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SPECIAL REPRINT

Do Your QMS's Design Procedures Aim for Defect-Free Product?

ISO 9001:2000 and Design for Six Sigma

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With the introduction of *ISO 9001:2000, Quality management systems—Requirements,* the approach to implementing quality management systems (QMSs) has changed. ISO 9001:2000 influences QMS practitioners to move away from just meeting requirements to making their organizations process-focused.

Under this approach, an organization is considered and treated as a holistic system, not a series of separate system elements, and one in which the pursuit of internal and external customer satisfaction is paramount to delivering value.

Survival in today's business environment requires an organization to deliver a resilient and focused response to heightened customer expectations and demand for superior overall product and service performance.

Providing defect-free product consistently is not only preferred by the customer, but the customer assumes that such product will be delivered, making it critical to long-term survival. It is no longer sufficient to correct products after they have been developed, manufactured and/or purchased by customers, whether they are another organization or a consumer.

Your organization's QMS will not be truly conforming with the requirements of ISO 9001:2000—and certainly not geared to the performance improvements sought by using *ISO 9004:2000, Quality management systems—Guidelines for performance improvements*—if it simply inspects for quality and focuses on corrective action to prevent nonconforming product from reaching the customer.

Today, the emphasis is on speed and performance, with the ability of an organization to design and institute an efficient product development process becoming a strong competitive advantage.

The fact is that shorter cycle times allow companies to recoup their investments at a faster rate and gain market share in the process. Therefore, it is no longer sufficient to make yearly improvements of 5-10%. Instead, organizations need to install systems and new technologies and apply new ideas that will ensure that they achieve exponential growth. An effective ISO 9001:2000-conforming QMS will need system tools that embody those new ideas.

Applying Six Sigma to QMS Design Processes

Six Sigma is a quality philosophy that was first developed by Motorola and reinforced by other innovative corporations, such as General Electric and Allied Signal. It is a project approach that offers a collection of tools and techniques to develop measurements and identify improvement opportunities. Six Sigma uses customer-focused measurements to drive continuous improvement throughout the organization. The philosophy of Six Sigma has been instrumental in identifying appropriate root causes and implementing corrective and preventive actions.

Some organizations are estimated to perform at a level between two and three sigma (308,700-66,810 defects per million opportunities or DPMO) with average being only slightly better. These levels indicate that there is considerable waste in the average organization due to common and special cause variation in products and processes.

By comparison, organizations at a Six Sigma level perform at a rate 3.4 DPMO. Although many average companies have experienced improvement that has resulted in substantial bottom-line benefits as a result of QMS implementation and use, it is rather evident that considerable effort will be needed to achieve the exponential gains required to move from one sigma level to another (see "Does Your QMS Really

Need Six Sigma for Success?", *THE OUTLOOK*, August 2001). This can be done by moving the concepts of Six Sigma into the design stage.

Design for Six Sigma (DFSS) is a rigorous approach to developing products and services that will enable processes to meet customer expectations prior to production. Techniques and concepts applied in product development and used throughout the design and development phase provide the means to move from a four to five sigma level or from a five to six sigma level of performance.

An improvement from four to five sigma represents a reduction in poor quality by 30 times, while change from five to six sigma results in a further reduction in poor quality by 70 times, as shown in Figure 1 on next page. DFSS complements QMS improvements by providing a positive impact on product reliability and maintainability.

The primary objective of DFSS is to serve as a methodology for providing a framework that enables the creation of cost-effective designs. The tools and techniques involved in DFSS ensure that choices leading to defect-free processes and product are made early in the design stage and that there is an understanding of the impact on downstream operations and the customer.

The result is the development of products/services that are robust and reduce or eliminate process variation. The framework of DFSS is not only concerned with the output of the process and the effective use of resources, but with the creation and use of a system that can be repeated for other products. Using a structured approach with a robust design, time to market can be reduced, resulting in increased overall profitability for the organization applying DFSS.

A Six-Phased Model for Achieving DFSS

Like a full Six Sigma program, DFSS is project-oriented. However, my organization's experience is that implementing a DFSS approach within an organization can best be achieved if each DFSS project is conducted in six phases. Each phase requires the use of specific tools and techniques that are integrated into the product development process.

