Understanding QS-9000 with its Preventive and Statistical Focus

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Abstract:

The automotive Quality System Requirements standard QS-9000 is often presented as "ISO 9000 plus specific automotive interpretations". However, QS-9000 and ISO 9000 are fundamentally different in their approach and philosophy. While ISO 9000 defines quality system requirements to control product quality through inspection and control, QS-9000's approach is to prevent poor quality first by focusing on the design and then by controlling the manufacturing processes that produce the product.

Statistics play a very important role in the effective implementation of QS-9000. Data collection and analysis are vital in maximizing the benefits from the quality system. This includes the use of company level data which are to be used to manage and prioritize the business activities. It also includes the collection and analysis of data on customer satisfaction and benchmarks on competition. Manufacturing processes are to be managed and controlled through the extensive use of Statistical Process Control (SPC) data. Suppliers are required to demonstrate minimum process capability and stability requirements in addition to showing continuous improvement in those same characteristics. Measurement systems and process machinery are to be monitored and maintained by continuous monitoring and analysis of measurement data.

1. Introduction:

The automotive Quality System Requirements, QS-9000 introduced in August 1994 is a harmonized Quality System Standard that was developed by the Chrysler, Ford and General Motors Supplier Quality Requirements Task Force. This standard must be implemented by all suppliers of Chrysler, Ford and General Motors. It is described in the manual "Quality System Requirements" with additional information given in the reference manuals: "Statistical Process Control", "Advanced Product Quality Planning and Control", "Measurement Systems Analysis", and "Production Part Approval process". These manuals are published by the Automotive Industry Action Group (AIAG) (1995). To conform with QS-9000 requirements, an automotive supplier must have designed and implemented a quality system that makes effective use of a wide variety of concepts and tools. Sometimes it is presented as "ISO 9000 plus specific automotive interpretation and requirements". However, QS-9000 and ISO 9000 are fundamentally different in their philosophy and approach. While ISO 9000 defines quality assurance system requirements to *control product* quality, QS-9000's approach is very much *prevention* driven by defining requirements to *control and improve the processes* which produce products using a wide variety of statistical concepts and tools. The QS-9000 provides many prescriptions designed to promote Quality Improvement and Consistency in manufacturing.

2. Quality Evolution:

Garvin's (1988) "Four Major Quality Eras" (see Table 1) is very useful in the understanding of the approaches imbedded in ISO 9000 and QS-9000. In the initial era, - "Inspection" quality was viewed as a problem to be solved primary through detection. Gauging and measurement methods were used by quality professionals as they inspected, sorted, counted and graded products. The quality role fell solely on the inspection department. This method was very expensive and time consuming which led eventually to the "Statistical Quality Control" era. The primary concern was control and quality was still viewed as a problem to be solved. The emphasis was product uniformity with reduced inspection. Quality professionals were involved in trouble shooting and the application of statistical methods. While the quality responsibility was being transferred to the manufacturing and engineering departments, the orientation and approach were trying to "control in" quality. Many organizations were unhappy with this approach as it was after the fact and did not have any real impact on quality. If poor quality was produced, some would be shipped to customers in spite of "best efforts".

This then led to the third era - "Quality Assurance" which was revolutionary in concept. The revolutionary thinking was that if one produces poor quality products, regardless of whether one uses 100% inspection or statistical quality control, poor quality products still exist and customers will likely receive them, therefore the only solution is not to *produce* poor quality products. This led to the understanding that the only way to produce quality products is to control the processes that produce the products. The quality Assurance era emphasized the coordination of all functions in the entire supply chain from design to customer, the contribution of all functional groups, especially designers, to prevent quality failures. The method used to address quality was

