

Determining Noncompliance

If the answer is **yes** to **1, 2, and 3** and **no** to **question 4**, then there is **no noncompliance that you would document**, because the establishment has already identified and addressed the situation.

Not writing an NR will not adversely affect your ability to track developing trends for deviations because the establishment must provide corrective actions. An establishment's failure to follow through on corrective actions or on further planned actions for HACCP noncompliances could lead to recurring noncompliances that would warrant an NR for recurring situations (trends).

If the answer is **no** to **questions 1, 2, or 3**, or **yes** to **question 4**, then there is a **noncompliance that you would document**.

Examples of Noncompliance Determinations

The following scenarios all use monitoring examples. The methodology applies to problems with verification, recordkeeping, corrective actions, and reassessment as well.

Situation 1

While performing an 01 HACCP procedure records review, you find that a plant employee missed a 9:00 a.m. monitoring check. You also find that the plant found the error during its records verification, demonstrated product safety with other records, and took immediate corrective and preventive measures for the noncompliance by retraining the employee. You looked at previous NRs and determined that the plant had not missed a monitoring check in over three months.

Outcome

In this situation no NR is necessary even though there was a missed monitoring check, and you mark the 01 procedure as performed. However, if you find that adequate preventive measures were **not** in place, and that the missed monitoring check and correction had occurred several times within the month, you may determine that a trend for monitoring noncompliance has developed. In this case, issue an NR and discuss this trend with plant management during the weekly meeting.

Situation 2

While performing an 01 HACCP procedure records review, you find that a plant employee missed a 9:00 a.m. monitoring check and there is no indication that the plant identified the missed monitoring check. You write an NR for the 01 procedure. When you perform the 02 procedure, you find that the product was shipped without a pre-shipment review.

Outcome

In this situation you write another NR, but for the 02 procedure this time, that explains this noncompliance. Next you determine whether the plant can provide other documentation that establishes product safety. If the plant cannot demonstrate product safety, take action per part 500.

Situation 3

While performing the recordkeeping component of the 01 HACCP procedure, you see that a plant employee recorded a deviation from a critical limit on the monitoring record. You verify that the corrective actions taken by the plant did meet the requirements of 417.3(a).

Outcome

There is no regulatory noncompliance, and an NR is not issued.

Situation 4

While performing an 02 procedure records review for a single lot of product, you see in the records that a plant employee missed a monitoring check at 10:00 a.m. and had a deviation from a critical limit at 11:00 a.m. You continue reviewing the records and find that at pre-shipment review the plant identified the deviation and took the proper §417.3 corrective and preventive measures but failed to address the monitoring error.

Outcome

In this situation, write an NR for the monitoring error and determine whether the plant can demonstrate product safety relevant to the missed monitoring check. If so, no other action is necessary. If the plant cannot support product safety, take action per part 500.