A primary prerequisite for a successful project is a structured product development process within your organization, such as that obtained by implementing a QMS conforming to the requirements in Section 7, Product Realization, and particularly Clauses 7.3, Design and Development, and 7.5, Production and Service Provision.

The roles and responsibilities of personnel involved in product development must be clearly outlined, and they must have knowledge of all tools required to ensure that the product meets its specified requirements as well as the organization's business objectives. For each product or service to be designed, developed and produced, applying the six phases of DFSS discussed below builds upon the foundation provided by the QMS processes noted above.

Phase 1. Define

The first phase of DFSS coincides with the development of a new product. It requires proper identification of the project, a statement of work and an understanding of the business case—why a new product is needed and what it must do and/or provide.

At this phase, the groundwork for the new product must be laid. At the start of the development process, the "history" for the new product, which is to be found in previous designs and products, needs to be collected and analyzed to develop a baseline for the new product and to take advantage of lessons learned.

A cross-functional team is selected, roles and responsibilities are identified and project timelines are established. This phase establishes the foundation for the entire project and ensures effective use of the project management tools that are available to or will be needed by the team.

Phase 2. Measure

The second phase is critical, because it sets the tone for evaluating the effectiveness and efficiency of the DFSS project. Two types of measurements to be applied are established:

1. Measurements that relate to the product. Product-related measurements include those used to measure the conformance of the final product to customer and other specifications when it is launched in full production (e.g., defective parts per million and rolled throughput yield) and those that measure the reliability of the product (e.g., Mean Time Between Failures). Although these product measures are used at the end of the product development process, additional product-related measures need to be identified and implemented at key design and development review points.
2. Measures that relate to the product development process. Process-related measures are concerned with the efficiency of the actual development process for the product (e.g., cycle time of key phases of the product development process).

The intent of a DFSS project is to improve product performance and increase the speed to market. The primary metrics therefore need to include an evaluation of cycle time, cost and the effective use of resources. Conducting Phase 2 is normally a short activity and can take place in combination with Phase 1.

Phase 3. Characterize

Once the foundation for the process is established in Phases 1 and 2, Phase 3 focuses on using the tool of Quality Function Deployment (QFD)

to capture the voice of the customer. In other words, the organization must design a product that meets the needs, both specified and unspecified but understood, of the customer. Design alternatives need to be identified and considered and a design option must be selected that will align the product design with customer requirements as well as your organization's objectives.

Tools such as value analysis must also be applied to ensure that the team is aware of where cost reduction opportunities exist, so that such opportunities can be evaluated to determine which are practical to implement and will maintain or enhance product and process quality or satisfy the customer through reduced cost. This phase sets the priorities that will be the focal point for the design of the new product.

Phase 4. Design

The focus in the fourth phase is on identifying and mitigating product and process risks in line with the QMS's preventive action program and performance improvement efforts. The cross-functional team needs to use a wide range of tools to identify problems that could occur and to take the necessary steps to design out product and/or process failures. The development of a set of Critical to Quality characteristics (CTQs) for the product is critical, because they are deployed throughout the development process.

CTQs are measurable and functionable characteristics that are derived from the voice of the customer. CTQs are also referred to as the "key results", "Ys" or "specification limits".

During this phase, the organization must also establish plans for verifying and validating product performance and predicting capability to ensure the outcomes of design will meet customer specifications for these product characteristics, thereby satisfying the customer.

Combining DFSS techniques used in the design stage with the design and development procedures for the product and its processes will produce a more robust design that will be subject to fewer engineering changes and fewer problems. One of the goals of a Six Sigma project is to reduce the number of potential changes to a product or process as well as the number of potential problems, since changes themselves can result in more defects.

Phase 5: Optimize

The primary objective of this phase is to reduce product variability and establish performance predictions. While the previous phase involved the identification of the CTQs for the product, the fifth phase goes further and requires the organization to use several other variability reduction techniques to reduce variation in the production processes and the product. Tools such as Design of Experiment and Signal to Noise Ratio are used to identify control factors—those factors having a critical impact on variation—that need to be monitored and/or controlled during prototype and full production.

Phase 6: Verify

The final phase of DFSS is used to evaluate and verify product performance with customer requirements. The testing and plans for product verification that were developed in the design stage (Phase 4) are implemented and used to evaluate performance and make reliability predictions. Activities in this phase need to be completed before full-scale production begins and must be used to assess product performance and compare it against baseline measures established in Phase 2 (measure).

