# Implementation Philosophy - ISO 9000 vs. QS-9000

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The automotive quality system standard **QS-9000** was introduced in August of 1994. However, there is still much confusion about how it relates to the international quality system standard **ISO 9000**. QS-9000 is often presented as "ISO 9000 plus specific automotive requirements". Unfortunately, this presentation is very misleading and adds further to the confusion and lack of understanding. QS-9000 and ISO 9000 are fundamentally different in their approach and philosophy. While ISO 9000 defines quality system requirements to *control product* quality, QS-9000's approach is very much *prevention* driven, defining requirements to *control and improve the processes* that produce products by using a wide variety of statistical concepts and tools.

## **Quality Evolution**

It is useful to refer to David Garvin's "Four Major Quality Eras", *Figure 1*, to help understand the differences between QS-9000 and ISO 9000. In Gavin's initial era, - "Inspection" quality was viewed as a problem to be solved primary through detection. In this first era the quality role fell solely on the inspection department, where product was gauged, measured, sorted and graded. This method was very expensive and time consuming and led eventually to the "Statistical Quality Control" era.

The primary concern during the second era was control with quality still being viewed as a problem to be solved. The emphasis was on product uniformity with reduced inspection. Quality professionals were involved in trouble shooting and in the application of statistical methods. While the quality responsibility was being transferred to the manufacturing and engineering departments, the orientation and approach attempted to "control in" quality. Many organizations were unhappy with this reactive approach as it detected poor quality only after production and led to much rework and containment costs. This approach also had no impact on actual product quality. Increased inspection found more problems however the quality of the product being produced was still the same. If poor quality products were produced, some would still be shipped to customers as this "detection" philosophy was not 100% effective.

This unfavourable situation led to the third era - "Quality Assurance" which was revolutionary in concept. In the Quality Assurance era, the emphasis shifted from trying

to control in quality to trying to not produce poor quality products. This led to the understanding that the only way to produce quality products was to control the processes that produced the products rather than trying to control the product quality. The Quality Assurance era emphasized the coordination of all functions in the entire supply chain from design to customer, and the contribution of all functional groups, especially designers, to prevent quality failures. Quality improvement programs and systems were used to address quality. The role of the quality professional was consultative in quality measurement, quality planning and program design. The quality responsibility now did not reside solely with the quality professional but was shared by all functions - engineering, manufacturing, materials, quality, etc. - with the view to "build in" product quality.

In the fourth era - Strategic Quality Management, the primary concern was strategic impact with the emphasis on market and customer needs. The methods used were strategic planning, goal setting, and mobilization of the entire organization. The role of the quality professional was goal setting, education and training, consultative work with other departments and program design. In this era everyone in the organization was responsible for quality, with the top management exercising strong leadership. The orientation and approach of this phase was to "manage in" quality.

Era 2	Era 3 Era 4
Statistical	Quality Assurance Strategic
Quality Control	* Process Focus Quality
	*Prevention Management
Control in -	Build in - Manage in -
QUALITY	QUALITY QUALITY
O 9000	ISO 9004 TOM
	Statistical Quality Control  Control in - QUALITY

Adapted from: David A. Garvin, Managing Quality

Figure 1: Four Major Quality Eras

## The Quality Standards

#### **ISO 9000 Philosophy**

The ISO Task Committee TC176 addresses the philosophy and strategy behind the development of the ISO series of standards in their document **ISO/TC 176/SC 2/N336.** *Figure 2* has been adopted from this document. Quality needs of customers are addressed through a three level hierarchy.

The base level, Level 1, is Quality Assurance. Level 2 is Quality Management and Level 3 is TQM (Total Quality Management). The goal of Quality Assurance is to put in place an effective system to produce products that conforms to customer requirements. The focus is on preventing customer dissatisfaction through control of the product, thereby preventing customer recalls and failures. Level 1 is similar to Garvin's Era 1 and 2 of the Quality Evolution.

Meeting customer needs at low cost through a system that addresses efficiency and effectiveness is the goal of Quality Management (Level 2). The focus is on customer satisfaction by improving the complaint process, reducing cycle time and waste reduction. Level 2 moves into Era 3 of Garvin's Quality Evolution.

