

- Determination of potential nonconformities and their causes;
- Evaluation of the need for action to ensure that these potential nonconformities will not occur;
- Determination of the actions needed; actions are appropriate to the effects of the potential problems;
- Implementation of the action;
- Establishment and maintenance of records of the results of the actions taken in compliance with Chapter 2.3;
- Review of the effectiveness of the preventive action taken.

Modification tips:

- If your company uses a software solution for the corrective and/or preventive action process, add the details to this procedure and make the necessary adjustments.
- Your company may have additional or different ways of identifying a problem; make any changes in “An existing problem is identified”.
- Be sure that any modification you make still stresses the importance of the root cause analysis as there is a common misconception that the repair/correction of the identified problem represents the corrective action. Even for potential problems, it is most important that the root cause is corrected; if the root cause is not identified and corrected, it is unlikely that the potential problem can be prevented from occurring. The “5 W Approach” is just one way of performing root cause analysis; feel free to replace it with a different approach if more appropriate for your company.
- We highly recommend that you keep the section “Do we need to do anything?”. It allows for flexibility. Remember that you will have to do what your procedure requires.
- You may be more specific on the documentation, record keeping and review process.
- Make any other modifications depending on your company’s processes.

Once you completed customization of these four chapters, you will have achieved the documentation of the six required ISO 9001:2008 Quality Procedures specifically for your company.

Customizing the Rest of this Manual

This manual not only fully integrates the six required procedures, it also goes a step beyond the requirements of a quality manual by including more detailed processes and procedures for all sections of ISO 9001:2008. While this feature makes this manual a very useful business tool, it also means that more customization may be required.

We recommend that you change the requirements of this manual only if they don’t apply to your company, as this manual contains excellent processes that are efficient and non-bureaucratic. If you make changes to the requirements, we advise you to consult the ISO 9001:2008 standard and a good interpretation of the standard.

The following tips will help you customize the rest of this manual. However, you should carefully review the entire manual in order to identify and modify any sections that don’t apply to your company’s specific circumstances.