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Best Practices for Implementing and Utilizing a Standards-based QMS

As industries grow increasingly competitive, it is important for companies, large and small, to certify to certain quality standards, such as ISO 9001 or sector-specific standards such as ISO/TS 16949 and AS9100. As companies consider registering to these standards, the challenge becomes how to best implement and utilize a quality management system.

A few general questions need to be asked when undertaking what could be a complex, and somewhat costly, effort. Why does a company need to implement a quality standard? How will this standard fit that company's particular business? What type of return on investment can be expected?

Why implement a Quality Management System

Most often, a company needs to implement a quality management system (QMS) based on a recognized standard, such as ISO 9001, because customers have begun to require it or have asked about a company's plan to implement such a standard. To become a preferred supplier, or even bid on contracts, many companies are required to be certified to ISO 9001 or similar standards. In these situations, the business case for a QMS is straight forward. Rather than lose the business of a valuable customer, the better choice often is to determine how the standard applies to overall business operations and implement it.

Benefits go beyond retaining existing customers or qualifying for new contracts. Implementing a quality management system that is ISO 9001 compliant also provides discipline, improves processes and increases the productivity and effectiveness of a company's operations. Consistent, reliable, well-documented management systems result in reduced scrap and waste, less human errors, and as a result, increased profitability and customer satisfaction.

One way to determine the value of a quality management system is to learn from those that have successfully implemented and certified their own systems. Over 20,000 companies have gone through the process and will openly discuss the results with suppliers and customers, as well as in user forums. Similarly, companies that are certified can answer important questions regarding measurable benefits, costs, timing, and challenges. In support of quality management systems, those that have undergone the process often will point out the following:

• QMS certification demonstrates a commitment to customers and stakeholders by top management.

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- It increases customer satisfaction through improved responsiveness and product/service reliability.
- QMS certification forms a strong, recognized foundation for meeting regulatory requirements.
- It enhances the image of an organization through proactive quality-focused leadership and international credentials.
- It reduces operating costs through error prevention, clear work instructions, consistent practices, and lower overall liability.
- QMS certification improves communications between employees, customers, and suppliers.
- QMS certification identifies opportunities for improvement through best practices, process metrics, and customer feedback.

Effective Utilization of a QMS

How a company implements a management system should be consistent with the company's existing objectives, business operations, and tasks performed, which ISO 9000 refers to as 'processes'. Companies have found that particular processes they have defined, or built the company around, are part of their competitive advantage, whether a manufacturing or service delivery process. ISO 9000 does not prescribe how a company operates but instead, identifies four processes (listed below) that all companies must perform. The standard instructs, "Document what you do, and do what you document." Often, companies have implemented requirements but have not associated those requirements with the particular requirements of a standard, such as ISO 9001:2000. The level of success and return for companies that implement and certify QMS comes from how well they do the following four clauses identified by ISO 9001.

Management Responsibility

Every business needs to know how it is performing in order to stay in business and preempt any problems with operations or customer dissatisfaction. Whether analyzing financial information, piece counts, yield data, shipment and return information, labor hours, machine hours, prompt payment, repeated service request, warranty claims, customer interviews, surveys, or other forms of customer feedback, measures will need to be set and monitored as to whether or not they are satisfactory or unsatisfactory. The monitoring may be referred to as management review under ISO 9000. In most cases, the unsatisfactory aspects will need to be fixed through some form of corrective action and likewise, the satisfactory aspects improved upon through some form of continual improvement procedure or program. Preventative action also will need to be taken to avoid the satisfactory from becoming unsatisfactory.

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Resource Management

When managing its resources, a company must identify each of its business operations and place it in one of the following categories:

- Key processes (a task directly related to satisfying the customer)
- Support processes (necessary to operate key processes)
- Management processes (used to help manage, measure, or report about the key process).

Organizing existing information under these processes will facilitate an understanding of and ideally, the implementation of the process approach. Many companies find it extremely beneficial to form a team and have each team member read the standard several times. This will ensure an overall understanding of the intent of the standard and the process approach.

After a company identifies its processes, it must take a general look at its business operations by mapping the processes in the logical sequence in which they occur. Processes that rely on an input and output from one operation to another must be connected in sequence, relating the processes to key support and management processes previously identified. It also is important to show how each of your existing records, procedures, work instructions and documents relate to one another. This will help to ensure each of the processes is followed and the company is meeting the requirements of the chosen standard.

Once operations have been mapped, the system must be tested by completing audits in the process approach. Interview those implementing the requirements and observe each process and requirement. Revisit, revise, improve or supplement those processes that do not meet the standard, and those that are not flexible, fluent, feasible or efficient, given the nature of the particular business.

Product Realization

A major part of implementing and maintaining a successful quality management system is product realization, or the process by which products are developed, designed, produced, marketed, and disposed. This will require a close look at the customer's needs as they relate to the strategies and products of the certifying company.

Prior to accepting an order from a customer, a review of what the customer has ordered will need to be performed, deciding such factors as whether or not the product can be manufactured or the service provided as expected, what the terms of the offer will be, and

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what are the associated costs. This is a typical customer-related process per ISO 9001:2000.

In conjunction with this customer-related process, a company also will select a supplier of material or other commodity, train employees, and discover the best methods to administer and implement the process in order to obtain the desired results. Along this path, companies maintain records of customer orders, invoices, purchases, and schedules. These activities may meet ISO 9001:2000 requirements, when formalized, for competence, awareness and training, control of records, and purchasing information.

Following receipt of a customer order, the realization of the product must be planned. In other words, plan the design of the product, the purchasing of materials or other commodities, and verify that the item meets what has been ordered. Other points to consider include the manufacture of material, component, or part to specific criteria and requirements that will provide a product acceptable to the customer, including identifying, tracking, preserving, packaging, measuring, testing, delivering and correcting any work in progress.

Measurement, Analysis, and Improvement

What is the Return on Investment (ROI)? This is a question that should always be asked by Senior Management, where resources, cost and/or capital are involved. The first and most obvious measurement of ROI is the retention and hit rate with customers who have required or inquired about a company's ISO 9001 or ISO/TS 16949 certified or compliant quality management system.

Objectives and targets should be set for other ROI measures, such as levels of scrap, rework, and customer rejects (spills in automotive). The objectives and targets should be reviewed periodically for adequacy, suitability, and effectiveness. Adjustments, redefinition and changes should be made where the targets or overall objectives are not consistent with the business environment. Likewise, corrective and preventive actions should be taken where expectations are not met or do not progress at a pace that meets the schedule for achievement.

Once targets are met and progress is satisfactory, continual improvement of the process should begin. The objectives and targets may need to be redefined or moved and additional objectives and targets identified. In the overall picture, a company's ROI should be consistent and correlate with the effect of quality management on its financial performance, and internal and external customer satisfaction levels.

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Success is a matter of discovering where a company's policies, requirements, and processes best fit the clauses of the standard. Defining, monitoring, measuring, redefining, adjusting and changing the processes will lead to achievement of the financial goals of the business.

-- Audit Staff, SRI Quality System Registrar

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