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Automotive Industry Action Group

CQI-16

ISO/TS 16949:2009 Guidance Manual

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OVERVIEW

This implementation guide is written to help transition the organization's current quality management system (QMS) to ISO/TS 16949:2009 and is intended to serve as only a guidance document. Keep in mind that ISO/TS 16949:2009 uses ISO 9001:2008 as its base specification. For better understanding and clarification purposes, you may access the AIAG Web site at www.aiag.org for information on how to purchase ISO standards prior to using this implementation guide.

It is important to remember that ISO/TS 16949:2009 uses the terminology of "Process Approach" and is further clarified in this implementation guide. Depending on how the organization's current quality management system is set up, the QMS may already be in compliance to the "Process Approach".

ISO/TS 16949:2009 focuses on customer satisfaction. It is important to design, implement and maintain the organization's quality management system based on this focus. This includes greater attention to customer specific requirements and the organization's ability to satisfy them. It is no longer good enough to document what you do and do what is documented, but also to verify the effectiveness of the organization's processes in meeting customer and internal requirements.

1 PROCESS APPROACH

The Introduction of ISO/TS 16949:2009, Section 0.2 Process Approach states:

... for an organization to function effectively, it has to determine and manage numerous linked activities. An activity or set of activities using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the "process approach".

An advantage of the process approach is the ongoing control that it provides over the linkages between the individual processes within the system of processes, as well as over their combination and interactions.

When used within a quality management system, such an approach emphasizes the importance of

- understanding and meeting requirements,
- need to consider processes in terms of added value,
- obtaining results of process performance and effectiveness, and
- continual improvement of processes based on objective measurement.

This is typically achieved through process mapping (e.g. flowcharting) the organization's quality management system and then reviewing what is done against all the requirements in the Technical Specification as a minimum.

1.1 Quality Management System Requirements

ISO/TS 16949:2009 states in clause 4.1 that the organization shall

- determine the processes needed for the quality management system and their application throughout the organization,

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- determine the sequence and interaction of these processes,
- determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
- ensure that availability of resources and information necessary to support the operation and monitoring of these processes,
- monitor, measure where applicable, and analyze these processes, and
- implement actions necessary to achieve planned results and continual improvement of these processes.

This is typically documented using the "process approach" through process mapping or documented policies, procedures and work instructions.

2 EXPLANATION OF PROCESS APPROACH / AUDIT

This section shows the suggested best practices on how to identify, define, document and audit processes to prepare for registration to ISO/TS 16949:2009.

2.1 Benefits of Using the Process Approach

- Improved understanding of process interfaces and interactions
- Alignment of organization activities to customer metrics (See Figure 1)
- Customer feedback through metrics provides a customer's perspective of the effectiveness of the organization's processes
- Process approach is a "common language" understood by the global automotive industry
- Improved organizational efficiency through reduction/elimination of non-value added activity
- Audits that are tailored to the individual organizations through their processes
- Focus of 3rd party and internal audits on the activities and objectives most important to customer satisfaction
- Process audits provide a basis for continual improvement when customer objectives are met

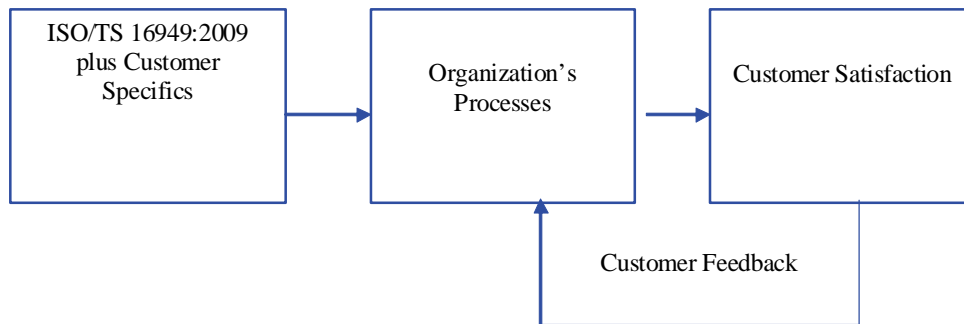


Figure 1. Alignment to Customer Metrics

2.2 What Is A Process?

Definition: ISO 9000 Quality Management systems – Fundamentals and Vocabulary provides the following definition:

Process = set of interrelated or interacting activities which transforms inputs into outputs

Note 1: Inputs to a process are generally outputs of other processes

Note 2: Processes in an organization are generally planned and carried out under controlled conditions to add value

The following Figure 2 describes this basic approach of inputs and outputs.



