

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 are examples of situations that will require a determination of noncompliance.

Example 1: While performing an 01 HACCP procedure records review, you find that an establishment employee missed a calibration procedure. You then find that the establishment found the error during its records verification, demonstrated product safety with other records, and took immediate and further planned actions for the noncompliance by re-training the employee. Also, you looked at previous NRs and determined that the establishment had not missed a calibration check in over a year. In this situation no NR is necessary, even though there was a missed calibration check, and the 01 procedure is marked as performed.

However, if you find that actions were not in place, and that the missed calibration check and correction had occurred several times recently, you may determine that a trend for verification/calibration noncompliance has developed. In this case you will issue an NR and discuss this trend with establishment management during the weekly meeting.

Example 2: While performing an 01 HACCP procedure records review, you find that an establishment employee missed a 9:00 a.m. monitoring check and find no indication that the establishment identified the missed monitoring check. You write an NR for the 01 procedure. Then you perform an 02 procedure and find that the product was shipped without a pre-shipment review. In this situation you would write an NR that explains this noncompliance. Next you would determine whether the establishment can provide other documentation that establishes product safety. If the establishment cannot demonstrate product safety, you would take action in accordance with the Rules of Practice, 9 CFR Part 500.

Example 3: While performing the 01 HACCP procedure records review, you observe that an establishment employee recorded a deviation from a critical limit on the monitoring record. You verify that the corrective actions taken by the establishment meet the requirements of §417.3(a). There is no regulatory noncompliance, and an NR is not necessary.

Example 4: While performing an 02 procedure records review for a lot of canned product, you see in the records that an establishment employee missed a can teardown check at 10:00 a.m. You continue to review the records and find that at pre-shipment review the establishment identified the missing check and took the action to demonstrate product safety relevant to the missed can teardown check. In this situation no NR is necessary even though there was a missed teardown check, and the 02 procedure is marked as performed.

However, if you find that actions were not in place, and that the missed teardown check and correction had occurred several times recently, you may determine that a trend for canning regulation noncompliance has developed. In this case you will issue an NR and discuss this trend with establishment management during the weekly meeting.

If the establishment cannot demonstrate product safety, you would take action in accordance with the Rules of Practice, 9 CFR Part 500.