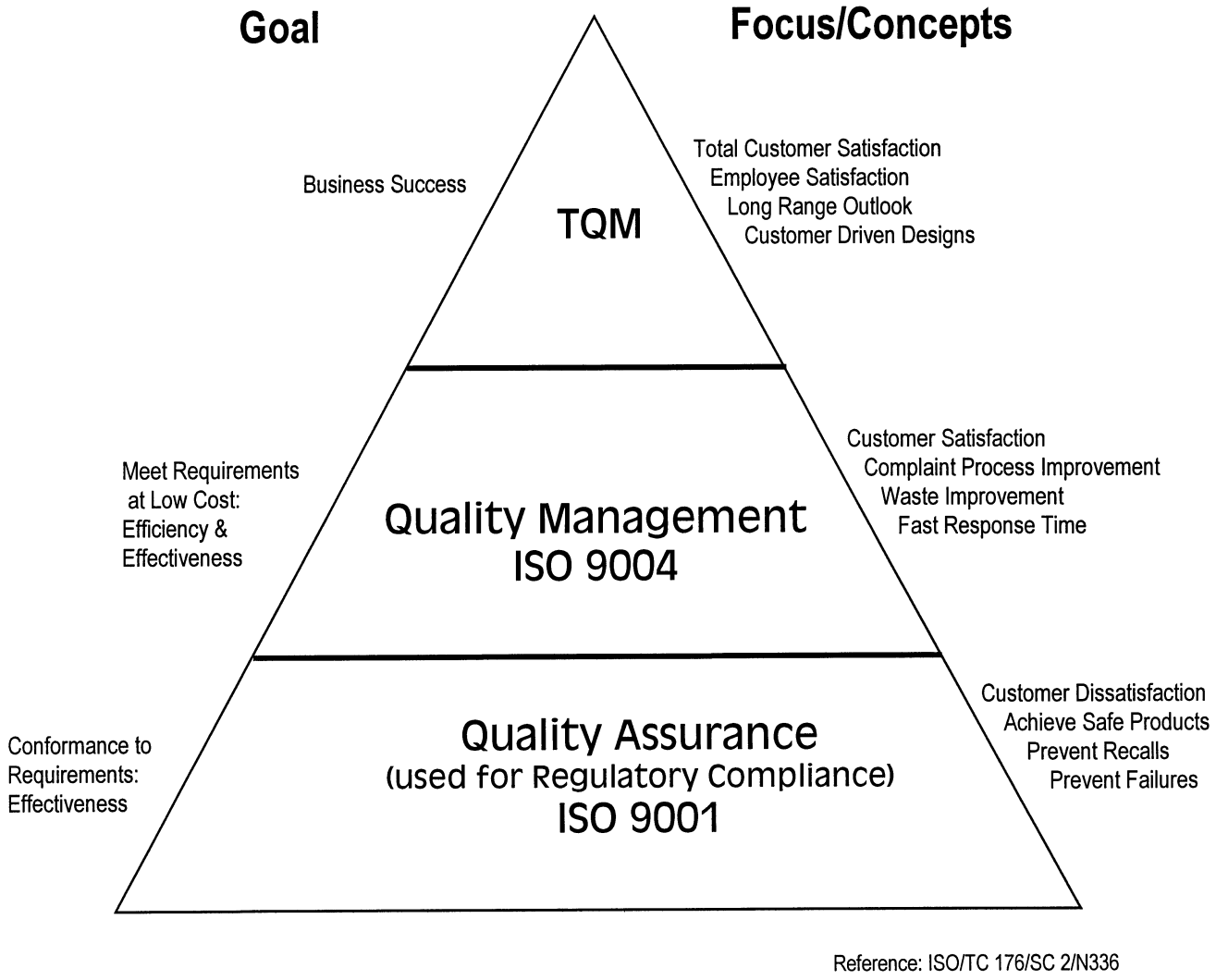

Figure 1: Quality Hierarchy of Customer Needs

to implement programs and systems. The role of the quality professional was quality measurement, quality planning and program design. The quality responsibility was now shared by all functions with the view to building in product quality.

Table 1: Four Major Quality Eras

Stage 1	**Stage 2**	**Stage 3**	**Stage 4**
Inspection	Statistical Quality Control	Quality Assurance - Process Focus - Prevention	Strategic Quality Management
Inspect in - Quality	Control in - Quality	Build in - Quality	Manage in - Quality
ISO 9000		QS-9000	

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

3. ISO 9000 Control Focus:

ISO 9000 Quality System Requirements are at the initial two eras of the quality evolution - "Inspection" and "Statistical Quality Control". This is further reinforced by a recently published document ISO/TC 176/SC 2/N336. Figure 1 shows ISO 9001 as the baseline standard requirement. Which is based on the following:

1) Say what you do (Quality Policy)
2) Document what you say (Document the Policy)
3) Do what you say that you do (Implement the Procedure)
4) Demonstrate that you do what you say (Auditing)

ISO 9001 defines the quality assurance requirements to be used for Regulatory Compliance focusing on conformance to requirements and customer dissatisfaction. The primary focus is to prevent customers receiving poor quality products thereby preventing recalls and customer failures. ISO 9004 is a Quality Management guideline which addresses customer satisfaction,

process improvement, waste reduction and response time. As a guideline, ISO 9004 is not part of the compliance requirements and therefore "optional". Evidence indicates that most companies do not use ISO 9004 to assist in the design and implementation of their quality systems because their "registration requirements" are ISO 9001.