Figure 2. Classical Process Model

An example of the Classical Process Model is described in Figure 3 below:

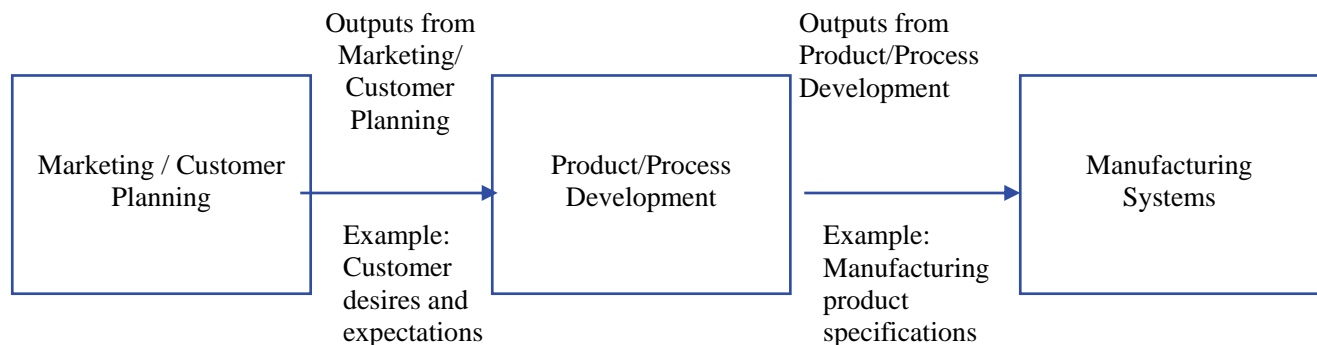


Figure 3. Interactions between Processes

2.3 The Building Blocks of a Process

Processes can be described as sequences of actions and responsibilities that include the following areas:

- Management Responsibility (who owns the process)
- Resource Management (personnel, skills, equipment, infrastructure, materials)
- Product Realization (the steps to make – realize – the product)
- Measurement, Analysis and Improvement (know what you need and what you have)

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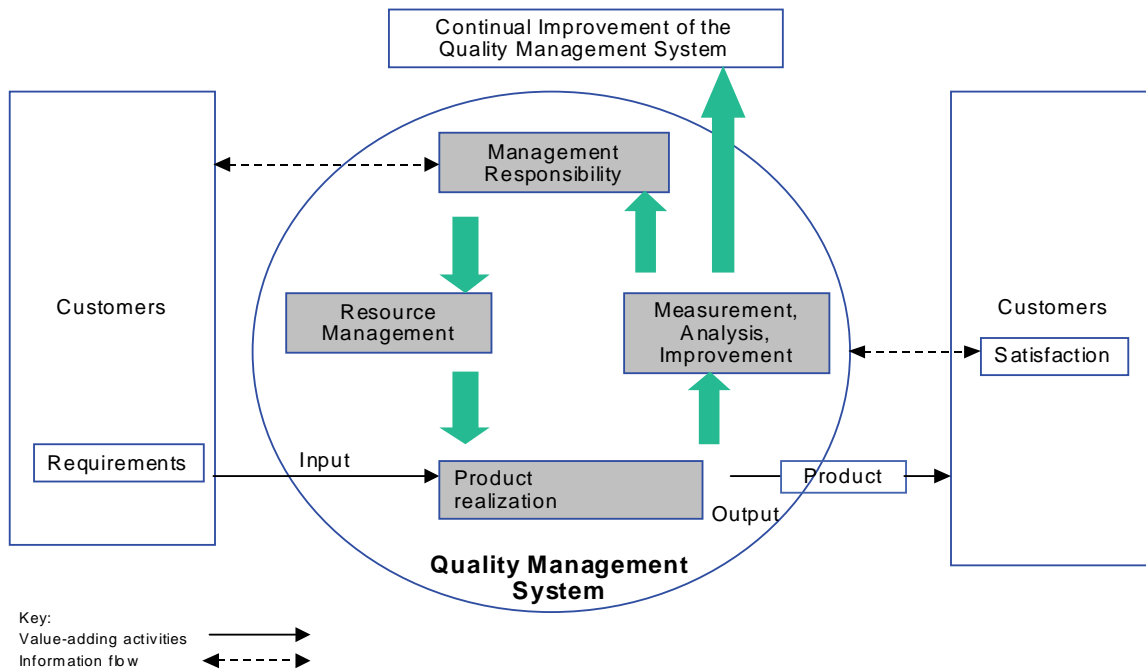


