

### *In this Issue:*

#### *Is Six Sigma a Replacement for a Quality Management System?*

Recently a very good article written by Mr. Mike Micklewright was published in *Inside Six Sigma*. The article identified that Six Sigma and lean manufacturing techniques should not be used as stand alone improvement methodologies, and are not replacements for an effective management system (e.g., ISO 9001). The article was used to conduct an on-line survey with affirming results...

Last month we asked, "In the Sept issue of 'InsideSixSigma,' Mike Micklewright affirmed that Six Sigma is no replacement for a company's quality management system. To what extent do you agree with this statement?" Here are the results:

Strongly agree 83.5%  
Somewhat agree 11.1%  
Unsure 2.0%  
Somewhat disagree 1.2%  
Strongly disagree 2.2%

Why then is ISO 9001 being overshadowed as Six Sigma and lean techniques are gaining popularity? In fact, according to the American Society for Quality, attendance at the ASQ Six Sigma Conference in 2003 to 2004 has increased significantly, whereas the attendance at the ASQ ISO9000 conference had less than half the number of attendees in 2004.

What gives? One possibility may be that some companies are not seeing a positive financial return from being ISO 9001:2000 registered. Now they are looking at the latest craze to bring home the returns (remember, quality circles, TQM, zero defects days, etc.)

When we work with companies that have been registered to an ISO-based standard for a number of years, we still find that corrective and preventive actions, internal audits, and management reviews are poorly executed. Inadequate determinations of root causes, actions that only address the symptoms, no formal problem, or process solving methodology, corrective actions called preventive actions, management review actions with no ownership, or results achieved. If a company has these and other issues that do not lead to improving the effectiveness of their system – then this company is not functioning under an effective quality management system.

Let's take a look at one of the main elements of Six Sigma:

#### Business Process Management

Business process management provides for management accountability of cross-functional processes so process goals can be attained while business objective responsibilities remain clear.

How does this relate to ISO 9001:2000?

- ✚ 4.1 “The organization shall a) identify the processes needed for quality management system and their application throughout the organization, b) determine the sequence and interaction of these processes.”
- ✚ 8.2.3 “The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results.”

From this, we can deduce that ISO9001:2000 requires business process management as defined in Six Sigma terms.

Another question for you: Have you ever read ISO 9004:2000? If you did, you may have noticed that the last sentence of the last section (8.5.4), “Continual Improvement of the Organization,” refers the reader to annex B. Annex B is entitled “Process for Continual Improvement” – the same words used in the definition of the Define-Measure-Analyze-and Improve (DMAIC) improvement model used in Six Sigma. DMAIC is a process for continual improvement that provides us with the methodology we can use to attain our process goals.

One more question: Have you ever noticed that Section 8 of ISO9001:2000 is entitled “Measurement, Analysis and Improvement” and that this is also the “MAI” of DMAIC? If three-fifths of DMAIC is addressed in section 8 of ISO 9001, where are the “Define” and “Control” steps?

Define is probably the least addressed step in ISO 9001:2000, but it’s easily learned and applicable. Define is most closely addressed in the “Analysis of Data” (8.4) section, which states “the organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continuous improvement can be made.”

The “Control” step is stated throughout the ISO 9001 standard. Control is addressed in section 4 of ISO 9001 as follows:

- ✚ 4.1 “The organization shall c) determine the criteria and methods needed to ensure that both the operation and control of these processes are effective, d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes
- ✚ 4.2.1 “The quality management system documentation shall include documents needed by the organization to ensure the effective planning, operation, and control of its processes.”

If a company follows the intent of ISO 9001:2000, the following controls should ensure the gains are permanent:

- ✚ Management review
- ✚ Control of documents
- ✚ Control of records
- ✚ Determining competency
- ✚ Design and development controls
- ✚ Control of monitoring and measurement devices
- ✚ Internal audits
- ✚ Corrective and Preventive actions
- ✚ Continuous Improvement

This should be proof that Six Sigma is part of the ISO9001:2000 and can greatly enhance the effectiveness of your management system. However, a good management system is the foundation of your business. The first step is to understand the potential of your company’s quality system. If quality and customer satisfaction isn’t increasing, that certificate on the wall is only taking up space.



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*Coming in the November Issue:*

*How Six Sigma and lean principles can be integrated  
into an ISO 9001 based quality system*