Finally, the goal of Level 3, TQM, like the goal of Garvin's Era 4 is business success. TQM focuses on Total Customer Satisfaction. This is accomplished through employee satisfaction, long range and strategic focus and customer driven designs.

ISO 9001(2) was developed to address Level 1, the Quality Assurance System. ISO 9004 addresses Level 2 the Quality Management System. To assist organizations in the implementation of TQM, Level 3, National Quality Awards, such as the Malcolm Baldrige National Quality Award, The Canada Awards for Excellence, and the European Award - European Foundation for Quality Management are used.

The ISO implementation strategy has not been particularly effective. Many organizations tend to "choose" either ISO 9000 or TQM and do not see each as a necessary component of an overall system. Those organizations that choose ISO 9000 tend to focus only on the basic Quality Assurance Standard - ISO 9001(2) and ignore the Quality Management Guideline of ISO 9004.

There are very good reasons why organizations choose this approach. The only contractual requirements for registration are for ISO 9001(2). Therefore, the training provided by educators and consultants only focuses on the ISO 9001(2) requirements. The benefits of ISO 9000 registration are very minimal as most organizations have not implemented ISO 9004 or TQM.

Even for those organizations who have incorporated both the basic Level 1 Quality Assurance requirements and the Level 2 Quality Management requirements into their quality systems it is very difficult for them to move to Level 3, TQM. The transition from Level 1 to 2 to 3 is not particularly well defined. In fact, many organizations in Europe, where the majority of ISO registrations exist, are presently struggling with the transition from their ISO quality systems to TQM.

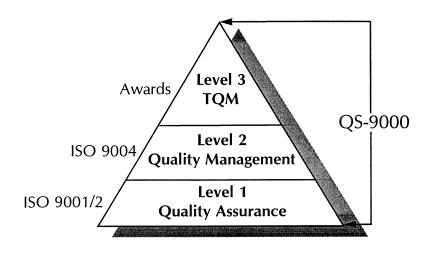


Figure 2: Customer Quality Needs Hierarchy

#### **OS-9000** Philosophy

QS-9000 Quality System Requirements, on the other hand, focus on all three levels in the quality hierarchy of customer needs. ISO 9001 is included completely in QS-9000. ISO 9004 was then used extensively by the QS-9000 task force in expanding the basic ISO 9001 requirements. QS-9000 was developed further to include many of the concepts and requirements of the TQM Awards, such as the Malcolm Baldrige National Quality Award. As a result, the underlying focus of QS-9000 is one of prevention in contrast to the focus of ISO 9000 which is defect detection.

#### Comparison of ISO 9000 and QS-9000

The differences in approaches of QS-9000 and ISO 9001 is immediately obvious in QS-9000's stated goal - "the development of fundamental quality systems that provide for continuous improvement, emphasizing defect prevention and the reduction of waste in the supply chain". This contrasts with the ISO 9001's goal to "control product quality". The differences are most obvious in three elements in both ISO 9000 and QS-9000 namely, 4.1 Management Responsibility, 4.2 Quality System and 4.9 Process Control.

#### Element 4.1, Management Responsibility

The ISO 9000 version of this element contains the requirements relating to: quality responsibility, organization and resources for quality relative to identification of nonconformances, resolution of problems and corrective action. The QS-9000 elements expand this management responsibility to include quality and quality improvement as part of the business plan. Under QS-9000 the quality improvement program must include specific initiatives that address improvement in product quality, service (including timing and delivery) and price for all customers. These improvement initiatives must use the appropriate current quality improvement tools and the supplier must demonstrate knowledge in all of these current tools. It further outlines management's role in ensuring that the organization's departments and functions interface with each other and not perform in isolation. The strategic focus is demonstrated in the business planning requirement by addressing not only short term goals (1 to 2 years) but also the long term plan of 3 years or more. The analysis and use of company level data requirement ensures that suppliers not only keep focused on their own business performance, but also benchmark both inside and outside their company as a means to support their ongoing success. Customer satisfaction has been added as an additional requirement of the standard. Suppliers must develop processes to determine current levels and trends in customer satisfaction and also use appropriate competitor trends and benchmarks.

