

HACCP Noncompliance Classification Indicators

1. Monitoring

You will use the monitoring noncompliance indicator when there is noncompliance with the monitoring requirement. The monitoring noncompliance 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 Noncompliance Example: You are verifying monitoring at the establishment's cooking CCP in a semi-dry sausage establishment. The establishment has a monitoring procedure of taking two temperatures at the completion of the cooking cycle for each smokehouse. You decide to perform review and observation, and proceed to the smokehouse area. You observe the smokehouse operator take only one temperature and record it. You look at the record and see that for most of the lots cooked today, only one temperature is recorded.

2. Verification

The verification noncompliance 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, *Listeria*, or *Salmonella* sampling result in its RTE product.

Verification Noncompliance Example: You are performing the 03F01 procedure in a jerky establishment, and have selected to verify the verification requirements. The jerky HACCP plans call for records review verification of monitoring records to be conducted daily. You review recent records and observe that for the last week, there are no verification records review results recorded. You gather more information and determine that the verification was not performed. (If it had been performed, but not recorded, then the verification

noncompliance indicator is not appropriate.)

3. Corrective Action

The corrective action noncompliance 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 after a deviation occurs.
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 Noncompliance Example: You are performing the 03D01 procedure at an establishment which produces meals in retortable pouches. You realize that you should verify the corrective actions whenever a deviation occurs. You regularly review the corrective action logs and ask QC personnel about any current corrective actions that are taking place. Today you observed that the QC department has placed a hold on a lot and you decide to investigate. You see that this morning's monitoring log for the metal detection equipment recorded a deviation, the equipment did not operate properly when checked with the seeded sample. You review the corrective action log and see that it includes documentation of the deviation, that all effected product is being held, with a notation showing it is to be destroyed. There is no documentation that the cause of the deviation was identified and eliminated, that the CCP is under control, or that measures were taken to prevent the deviation from recurring.

4. Recordkeeping

The recordkeeping noncompliance 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.
5. The establishment does not have controls to ensure the integrity of computer-maintained records.

Recordkeeping Noncompliance Example: You are performing the 03F01 procedure in a dry sausage operation and have randomly selected to verify the establishment recordkeeping requirement for pH at the fermentation CCP. You review the HACCP plan and find that the monitoring procedure is that QC will take three pieces from each smokehouse, check the pH of each, and record the results. The critical limit is 4.9 or less. You review the current fermentation log.

Fermentation log		Date: second shift	
Time	pH	Temperature	Monitor initials
1:00 pm lot c	4.9, 4.8, 4.8	109, 110, 108	X
1:29 pm lot d	4.8, 4.7, 4.8	111, 110, 110	
1:58 pm lot f	4.9, 4.9, 4.8	109, 110, 109	FT

Based on your observations, you determine that this part of the recordkeeping requirement is not in compliance because the date is not recorded and the monitor did not initial the results.