

Date: November 28, 2003

Topic: Quality Manual Development

How did you accomplish this topic during your implementation?

We assigned a senior Quality Engineer as the chief editor of this document. The person needs to be familiar with the processes in use, organizations and their functions, as well as good knowledge of the standard. Numerous reviews were conducted within QE, with the Core Team and management team. Executive Sponsor approved the final version before release.

What resources/tools/vendors were used to accomplish this task?

Just use the simple Microsoft Word. We got rid off the old tool: Frame.

Was there any benchmarking activity?

No.

What lead you to use this method?

Nothing particular.

What worked and what didn't work?

Those worked well:

- We had a much-focused effort with some good support from the team. Having the right person for this job is important.
- Teamwork is also essential since its contents are so diversified.

Those did not work well:

- Identify exceptions may not be a straightforward exercise.
- Keep up with organization changes during the development of this document is also a challenge.
- Find process linkages to groups outside our scope, especially those who have not implemented QMS yet, may not be easy too.

What recommendations do you have for others attempting to use your method?

Don't underestimate the total effort of this task. It is a major governing document. Clear and precise description will benefit not just the team member to understand the system and also the external auditors that can make the audit smoother.

How did you measure the effectiveness of this method?

No significant comments back from the external auditors. We got the acceptance of our Quality Manual from our auditor within days with no questions asked.

Other comments on the Implementation Guide TOC:

Standard-oriented versus business process oriented Pros and Cons:

We have started the initiative of developing a Business System Management Document (BMSD) to replace the Quality Manual as the top-governing document. This BMSD incorporates the idea of Malcolm Baldrige and other industry quality benchmark, along with the TL 9000 requirements, on top of our business model. The goal of QMS is to improve our business performance. It has to link to our business objectives. Today's Quality Manual normally covers only the specific group in the QMS scope. BMSD allows us to look end-to end in our company and describes how all

groups can interact together to achieve the final objectives. This will also help us to achieve a consolidated QMS across our business line.

BMSD does not describe the standard compliance in details any more. I think we still need to keep most of the contents described in the Quality Manual and down grade it as the standard compliance document which is still required for implementing and managing the QMS.

Handling of exceptions:

My QMS scope is R&D for product development (mainly software). There are areas outside our scope but covered by other functional groups within the company. There are also areas not applicable to our company (either not performed or done by outsourcing). We developed a Matrix of Applicability and went through the rational of exception for each clause. This Matrix needs to be updated every year.