### Element 4.2, Quality System

Element 4.2, Quality System is one of the most significant differences in terms of approach of ISO 9001 and QS-9000. The requirement of a quality plan is usually addressed in ISO-9001 with an Inspection/Test Plan. This plan defines the inspections or tests to be conducted with the acceptance criteria being specified. These tests and inspections are performed on the product at different points throughout the manufacturing process - incoming, in process, and final inspection or test for very specific product parameters to evaluate the acceptability of the product.

The QS-9000 quality plan, on the other hand, involves a "Control Plan", which is very different from an inspection/test plan. While a control plan lists key product characteristics to be checked, it also includes the key process control characteristics to be monitored to ensure that the manufacturing processes are producing only good products. The control plans are developed as an output of the quality planning activity. Quality planning should use multi-function teams of engineering and manufacturing personnel, and sometimes even suppliers and/or customers.

Disciplined processes such as Potential Failure Mode and Effects Analysis (FMEA), in both design and manufacturing, and preliminary capability studies are used to assist in the quality planning process. The control plan defines the statistical tools used to monitor and control the processes. The concept of error proofing is introduced as a tool to eliminate the requirement of process monitoring. During the quality planning process, particularly

the process FMEA process, potential modes of failure during the manufacturing of the product are identified. The ideal solution is to use error proofing to prevent a particular failure mode.

Process capability studies are required as part of the PPAP (Production Part Approval Process) that is required in the initial planning phase of the product introduction. PPAP attempts to ensure that the manufacturing system is capable of meeting the product specifications. In addition, measurement systems analysis is a key component of the control planning activity. Studies such as Gauge R & R's (Repeatability and Reproducibility), are required to that the proposed measurement system is adequate.

Control plans are designed to be "living documents" under continuous review and improvement as process and product parameters change with improving systems. Review is triggered by both internal and external inputs of information. External inputs could be from customer feedback or product returns and/or product quality improvement requirements. Internal inputs can include nonconformances during the manufacturing process and/or other initiatives identified in the continuous improvement plans.

#### **Element 4.9, Process Control**

Element 4.9, Process Control also clearly illustrates the differences between ISO 9001 and QS-9000. Element 4.9 requires those processes that directly impact quality to be controlled. Many organizations that have implemented ISO 9000 have interpreted this to mean that only the inspection and testing functions performed on the product must be controlled. The rationale here is that if any of the other operations negatively impact product quality, the poor quality would be detected by these test/inspection functions where decisions of product acceptability are made. Under this interpretation, only the test/inspection operations require operator instructions or procedures to ensure that these tasks were executed properly. Special training of operators of special processes is sometimes used to ensure product quality depending on the tasks being performed. ISO 9001 defines "special processes" as processes "where the results of the processes cannot be fully verified by subsequent inspection and testing of the product..." for example, welding or plating. With these types of processes the emphasis is shifted from verification of product to focusing on the capabilities of the people performing the functions rather than trying to control the process parameters.

QS-9000, in contrast, interprets Process Control 4.9 requirements to apply to *all functions: e.g.*, manufacturing, design, materials and contract review. QS-9000 requires that any key process, defined as those controlling key characteristics, must be monitored continually to demonstrate process control, capability and stability. It is further required that suppliers demonstrate continuous improvement in these processes. Preventive maintenance, including predictive maintenance methodologies, is also required on the equipment used for these processes. The tooling and fixturing repair/replacement for equipment used in all processes must be managed effectively to assure their performance.

#### Conclusion

The above examples illustrate the differences in approach and philosophy of ISO 9000 and QS-9000. ISO 9001 is an excellent base on which to build. However, in order to achieve maximum benefit from a quality system, the quality system must be designed to operate in Era 3 and 4 of the Quality Evolution.

The implementation of QS-9000 should be more successful than ISO 9000 since QS-9000 integrates all three levels of the customer needs hierarchy. QS-9000, like ISO 9000, is also subject to third party registration by external registrars. For this reason education and training programs for QS-9000 will now focus on all three levels. Finally, although QS-9000 includes some of the TQM requirements, QS-9000 quality systems will need further expansion. However, compared to ISO, it is much easier for organizations to understand how to integrate the additional TQM requirements, as outlined in the national award programs, into their QS-9000 based quality systems successfully.

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