calibration of process monitoring instruments, corrective actions, verification procedures and results, product identity, signature or initials of the person making the entry, or the date the record is made.
2. The establishment does not have the decision-making documents associated with the selection and development of the CCPs and critical limits, and documents supporting both the monitoring and verification procedures and frequencies.
3. The establishment did not conduct the pre-shipment review.
4. The establishment is not retaining HACCP records for the required length of time.

Recordkeeping Trend Example 1: *You are performing the 03B01 procedure in a raw ground beef patty 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 monitoring procedure is that QC personnel will check the product storage area temperature every two hours, and record results on the room temperature log. The critical limit at this CCP is room temperature not to exceed 45° F. You review the current room temperature log.*

Temperature Log		Date: 5-11-04
Time	Temperature	Monitor initials
1:00 pm		JP
3:00 pm		JP

Based on your observations, you determine that this part of the recordkeeping requirement is not in compliance because check marks rather than the actual temperature results are being recorded. You would document this finding on an NR and mark the recordkeeping trend indicator.

Recordkeeping Trend Example 2: *Continuing with the above example, you request supporting documentation from the establishment. Specifically, you ask the establishment how it has validated that the room temperature correlates with the product temperature, how it has determined the critical limit is adequate to control the hazard, and how it has determined that the monitoring frequency is adequate. The plant manager responds with "we have plenty of historical data," provides you with all of the past room temperature logs, and notifies you that they have never had a deviation from the critical limit at this CCP. You determine that the establishment has not met the requirements of 9 CFR 417.5(a) because it does not have decision-making documents associated with the selection and development of CCPs and critical limits, and documents supporting the monitoring procedures and the frequency of those procedures. You decide to contact the District Office to inform them that you have concerns about the design of this HACCP plan.*