

Quality & Productivity Solutions, Inc.

Getting Ready for ISO 9001:2008

What are the changes in the new standard?

Mostly minor changes or additions to the notes sections to help clarify some of the requirements. Some of the changes are to improve compatibility with ISO 14001 the environmental standard. If you are not moving towards ISO 14001, you should, even if you do not have hazardous waste or use chemicals. ISO 14001 demonstrates to your customers and communities that you are doing your part to keep the environment clean. ISO 14001 fits very nicely into your existing QMS with a few additions. There have been changes to the notes sections to be a little more specific and some wording changes, so read carefully. Even though the changes are minor, this is a good time to evaluate your QMS. Do you have all the processes identified vs the process approach? Is your QMS still based on the old element approach? It's time to improve the QMS and make it more effective.

When does the new standard take affect?

It will be published late in 2008 and will take affect at your next surveillance or re-certification audit. Basically starting in 2009 registrars will be asking some questions based on the new standard and checking to ensure you have a copy of the latest standard as part of your external document list. (Hint: order one and update your list) Your company has actually 24 months to comply with the new standard, but once released the auditor can ask questions based on the new standard.

This is also a good time to review your entire QMS.

Does it match what we are doing today?

Have there been any changes in the business that we should revisit?

How effective are our corrective actions?

What metrics are not improving?

Do our policies and procedures make sense?

Is the QMS meeting our needs?

Will our QMS meet our future needs?

Why don't we have preventive actions?

Is our training effective? Are our employees competent?

These are just a few questions you should be asking about your QMS. In addition if you are registered to industry specific ISO standards, such as the Automotive 16949 or Aerospace 9100 they will eventually be upgraded to the new 2008 ISO structure.

Other questions that people are asking; do my auditors need to be retrained on the new standard? They should be updated on the new standard and ensure they are using the process approach when auditing. They should have a copy of the new release for reference purposes. Do employees need to be retrained on the new standard? Again, this would be a good time to refresh everyone on objectives, training and awareness.

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Employees should be informed that there is a new version of ISO 9001:2008. There is one change that you may need to investigate; the management representative must be a member of the (top) management team. Some companies are using consultants or third party people acting as management representatives or lower level people who do not represent management.

Recommendations:

1. As soon as the standard is released, purchase a copy and review the changes and determine how they will affect your QMS. Make sure you update your external document list (New Standard).
2. Present the changes at the next management review to discuss. This could be a finding because the requirements have changed and there should be discussion on how they affect our QMS.
3. Have the management representative and/or auditors attend a training class on 9001:2008 to ensure understanding. (see our website www.qpsinc.com)
4. Start reviewing with your registrar during surveillance audits to determine any gaps that may exist.
5. Start discussing how the QMS can be improved to make the company more successful. (see our website for more information))
6. Incorporate Lean & Six Sigma into the improvement process. (see our website for more information)

How can my QMS save me time and money?

Incorporating Lean & Six Sigma into the QMS will help you save time and money by eliminating waste and reducing variation in the process. ISO is not a method to save money, it is a management system designed to establish a foundation for improvement. We document the order entry process, but ISO does not address the time consumed or the cost of the process or the cause of defects or errors. ISO 9001:2008 is only a basic quality system, we need to use Lean & Six Sigma to take it further and continue to make more effective.

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