4. QS-9000 Prevention Focus:

QS-9000 Quality System Requirements focus on both the third and fourth quality evolution eras - Quality Assurance and Strategic Quality Management. This is particularly evident through its focus on prevention, control of processes - throughout the supply chain, and strategic focus on customers, business planning and training. The QS-9000 task force chose to address all three levels in the Quality Hierarchy of Customer Needs in Figure 1 incorporating much of what is in ISO 9004 and the criterion Total Quality Management (TQM) awards, such as the Malcolm Baldrige National Quality Award (NIST Publications, 1996), as part of the contractual standard.

The differences in approaches of ISO 9000 and QS-9000 are immediately obvious in the QS-9000's stated goal - "is 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 implied goal to "control product quality".

Management Responsibility for QS-9000 and ISO 9001 are the same requirements for the overall quality responsibility, organization and resources for quality relative to identification of nonconformances, resolution of problems and corrective action. However QS-9000 expanded this management responsibility to include quality and quality improvement as part of the business plan. The quality improvement must include specific initiatives addressing improvements 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 the interface of the organization's departments and functions. The strategic focus is demonstrated by the business planning requirement addressing not only the short term (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 keep focused not only on their own business performance but also to benchmark both inside and outside their organizations as a means to supporting their ongoing success. Customer satisfaction has also been added as an additional requirement. Suppliers are required to develop processes to determine current levels and trends in customer satisfaction and also use appropriate competitor trends and benchmarks.

Element 4.2, Quality System is one of the most important elements in terms of understanding the difference in approach of ISO 9000 and QS-9000. The requirement of a quality plan is usually addressed in ISO-9001 with an Inspection/Test Plan, see Figure 2. This plan defines the inspections or tests to be conducted with the acceptance criteria being specified. These tests and inspections are 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.

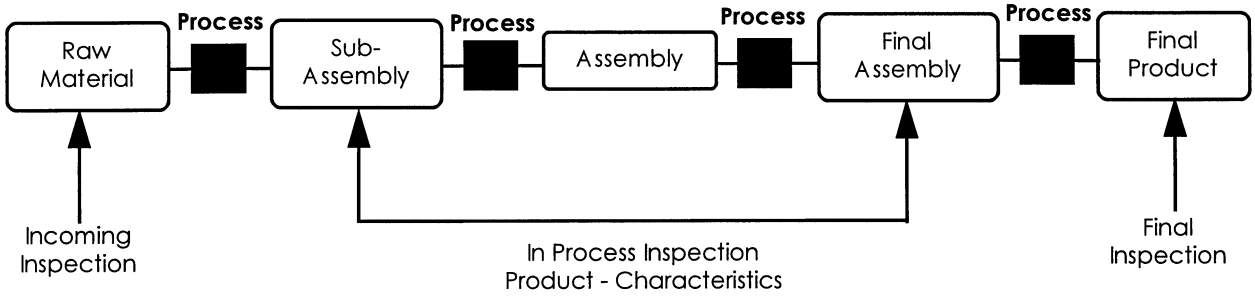

Figure 2: ISO 9001 Test/Inspection Plan

The quality plan for QS-9000 however is a "Control Plan" - Figure 3, which is very different from an inspection/test plan. While a control plan may include key product characteristics, 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 uses 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 (PFMEA), both design and manufacturing, and capability studies are used to assist in the quality planning process. The control plan defines the statistical tools which are to be used to monitor and control the processes. The concept of mistake proofing is introduced as a tool to eliminate the requirement of process monitoring. During the quality planning process, particularly the PFMEA process, potential modes of failure during the manufacturing of the product are identified. An ideal solution is to use error proofing to prevent a particular failure mode.