Figure 4. ISO/TS 16949:2009 Model of a Process-Based Quality Management System

Figure 4 shows the structure of a process-based quality management system. Although this structure is not explicitly required by ISO/TS 16949:2009, the four highlighted areas shown above in Figure 4 are both relevant to the automotive industry and useful to describe a process. These four highlighted areas correspond to Clauses 5 through 8 of ISO/TS 16949:2009. Clause 4 (Quality Management System) gives the requirements for documentation and structure applicable to the entire quality management system.

Application of Clauses 5 through 8 as applied to any process (Applicable to all types of processes, not limited to manufacturing):

Clause 5: Management Responsibility represents the action of management oversight to ensure that all process steps contribute to the fulfillment of customer requirements.

Clause 6: Resource Management is the provision to processes of appropriate and sufficient resources (skills, personnel, equipment, and infrastructure) to permit fulfillment of customer satisfaction.

Clause 7: Product Realization includes the steps for planning, understanding customer requirements, design, procurement, production, quality control, and logistics necessary to produce the intended product.

Clause 8: Measurement, analysis and improvement include validation of conformity of the process and of the final product to customer requirements, and continual improvement through corrective and preventive actions.

See Appendix A - Heat Treat Process Example. The example demonstrates the usage of the four clauses listed above in an automotive process example.

2.4 The Process Approach

The process approach is a methodology for the design, implementation and maintenance of the Quality Management System. This method identifies the process inputs and outputs of each requirement as stated in ISO/TS 16949:2009. Methods may include graphical representation (see Appendix D, Process Mapping Example Fig 1.), written instructions (such as policies, procedures), flowcharts, visual media, or electronic methods

Customer requirements form a vital part of the Quality Management System. Refer to each specific customer for this information (e.g. customer Web sites).

The process approach identified in Figure 6 below structures the organization's QMS around customer satisfaction and the organization's processes. By identifying inputs and outputs as well as the sequence and interactions, the QMS can then be measured to verify its effectiveness per customer requirements (horizontal integration).

Figure 6 shows attributes of each process that need to be reviewed during a process audit. The horizontal arrow represents the applicability of those areas to each process in the organization.

