10.2 Nonconformity and Corrective Action

This procedure sets the requirements for a minimal, efficient and non-bureaucratic corrective action plan system; they represent an excellent corrective action system, and we highly recommend adopting this simple system.

However, your company may already have a different system that meets ISO 9001:2026 requirements, or your company's culture may require a more formal process or a completely electronic or intranet-based process. In either case, feel free to make your modifications, but the modified procedure must still define how your company takes corrective actions to eliminate the causes of nonconformities in order to prevent those nonconformities from recurring or occurring elsewhere.

If your company uses a software solution for the corrective action process, add the details to this procedure and make the necessary adjustments. Existing systems can be used; dedicated corrective-action software is not required.

Step 1: An Existing Problem Is Identified and Handled

Your company may have additional or different ways of identifying a problem; make any changes in this section.

Keep the distinction between correcting the immediate problem and preventing its recurrence. For example, replacing an incorrect delivery fixes that delivery. Finding and addressing why the wrong item was selected prevents further incorrect deliveries.

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Step 2: Root Cause Analysis

Be sure that any modification you make still stresses the importance of root cause analysis, as there is a common misconception that the repair or correction of the identified problem represents the corrective action. If the root cause is not identified and corrected, the problem is likely to recur.

The “5 Whys” approach is just one way of performing root cause analysis; it is a simple yet effective method that is easy to explain to management and staff. However, feel free to replace it with a different approach if more appropriate for your company. There is no need to ask exactly five questions or prepare a lengthy investigation for a simple problem.

Check whether the same cause could affect other work. For example, an outdated instruction may also be in use on another shift, or the same incorrect setting may be used on other machines. Address the relevant work together rather than waiting for another failure.

Step 3: Do We Need to Do Anything?

We highly recommend that you keep this section. It allows for flexibility. Remember that you will have to do what your procedure requires.

Match the response to the likelihood of recurrence and the effects of the problem. Consider customer and legal requirements as well as the cost and benefit of action. A simple correction may be enough for an isolated mistake; repeated mistakes may indicate a process problem that needs corrective action.

Example: An employee enters the wrong reference on an internal filing label. The error is corrected, and a brief check shows that the instructions are clear and this is an isolated mistake. No wider action may be needed. If incorrect references keep appearing because two fields on the screen are easily confused, changing the screen or instructions and checking the result would address the cause.

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