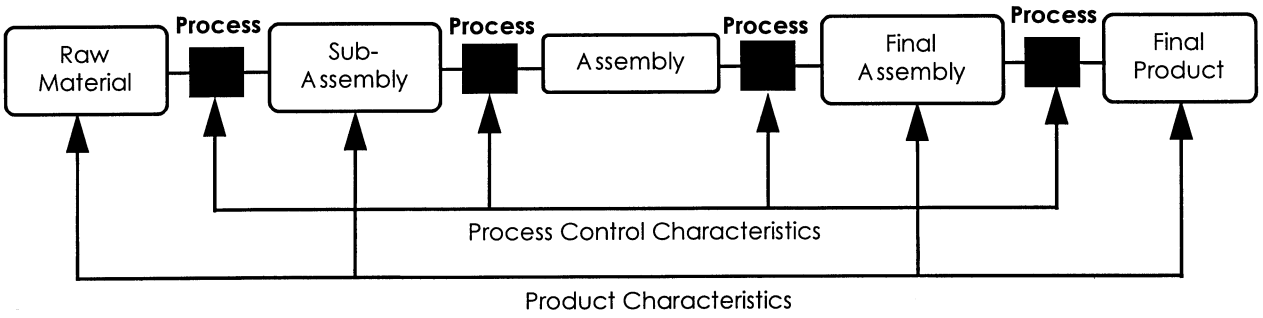

Figure 3: QS-9000 Control Plan

Process capability studies are required as part of the Production Part Approval Process (PPAP) to be done at the initial planning phase of the product introduction. This is to ensure that the manufacturing system is capable of meeting the product characteristics. Measurement systems analysis is a key component of the control planning activity. Studies, such as Gauge Repeatability and Reproducibility (R&R), are required to ensure the capability and

reproducibility of the process and product monitoring systems. The control plan is a "living document" under continuous review as process and product parameters change as a result of improving systems. Review is triggered by both internal and external inputs. External inputs could be from customer feedback or returns and/or quality improvement requirements. Internal inputs include nonconformances found during the manufacturing process and the initiatives identified in the continuous improvement plans.

Element 4.9 Process Control represents a major difference between ISO 9000 and QS-9000. The requirement is to control those processes that directly impact quality. Many organizations that have implemented ISO 9000 quality systems have interpreted this to mean only those inspection and testing functions as it is during these operations that the decisions of product acceptability are being made. The rationale here is that anything that anyone else does to impact product quality would be detected and verified by these test/inspection functions. These test/inspection operations would then require operator instructions or procedures to ensure that these tasks were executed properly. Special training of some operators is sometimes used to ensure product quality depending on the tasks being performed. For example ISO 9000 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. Here the emphasis moves from verification of product to focusing on the capabilities of the people performing the functions. QS-9000, on the other hand, interprets Process Control 4.9 requirements to apply to *all* operations in manufacturing, design, materials and contract review functions. The manufacturing equipment and facilities, in addition to inspection, measuring and test equipment, are given special attention in QS-9000.

It is a requirement 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 the supplier demonstrate continuous improvement in these processes. Preventive maintenance, including predictive maintenance methodologies, is required on this equipment. The tooling and fixturing repair/replacement is to be managed effectively to assure process performance.

The differences in approach and philosophy of ISO 9000 and QS-9000 should now be much clearer. While ISO 9000 is an excellent base to build upon, in order to achieve maximum benefit from a Quality System it must be designed to operate in Phases 3 and 4 of the Quality Evolution.

5. Statistical Requirements in QS-9000

Continuous improvement is a key element in QS-9000 and this implies that QS-9000 is knowledge driven (current knowledge to control processes and new knowledge to improve processes). Statistics deals with the acquisition of knowledge by observation. Planning for data collection, the actual data collection, processing of data into information and the communication of acquired knowledge are part of Statistics. Thus it forms a nervous system which senses the data and communicates the knowledge for the implementation of QS-9000.

Statistical thinking and tools are required in many areas in QS-9000. Some of these are listed below (as seen in the manual "Quality System Requirements", AIAG, 1995):

(i) 4.1.5: Analysis and use of company level data

"Shall document trends in quality, operational performance (productivity, efficiency, effectiveness) and current quality levels for key product and service features." Trends does not mean comparing last months numbers with this month's. It usually requires the monitoring of company level information on a run chart or a "chart for individuals". Section 4.1.6 discusses trends in customer satisfaction which points to the need for statistical tools.

(ii) 4.4.5: Design Output - Supplemental

"Utilization of techniques such as Quality Function Deployment (QFD), Design of Experiments (DOE), Tolerance Studies, Response Surface Methodology (RSM), Geometric dimensioning and tolerancing are required."

(iii) 4.9: Process Control

"Suppliers shall comply with all customer requirements for designation, documentation and control of special characteristics." The subsections process monitoring and operator instructions (4.9.1), preliminary process capability requirement (4.9.2), and ongoing process performance (4.9.3) involve Statistical Thinking and tools such as Control Charts, C_{pk}, and P_{pk}. In this section specific requirements for process performance are given in terms of C_{pk} and P_{pk}. It should also be noted that the APQP and PPAP manuals, AIAG (1995) also refer to specific requirements for process performance in terms of C_{pk} and P_{pk}.

(iv) 4.11.4: Measurement System Analysis

"Evidence is required that appropriate statistical studies have been conducted to analyse the variation present in the results of each type of measuring and test equipment system."

(v) 4.20: Statistical Techniques

"The supplier shall identify the need for statistical techniques required for establishing, controlling and verifying process capability and product characteristics."(4.20.1)
"The supplier shall establish and maintain documented procedures to implement and control the application of the statistical techniques identified in 4.20.1." (4.20.2)
Understanding of variation, stability, capability and over adjustment through out the supplier's organization is expected.

(vi) Section II, Part 2: Continuous Improvement

"Continuous improvement philosophy shall be fully deployed throughout the supplier's organization." This calls for various statistical tools (C_p, C_{pk}, Control Charts, Design of Experiments, etc.). This part (Continuous Improvement) is unique to QS-9000 and it implies that for the implementation of QS-9000 Statistical Thinking and methods play a major role.

Advanced Product Quality Planning and Control Plan reference manual AIAG (1995) describes a product Quality Planning Timing Chart with five phases: Planning stage; Product Design and

Development; Process Design and Development; Product and Process Validation stage; and Feedback, Assessment and Corrective Action stage. In each phase Statistical Thinking and tools are required.

In the planning stage, voice of internal and external customers is utilized (recommendations, complaints, etc.). Such information can be obtained by proper data collection via appropriate questionnaires or customer interviews. Information can also be obtained by analysing historical warranty and quality information. At the product design and development phase issues of design for manufacturability, design sensitivity to manufacturing variation etc. need to be considered and statistical techniques such as Design of Experiments, and Robust Design are very useful. In building specifications, understanding of variation is crucial. In process design and development, Statistical evaluations, Measurement system analysis and preliminary Process Capability studies are required. Product and process validation stage also calls for Measurement system analysis plan and evaluation, and Process Capability studies. For appropriate feedback, assessment and corrective action, understanding of variation is essential. Effective plans for dealing with variation are part of this phase. Also assessing customer satisfaction forms an important part.

Because of the overwhelming intermingling of statistical tools in the implementation of QS-9000, the requirements refer to two AIAG reference manuals indicated before, SPC and MSA.

The following statistical concepts and procedures are essential for the proper implementation of QS-9000:

i) Control Charts
- Run charts, charts for individuals, $\bar{x}$ and R charts, attribute charts, etc., need to be implemented depending on the context. Concepts of stability and tampering need to be understood.

ii) Capability ratios
- Process capability measures such as C_{pk}, P_{pk} are to be employed for normal and non-normal data.

iii) Measurement System Analysis
- The concepts of precision, bias, linearity, and stability need to be understood. Repeatability and Reproducibility studies are to be performed to control variation from different sources. Strategies for improving (reducing bias and variability) measurement systems need to be part of the system).

iv) Designed Experiments
- Factorial and fractional experiments are very useful for identifying important design and process factors. For efficient process improvement (adjusting to target and reducing variation) designed experiments are essential.

v) Continuous Improvement
- There needs to be a structured approach for CI. This helps to identify and understand families of variation.

6. Concluding Remarks

This paper gave a brief comparison of ISO 9000 and QS-9000, and the prevention and process focus of QS-9000 was emphasized. This quality system cannot function without the factual information and the continual growth of knowledge about all processes used in the design and manufacturing of the product. QS-9000 is knowledge driven and Statistics deals with the acquisition of knowledge by observation. We think of statistics as the nervous system of QS-9000 and it has a major role in the implementation of QS-9000.

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