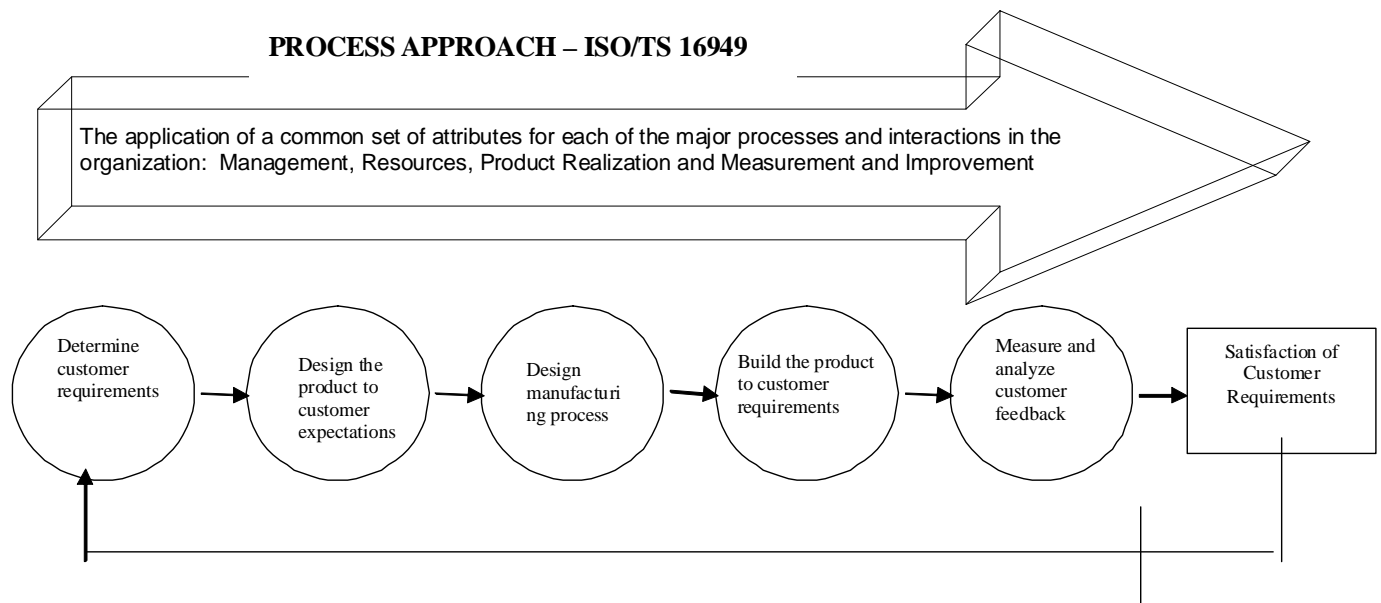


Figure 6. Process Approach – ISO/TS 16949:2009 Process Attributes

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3 SETTING UP THE QUALITY MANAGEMENT SYSTEM

3.1 Step 1 – Process Identification

ISO/TS 16949:2009 clause 4.1a states, "The organization shall determine the processes needed for the quality management system and their application throughout the organization". The organization needs to show how all the requirements of ISO/TS 16949:2009 are met.

In this document review, the organization identifies where in the quality management system each requirement of ISO/TS 16949:2009 is addressed. The auditor then focuses on the effectiveness of the organization through the organization's processes.

Customer requirements form an integral part of the Quality Management System. Refer to each specific customer for this information (e.g. customer Web sites).

3.2 Step 2 – Process Mapping

ISO/TS 16949:2009 clause 4.1b states, "the organization shall determine the sequence and interactions of these processes". The organization needs to show how its process inputs → process steps → process outputs interact in a logical sequence to meet the requirements of ISO/TS 16949:2009. Another term for this step is called "process mapping".

See Appendix D - Process Mapping Examples for additional information.

Once the organization's processes have been mapped to the requirements, the organization is ready to plan its internal process-based audits.

As shown in Figure 7, fundamentally, a process audit approach follows the organization's quality management system through its natural workflow.