In addition, once the organization has been manufacturing the product or providing the service for a period of 4-6 months, it needs to take measurements on the actual performance of the product and the production/service processes and document those measurements.

This data on the actual product and the organization's operations relating to the product will serve as the starting point for continual improvement activities intended to increase the sigma level of the organization and its operations.

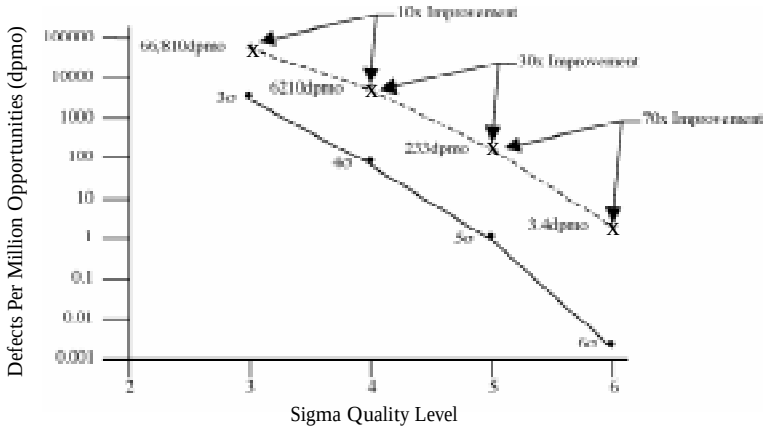
Can an organization implement a Design for Six Sigma program ahead of a Six Sigma program? It depends on organizational readiness. If the existing QMS within the organization is not producing a lot of product and process defects/nonconformances, then it is very likely that the necessary culture shift has already been made. Such an organization would be successful implementing DFSS with no Black Belts already trained and ready to pursue Six Sigma projects.

How Does ISO 9001:2000 Support DFSS?

An effective DFSS project is dependent on a well-defined product design and development process. As noted earlier, ISO 9001:2000 provides a foundation for Six Sigma and DFSS by providing a customer-driven, information-based management system.

The following is an abbreviated checklist consisting of questions regarding elements of an ISO 9001:2000-conforming QMS that an organization needs to answer and act upon. Because it is impossible to effectively implement, maintain and obtain results from a Six

Figure 1. Defect Rates (DPMO) Versus Sigma Quality Level



Sigma program without an effective QMS, this checklist should be used to evaluate an organization's readiness to embark on a DFSS initiative. See if your organization can answer affirmatively to each of the following questions:

- Has the organization established a formal planning process for product development?
- Is there a well-developed system for identifying customer requirements?
- Does the organization have a method for identifying customer requirements implied but not specified by the customer?
- Do product requirements consider compliance with government regulations?
- Is there a formal process for the review of a potential customer's product requirements prior to submitting a quote?
- Is there a process for communicating with the customer concerning product information?
- Is there a documented product design and development process?
- Are there documented design and development review points?
- Are there special checklists and requirements for review and sign-off at each milestone in the organization's product realization procedures?
- Are roles and responsibilities of key personnel involved in the design effort defined?
- Are inputs relating to product requirements properly defined and documented?
- Is there a process of product verification that ensures that the design and development outputs meet the design and development inputs?
- Do design validation results provide evidence that the product meets customer performance requirements?
- Is there a system of measurements that ensures that the product development process continually improves?

If your organization cannot answer yes to every question in this checklist, it needs to focus first on improving its QMS so as to ensure baseline conformance with ISO 9001:2000 before pursuing DFSS. DFSS is the solution only if your organization's QMS can support a Design for Six Sigma approach and its long-term strategic goals include becoming more responsive to heightened customer expectations and providing product of superior quality, consistently and expediently, with shorter cycle times.

It is then that your organization's processes will permit you to recoup its investments at a faster rate and gain market share. Especially during a recession, when customers can be most selective about their suppliers, and at a time of heightened awareness, when customers globally want assurance that the product and services they purchase will be consistently effective and defect-free, organizations need a QMS beyond baseline ISO 9001:2000 conformance and DFSS to show customers that they can satisfy their needs. ###

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