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Six Sigma and ISO 9000:2000

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The ISO 9000 standards were revised in 2000 to improve the effectiveness of the quality system and to positively impact certified companies' performance. The new ISO 9001:2000 version incorporates input from various sources about the effectiveness of the standard in general. Its focus has shifted from documentation to a process-based model for effectiveness. The emphasis has changed from procedures to methods to collect, analyze and act on data. The requirements have been reorganized and regrouped based on the process model.

According to the process model, any activity or set of activities that uses resources to transform inputs to outputs can be considered a process. For a company to effectively implement a quality management system, it must identify and manage various processes and their interactions. The output of one process is an input to another process or processes. To implement a company-wide quality management system, the company must implement process management at each process (function or subsystem) level.

To manage a process, the process owner must control inputs, in-process and output (Figure 1). The control means understanding requirements, and receiving, producing or supplying according to the requirements. To ensure compliance to the requirements at various stages, verification methods are implemented. For example, the verification methods could be controlling suppliers or monitoring the product or process through data analysis, inspection, test or measurements. If the verification shows that the requirements are not met, a corrective action must be initiated.

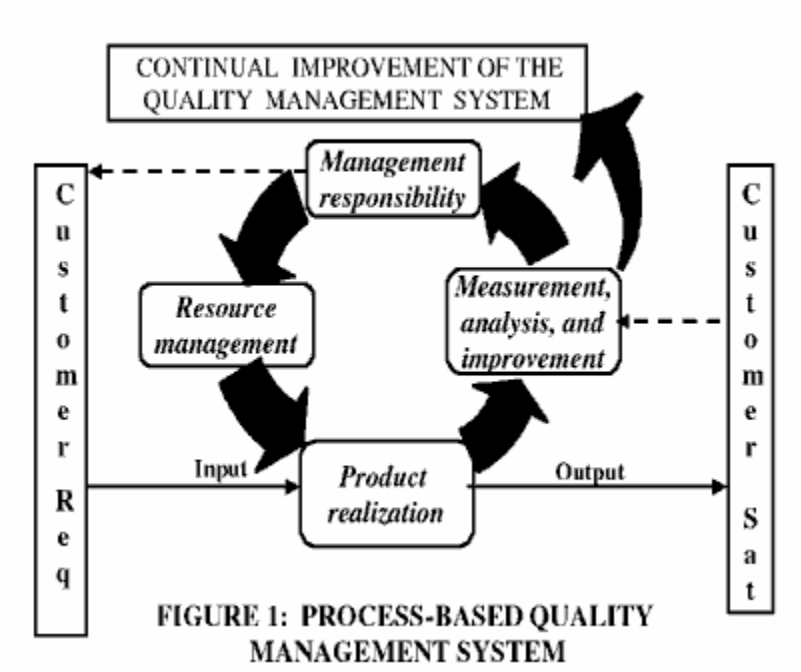

FIGURE 1: PROCESS-BASED QUALITY MANAGEMENT SYSTEM

The most significant changes incorporated in the new standards are the addition of measurements, data analysis and continual improvement. The standards require monitoring of input, in-process and output based on data collection and analysis.

The six sigma methodology has been implemented by many corporations worldwide to improve processes utilizing data analysis and statistical techniques. The ISO 9000:2000 requirements are as follows:

- Measurement, analysis and improvement
  - General
  - Monitoring and measurement: Customer satisfaction, internal audits, monitoring and measurement of processes, monitoring and measurement of product
  - Control of nonconforming product
  - Analysis of data
  - Improvement: Continual improvement, corrective action, preventive action.

Being a recognized and proven methodology, six sigma will be accepted by auditors with minimal challenges during the audit. An audit may also be an excellent opportunity to launch a strategic initiative for real quality improvements while also implementing an ISO 9000:2000 system. The six sigma methodology is very well documented and understood and sufficient resources are available, enabling compliance to the requirements.

To implement six sigma and the ISO 9000:2000 requirements simultaneously, a company's executives must decide to implement six sigma. Then, a phased approach to institutionalizing six sigma can be developed and implemented. Accordingly, a methodology must be developed to qualify employees for the training, project selection, employee recognition, performance measurement and continual improvement.

Six sigma methodology has two components: measurement and process. The measurement aspect relates to the quantification of quality. The quantification depends on the actual defects observed in a process and normalized to opportunities for creating those defects. The measurements are an important aspect of the six sigma methodology to establish goals and measure progress towards six sigma.

The process aspect of the six sigma methodology includes six steps that relate customer needs to the process to deliver products, services or process improvement. Ultimately, the core of the six sigma methodology is an implementation of the six process steps. Once the six steps are implemented successfully, the measurements are utilized to measure progress and drive further improvement.

Key aspects of continual improvement in today's competitive environment are dramatic improvement, innovation and process thinking. Typically, a company sets improvement goals of 10 to 20 percent per year in quality and other business measurements. The six sigma methodology inspires improvement of 60 percent or more every year, forcing everyone to be creative to achieve this goal.

Setting improved goals incrementally makes people think some tweaking will be sufficient to achieve those goals. However, achieving dramatic improvement requires

more than minor adjustments in processes. Out-of-the-box thinking, teamwork and active management participation are really required. This approach keeps people interested in what they are doing and encourages them to accomplish much better results.

Confusion exists regarding how to apply six sigma on different products, services or functions. The six sigma methodology reinforces the process thinking as it requires analysis of workflow. The ISO 9000:2000 standards are all about process thinking, process documentation, compliance and effectiveness. Ensuring the process is performing as desired and achieving continual improvement towards perfection, six sigma is an excellent approach that compliments the ISO 9000:2000 standards.