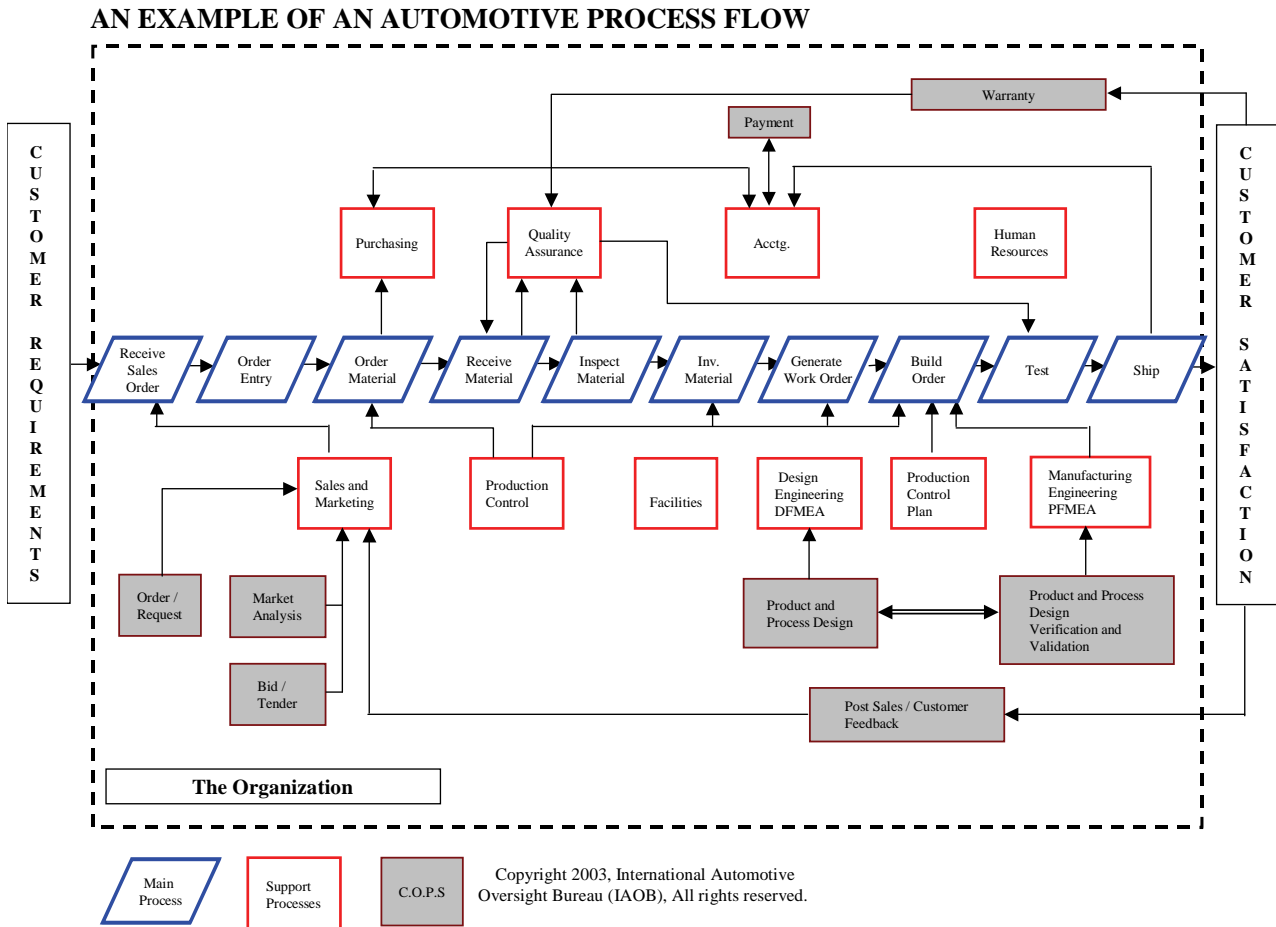


Figure 7. An Example of an Automotive Process Flow

3.3 Step 3 – Effectiveness

ISO/TS 16949:2009 clause 4.1c states, "The organization shall determine criteria and methods needed to ensure that both the operation and control of these processes are effective."

ISO 9000:2000 defines "effectiveness" as, "the extent to which planned activities are realized and planned results achieved."

When mapping the process, review the process outputs to inputs. Compare the outputs of the process to the organization's objectives. Analyze the metrics being used – or determine metrics to be used. These metrics are used to track progress, indicate correction or drive improvement in the quality management system. Metrics are not always quantitative. Action items resulting from management reviews may also apply.

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3.4 Step 4 - Auditing

Three types of audits are required in ISO/TS 16949:2009:

- 8.2.2.1 Quality Management System Audit
- 8.2.2.2 Manufacturing process audit
- 8.2.2.3 Product Audit

All of these audits must be conducted using the process approach.

ISO/TS 16949:2009 section 8.2.2.5 Internal auditor qualifications are: "The organization shall have internal auditors who are qualified to audit the requirements of this Technical Specification (see 6.2.2.2)." Refer to customer specific requirements for specific criteria.

The basic steps in a process approach audit can include:

- reviewing the list of customers and their customer specific requirements
- identifying process owners, their responsibilities and authority
- reviewing the process measurements before conducting the audit, especially those metrics important to the customer. Compare business goals and objectives to customer goals and objectives
- understanding the basic business processes within the organization and following them through the process
- reviewing linkages (process handoffs) and interactions (e.g., from employee to employee, shift to shift, function to function, plant to plant, process to process)

If the product / process meet specification with no negative trends:

- ask about the basic building blocks of the process and the inputs/outputs, to determine knowledge of the process
- ask about how the organization measures effectiveness of its processes and ask them how they interpret the results
- ask how they build on steps to achieve continual improvement
- ask if they use benchmarking to achieve continual improvement

If the product / process does not meet specification or has negative trends:

- is top management involved
- ask who is responsible (process owner)
- concentrate on product realization (the steps involved). What step is not being followed or is not effective
- does the organization know where the negative trend begins (Where do the measurements begin to show issues?)
- how does the organization contain the problem (protect the customer)
- how does the organization investigate to find the root cause of the out-of-specification part or process
- what progress has been made towards correction
- have similar processes been reviewed to prevent recurrence
- if the process involves manufacturing: