CQI-7

# ISO/TS 16949:2002 IMPLEMENTATION GUIDE

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# FOREWORD

The purpose of this implementation guide is twofold:

- Guide an automotive manufacturing organization to ISO/TS 16949:2002 registration when starting without registration to any of the current automotive certifications (e.g. QS-9000 3rd, ISO/TS 16949:1999, VDA 6.1, etc.).
- To provide automotive suppliers with a guide to help transition their current QS-9000 3rd edition-based quality management systems to ISO/TS 16949:2002.

One lesson learned from QS-9000 is the importance of utilizing proper planning when designing and implementing the organization's Quality Management System (QMS). This implementation guide builds upon this lesson by explaining what's new and different (between QS-9000 3rd edition and ISO/TS 16949:2002) and providing strategies for implementation and clarification on how to conduct a process audit, which is new to ISO/TS 16949:2002.

ISO/TS 16949:2002 utilizes the "Process Approach" to the Quality Management System development and improvement by identifying the organization’s processes, how these processes link to customer satisfaction, and the organization’s methods to measure and improve process effectiveness.

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# 1.0 OVERVIEW

This implementation guide is written to help transition the organization's current quality management system (QMS) from QS-9000 3rd edition to ISO/TS 16949:2002. Since this implementation guide serves as only a guidance document there will be some duplication. This was done intentionally so that the reader does not have to read different sections to find an answer to a question.

Keep in mind that ISO/TS 16949:2002 uses ISO 9001:2000 as its base specification. For better understanding and clarification purposes, it will be important to access the International Organization for Standardization Web site at www.iso.org for additional information prior to using this implementation guide.

The following IATF ISO/TS 16949:2002 publications (e.g. 4 pack) are available through the AIAG:

- IATF ISO/TS 16949:2002 Technical Specification (required document)
- IATF Guidance to ISO/TS 16949:2002
- IATF Quality System Assessment Checklist
- IATF Rules for achieving IATF recognition

Some of the ISO/TS 16949:2002 customer specifics still require use of the core tools identified in the QS-9000 manual. It is suggested that copies of these manuals are on hand when designing and implementing a quality management system.

- Production Part Approval Process (PPAP)
- Advanced Product Quality Planning (APQP)
- Measurement Systems Analysis (MSA)
- Statistical Process Control (SPC)
- Potential Failure Mode and Effects Analysis (FMEA)

Refer to each customer's requirements for applicability.

When transitioning to ISO/TS 16949:2002, it is recommended that the certification body be contacted with any questions regarding the interpretation of any requirements. Sanctioned Interpretations, Frequently Asked Questions (FAQs) and other useful information can be found on the International Automotive Oversight Bureau Web site at www.iaob.org.

It is important to remember that ISO/TS 16949:2002 uses the new 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" (versus QS-9000 traditionally using an "Elemental Approach").

ISO/TS 16949:2002 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.

As part of the continual improvement process, all changes/revisions to this guidance document and responses to questions are posted on the AIAG Web site at www.aiag.org. Refer to the *Maintenance Request* form at the end of this manual to see how to submit comments.

## 2.0 WHAT'S "NEW AND DIFFERENT"

It is important to understand what is new and different before converting the organization's quality management system from QS-9000 3rd to ISO/TS 16949:2002. The following are some key points of interest:

| | QS-9000 3rd | ISO/TS 16949:2002 |
|---|---|---|
| **AIAG Manuals** | QS-9000 7 Pack | ISO/TS 4 Pack plus APQP, FMEA, MSA, SPC, PPAP |
| **Base Standard** | ISO 9001:1994 (italicized text) | ISO 9001:2000 (boxed text) |
| **Change in Terms** | • Supplier / Sub contractor<br>• Procedures<br>• Executive Management<br>• Specified Requirements | • Organization / Supplier<br>• Process and Procedures<br>• Top Management<br>• ISO/TS 16949 and Customer Requirements |
| **Changes in Intent** | • Conformity<br>• Quality Assurance<br>• Documented Procedures<br>• Meeting Product Requirements<br>• Skills<br>• Order Driven<br>• Documentation for conformity<br>• Product measurement | • Performance<br>• Customer Satisfaction<br>• Managed Processes<br>• Meeting needs and expectations of parties<br>• Competence<br>• Customer Driven<br>• Documentation for effective management<br>• Product, process and system, measurement |
| **Format** | 20 element | Process approach, 5 clauses |
| **Shalls** | 292 | 284 |
| **Focus** | • Documented quality system<br>• Conformity | • Meeting customer expectations and other stakeholder needs.<br>• Part and Process Performance to customer specification. |
| **Documentation** | 18 – minimum procedures | 7 – minimum procedures<br>(ISO/TS 16949:2002 identifies areas where procedures have to be documented.) |
| **Customer Specifics** | Documented in QS-9000 | Posted on customer / IAOB Web site |
| **Auditing** | Element approach | Process approach based on customer metrics. |

| | QS-9000 3rd | ISO/TS 16949:2002 |
|---|---|---|
| **Certification Body Oversight** | Globally, 22 accreditation bodies | Globally, 5 oversight bodies |
| **Certification Body Recognition Process** | Certification number issued by certification body | Certification number issued by IATF |
| **Certification Body De-Certification Process** | Managed by Accreditation Boards | Requires consensus of IATF members |
| **Who can be registered** | Manufacturing sites and distribution centers | Manufacturing sites & assembly centers |

To further illustrate the difference between QS-9000 and ISO/TS 16949:2002, cross over matrices have been developed (reference *Appendix A & B*).

- Appendix A is a cross over from QS-9000 3rd to ISO/TS 16949:2002.
- Appendix B is a cross over from ISO/TS 16949:2002 to QS-9000 3rd.

**Note:** These crossover matrices should only be used as a tool for understanding the differences between QS-9000 3rd and ISO/TS 16949:2002. It is important that the Quality Management System (QMS) be designed and implemented based on the process approach to achieve customer satisfaction.

## 2.1 Customer Oriented Processes

In ISO/TS 16949:2002, the IATF has adopted a concept called "Customer Oriented Processes," or COPs. COPs are referred to in the *Checklist to ISO/TS 16949:2002*, where it is stated:

> The IATF expects ISO/TS 16949:2002 auditors to audit based upon the Customer Oriented Processes (COP). The COP is a model that was introduced by ISO 9001:2000 and refers to the fact that any organization needs customer input to comply to specified and expected needs of the customer (output) in order to achieve customer satisfaction. This is accomplished by value adding processes of product realization and appropriate support processes, both enabled by management processes and provided resources.
>
> QS-9000 emphasized that a supplier have a "documented quality system" with insufficient emphasis upon achieving customer satisfaction.

### 2.1.1 Process Approach

The Introduction of ISO/TS 16949:2002, Section 0.2 Process Approach states:

> . . .for an organization to function effectively, it has to identify and manage numerous linked activities. An activity 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, 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 or among the individual processes within a quality management system, as well as over their sequences and interactions.

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

a) understanding and meeting requirements,
b) need to consider processes in terms of added value,
c) obtaining results of process performance and effectiveness, and
d) 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.

QS-9000 created in many cases an elemental structure of policies, procedures and work instructions but often failed to show process interaction of inputs, outputs and their overall effectiveness.

### 2.1.2 Quality Management System Requirements

ISO/TS 16949:2002 states in clause 4.1 that the organization shall

a) identify the processes needed for the quality management system and their application throughout the organization,
b) determine the sequence and interaction of these processes,
c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
d) ensure that availability of resources and information necessary to support the operation and monitoring of these processes,
e) monitor, measure and analyze these processes, and
f) 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.

QS-9000 defined specific elements where the supplier's quality management system had to be in compliance. ISO/TS 16949:2002 focuses on the approach by which the organization's quality management system is developed and implemented to satisfy customer requirements.

### 2.1.3 New Requirements

Although there are several differences between QS-9000 3rd and ISO/TS 16949:2002, the following are 15 requirements that are either new or contain significant changes.

| REQUIREMENTS | | |
|---|---|---|
| **1** | 5.1 | **Management commitment**<br>Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improve its effectiveness by:<br>a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,<br>b) establishing the quality policy,<br>c) ensuring that quality objectives are established,<br>d) conducting management reviews, and<br>e) ensuring the availability of resources. |
| **2** | 5.1.1 | **Process efficiency**<br>Top management shall review the product realization processes and the support processes to assure their effectiveness and efficiency. |
| **3** | 5.4.1 | **Quality objectives**<br>Top management shall ensure that quality objectives, including those needed to meet requirements for product (see 7.1.a) are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy. |
| **4** | 5.5.2.1 | **Customer representative**<br>Top management shall designate personnel with responsibility and authority to ensure that customer requirements are addressed. This includes selection of special characteristics, setting quality objectives and related training, corrective and preventive actions, product design and development. |
| **5** | 5.5.3 | **Internal communication**<br>Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system. |

| REQUIREMENTS (continued) | | |
|---|---|---|
| **6** | 6.2.2.4 | **Employee motivation and empowerment**<br>The organization shall have a process to motivate employees to achieve quality objectives, to make continual improvements, and to create an environment to promote innovation. The process shall include the promotion of quality and technological awareness throughout the whole organization. The organization shall have a process to measure the extent to which its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives (see 6.2.2 d). |
| **7** | 6.3 | **Infrastructure**<br>The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:<br>a) buildings, workspace and associated utilities<br>b) process equipment (both hardware and software)<br>c) support services (such as transport or communication) |
| **8** | 7.2.3 | **Customer communication**<br>The organization shall determine and implement effective arrangements for communicating with customers in relation to;<br>a) product information,<br>b) enquiries, contracts or order handling, including amendments, and<br>c) customer feedback, including customer complaints. |
| **9** | 7.3.2.1 | **Product design input**<br>The organization shall identify, document and review the product design inputs requirements, including the following:<br>– customer requirements (contract review) such as special characteristics (see 7.3.2.3), identification, traceability and packaging<br>– use of information: the organization shall have a process to deploy information gained from previous design projects, competitor analysis supplier feedback, internal input, field data, and other relevant sources, for current and future projects of a similar nature<br>– targets for product quality, life, reliability, durability, maintainability, timing and cost |
| **10** | 7.3.2.2 | **Manufacturing process design input**<br>The organization shall identify, document and review the manufacturing process design input requirements, including:<br>– product design output data<br>– targets for productivity, process capability and cost<br>– customers requirements, if any<br>– experience from previous developments |

| REQUIREMENTS (continued) | | |
|---|---|---|
| **11** | 7.3.3.2 | **Manufacturing process design output**<br>The manufacturing process design output shall be expressed in terms that can be verified against manufacturing process design input requirements and validated. The manufacturing process design output shall include:<br>– specifications and drawings<br>– manufacturing process flow chart/layout<br>– manufacturing process FMEAs<br>– control plan (see 7.5.1.1)<br>– work instructions<br>– process approval acceptance criteria<br>– data for quality, reliability, maintainability and measurability<br>– results of error-proofing activities, as appropriate<br>– methods of rapid detection and feedback of product/manufacturing process nonconformities |
| **12** | 7.4.3.2 | **Supplier monitoring**<br>Supplier performance shall be monitored through the following indicators:<br>– delivered product quality<br>– customer disruptions including field returns<br>– delivery schedule performance (including incidents of premium freight)<br>– special status customer notifications related to quality or delivery issues<br>The organization shall promote supplier monitoring of the performance of their manufacturing processes. |
| **13** | 8.1 | **Measurement, analysis and improvement – General**<br>The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed<br>a) to demonstrate conformity of the product,<br>b) to ensure conformity of the quality management system, and<br>c) to continually improve the effectiveness of the quality management system.<br>This shall include determination of applicable methods, including statistical techniques, and the extent of their use. |
| **14** | 8.2.2.5 | **Internal auditor qualifications**<br>The organization shall have internal auditors who are qualified to audit the requirements of this Technical Specification (see 6.2.2.2). |
| **15** | 8.5.1.2 | **Manufacturing process improvement**<br>Manufacturing process improvement shall continually focus upon control and reduction of variation in product characteristics and manufacturing process parameters.<br>**Note 1:** Controlled characteristics are documented in the control plan.<br>**Note 2:** Continual improvement is implemented once manufacturing processes are capable and stable; product characteristics are predictable and meet customer requirements. |

Refer to *Appendix A & B* of this manual for a complete list of requirement changes by element/clause.

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

# 3.0 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 16949:2002.

## 3.1 What to Expect From the Process Approach Section

- How to identify, define and understand processes within an organization applying for registration to ISO/TS 16949:2002.
- How to understand the process approach to auditing to ISO/TS 16949:2002.

## 3.2 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

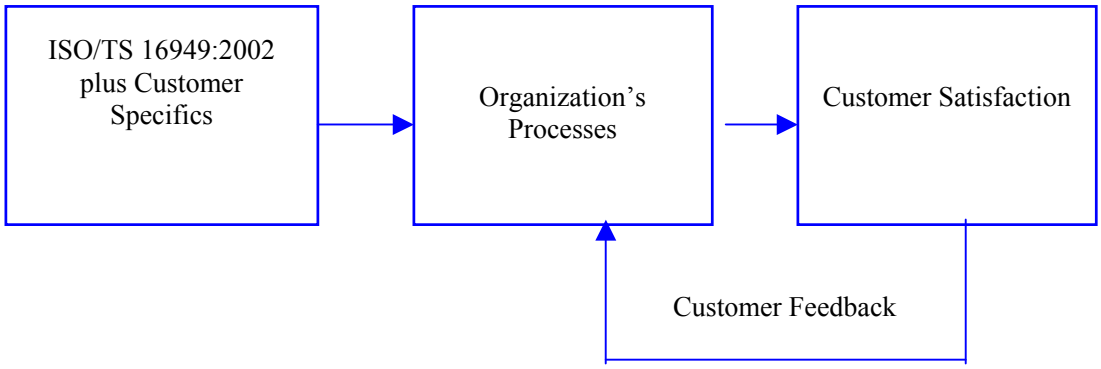



**Figure 1. Alignment to Customer Metrics**

## 3.3 What Is A Process?

**Definition:** ISO 9000:2000 *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:

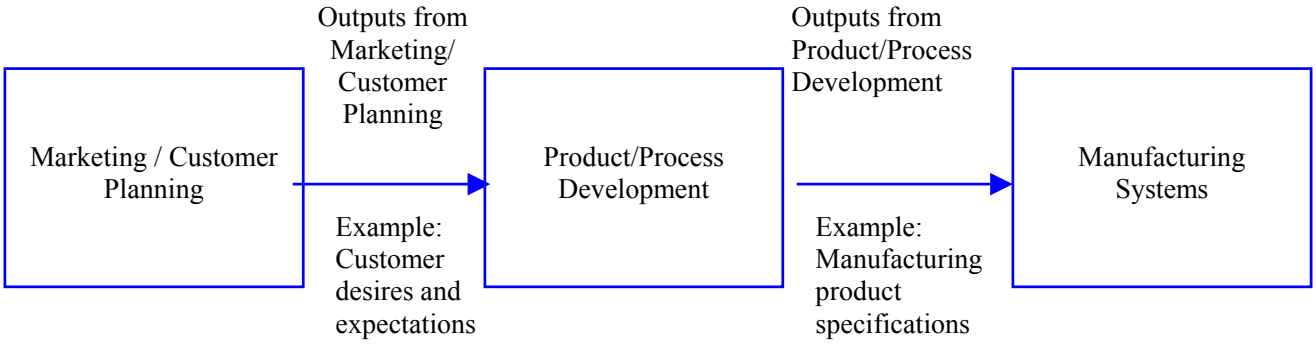



**Figure 3. Interactions Between Processes**

## 3.4 The Building Blocks of a Process

ISO/TS 16949:2002 describes processes 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)

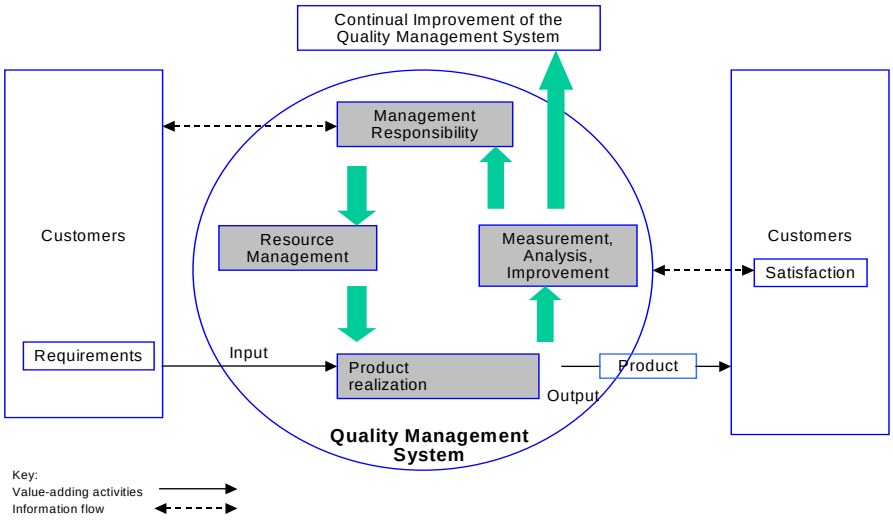



**Figure 4. ISO/TS 16949:2002 Model of a Process-Based Quality Management System**

Figure 4 shows the structure of a process-based quality management system. Although this structure is not explicitly required by ISO/TS 16949:2002, 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 16949:2002. Clause 4 (Quality Management System) gives the requirements for documentation and structure applicable to the entire quality management system.

**Application of Clauses 5 though 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 G - Heat Treat Process Example*. The example demonstrates the usage of the four clauses listed above in an automotive process example.

## 3.5 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 16949:2002. Methods may include graphical representation (*see Appendix J, Process Mapping Example Fig 1.*), written instructions (such as policies, procedures), flowcharts, visual media, or electronic methods (For additional information reference www.iso.org web site for *ISO-9000 Introduction and Support Package: Guidance on the Process Approach to quality management system Document: ISO/TC 176/SWC 2/N 544R*).

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 elemental approach identified in Figure 5 below structures the organization's QMS by element (vertical integration). These elements are then typically audited by element as described in the QS-9000 *Quality System Assessment Checklist*. This approach typically does not consider the sequence and interaction of related processes. Therefore, each element of the standard could be compliant, but could result in a fragmented or ineffective QMS. This approach was not focused on customer satisfaction.

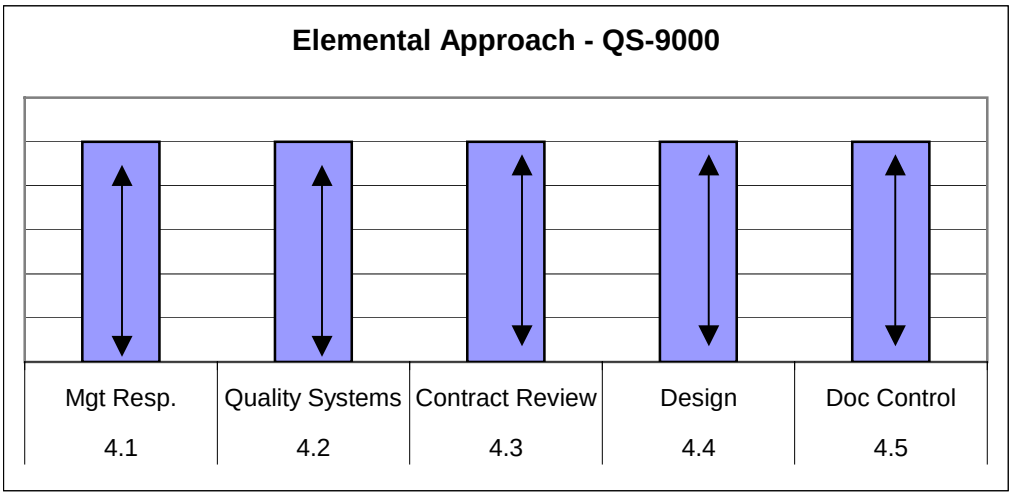



**Figure 5. Elemental Approach – QS-9000**

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.

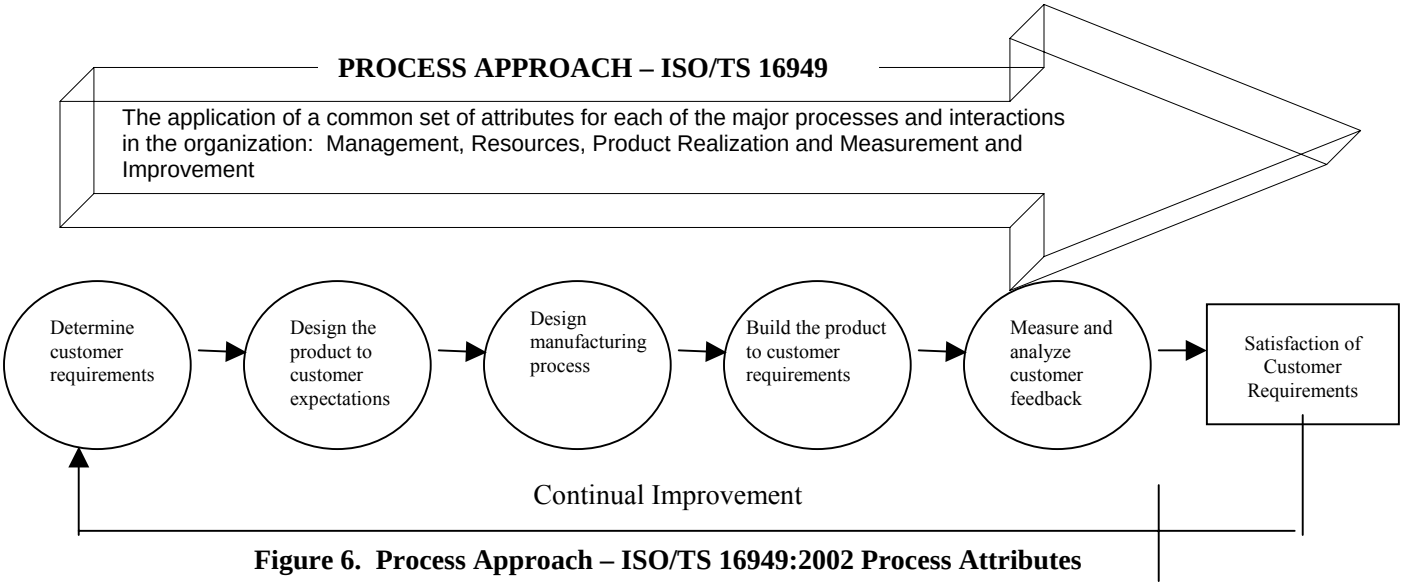



**Figure 6. Process Approach – ISO/TS 16949:2002 Process Attributes**

# 4.0 SETTING UP THE QUALITY MANAGEMENT SYSTEM

## 4.1 Step 1 – Process Identification

ISO/TS 16949:2002 clause 4.1a states, "The organization shall identify 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 16949:2002 are met.

The *Process Identification Tool* (a Microsoft Excel-based mapping tool) provides step-by-step instructions on how to identify the processes in an organization and how to map those internal processes to the requirements of ISO/TS 16949:2002. *(See Appendix C, Process Identification Tool)*

The *Process Identification Tool* is available on line at http://www.aiag.org/isots_tool/isots_tool.asp.

> **Note:** This *Process Identification Tool* is to be used to map the processes, and is not recommended for use during audits, since doing so may encourage an elemental style audit.

In this document review, the organization identifies where in the quality management system each requirement of ISO/TS 16949:2002 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). The *Process Identification Tool* also shows how to map the customer requirements to the organization's processes.

## 4.2 Step 2 – Process Mapping

ISO/TS 16949:2002 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 16949:2002. Another term for this step is called "process mapping".

See *Appendix J - 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.

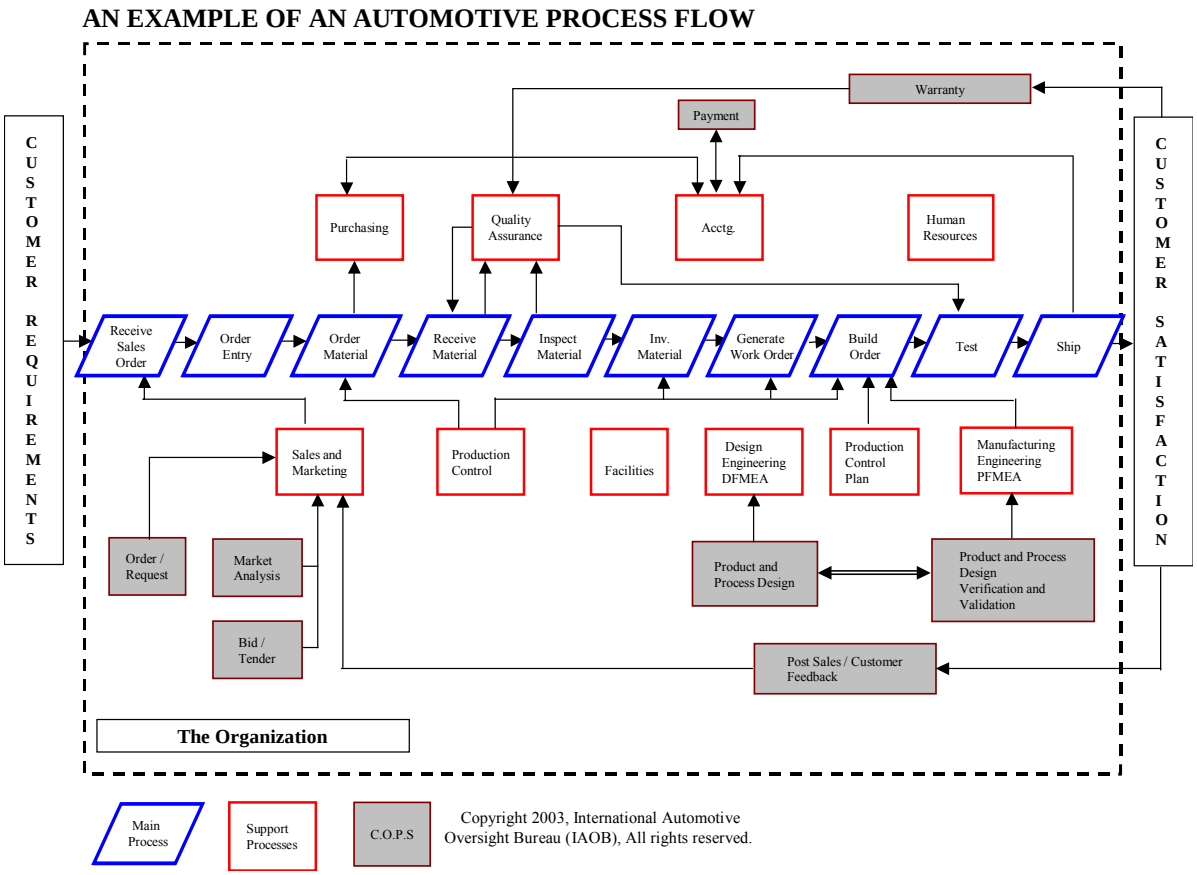



**Figure 7. An Example of an Automotive Process Flow**

## 4.3 Step 3 – Effectiveness

ISO/TS 16949:2002 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.

## 4.4 Step 4 - Auditing

Three types of audits are required in ISO/TS 16949:2002:

- 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 16949:2002 section 8.2.2.5 Internal auditor qualifications are: "The organization shall have internal auditors who are qualified to audit the requirements of this ISO/TS 16949:2002 (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:
    - were the FMEAs and control plan(s) reviewed or updated
    - were product audits reviewed and/or increased

These three types of audits are interrelated, as shown in Figure 8:

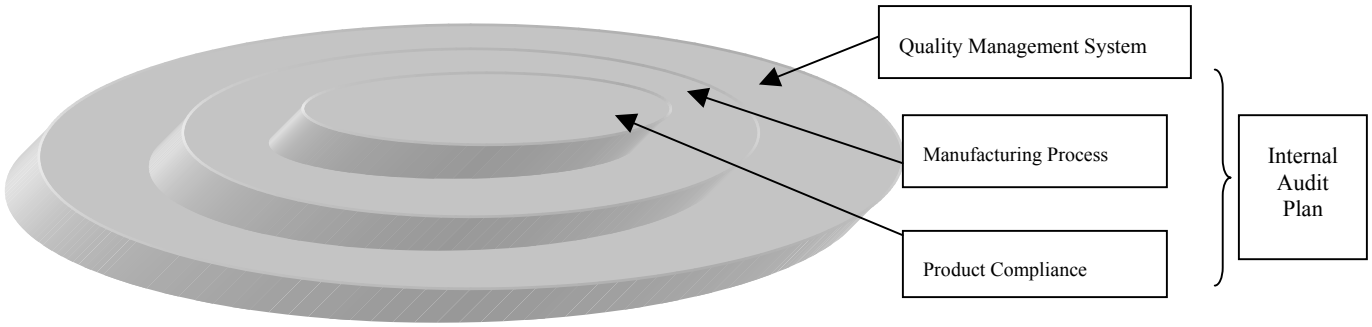



**Figure 8. The Three Audits Types build upon each other.**

- A **Quality Management System Audit** uses the process approach to monitor the organization through its natural flow, from process to process, to verify compliance to ISO/TS 16949:2002 and customer requirements.
- The **Manufacturing Process Audit** focuses on the manufacturing process within the total quality management system.
- The **Product Audit** focuses on product characteristics that lead to the verification of the achievement of product requirements.

The three types of audits required by ISO/TS 16949:2002 may be performed as separate or combined events as shown in Figure 9.

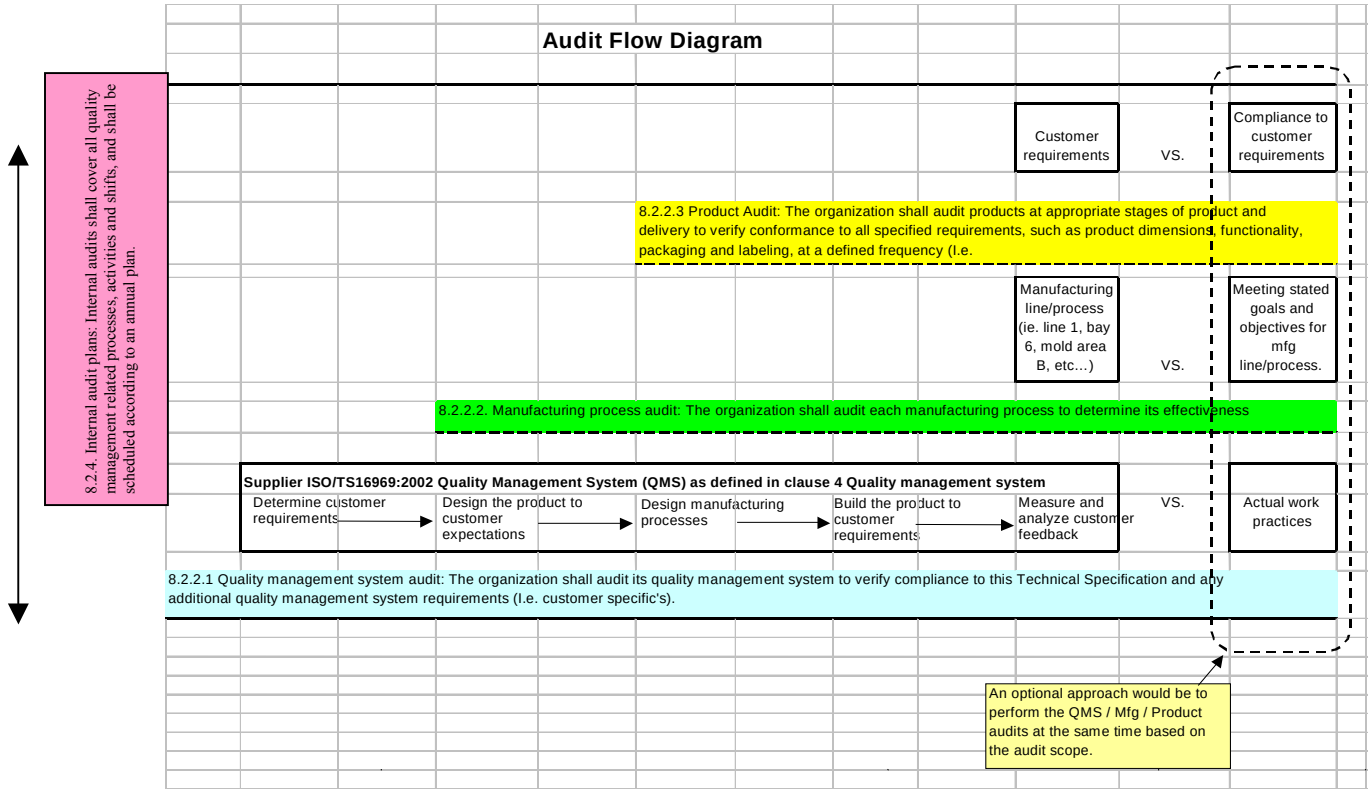



**Figure 9. Audit Flow Diagram**

### 4.4.1 Quality Management System (QMS) Audit

Clause 8.2.2.1 requires that the Quality Management System (i.e. clauses 4.1a-f) be in compliance to ISO/TS 16949:2002.

- The first step in implementing the QMS is to assure that the QMS is in compliance to all requirements including customer specific requirements (example – traditional document review using ISO/TS 16949:2002). This may be accomplished by using the *Process Identification Tool.* (Refer to Appendix C, *Process Identification Tool* ***or*** at http://www.aiag.org/isots_tool/isots_tool.asp.).
- The second step is to assure that the QMS is being followed (i.e. Process Approach to auditing). An example of this would be auditing to the organization's procedures, work instructions, process maps, etc., at the defined frequency in the audit schedule according to clause 8.2.2.4. The complete list of processes can serve as an audit check sheet to ensure that the organization has covered the entire QMS, and therefore all requirements of ISO/TS 16949:2002.

**Per clause 4.1c, it is critical to verify the effectiveness of each of these processes during the Quality Management System audit. The audit should include focus on customer satisfaction metrics including but not limited to cost, quality, delivery, customer disruptions, etc.**

The Manufacturing Process Audit and/or Product Compliance Audits may also be performed in conjunction with this audit.

See *Appendix H - The Quality Management System Audit* for examples of a QMS process audit.

### 4.4.2 Manufacturing Process Audit

Section 8.2.2.2 states, "The organization shall audit each manufacturing process to determine its effectiveness."

The application of the phrase, "each manufacturing process" is defined by the organization, often in the form of control plans. The organization also defines the scope of its manufacturing process audits. The manufacturing process audit needs to concentrate on verifying that the planned performance for the manufacturing process is being achieved, e.g., does the process achieve what the process design output defines?

All different types of processes must be audited. For example, if an identical process is repeated on three manufacturing lines, one process may be audited, provided measurement indicators show no difference among the three lines.

The Manufacturing Process Audit emphasizes the importance of manufacturing within the quality management system. The manufacturing process audit is a process audit of an organization's manufacturing processes (e.g. an audit of assembly, machining, heat treat, paint, casting, etc.).

Typically the manufacturing process audit uses control plan effectiveness as its primary focus. The following key indicators are addressed:

- What are the planned activities?
- Does actual practice follow those planned activities?
- Do the customer metrics indicate that the control plan is effective?

The manufacturing process may include interfaces/linkages between or among the following:

- customer ratings and customer complaints
- internal nonconformities
- process flow charts, PFMEAs, control plans, work instructions
- internal communication
- employee competency
- quoted production capacity
- preventive/predictive maintenance

**Note:** The manufacturing process audit may use physical measurements of the product audit to validate the effectiveness of the manufacturing processes.

An example of a typical manufacturing process audit flow diagram is shown in Figure 10.

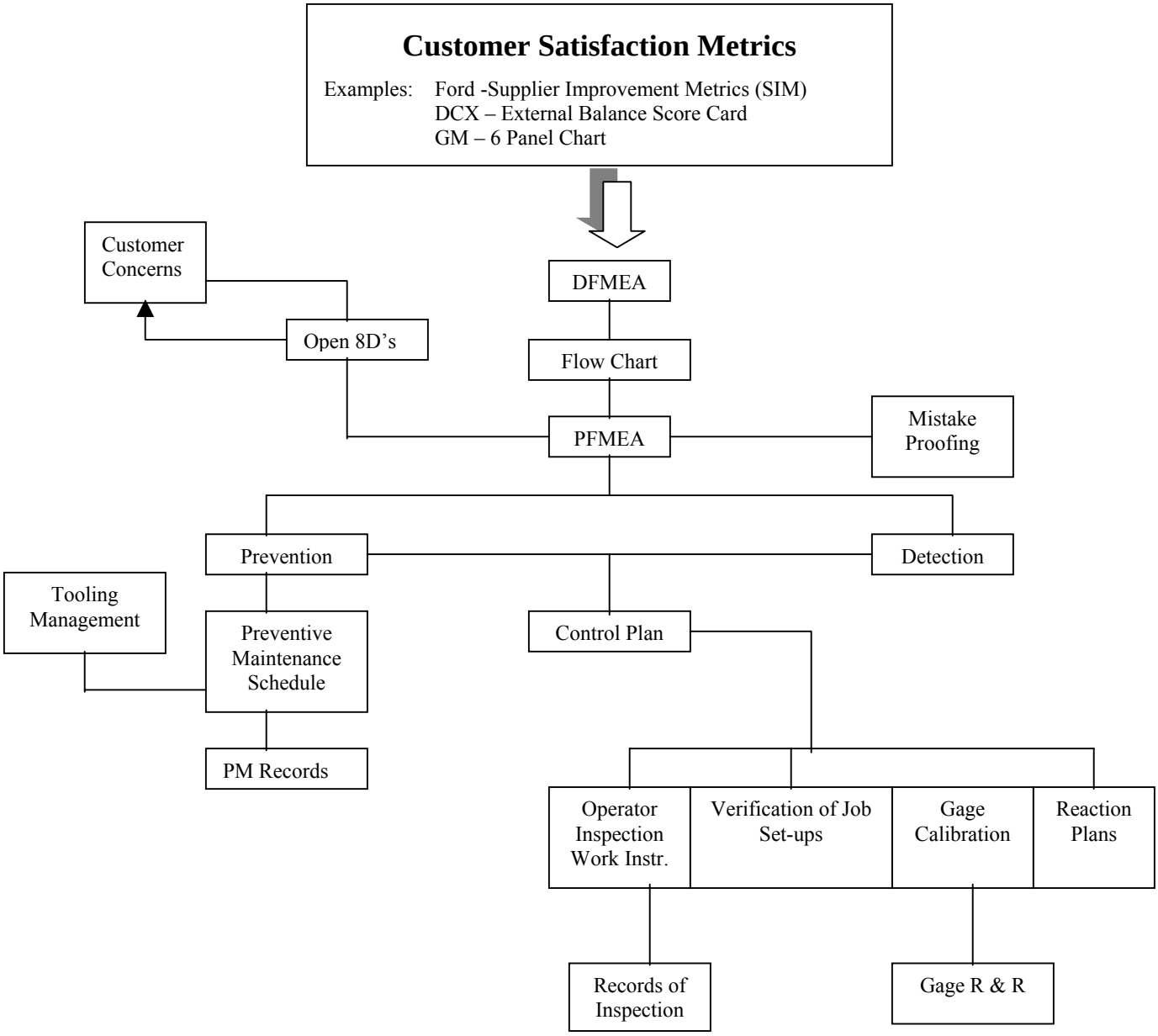



**Figure 10. Typical Manufacturing Process Audit Flow Diagram**

See *Appendix I - The Manufacturing Process Audit* for more information regarding the manufacturing process audit.

### 4.4.3 Product Audit

As stated in 8.2.2.3 of ISO/TS 16949:2002, "The organization shall audit products at appropriate stages of production and delivery to verify conformity to all specified requirements, such as product dimensions, functionality, packaging and labeling, at a defined frequency."

As shown in Figure 11, this type of audit verifies that customer inputs (such as the part print) lead to the correct outputs (correct dimensional, functional part to print, correct packaging and labeling). Those who audit product measure the product and compare to the customer product requirements. The product audit monitors the product as it progresses from one step of the manufacturing process to the next. The physical part measurements of the product audit can be used to identify the manufacturing process steps that fail to meet specifications.

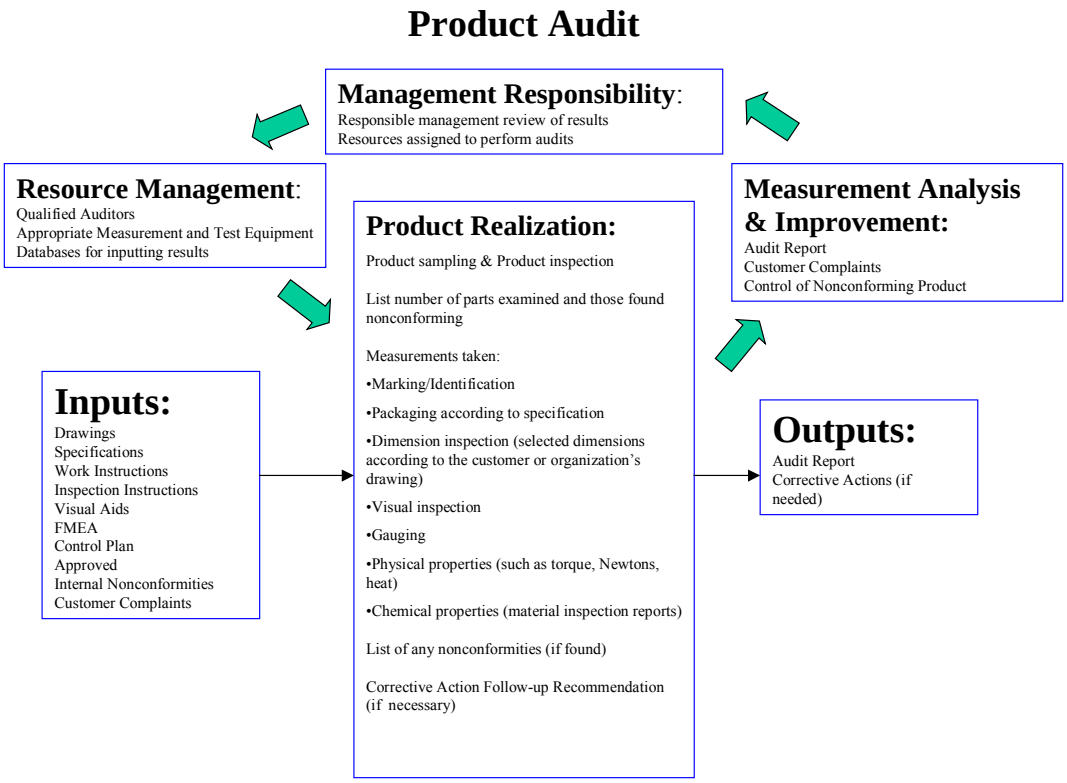



**Figure 11. Product Audit**

Using the process audit approach, the output of the product audit (results, measurements, metrics) may become the input of the Manufacturing Process Audit. During the manufacturing process audit, the auditor can see how the Product Audit results are used in correcting or improving the effectiveness of the manufacturing process.

### 4.4.4 Internal Audit Plans

As stated in 8.2.2.4 of ISO/TS 16949:2002, "Internal audits shall cover all quality management related processes, activities and shifts, and shall be scheduled according to an annual plan. When internal/external nonconformities or customer complaints occur, the audit frequency shall be appropriately increased."

The annual plan(s) defines the scope, frequency, and type of audits conducted during the year. The plan(s) must include all the types of audits required by ISO/TS 16949:2002 (e.g., Quality System Audit Plan, Manufacturing Process Audit Plan, Product Audit Plan) and cover all quality management related processes, activities and shifts. These three types of audits may be performed either as a sequential or integrated process. The auditor would simply need to reflect all information within their notes. In determining the frequency of audits, the status and importance of the processes and areas to be audited is taken into account as well as the results of previous audits. When customer complaints, external nonconformities, or internal nonconformities occur, the frequency of audits conducted in areas related to the issues are appropriately increased to ensure proper focus on those activities.

## 4.5 Step 5 – Documentation to Certification Body

*The Automotive Certification Scheme for ISO/TS 16949:2002 Annex 1* requires that the organization first provide the following information to the Certification Body:

- number of employees, address, etc.
- scope of the certification
- product design responsibility
- sites to be registered
- remote activities
- quality management systems certifications obtained
- quality manual (for each site audited)
- internal audit and management review planning and results from previous twelve months
- list of customers specific requirements
- customer complaints status
- operational performance trends for the previous twelve months, minimum

The *IATF Guidance to ISO/TS 16949:2002*, page 30 provides a Readiness Evaluation work sheet. This or a similar document may be used.

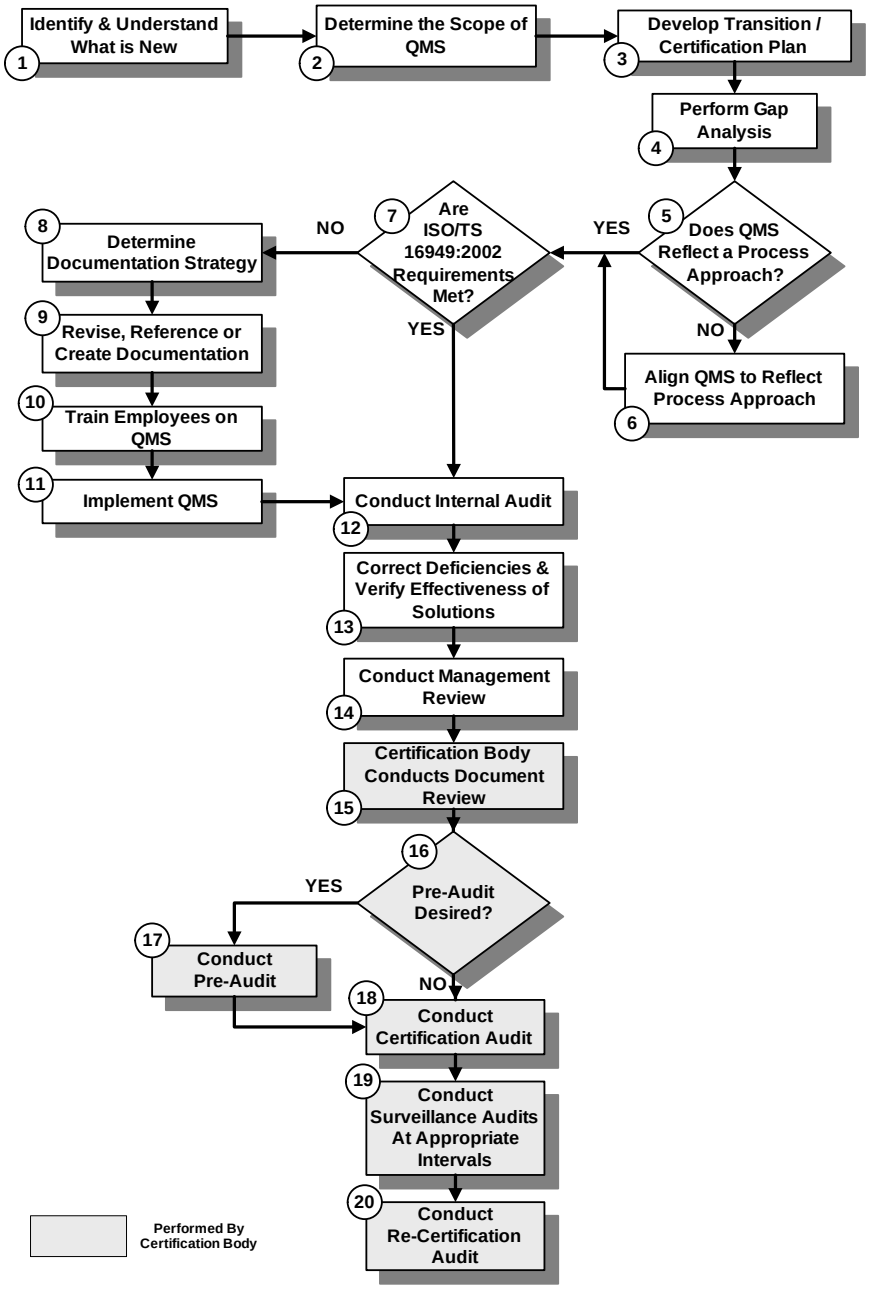
**Putting the Process Approach into Use**

By following the natural flow of the organization from function to function and process to process and comparing the actual process with customer requirements and metrics, the organization can quickly identify areas for improvement as well as areas to benchmark. The same "walk-the-process" approach is used effectively in problem solving techniques. The output of the auditing process is the audit report. The audit report is an important input into the management review process.

# 5.0 STRATEGY FOR IMPLEMENTING ISO/TS 16949:2002

**Objective:** The objective of this section is to outline a strategy organizations may use to implement an ISO/TS 16949:2002 Quality Management System (QMS). In addition, key decisions that organizations may face whether transitioning a current QMS to ISO/TS 16949:2002 or going for initial certification are highlighted along with some action options.

**Strategy:**



1. **Identify and Understand What Is New:** The first step is to identify and understand what is new and different in ISO/TS 16949:2002 from the organization's current quality management system requirements. It is recommended that key individuals in the organization receive training in the requirements from a reputable training provider so that the process can be started with clear understanding of the requirements and how these requirements apply to the organization. (Refer to *What's New and Different* in this manual for more guidance).

2. **Determine the Scope of the Quality Management System:** Organizations will need to determine what the scope of the quality management system and their certification will be. The following may be considered:

   - Will the organization be seeking a corporate certification that encompasses several different sites or will individual certifications be sought for each applicable site?
   - Does the organization supply only to the automotive industry or are some product lines non-automotive?

   In the case of the latter, the non-automotive product processes may need to certify to ISO 9001:2000 and the automotive processes to ISO/TS 16949:2002. Also, keep in mind that some organizations that were previously certified to QS-9000 may not meet the manufacturing and/or assembly (manufacturing value added) applicability requirement for ISO/TS 16949:2002.

3. **Develop a Transition or Certification Plan:** Once the scope of the organization's ISO/TS 16949:2002 quality management system has been determined; it is time to develop a plan to guide the organization through the transition and/or certification process. The transition plan should include key milestones, task sequencing, specific timing requirements and resource requirements. Also, the organization's top management must ensure that the integrity of the existing QMS is maintained throughout the process of developing and implementing the ISO/TS 16949:2002 QMS. It is recommended that organizations review timeline requirements with their certification body, taking into consideration any organizational, operational, and resource limitations; certification body availability; and any customer-specified timing requirements.

   **Note:** Not every QS-9000 qualified certification body is recognized by the IATF to audit ISO/TS 16949:2002. For a list of recognized ISO/TS 16949:2002 certification bodies, refer to **http://www.iaob.org**. (Refer to *Registration Process* in this manual)

4. **Perform a Gap Analysis:** A gap analysis should be conducted to determine the conformance of the organization's current QMS to the requirements of ISO/TS 16949:2002. The ISO/TS 16949:2002 *Process Identification Tool* provides guidance to help the organization determine the QMS's conformance to the basic requirements of ISO/TS 16949:2002 and any applicable customer-specific requirements. Use of this tool or equivalent will allow an organization to interpret their processes in terms of ISO/TS 16949:2002 and customer-specific requirements. Any requirements not covered by an organization's processes will be considered to be a gap and require correction. (Refer to *ISO/TS 16949:2002 Process Identification Tool* at http://www.aiag.org/isots_tool/isots_tool.asp www.aiag.org.)

5. **Determine if the QMS Reflects the Process Approach:** If the QMS reflects the process approach, proceed to step 7. If not, proceed to Step 6. (Refer to *Explanation of the Process Approach* in this manual).

6. **Align the Quality Management System to Reflect the Process Approach:** If the organization's QMS does not reflect the process approach, the organization will need to align their QMS so that it identifies the key processes, their sequence and interrelationships as described in step 5. Although at first impression it may appear that the QMS might not reflect the process approach, process mapping will identify QMS interactions, inputs and outputs and may reveal that the existing QMS will not require a complete rebuilding to incorporate the process approach.

   **Hint 1:** In realigning the QMS to the process approach, it is recommended that ISO/TS 16949:2002 clause numbers ***not*** be used to identify processes or procedures since use of those clause numbers tends to reinforce the habit of the elemental approach.

   **Hint 2:** Documentation of processes can be a variety of formats such as procedures, work instructions, forms, etc. (Refer to the *Explanation of the Process Approach* and *Appendix J - Process Mapping Examples* in this manual for more information). Using flowcharts and other graphical methods can also often effectively communicate the needed information.

7. **Determine if All Requirements of ISO/TS 16949:2002 Are Met:** Review the results of the gap analysis performed in step 4 and determine if all of the requirements of ISO/TS 16949:2002 have been addressed and met in the organization's QMS. If after completing the gap analysis the organization confirms that the current system reflects the process approach (Step 5), then the organization may be ready to start the audit process in preparation for certification (Step 12). If not, proceed to step 8.

8. **Determine the Documentation Strategy:** Many organizations will find that some modification to their quality system documentation will be necessary to meet the requirements of ISO/TS 16949:2002.

   - The Matrix Approach
   - Revise Current Documentation
   - Create New or Reinvigorate Existing Systems

   **Note:** These strategies are not listed in any order of preference and the organization should consider the benefits and disadvantages of each carefully. Explanation of strategies can be found in Appendix L.

9. **Revise, Reference or Create the QMS Documentation:** Once the organization's documentation strategy has been determined the documents must be updated. The development or modification of any QMS documents should be done using a cross-functional team approach with appropriate representation from key stakeholders. Once completed, be sure to validate the accuracy, clarity and relevance of the content with the users of the document.

10. **Train Employees on the New QMS:** Organizations will have to provide training to personnel to ensure that they understand the new system and the applicable ISO/TS 16949:2002 and customer-specific requirements. The following are areas where the organization may require training:

    - The role of top management is of greater importance with ISO/TS 16949:2002 than was recognized with QS-9000. Top management has certain responsibilities that they must accept and not delegate to others. There are instances where top management can delegate tasks to others. In those instances, top management must ensure that the tasks are completed. In general the following applies:

| ISO/TS 16949:2002 States | Top Management Role |
|---|---|
| Top management shall ensure | Top management can delegate these items. Follow up must occur by top management to ensure requirements are effectively met. |
| Top management shall review | Top management must conduct the review. |
| Top management shall provide | It is the responsibility of top management to provide the noted items. |
| Top management shall define | It is the responsibility of top management to define the noted items. |
| Top management shall appoint/designate | It is the responsibility of top management to appoint/designate the appropriate employees. |

- Effective implementation of a QMS that meets ISO/TS 16949:2002 requirements cannot occur without top management possessing general knowledge of all the requirements and in depth knowledge of the requirements in clause 5 of ISO/TS 16949:2002.
- Management awareness (focusing on the benefits that can be added to business as a result of the new customer-focused approach to ISO/TS 16949:2002).
- Internal auditor training (focusing on process auditing and the changes between the current and the new technical specifications). Ensure they are trained/qualified to audit to customer-specific requirements and process metrics.
- General staff awareness programs (to encourage total involvement and understanding of the ISO/TS 16949:2002 requirements, the process approach, quality objectives, and monitoring, measurement, and improvement activities).
- All personnel training in the processes, procedures and quality objectives applicable to their areas of responsibilities and how their activities help the organization achieve their objectives.

**11. Implement the QMS:** After everyone has been trained on the new QMS and their responsibilities, it is time to implement the new system. Organizations may consider either a phased-in approach or a complete implementation approach.

- **Phased-in Approach:** The organization implements selective QMS processes and procedures during one phase and when they are up and running implements some more processes and procedures in another phase. This method continues until all of the QMS processes and procedures are implemented. Of course, the order of actual processes implemented will vary based on each organization. The order of implementation should consider customer satisfaction considerations or scope of registration.

  **Advantage**

  - Allows gradual introduction of the changes with little disruption to ongoing operations.

  **Disadvantage**

  - The process approach of the new parts of the QMS will not be completely compatible with the elemental portions of the legacy system.

- **Complete Implementation Approach:** The organization completes all QMS processes and procedures and transition all at once. The new processes and procedures are implemented and any obsolete documents from the old system, if applicable, are removed from service simultaneously.

  **Advantage**

  - Avoid compatibility issues. All processes, interactions, inputs and outputs have been defined.

  **Disadvantage**

  - May be disruptive to ongoing operations, steep learning curve required to understand the new system all at once.

12. **Conduct Internal Audits:** The entire QMS is audited to assess the effective implementation of the system, processes and conformance to the ISO/TS 16949:2002 and customer-specific requirements.

13. **Correct Deficiencies and Verify the Effectiveness of Solutions:** The organization must correct all deficiencies identified during the internal audit. Implement the organization's corrective action process to ensure that root causes are identified and effective solutions are produced. After the corrective actions have been implemented in all affected processes the organization must follow-up to verify that the solution effectively resolved the nonconformance. Where deficiencies do not result in nonconformance but predict potential nonconformance, process improvements should be made to effect preventive action.

14. **Conduct Management Review:** Once the audit has been conducted and the deficiencies corrected and verified, the organization analyzes all of the required inputs and conducts a management review. Top management evaluates all of the required information and determines if the QMS meets expectations. Expectations include requirements to ISO/TS 16949:2002, organizational and customer-specific requirements. If not, top management provides the direction and resources necessary to make the appropriate corrections and improvements. Several management reviews may be necessary to achieve this. For example, quality system metrics may be reviewed monthly with summary reviews conducted as needed. (Reference 5.6 Management Review section of ISO/TS 16949:2002 for guidelines on required data and required input.)

## STEPS 15 THROUGH 20 ARE CONDUCTED BY THE CERTIFICATION BODY

15. **Document Review:** When top management believes that the organization is in conformance with requirements and is operating effectively, it is time to have the certification body review the QMS documentation. (Refer to the *Automotive Certification Scheme For ISO/TS 16949:2002 Annex 1* developed by the IATF).

    **Note:** If the organization used the Process Identification Tool to demonstrate equivalence of its Quality Management System to the requirements of ISO/TS 16949:2002, this information may be used by the certification body for document review.

**16. Determine if a Pre-Audit of the Organization's QMS Should Be Conducted:**

Organizations may elect to have a pre-audit of their QMS prior to their certification audit. Pre-audits assess the organization's conformance to the ISO/TS 16949:2002 requirements as well as any applicable customer-specific requirements.

The pre-audit is strictly optional; however, many organizations like the reassurance from an objective third party that their QMS is ready for certification. Keep in mind that the pre-audit will not reduce the number of days required for the certification audit even if the pre-audit is accomplished by the certification body.

Training identified in *Appendix D - Recommended Training* section of this manual may assist the organization in determining if a pre-audit is beneficial.

**17. Conduct Pre-Audit (optional):** Conduct a pre-audit to determine QMS readiness.

**Note:** The pre-audit does not need to be performed by your certification body.
If your certification body is use for this audit, they must follow *Annex 1 of the Automotive Certification Scheme for ISO/TS 16949:2002 Rules for Achieving IATF Recognition*

**18. Conduct Certification Audit:** When the organization is ready for certification, a certification body that is recognized by the IATF conducts the audit. Refer to the International Automotive Oversight Bureau Web site at: www.iaob.org for a current list of IATF recognized certification bodies.

The IAAR (Independent Association of Automotive Registrars) audit planning template can be used to assist in planning process-based audits. Refer to *Appendix K – IAAR Audit Planning* example.

**19. Conduct Surveillance Audit At Appropriate Intervals**: Refer to the Automotive Certification Scheme for ISO/TS 16949:2002 Rules for Achieving IATF Recognition, 2.11 and Annex 3, Audit days for certification to ISO/TS 16949:2002.

The organization shall provide the following documentation to the certification body for review, and for use in planning the audit:

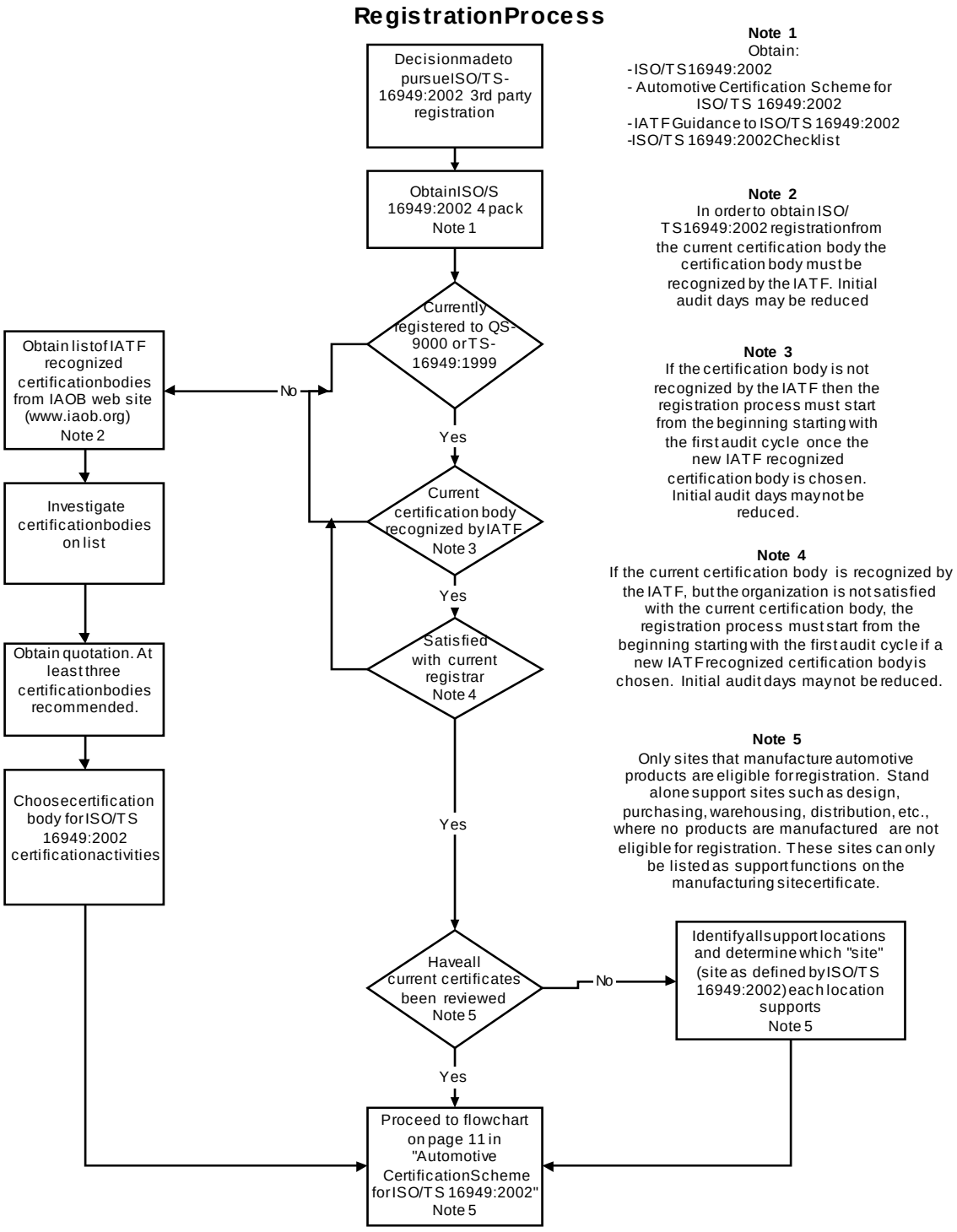
- quality manual system changes (usually only updated information/sections, and only if requested by the certification body.)
- customer complaints, response, current status
- internal audit and management review planning and results from previous twelve months
- operational performance trends for the previous twelve months, minimum
- progress made toward continual improvement targets
- effectiveness of the corrective actions and verification since last surveillance audit

The certification body analyzes the organization's documentation to plan the audit.

**Note:** Operational performance trends should include both internal organizational performance measures and customer results.

**20. Conduct the Re-certification Audit:** ISO/TS 16949:2002 certification is limited to three years. Re-certification audits require a full submission of all documentation and information, unless otherwise specified by the certification body.

# 6.0 REGISTRATION PROCESS



## 7.0 PITFALLS TO AVOID

| Stage/Topic | Main Issue | Pitfall to Avoid | Reason to Avoid |
|---|---|---|---|
| Pre-audit | Selecting a Certification Body | Only a limited amount of certification bodies are able to perform assessments to ISO/TS 16949:2002. In the U.S., to find out if a certification body is on ISO/TS 16949:2002 certification body list, visit www.iaob.org. As part of being recognized, the certification body must have gone through and passed a witness audit by an IATF Oversight Body. Certification bodies may be able to perform ISO/TS 16949:2002 audits, but will not be able to issue certificates until they successfully pass this audit. | Only ISO/TS 16949:2002 authorized certification bodies are able to perform ISO/TS 16949:2002 assessments. With the limited number of ISO/TS 16949:2002 certification bodies (CB) compared with QS-9000, it is important that the organization begins its relationship with its certification body as soon as possible to help ensure a successful/smooth transition. If the organization's certification body is able to perform ISO/TS 16949:2002 assessments, but has not yet passed its IATF witness audit, the issuance of the organization's ISO/TS 16949:2002 certificate could be delayed. |
| | Switching Certification Bodies | If the organization switches certification bodies, for any reason, it will not be eligible for the man-day reduction outlined in the "Rules for achieving IATF recognition" (see Rules for achieving IATF recognition section 4.9) | The reason for switching certification bodies is irrelevant to this rule. Even companies who are "forced" to change certification bodies because their old certification body is not able to perform ISO/TS 16949:2002 audits will still lose their eligibility for man-day discounts. The organization's old certification and its new ISO/TS 16949:2002 certification must be performed by the same CB in order to be eligible for the discount. If the client needs to switch certification bodies, it is more beneficial to change while under their existing registration, e.g. QS-9000, then transition to ISO/TS 16949:2002. |

| Stage/Topic | Main Issue | Pitfall to Avoid | Reason to Avoid |
|---|---|---|---|
| | Timeliness of Certification | Some OEMs have set dates for their suppliers to become registered to ISO/TS 6949:2002. | OEMs will not be sympathetic to suppliers who "miss" the required certification date. Organizations should plan well in advance for their transition. Keep in mind that there are significantly fewer recognized CBs and auditors available to perform ISO/TS 16949:2002 certifications. The organization needs to know/understand its customer requirements for registration and plan accordingly. |
| | Eligibility for TS Certification | Not every organization meets the requirements to be ISO/TS 16949:2002 certified. Do not assume that the organization needs to upgrade to ISO/TS 16949:2002. Section 1.1 of ISO/TS 16949:2002 outlines the applicability requirements. When in doubt, contact the certification body. | Organizations can waste resources in the effort to upgrade to ISO/TS 16949:2002. The organization should be sure it meets the ISO/TS 16949:2002 eligibility requirements before investing the resources. |
| | Scheduling of Multiple Sites | When several sites are involved in a company certification, it is advisable that the sites with the supporting processes be audited first. | During multiple site certifications, the auditing of the supporting processes during the beginning of the certification process allows the audit team to adequately assess the interactions among all the sites. The manufacturing site can not receive certification until the support sites have been audited. |

| Stage/Topic | Main Issue | Pitfall to Avoid | Reason to Avoid |
|---|---|---|---|
| | Pricing | Every certification body structures its pricing scheme differently. It is very important that the requirements contained in the *Automotive Certification Scheme for ISO/TS 16949:2002* are understood regarding audit days, follow-up of non-conformances, re-certification requirements, etc. | Common things that are overlooked by companies include:<br><br>1.) Re-certification requirements - a complete round of ISO/TS 16949:2002 audits include a registration audit, surveillance audits and a re-certification audit. Re-certification audits require more time on site than surveillance audits. When considering pricing, it is important to ensure that the certification body has included this into the organization's contract.<br><br>2.) Follow-up of non-conformances - often it is required or recommended that follow-up activities for non-conformances or other customer issues take place on site. The certification body should explain their policies/prices.<br><br>3.) Flat Rates vs. Expenses –Some certification bodies offer the option of having billing done at a flat rate. This should be explored when the organization has multiple sites with travel involved. |
| Preparing the Quality Management System | Understanding the Process Approach | ISO/TS 16949:2002 focuses on the processes of the organization's system and how these processes interact with each other. Using the old "elemental" approach puts the organization's system in serious danger for gaps among/between those processes. | The "process approach" is one of the main focuses of ISO/TS 16949:2002 and one of the main differences between ISO/TS 16949:2002 and QS-9000. A strong working knowledge of how to use the process approach is fundamental in successfully applying ISO/TS 16949:2002. |

| Stage/Topic | Main Issue | Pitfall to Avoid | Reason to Avoid |
|---|---|---|---|
| | "Measuring" the Processes | According to ISO/TS 16949:2002, not only do the organization's processes (including support processes such as purchasing, engineering, training, etc.) have to be conforming and working, but the organization must measure the effectiveness of the process. Measurement on the manufacturing floor is done in a variety of ways, but measuring a process in an office environment can be more difficult. | Measurement of processes and the communication of those measurements to the applicable employees and top management are essential in determining the effectiveness of ISO/TS 16949:2002 as well as being instrumental to the continual improvement process. |
| | Effectiveness | Not only must the organization have processes implemented that meet the requirements of ISO/TS 16949:2002 and customer requirements, but it must also provide evidence that the processes are effective. | Implementation of processes and effectiveness of processes are different from each other. Ensuring that processes are effective is crucial to improvement and customer satisfaction. |
| | Proper Training | Employees must be trained as necessary to ensure the knowledge of the ISO/TS 16949:2002 and customer requirements. | Because of the interpretative nature of ISO/TS 16949:2002, it is necessary that employees responsible for ensuring the QMS meets ISO/TS 16949:2002 requirements are knowledgeable of the intent of ISO/TS 16949:2002 as well as the requirements and rules. |
| | Customer Requirements | ISO/TS 16949:2002 are a customer-focused specification. Knowledge of the customer requirements is crucial to the successful implementation of ISO/TS 16949:2002. | Often in QS-9000, customer specific requirements fell by the way side. ISO/TS 16949:2002 is customer driven and puts a great deal of emphasis on customer satisfaction and quality of product to the customer. |

| Stage/Topic | Main Issue | Pitfall to Avoid | Reason to Avoid |
|---|---|---|---|
| | Clarification of Requirements | ISO/TS 16949:2002 was specifically written to ensure that companies have maximum flexibility to implement an effective quality system. ISO/TS 16949:2002, like other quality standards, gives requirements on what the organization must do, but how the "shalls" are accomplished is up to the individual organization. Therefore, a lot in ISO/TS 16949:2002 is open for interpretation. While the organization's certification body cannot provide "consulting services", they can give their interpretations on specific sections of ISO/TS 16949:2002. The IAOB is also available to answer interpretation questions via their Web site. | Many resources can be wasted because of misinterpretation of ISO/TS 16949:2002. When in doubt of a particular interpretation, it is usually beneficial to put the organization in the place of the OEM and arrange the organization's system around what is best for its customer. As always, the IAOB (or local branch of the IATF) and the certification body can assist in interpreting ISO/TS 16949:2002. |
| | Using the 4 Pack Books | The other books that comprise the "4 pack" of ISO/TS 16949:2002 contain vital information as to how audits are conducted, what requirements of the audit process and system are, and how to improve the organization's system. | Often the only book used is the "requirements" book. Reading and understanding the other books in the "4 pack" will provide a better understanding of ISO/TS 16949:2002 and how to use it to its full potential. The books contain a great deal of information that will save time and resources in the organization's planning and implementation process. |

| Stage/Topic | Main Issue | Pitfall to Avoid | Reason to Avoid |
|---|---|---|---|
| | Using Checklists and Other Audit Tools | Checklists and other audit tools should be used as a guide to ensure that all the requirements and areas of ISO/TS 16949:2002 are covered. They are not meant to be a check sheet for compliance – in other words, the organization may have all the boxes of a checklist marked off as acceptable, and still have serious holes in its ISO/TS 16949:2002 system. | ISO/TS 16949:2002 cannot be implemented by doing a few things on a checklist. Only a thorough review and assessment of all the organization's systems, processes and their interactions can determine the state of the QMS to ISO/TS 16949:2002 requirements. Use the Checklist of ISO/TS 16949:2002 to plan coverage and check coverage following the audit. Use process audit checklists to conduct the audit. |
| During the Audit | Customer Performance Metrics | When formulating audits, the certification body will look at the organization's customer performance metrics and take into consideration:<br><br>1. Who are the organization's biggest customers? These customers will have more weight during the audit.<br><br>2. Where are the organization's problem areas? What is the organization doing to correct the issues?<br><br>3. Does the organization have recurring issues? Recurring issues could point to an ineffective corrective action system. | Customer performance is the basis of an ISO/TS 16949:2002 audit. Keeping in mind the process approach of ISO/TS 16949:2002, it is easy to see how customer performance metrics will help determine audit areas and focuses. |

| Stage/Topic | Main Issue | Pitfall to Avoid | Reason to Avoid |
|---|---|---|---|
| | Management Responsibility | Some OEMs have set dates for their suppliers to become registered to ISO/TS 16949:2002. | Management should be playing a supportive and overall directive role in the organization's QMS. A show of management support and direction for ISO/TS 16949:2002 is necessary and required. |
| | Documentation Requirements | While there are only seven required "documented procedures" by ISO/TS 16949:2002, the organization must be careful not to cut its system too "thin" and thereby compromise the integrity of the system. | Many organizations see the "seven documented procedures requirement" and proceed to "throw out" most of its current procedures. While it is true that most organizations can benefit from a cleaning of their system, remember that ISO/TS 16949:2002 require that system documentation include "documents needed by the organization to ensure the effective planning, operation and control of its processes." |
| | Competence, Awareness and Training | The training requirement now goes beyond what QS-9000 required. Not only must the organization show that it has trained its employees appropriately, but it must show that the employees are competent in their job, and that they are aware of their effect on the quality objectives and goals. | A sign off in a book will not necessarily be enough anymore. Requirements for competence and proof of employees meeting those requirements will be looked at. Also, employees will be expected to know their contribution to the objectives and goals. Operators on the line will be asked how their function contributes to the bottom line of quality. |

| Stage/Topic | Main Issue | Pitfall to Avoid | Reason to Avoid |
|---|---|---|---|
| 3rd Party Auditors | Value Added Audits | Third party auditors should be adding value to the organization's system. By focusing on the issues most important to the customer, and finding areas that may lead to non-conforming product, the third party audits should be finding areas of the system that will help organizations improve customer satisfaction. | ISO/TS 16949:2002 is a customer-focused specification that is driven by customer satisfaction. Therefore, the role of the third party ISO/TS 16949:2002 auditor is to determine where the system can be improved in order to ensure and improve customer satisfaction. If the organization believes it is in a situation where the auditor(s) are consistently not adding value to the system, a meeting with the certification body to discuss concerns may be necessary. |
| | Auditor Qualifications | ISO/TS 16949:2002 has certain requirements for third party auditors, including that they have experience in the organization's field. Knowing the auditor's background may assist the organization in determining what their areas of expertise are. | It is common to ask for a biography or other information of a new auditor to understand his/her background. |

| Stage/Topic | Main Issue | Pitfall to Avoid | Reason to Avoid |
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| | Consistent Auditor(s) Assigned | It is highly recommended that at least one member of the original audit team remain consistent throughout the organization's three-year certification cycle. Refer to paragraph 3.2 of *Automotive Certification Scheme for ISO/TS 16949:2002.* | By keeping at least one member of the audit team consistent, the organization will experience a more value-added audit experience. The ability to determine continual improvement as well as familiarity with the organization's system will be invaluable to ISO/TS 16949:2002 certification. |
| Post-Audit Activities | Follow-up of nonconformances | Minor or major non-conformances can be reviewed either on-site or off-site depending on the individual nonconformance and the decision of the auditor. | During the initial audit, if a major or minor nonconformance is issued, the certification body will inform the organization of the timing requirements for submitting corrective action. |

# APPENDIX A - CROSSOVER MATRIX QS-9000 3RD TO ISO/TS 16949:2002

| QS-9000 3rd | | ISO/TS 16949:2002 | |
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| **Element** | **Title** | **Element** | **Title** |
| 4.1 | Management Responsibility | | |
| 4.1.1 | Quality Policy<br>The supplier's management with executive responsibility shall define and document its policy for quality, including objectives for quality and its commitment to quality. The quality policy shall be relevant to the supplier's organizational goals and the expectations and needs of its customers. The supplier shall ensure that this policy is understood, implemented and maintained at all levels of the organization. | 5.3 | Quality Policy<br>Top management shall ensure that the quality policy; a) is appropriate to the purpose of the organization; b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system; c) provides a framework for establishing and reviewing quality objectives; d) is communicated and understood within the organization; and e) is reviewed for continuing suitability. |
| 4.1.2 | Organization | | |
| 4.1.2.1 | Responsibility and Authority<br>The responsibility, authority and the interrelation of personnel who manage, perform and verify work effecting quality shall be defined and documented, particularly for personnel who need the organizational freedom and authority to; a) initiate action to prevent the occurrence of any nonconformities relating to product, process and quality system. **Note:** It is recommended that the personnel responsible for quality have the authority to stop production, if necessary to correct quality problems; b) identify and record any problems relating to the product, process and quality system; c) initiate, recommend or provide solutions through designated channels; d) verify the implementation of solutions; e) control further processing, delivery or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected; f) represent the needs of the customer in internal functions in addressing QS-9000 requirements (e.g. selection of special characteristics, setting quality objectives, training, corrective & preventive actions, product design and development). | 5.5.1 | Responsibility and Authority<br>Top management shall ensure that the responsibilities and authorities are defined and communicated within the organization. |

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| **Element** | **Title** | **Element** | **Title** |
| 4.1.2.2 | Resources<br>The supplier shall identify resource requirement and provide adequate resources, including the assignment of trained personnel (see 4.18), for management, performance of work and verification activities, including internal quality audits. | 6.1 | Provision of Resources<br>The organization shall determine and provide the resources needed; a) to implement and maintain the quality management system and continually improve its effectiveness, and; b) to enhance customer satisfaction by meeting customer requirements. |
| 4.1.2.3 | Management Representative<br>The supplier's management with executive responsibility shall appoint a member of the supplier's own management who, irrespective of other responsibilities, shall have defined authority for; a) ensuring that a quality system is established, implemented and maintained in accordance with this International Standard; and b) reporting on the performance of the quality system to the supplier's management for review and as a basis for improvement of the quality system. **Note 5:** The responsibility of a management representative may also include liaison with external parties on matters relating to the supplier's quality system. | 5.5.2 | Management Representative<br>Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes; a) ensuring that processes needed for the quality management system are established, implemented and maintained; b) reporting to top management on the performance of the quality management system and any need for improvement; and c) ensuring that promotion of awareness of customer requirements throughout the organization. **Note:** The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system. |
| 4.1.2.4 | Organizational Interfaces<br>The supplier shall have systems in place to ensure management of appropriate activities during concept development through production (refer to Advanced Product Quality Planning and Control Plan reference manual). The supplier shall use a multi-disciplinary approach for decision-making and have the ability to communicate necessary information and data in the customer-prescribed format. **Note:** Typical functions to be included are: * Engineering /Technical * Manufacturing/Production * Industrial Engineering * Purchasing/Materials Management * Quality/Reliability * Cost Estimating * Product Service * Management Information Systems/Data Processing * Packaging Engineering * Tooling Engineering/Maintenance * Marketing and Sales * Subcontractors, as necessary. | 7.1.1 | Planning of Produce Realization - Supplemental<br>Customer requirements and references to its technical specifications shall be included in the planning of product realization as a component of the quality plan. |

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| **Element** | **Title** | **Element** | **Title** |
| 4.1.2.5 | Information to Management<br>Management with responsibility and authority for corrective actions shall be promptly informed of products or processes that become noncompliant with specified requirements. | 5.5.1.1 | Responsibility for Quality<br>Managers with responsibility and authority for corrective actions shall be promptly informed of products or processes, which do not conform to requirements. Personnel responsible for product quality shall have the authority to stop production to correct quality problems. Production operations across all shifts shall be staffed with personnel in charge of, or delegated responsibility for ensuring product quality. |
| | | 8.3.3 | Customer Information<br>Customers shall be informed promptly in the event that nonconforming product has been shipped. |
| 4.1.3 | Management Review | 5.6.1 | Management Review - General |
| | The supplier's management with executive responsibility shall review the quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of this International Standard and the supplier's stated quality policy and objectives (see 4.1.1). Records of such reviews shall be maintained (see 4.16). | | The management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained (see 4.2.4). |
| | | 5.6.1.1 | Quality Management System Performance<br>These reviews shall include all requirements of the quality management system and its performance trends as an essential part of the continual improvement process. Part of the management review shall be the monitoring of quality objectives, and the regular reporting and evaluation for the cost of poor quality (see 8.4.1 and 8.5.1). These results shall be recorded to provide, as a minimum, evidence of the achievement of * the quality objectives specified in the business plan, and * customer satisfaction with product supplied. |
| | | 5.6.2 | Review Input<br>The input to management review shall include information on; a) results of audits; b) customer feedback; c) process performance and product conformity; d) status of preventive and corrective actions; e) follow-up actions from previous management reviews; f) changes that could affect the quality management system; and g) recommendations for improvement. |
| | | 5.6.2.1 | Review Input - Supplemental<br>Input to management review shall include an analysis of actual and potential field-failures and their impact on quality, safety, or the environment. |

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| **Element** | **Title** | **Element** | **Title** |
| | | 5.6.3 | Review Output<br>The output from the management review shall include any decision and actions related to; a) improvement of the effectiveness of the quality management system and its processes; b) improvement of product related to customer requirements; and c) resource needs. |
| 4.1.3.1 | Management Review<br>This Management Review requirement shall include all elements of the entire quality system, not only those specifically required in other elements. (e.g. 4.14.3.d). **Note:** Management Review should be conducted with a multi-disciplinary approach (see Glossary). | | |
| 4.1.4 | Business Plan<br>The supplier shall utilize a formal, documented, comprehensive business plan. The Business Plan shall be a controlled document. The content of the Business Plan is not subject to third party audit. This plan may typically include as applicable: * Market-related Issues * Financial Planning and Cost * Growth Projections * Plant/Facilities Plan * Cost Objectives * Human Resource Development * R&D Plans, Projections, and Projects with appropriate funding * Projected Sales Figures * Quality Objectives * Customer Satisfaction Plans * Key Internal Quality and Operational Performance Measurables * Health, Safety and Environmental Issues. Goals and plans shall cover short-term (1-2 years) and longer-term (3 years or more). The goals and plans should be based on analysis of competitive products and on benchmarking inside and outside the automotive industry and the supplier's commodity. Methods to determine current and future customer expectations shall be in place.<br><br>An objective process shall be used to define the scope and collection of information, including the frequency and methods of collection. Methods to track, update, revise, and review the plan shall be documented to ensure that the plan is followed and communicated throughout the organization as appropriate. **Note:** Data and information should drive process improvement plans. **Note:** The supplier should provide means for employee empowerment in meeting business goals. | 5.4.1.1 | Quality Objectives - Supplemental<br>Top management shall define quality objectives and measurements that shall be included in the business plan and used to deploy the quality policy. **Note:** Quality objectives should address customer expectations and be achievable within a defined time period. |

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| **Element** | **Title** | **Element** | **Title** |
| 4.15 | Analysis and Use of Company Level Data<br>The supplier shall document trends in quality, operational performance (productivity, efficiency, effectiveness, cost of poor quality) and current quality levels for key product and service features. These should be compared with those of competitors and/or appropriate benchmarks. Trends in data and information should be compared with progress toward overall business objectives and lead to action to support; 1) Development of priorities for prompt solutions to customer-related problems; 2) Determination of key customer-related trends and correlations to support status review, decision-making and longer-term planning. | 8.4 | Analysis of Data<br>The organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data shall provide information relating to; a) customer satisfaction (see 8.2.1); b) conformity to product requirements (see 7.2.1); c) characteristics and trends of processes and products including opportunities for preventive action; and d) suppliers. |
| | | 8.4.1 | Analysis and Use of Data<br>Trends in quality and operational performance shall be compared with progress toward objectives and lead to action to support the following: * development of priorities for prompt solutions to customer-related problems; * determination of key customer-related trends and correlation for status review, decision-making and longer term planning; * an informational system for the timely reporting of product information arising from usage. **Note:** Data should be compared with those of competitors and/or appropriate benchmarks. |
| 4.1.6 | Customer Satisfaction<br>The supplier shall have a documented process for determining customer satisfaction, including frequency of determination, and how objectivity and validity are assured. Trends in customer satisfaction and key indicators of customer dissatisfaction shall be documented and supported by objective information. These trends should be compared to those of competitors, or appropriate benchmarks, and reviewed by senior management. **Note:** Considerations should be given to internal, external and final customers. | 5.2 | Customer Focus<br>Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1). |

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| **Element** | **Title** | **Element** | **Title** |
| | | 8.2.1 | Customer Satisfaction<br>As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined. **Note:** Consideration should be given to both internal and external customers. |
| | | 8.2.1.1 | Customer Satisfaction - Supplemental<br>Customer satisfaction with the organization shall be monitored through continual evaluation of performance to the realization processes. Performance indicators shall be based on objective data and include, but not limited to: * delivered part quality performance; * customer disruptions including field actions; * delivery schedule performance (including incidents of premium freight); and * customer notification related to quality or delivery issues. The organization shall monitor the performance of manufacturing processes to demonstrate compliance with customer requirements for product quality and efficiency of the process.<br>See customer specific requirements. |
| 4.1.6.1 | Certification Body/Registrar Notification<br>A supplier shall notify their certification body/registrar in writing within five (5) working days when a customer places the site in any of the following statuses; * Ford Q-1 Revocation; * General Motors Level II Containment. | | |
| 4.2 | Quality Systems | | |
| 4.2.1 | General<br>The supplier shall establish, document and maintain quality system as a means of ensuring that product conforms to specified requirements. The supplier shall prepare a quality manual covering the requirements of this International Standard. The quality manual shall include or make reference to the quality system procedures and outline the structure to the documentation used in the quality system. **Note:** Guidance on quality manuals is given in ISO 10013. | 4.1 | General Requirements<br>The organization shall establish, document, implement a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard. The organization shall; a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2); b) determine the sequence and interaction of these processes; c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective; d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes; e) monitor, measure and analyze these processes; and f) implement actions necessary to achieve planned results and continual improvement of these processes. These processes shall be managed by the organization in accordance with the requirements of this International Standard. |

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| **Element** | **Title** | **Element** | **Title** |
| | | | Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system. **Note:** Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement. |
| | | 4.1.1 | General Requirements - Supplemental<br>Ensuring control over outsourced processes shall not absolve the organization of the responsibility of conformity to all customer requirements (see also 7.4.1 and 7.4.1.3). |
| 4.2.2 | Quality Systems Procedures<br>The supplier shall; a) prepare documented procedures consistent with requirements of this International Standard and the supplier's stated quality policy; and b) effectively implement the quality system and its documented procedures. For purposes of this International standard, the range and detail of the procedures that form part of the quality system shall be dependent upon the complexity of the work, the methods used, and the skills and training needed by personnel involved in carrying out the activity. **Note:** Documented procedures may make reference to work instructions that define how an activity is performed. | 4.2.1 | Document Requirements - General<br>The quality management system documentation shall include; a) documented statements of a quality policy and quality objectives; b) a quality manual; c) documented procedures required by this International standard; d) documents needed by the organization to ensure the effective planning, operation and control of its processes; and e) records required by this International Standard (see 4.2.4). **Note 1:** Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. **Note 2:** The extent of the quality management system documentation can differ from one organization to another due to; a) the size of the organization and type of activities; b) the complexity of processes and their interactions; and c) the competence of personnel. **Note 3:** The documentation can be in any form or type of medium. |
| | | 4.2.2 | Quality Manual<br>The organization shall establish and maintain a quality manual that includes; a) the scope of the quality management system, including details of and justification for any exclusion (see 1.2); b) the documented procedures established for the quality management system, or referenced to them; and c) a description of the interaction between the processes of the quality management system. |

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| **Element** | **Title** | **Element** | **Title** |
| 4.2.3 | Quality Planning<br>The supplier shall define and document how the requirements for quality will be met. Quality planning shall be consistent with all other requirements of a supplier's quality system and shall be documented in a format to suit the supplier's method of operation. The supplier shall give consideration to the following activities, as appropriate, in meeting the specified requirements for products, projects or contracts; a) the preparation of quality plans; b) the identification and acquisition of any controls, processes, equipment (including inspection and test equipment), fixtures, resources and skills that may be needed to achieve the required quality; c) ensuring the compatibility of the design, the production process, installation, servicing, inspection and test procedures and the applicable documentation; d) the updating, as necessary, of quality control, inspection and testing techniques, including the development of new instrumentation; e) the identification of any measurement requirement involving capability that exceeds the known state of are, in sufficient time for the needed capability to be developed; f) the identification of suitable verification at appropriate stages in the realization of product; g) the clarification of standards of acceptability for all features and requirements, including those which contain a subjective element; h) the identification and preparation of quality records (see 4.16). **Note:** The quality plans referred to (see 4.2.3.a) may be in the form of a reference to the appropriate documented procedures that form an integral part of the supplier's quality systems. | 5.4.2 | Quality Management Systems Planning<br>Top management shall ensure that; a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives; and b) the integrity of the quality management system is maintained when changes to the quality management systems are planned and implemented. |

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| **Element** | **Title** | **Element** | **Title** |
| 4.2.3.1 | Advanced Quality Planning<br>The supplier shall establish and implement an advanced product quality planning process. The supplier should convene internal multidisciplinary teams to prepare for production of new or changed products. These teams should use appropriate techniques identified in the Advanced Product Quality Planning and Control Plan reference manual. Similar techniques that accomplish the intent are acceptable. Team actions should include: * Development/finalization of special characteristics * Development and review of FMEAs * Establish of actions to reduce the potential failure modes with high risk priority numbers * Development or review of Control Plans. | 7.1 | Planning of Product Realization<br>The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate; a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4). The output of this planning shall be in a form suitable for the organization's methods of operation.<br><br>**Note 1:** A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan. **Note 2:** The organization may also apply the requirements given in 7.3 to the development of product realization processes. **Note:** Some customers refer to project management or advanced product quality planning as a means to achieve product realization. Advanced product planning embodies the concepts of error prevention and continual improvement as contrasted with error detection, and is based on a multidisciplinary approach. |
| | | 7.1.1 | Planning of Product Realization - Supplemental<br>Customer requirements and references to its technical specification shall be included in the planning of product realization as a component of the quality plan. |

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| **Element** | **Title** | **Element** | **Title** |
| 4.2.3.2 | Special Characteristics<br>The suppliers process control guidelines and similar documents (e.g. FMEA's, Control Plans, Operator Instructions) shall be marked with the customer's special characteristics symbol (or the supplier's equivalent symbol or notation) to indicate those process steps that affect Special Characteristics, when Special Characteristics are identified on the customer design record (see Glossary) (see Appendix C) **Note:** Initially, the customer may determine Special Characteristics and identify them. Special Characteristics may be identified from any product characteristic category, e.g. dimensional, material, appearance, and performance. | 7.2.1.1 | Customer-Designated Special Characteristics<br>The organization shall demonstrate conformity to customer requirements for designation, documentation and control of special characteristics. |
| | | 7.3.2.3 | Special Characteristics<br>The organization shall identify special characteristics (see 7.3.3d) and, * include all special characteristics in the control plan, * comply with customer-specified definitions and symbols, and * identify process control documents including drawings, FMEAs, control plans, and operator instructions with the customer's special characteristic symbol or the organization's equivalent symbol or notation to include those process steps that affect special characteristics. **Note:** Special characteristic can include product characteristics and process parameters. |
| 4.2.3.3 | Feasibility Reviews<br>The supplier shall investigate and confirm the manufacturing feasibility of proposed products prior to contracting to produce those products. Feasibility is an assessment of the suitability of a particular design, material, or process for production, while conforming to all engineering requirements at the required statistical process capability and at specified volumes. Feasibility reviews should be documented using the Team Feasibility Commitment in the Advanced Product Quality Planning and Control Plan reference manual. | 7.2.2.2 | Organization Manufacturing Feasibility<br>The organization shall investigate, conform and document the manufacturing feasibility of the proposed products in the contract review process, including risk analysis. |

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| **Element** | **Title** | **Element** | **Title** |
| 4.2.3.4 | Product Safety<br>Due care and product safety shall be considered in the supplier's design control (element 4.4) and process control (element 4.9) policies and practices. The supplier should promote internal awareness of safety considerations relative to the supplier's product. | 6.4.1 | Personal Safety to Achieve Product Quality<br>Product safety and means to minimize potential risks to employees shall be addressed by the organization, especially in the design and development process and in manufacturing process activities. |
| 4.2.3.5 | Failure Mode and Effects Analysis<br>Process FMEAs shall consider all Special Characteristics. Efforts shall be taken to improve the process to achieve defect prevention rather than defect detection. Certain customers have FMEA review and approval requirements that shall be met prior to production part approval (see Section II). Refer to the Potential Failure Mode and Effects Analysis reference manual. | 7.3 | Design and Development<br>**Note:** The requirements of 7.3 include product and manufacturing process design and development, and focus on error prevention rather on detection. |
| 4.2.3.6 | Mistake Proofing<br>The supplier shall utilize appropriate mistake proofing methodologies during the planning of processes, facilities, equipment and tooling. | 8.5.2.2 | Error Proofing<br>The organization shall use error proofing methods in their corrective action process. |
| 4.2.3.7 | The Control Plan<br>The supplier shall develop Control Plans at the system, subsystem, components and/or material level, as appropriate for the product supplied. The Control Plan shall include the information required in the Control Plan form in Appendix J. The Control Plan requirement encompasses processes producing bulk materials (e.g. steel, plastic resin, paint) as well as those producing parts. The output of the advanced quality planning process, beyond the development of robust processes, is a Control Plan. Control Plans shall be revised or updated when products or processes differ significantly from those in current production. The Control Plan should list the controls used for process control (see 4.9). | 7.5.1.1 | Control Plan<br>The organization shall * develop control plans (see Appendix A) at the system, subsystem, component and/or material level for the product supplied, including those for processes producing bulk materials as well as parts, and * have a control plan for pre-launch and production that takes into account the design FMEA and manufacturing process FMEA outputs. The control plan shall * list the controls used for the manufacturing process control, * including methods for monitoring of control exercised over special characteristics (see 7.3.2.3) defined by bother the customer and the organization, * include the customer-required information, if any, and * initiate the specified reaction plan (see 8.2.3.1) when the process becomes unstable or not statistically capable. Control plans shall be reviewed and updated when any change occurs affecting product, manufacturing process, measurement, logistics, supply resources or FMEA (see 7.1.4). **Note:** Customer approval may be required after review or update of the control plan. |

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| **Element** | **Title** | **Element** | **Title** |
| | The Control Plan shall cover three distinct phased as appropriate: * Prototype * Prelaunch * Production. **Note:** A multi-disciplinary approach typically includes the supplier's design, manufacturing, engineering, quality, production, and other appropriate personnel. **Note:** For external suppliers, it may include the customer's Purchasing, Quality, Product Engineering, customer plant personnel as well as subcontractors. Control Plans shall be reviewed and updated as appropriate when any of the following occur: * The product is changed * The processes are changed * The processes become unstable * The process become non-capable * Inspection method, frequency, etc., is revised. | | |
| 4.2.4 | Product Approval Process | | |
| 4.2.4.1 | General<br>The supplier shall fully comply with all requirements set forth in the Production Part Approval Process (PPAP) manual. | 7.3.6.3 | Product Approval Process<br>The organization shall conform to a product and manufacturing process approval procedure recognized by the customer. **Note:** Product approval should be subsequent to the verification of the manufacturing process. The product and manufacturing process approval procedure shall also be applied to suppliers. |
| 4.2.4.2 | Subcontractor Requirements<br>Suppliers should utilize a part approval process (e.g. PPAP) for subcontractors (see Glossary). **Note:** Certain customers require that their suppliers use PPAP with their subcontractors (see Section II). | | |
| 4.2.4.3 | Engineering Change Validation<br>The supplier shall verify that changes are properly validated. See 4.12, 4.16 and PPAP. **Note:** This applies equally to suppliers and subcontractors. | | |

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| **Element** | **Title** | **Element** | **Title** |
| 4.2.5 | Continuous Improvement | | |
| 4.2.5.1 | General<br>The supplier shall continuously improve in quality, service (including timing delivery) and price that benefit all customers. This requirement does not replace the need for innovative improvements. **Note:** A continuous improvement philosophy should be fully deployed throughout the supplier's organization. Continuous improvement shall extend to product characteristics with the highest priority on special characteristics. **Note:** Cost elements or price should be one of the key indicators within a continuous improvement system. **Note:** For those product characteristics and process parameters that can only be evaluated using attribute data, continuous improvement is not possible until characteristics are conforming. If attribute data results do not equal zero defects, it is by definition nonconforming product (see 4.10.1.1, 4.13, 4.14). Improvements made in these situations are by definition corrective actions, not continuous improvement. The supplier shall develop a prioritized action plan for continuous improvement in processes that have demonstrated stability, acceptable capability and performance. **Note:** Processes with unacceptable capability/performance require corrective action (see 4.14.2). | 8.5.1 | Continual Improvement<br>The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. |
| | | 8.5.1.1 | Continual Improvement of the Organization<br>The organization shall define a process for continual improvement (see examples in Appendix B of ISO 9004:2000). |

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| **Element** | **Title** | **Element** | **Title** |
| 4.2.5.2 | Quality and Productivity Improvements<br>The supplier shall identify opportunities for quality and productivity improvement and implement appropriate improvement projects. **Note:** Examples of situation which might lead to improvement projects are: * Unscheduled Machine Downtime * Machine Setup, Die Change and Machine Changeover Times * Excessive Cycle Time * Scrap, Rework and Repair * Non Value-added Use of Floor Space * Excessive Variation * Less Than 100% First Run Capability * Process Averages Not Centered on Target Values (bilateral tolerance) * Testing Requirements Not Justified By Accumulated Results * Waste of Labor and Materials * Cost of Poor Quality * Difficult Assembly or Installation of the Product * Excessive Handling and Storage * New Target Values to Optimize Customer Processes * Marginal Measurement System Capability (see MSA and ISO 10012-1) * Customer Dissatisfaction, e.g. complaints, repairs, returns, mis-shipments, incomplete orders, customer plant concerns, warranty, etc. | 8.5.1.2 | Manufacturing Process Improvement<br>Manufacturing process improvement shall continually focus upon control and reduction of variation in product characteristics and manufacturing process parameters. **Note 1:** Controlled characteristics are documented in the control plan. **Note 2:** Continual improvement is implemented once manufacturing processes are capable and stable, or product characteristics are predictable and meet customer requirements. |
| 4.2.5.3 | Techniques for Continuous Improvement<br>The supplier shall demonstrate knowledge of appropriate continuous improvement measures and methodologies and shall use those that are appropriate. **Note:** The following list shows examples of possible techniques that might be used. There may be many other methods that meet specific supplier needs more appropriately. | | |
| 4.2.6 | Facility and Tooling Management | | |

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| **Element** | **Title** | **Element** | **Title** |
| 4.2.6.1 | Facilities, Equipment, and Process Planning Effectiveness<br>The supplier shall use a multi-disciplinary approach for developing facilities, processes and equipment plans in conjunction with the advanced quality planning process. Plant layout should minimize material travel and handling, facilitate synchronous material flow, and maximize value-added use of floor space. Methods shall be developed for evaluating the effectiveness of existing operations and processes considering the following factors: overall work plan, appropriate automation, ergonomics and human factors, operator and line balance, storage and buffer inventory levels, value-added labor content. Note: The supplier should identify and define appropriate metrics and monitor the effectiveness of existing operations. | 6.3.1 | Plant, Facility and Equipment Planning<br>The organization shall use a multi-disciplinary approach (see 7.3.1.1) for developing plant, facility and equipment plans. Plant layouts shall optimize material travel, handling and value-added use of floor space, and shall facilitate synchronous material flow. Methods shall be developed and implemented to evaluate and monitor the effectiveness of existing operations. **Note:** These requirements should focus on lean manufacturing principles and the link to the effectiveness of the quality management system. |
| 4.2.6.2 | Tooling Management<br>The supplier shall establish and implement a system for tooling management including: * Maintenance and Repair Facilities and Personnel * Storage and Recovery * Setup * Tool Change Programs for Perishable Tools * Tool Modification, including tool design documentation. The supplier shall provide appropriate technical resources for tool (see Glossary) and gages design, fabrication and full dimensional inspection. The supplier shall implement a system to track and follow-up on these activities if any of this work is subcontracted. **Note:** Tooling Management (4.2.6.2) is not required of warehouses of distributors. | 7.5.1.5 | Management of Production Tooling<br>The organization shall provide resources for tool and gage design, fabrication and verification activities. The organization shall establish and implement a system for production tooling management including: * Maintenance and Repair Facilities and Personnel * Storage and Recovery * Setup * Tool-Change Programs for Perishable Tools * Tool Design Modification Documentation, including engineering change level * Tool Modification and Revision to Documentation * Tool Identification, defining the status, such as production, repair or disposal. The organization shall implement a system to monitor these activities if any work is outsourced. **Note:** This requirement also applies to the availability of tools for vehicle service parts. |

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| 4.3 | Contract Review | | |
| 4.3.1 | General<br><br>The supplier shall establish and maintain documented procedures for contact review and for the coordination of these activities. **Note:** The supplier is not required to return signed Purchase Order Acknowledgements unless otherwise specified by the customer. | 7.2.1 | Determination of Requirements Related to the Product<br>The organization shall determine; a) requirements specified by the customer, including the requirements for delivery and post-delivery activities; b) requirements not stated by the customer but necessary for specified or intended use, where known; c) statutory and regulatory requirements related to the product; and d) any additional requirements determined by the organization. **Note 1:** Post-delivery activities include any after-sales product service provided as part of the customer contract or purchase order. **Note 2:** The requirement includes recycling, environmental impact and characteristics identified as a result of the organization's knowledge of the product and manufacturing processes (see 7.3.2.3). **Note 3:** Compliance to item "c" includes all applicable governmental regulations, applies to acquisition, storage, handling, recycling, elimination or disposal of materials. |
| | | 7.2.2 | Review of Requirements Related to the Product<br>The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or order, acceptance of changes to contracts or orders) and shall ensure that; a) product requirements are defined; b) contract or order requirements differing from those previously expressed are resolved; and c) the organization has the ability to meet the defined requirements. Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4). Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.<br><br>Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance. Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements. **Note:** In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material. |

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| 4.3.2 | Review<br>Before the submission of a tender, or the acceptance of a contract or order (statement or requirement), the tender, contract or order shall be reviewed by the supplier to ensure that; a) the requirements are adequately defined and documented; where no written statement of requirement is available for an order received by verbal means, the supplier shall ensure that the order requirements are agreed before their acceptance; b) any difference between the contract or order requirements and those in the tender are resolved; c) the supplier has the capability to meet contract or order requirements; d) all customer requirements, including those in Section II of this document, shall be met. | | |
| 4.3.3 | Amendment to Contract<br>The supplier shall identify how an amendment to a contract is made and correctly transferred to the functions concerned within the supplier's organization | | |
| 4.3.4 | Records<br>Records of contract reviews shall be maintained (see 4.16) **Note:** Channels for communication and interfaces with the customer's organization in these contract matters should be established. | | |
| 4.4 | Design Control<br>**Note:** THIS ELEMENT APPLIES TO DESIGN RESPONSIBLE SUPPLIERS ONLY. A supplier is defined as design-responsible if it has the authority to establish a new, or change an existing product specification for any product shipped to a customer. Customer approval of a design responsible supplier's product does not waive the supplier's design responsible status. Consult your customer for further clarification of needed. | | |
| 4.4.1 | General<br>The supplier shall establish and maintain documented procedures to control and verify the design of the product in order to ensure that the specified requirements are met. | | |

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| 4.4.1.1 | Use of Design Data<br>The supplier shall have a process to deploy information gained from previous design projects to current and future projects of a similar nature. | | |
| 4.4.2 | Design and Development Planning<br>The supplier shall prepare plans for each design and development activity. The plans shall describe or reference those activities, and define responsibility for their implementation. The design and development activities shall be assigned to qualified personnel equipped with adequate resources. The plans shall be updated, as the design evolves. | 7.3.1 | Design and Development Planning<br>The organization shall plan and control the design and development of product. During the design and development planning, the organization shall determine; a) the design and development stages; b) the review, verification and validation that are appropriate to each design and development stage; and c) the responsibilities and authorities for design and development. The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output shall be updated, as appropriate, as the design and development progresses. |
| 4.4.2.1 | Required Skills<br>The supplier's design activity should be qualified in the following skills as appropriate: * Geometric Dimensioning and Tolerancing (GD&T) * Quality Function Deployment (QFD) * Design for Manufacturing (DFM)/Design for Assembly (DFA) * Value Engineering (VE) * Design of Experiments (DOE) * Failure Mode and Effects Analysis (DFMEA/PFMEA, etc…) * Finite Element Analysis (FEA) * Solid Modeling * Simulation Techniques * Computer aided Design (CAD)/Computer Aided Engineering (CAE) * Reliability Engineering Plans | 6.2.2.1 | Product Design Skills<br>The organization shall ensure that personnel with product design responsibility are competent to achieve design requirements and are skilled in appropriate tools and techniques. Applicable tolls and techniques shall be identified by the organization. |
| 4.4.3 | Organization and Technical Interfaces<br>Organization and technical interfaces between different groups which input to the design process shall be defined and the necessary information documented, transmitted and regularly reviewed. | 7.3.1.1 | Multidisciplinary Approach<br>The organization shall use a multidisciplinary approach to prepare of product realization, including: * Development/Finalization and Monitoring of Special Characteristics, * Development and Review of FMEA's, including actions to reduce potential risks, and development and review of control plans. **Note:** A multidisciplinary approach typically include the organization's design, manufacturing, engineering, quality, production and other appropriate personnel. |

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| 4.4.4 | Design Input<br>Design input requirements relating to the product, including applicable statutory and regulatory requirements, shall be identified, documented and their selection reviewed by the supplier for adequacy. Incomplete, ambiguous or conflicting requirements shall be resolved with those responsible for imposing these requirements. Design input shall take into consideration the results of any contract review activities. | 7.3.2 | Design and Development Inputs<br>Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include; a) functional and performance requirements; b) applicable statutory and regulatory requirements; c) where applicable, information derived from previous similar designs; and d) other requirements essentials for design and development. These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other. **Note:** Special characteristics see (7.2.1.1) are included in this requirement. |
| | | 7.3.2.1 | Product Design Input<br>The organization shall identify, document and review the product design inputs requirements, including the following: * Customer Requirements (see 7.3.2.3), Identification, Traceability and Packaging, * Use of Information, the organization shall have a process to deploy information gained from previous design projects, competitor analysis, supplier feedback, internal input, field data, and other relevant sources, for current and future projects of similar nature, * targets for product quality, life, reliability, durability, maintainability, timing and cost. |
| 4.4.4.1 | Design Input – Supplemental<br>The supplier shall have appropriate resources and facilities to utilize compute-aided product design, engineering and analysis. If these functions are subcontracted, the suppliers shall provide technical leadership. The CAD/CAE systems shall be capable of two-way interface with customer systems. The customer requirement for computer-aided systems can be waived by the customer. | | |
| 4.4.5 | Design Output<br>Design output shall be documented and expressed in terms that can be verified and validated against design input requirements. Design output shall; a) meet the design input requirements; b) contain or make reference to acceptance criteria; c) identify those characteristics of the design that are critical ("Special Characteristics" – see Appendix C) to the safe and proper functioning of the product (e.g. operating, storage, handling, maintenance and disposal requirements). Design output documents shall be reviewed before release. | 7.3.3 | Design and Development Outputs<br>The output of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release. Design and development outputs shall; a) meet the input requirements for design and development; b) provide appropriate information for purchasing, production and for service provision; c) contain or reference product acceptance criteria; and d) specify the characteristics of the product that are essential for its safe and proper use. |

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| 4.4.5.1 | Design Output – Supplemental<br>The supplier's design output shall be the results of a process that includes: * Efforts to Simplify, Optimize, Innovate, and Reduce Waste (e.g. QFD, DFM/DFA, VE, DOE, tolerance studies, response surface methodology, or appropriate alternatives) * Utilization of Geometric Dimensioning and Tolerance As Applicable * Analysis of Cost/Performance/Risk Trade-offs * Use of Design FMEAs. | 7.3.3.1 | Product Design Output – Supplemental<br>The product design output shall be expressed in terms that can be verified and validated against product design input requirements. The product design output shall include: * Design FMEA, Reliability Results * Product Special Characteristics and Specifications * Product Error-Proofing As Appropriate * Product Definition, including drawings or mathematically based data * Product Design Reviews, Results * Diagnostic Guidelines Where Applicable |
| 4.4.6 | Design Review<br>At appropriate stages of design, formal documented reviews of the design results shall be planned and conducted. Participants at each design review shall include representatives of all functions concerned with the design stage being reviewed, as well as other specialist personnel, as required. Records of such reviews shall be maintained (see 4.16). | 7.3.4 | Design and Development Review<br>At suitable stages, systematic reviews and design and development shall be performed in accordance with planned arrangements (see 7.3.1); a) to evaluate the ability of the results of design and development to meet requirements; and b) to identify and problems and propose necessary actions. Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4). **Note:** These reviews are normally coordinated with the design phase and include manufacturing process design and development. |
| | | 7.3.4.1 | Monitoring<br>Measurements at specified stages of design and development shall be defined, analyzed and reported with summary results as an input to management review. **Note:** These measurements include quality risks, costs, lead-times, critical paths and others, as appropriate. |
| 4.4.7 | Design Verification<br>At appropriate stages of design, design verification shall be performed to ensure that the design stage output meets the design stage input requirements. The design verification measures shall be recorded (see 4.16) **Note 10:** In addition to conducting design reviews (see 4.4.6) design verification may include activities such as the following: * Performing alternative Calculations * Comparing the New Design With a Similar Proven Design, if available * Undertaking Tests and Demonstrations * Reviewing the Design Stage Documents Before Release | 7.3.5 | Design and Development Verification<br>Verification shall be performed in accordance with planned arrangement (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4). |
| 4.4.8 | Design Validation | 7.3.6 | Design and Development Validation |
| | Design validation shall be performed to ensure that product conforms to define user needs and/or requirements. | | Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Where ever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4). |

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| | | | **Note 1:** The validation process normally includes an analysis of field reports for similar products. **Note 2:** The requirements or 7.3.5 and 7.3.6 above apply to both product and manufacturing processes. |
| 4.4.8.1 | Design Validation – Supplemental<br>Design validation shall be performed in conjunction with customer programming timing requirements. Validation results shall be recorded (see 4.16). Design failures shall be documented in the validation records. Procedures for corrective and preventive action shall be followed in addressing such design failures. **Note 11:** Design validation follows successful design verification (see 4.4.7) **12**: Validation is normally performed under defined operating conditions. **13:** Validation is normally performed on the final product, but may be necessary in earlier stages prior to product completion. **14:** Multiple validations may be performed if there are different intended uses. | 7.3.6.1 | Design and Development Validation – Supplemental<br>Design and development validation shall be performed in accordance with customer requirements, including program timing. |
| 4.4.9 | Design Changes<br>All design changes and modifications shall be identified, documented, reviewed and approved by authorized personnel before their implementation. | 7.3.7 | Control of Design and Development Changes<br>Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the change on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4). **Note:** Design and development changes include all changes during the product program life (see 7.1.4). |
| 4.4.9.1 | Design Changes - Supplemental<br>All design changes, including those proposed by subcontractors, shall have written customer approval, or waiver of such approval, prior to production implementation. See the Productions Part Approval Process manual and the customer-specific pages of this document. For proprietary designs, impact on form, fit, function, performance, and/or durability shall be determined with the customer so that all effects can be properly evaluated. | 7.3.6.3 | Product Approval Process<br>The organization shall conform to the product and manufacturing process approval procedure recognized by the customer. **Note:** Product approval should be subsequent to the verification of the manufacturing process. The product and manufacturing process approval procedure shall also be applied to suppliers. |
| 4.4.9.2 | Design Change Impact<br>The supplier shall consider the impact of the design change on the system in which the product is used. | | |

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| 4.4.10 | Customer Prototype Support<br>When required by the customer, the supplier shall have a comprehensive prototype program. The supplier shall use the same subcontractors, tooling and processes, as will be used in production wherever possible. Performance tests shall consider and include as appropriate product life, reliability and durability. All performance testing activities shall be tracked to monitor timely completion and conformance to requirements. While these services may be contracted, the supplier shall provide technical leadership. | 7.3.6.2 | Prototype Programme<br>When required by the customer, the organization shall have a prototype programme and control plan. The organization shall use, wherever possible, the same suppliers, tooling and manufacturing processes as will be used in production. All performance-testing activities shall be monitored for timely completion and conformity to requirements. While services may be outsourced, the organization shall be responsible for the outsourced services, including technical leadership. |
| 4.4.11 | Confidentiality<br>The supplier shall ensure the confidentiality of customer-contracted products under development and related product information. | 7.1.3 | Confidentiality<br>The organization shall ensure the confidentiality of customer-contracted products and projects under development, and related product information. |
| 4.5 | Document and Data Control | | |
| 4.5.1 | General<br>The supplier shall establish and maintain documented procedures to control all documents and data that relate to the requirements of this International Standard including, to the extent applicable, documents of external origin such as standards and customer drawings. **Note 15:** Documents and data can be in the form of any type of media, such as hard copy or electronic media. | 4.2.3 | Control of Documents<br>Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4. A documented procedure shall be established to define the controls needed; a) to approve documents for adequacy prior to issue; b) to review and update as necessary and re-approve documents; c) to ensure that changes and the current revision status of documents are identified; d) to ensure that relevant versions of applicable documents are available at point of use; e) ensure that documents remain legible and readily identifiable; f) to ensure that documents of external origin are identified and their distribution controlled; and g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose. |

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| 4.5.2 | Document and Data Approval and Issue<br>The documents and data shall be reviewed and approved for adequacy by authorized personnel prior to issue. A master list of equivalent document control procedure identifying the current revision status of documents shall be established and be readily available to preclude the use of invalid and/or obsolete documents. This control shall ensure that; a) the pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality essential to the effective functioning of the quality system are performed. **Note:** Examples of appropriate documents include: * Engineering Drawings * Engineering Standards * Math (CAD) Data * Inspection Instructions * Test Procedures * Work Instructions * Operations Sheets * Quality Manual * Operational Procedures * Quality Assurance Procedures * Material Specifications Invalid and/or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use. Any obsolete documents retained for legal and/or knowledge preservation purposes are suitably identified | | |
| 4.5.2.1 | Engineering Specifications<br>The supplier shall establish a procedure to assure the timely review (e.g. business "days", not weeks or months), distribution and implementation of all customer engineering standards/specifications and changes. The supplier shall maintain a record of the date on which each change is implemented in production (subject to record control, see 4.16). Implementation shall include updates to all appropriate documents. **Note:** A change in these specifications should require an updated PPAP record when these specifications are referenced on the design record (see Glossary) or if they affect PPAP documents (e.g. Control Plan, FMEAs, etc…) (see PPAP). | 4.2.3.1 | Engineering Specifications<br>The organization shall have a process to assure the timely review, distribution and implementation of all customer engineering standards/specifications and changes based on customer-required schedule. Timely review should be as soon as possible, and shall not exceed two working weeks. The organization shall maintain a record of the date on which each change is implemented in production. Implementation shall include updated documents. **Note:** A change in these standards/specifications requires an updated record of customer production part approval when these specifications are referenced on the design records or it they affect documents of production part approval process, such as Control Plan, FMEA, etc. |

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| | | 7.3.7 | Control of Design and Development Changes<br>Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4). **Note:** Design and development changes include all changes during the product programme life (see 7.1.4). |
| 4.5.3 | Document and Data Changes<br>Changes to documents and data shall be reviewed and approved by the same functions/organizations that performed the original review and approval, unless specifically designated otherwise. The designated functions/organizations shall have access to pertinent background information upon which to base their review and approval. Where practicable, the nature of the change shall be identified in the document or the appropriate attachments. | | |
| 4.6 | Purchasing | | |
| 4.6.1 | General<br>The supplier shall establish and maintain documented procedures to ensure that purchase products (see 3.1) conform to specified requirements. **Note:** The reference above, "see 3.1" is to Section 3.1 in ISO 9001 or 9002 where "product" is defined. | 7.4.1 | Purchasing Process<br>The organization shall ensure that purchased products conform to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. The organization shall evaluate and select suppliers based on their ability to supply products in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluation and any necessary actions arising from the evaluation shall be maintained (see 4.2.4). **Note 1:** Purchased products above include all products and services that affect customer requirements such as subassembly, sequencing, sorting, rework and calibration services. **Note 2:** When there are mergers, acquisitions or affiliations associated with suppliers, the organization should verify the continuity of the supplier's quality management system and its effectiveness. |

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| 4.6.1.1 | Approved Material for Ongoing Production<br>Where the customer has an approved subcontractor list, the supplier shall purchase the relevant materials from subcontractors on the list. Any additional subcontractors may only be used after they have been added to the list by the customer's Materials Engineering activity. **Note:** To be added to any existing customer "approved subcontractor list", a company should contact the appropriate customer engineering function to be considered. These lists exist only for certain commodities and, where they do exist, they may be found in the customer design record. (See Glossary) | 7.4.1.3 | Customer-Approved Sources<br>Where specified by the contract (e.g. customer engineering drawing, specification), the organization shall purchase products, materials or services from approved sources. The use of customer-designated sources, including tool/gauge suppliers, does not relieve the organization of the responsibility for ensuring the quality of purchased products. |
| 4.6.1.2 | Government, Safety and Environmental Regulations<br>All purchased materials used in part manufacture shall satisfy current governmental and safety constraints on restricted, toxic and hazardous materials; as well as environmental, electrical and electromagnetic considerations applicable to the country of manufacture and sale (see Glossary – Approved Materials). | 7.4.1.1 | Regulatory Conformity<br>All purchased products or materials use in product shall conform to applicable regulatory requirements. |
| 4.6.2 | Evaluations of Subcontractors<br>The supplier shall; a) evaluate and select subcontractor on the basis of their ability to meet subcontract requirements including the quality system and any specific quality assurance requirements; b) define the type and extent of control exercised by the supplier over subcontractors. This shall be dependent upon the type of product, the impact of subcontracted product on the quality of final product and, where applicable, on the quality audit reports and/or quality records of the previously demonstrated capability and performance of subcontractors; c) establish and maintain quality records of acceptable subcontractors (see 4.16). **Note:** Methods other than an "Approved subcontractors list" may be utilized to meet this requirement. | | |

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| 4.6.2.1 | Subcontractor Development<br><br>The supplier shall perform subcontractor (see Glossary) quality system development with the goal of subcontractor compliance to QS-9000 using section 1 of QS-9000 as their fundamental quality system requirement. Assessments, if part of subcontractor development, should occur at supplier specified frequency. Subcontractor assessments to QS-9000 by the OEM customer, and OEM customer-approved second party, or an accredited third party certification body/registrar will be recognized in lieu of audits by the supplier. **Note:** Acceptance of the above audits or ISO 9001/9002 registration is not intended to limit more specific supplier/subcontractor quality system and product development. **Note:** The prioritization of subcontractors for development is dependent upon the needs of the subcontractor relative to the requirements of QS-9000 and the importance of the product or service they supply. The use of customer-designated subcontractors does not relieve the supplier of the responsibility for ensuring the quality of subcontracted parts, materials and services. | 7.4.1.2 | Supplier Quality Management System Development<br>The organization shall perform supplier quality management system development with the goal of supplier conformity with this Technical specification. Conformity with ISO 9001:2000 is the first step in achieving this goal. **Note:** The prioritization of suppliers for development depends upon, for example, the supplier's quality performance and the importance of the product supplied. Unless otherwise specified by the customer, suppliers to the organization shall be third party registered to ISO 9001:2000 by an accredited third-party certification body. |
| 4.6.2.2 | Scheduling Subcontractors<br>The supplier shall require 100% on time delivery performance from subcontractors. The supplier shall provide appropriate planning information and purchase commitments to enable subcontractors to meet this expectation. The supplier shall implement a system to monitor the delivery performance of subcontractors with corrective actions taken as appropriate. Records of premium freight shall include both supplier and subcontractor paid charges. | | |

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| 4.6.3 | Purchasing Data<br>Purchasing documents shall contain data clearly describing the product ordered, including where applicable; a) the type, class, grade or other precise identification; b) the title or other positive identification and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data, including requirements for approval or qualification of product, procedures, process equipment and personnel; c) the title, number and issue of the quality system standard to be applied. The supplier shall review and approve purchasing documents for adequacy of specified requirements prior to release. | 7.4.2 | Purchasing Information<br>Purchasing information shall describe the product to be purchased, including where appropriate; a) requirements for approval of product, procedures, processes and equipment; b) requirements for qualification of personnel; and c) quality management system requirements. The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier. |
| 4.6.4 | Verification of Purchased Product | | |
| 4.6.4.1 | Supplier Verification at Subcontractor's Premises<br>Where the supplier proposes to verify purchased product at the subcontractor' premises, the supplier shall specify verification arrangements and the method of product release in the purchasing documents. | 7.4.3 | Verification of Purchased Product<br>The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information. |
| 4.6.4.2 | Customer Verification of Subcontracted Product<br>Where specified in the contract, the supplier's customer or the customer's representative shall be afforded the right to verify at the subcontractor's premises and the supplier's premises that subcontracted product conforms to specified requirements. Such verification shall not be used by the supplier as evidence or effective control of quality by the subcontractor. Verification by the customer shall not absolve the supplier of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer. | | |

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| 4.7 | Control of Customer Supplier Product<br>The supplier shall establish and maintain documented procedures for the control of verification, storage and maintenance of customer-supplied product provided for incorporation into the suppliers or for related activities. Any such product that is lost, damaged or is otherwise unsuitable for use shall be recorded and reported to the customer (see 4.16). Verification by the supplier does not absolve the customer of the responsibility to provide acceptable product. **Note:** Customer-owned returnable packaging is included in this element (see 4.15.4). | 7.5.4 | Customer Property<br>The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4). **Note:** Customer property can include intellectual property. **Note:** Customer-owned returnable packaging is included in this clause. |
| 4.7.1 | Customer-Owned Tooling<br>Customer-owned tools and equipment shall be permanently marked so that the ownership of each item is visually apparent. **Note:** An affixed tag specifically containing the part number and/or customer name to identify ownership is the preferred approach. However, this requirement may be met by using a supplier-designated number cross-referenced with clear traceability back to the customer. | 7.5.4.1 | Customer-Owned Production Tooling<br>Customer-owned tools, manufacturing, test, inspection tooling and equipment shall be permanently marked so that the ownership of each item is visible, and can be determined. |
| 4.8 | Product Identification and Traceability<br>Where appropriate, the supplier shall establish and maintain documented procedures for identifying the product by suitable means from receipt and during all stages of production, delivery and installation. **Note:** For QS-9000, the words "where appropriate" above are not applicable. Where and to the extent that traceability is a specified requirement, the supplier shall establish and maintained documented procedures for unique identification of individual product or batches. This identification shall be recorded (see 4.16). | 7.5.3 | Identification and Traceability<br>Where appropriate, the organization shall identify the product by suitable means throughout product realization. The organization shall identify the product status with respect to monitoring and measurement requirements. Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4). **Note:** In some industry sectors, configuration management is a means by which identification and traceability are maintained. **Note:** Inspection and test status is not indicated by the location of product in the production flow unless inherently obvious, such as material in an automated production transfer process. Alternatives are permitted, if the status is clearly identified, documented and achieves the designated purpose. |
| | | 7.5.3.1 | Identification and Traceability-Supplemental<br>The words "Where appropriate" in 7.5.3 shall not apply. |

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| **Element** | **Title** | **Element** | **Title** |
| 4.9 | Process Control<br>The supplier shall identify and plan the production, installation and servicing processes which directly affect quality and shall ensure that these processes are carried out under controlled conditions. Controlled conditions shall include the following; a) documented procedures defining the manner of production, installation and servicing, where the absence of such procedures could adversely affect quality; b) use of suitable production, installation and servicing equipment, and a suitable working environment (see Glossary); c) compliance with reference standards/codes, quality plans and/or documented procedures; d) monitoring and control of suitable process parameters and product characteristics; e) the approval of processes and equipment, as appropriate; f) criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g. written standards, representative samples or illustrations); g) suitable maintenance of equipment to ensure continuing process capability<br><br>Where the results of processes cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use, the processes shall be carried out by qualified operators and/or shall require continuous monitoring and control of process parameters to ensure that the specified requirements are met. The requirements for any qualification of process operations, including associated equipment and personnel (see 4.18), shall be specified. **Note 16:** Such processes requiring pre-qualification of their process capability are frequently referred to as special processes. Records shall be maintained for qualified processes, equipment and personnel, as appropriate (see 4.16). | 6.4 | Work Environment<br>The organization shall determine and manage the work environment needed to achieve conformity to product requirements. |

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| **Element** | **Title** | **Element** | **Title** |
| | | 7.5.1 | Control of Production and Service Provision<br>The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable; a) the availability of information that describes the characteristics of the product; b) the availability of work instructions, as necessary; c) the use of suitable equipment; d) the availability and use of monitoring and measuring devices; e) the implementation of monitoring and measurement; and f) the implementation of release, delivery and post-delivery activities. |
| | | 7.5.2 | Validation of Processes for Production and Service Provision.<br>The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes including, as applicable; a) defined criteria for review and approval of the processes; b) approval of equipment and qualification of personnel; c) use of specific methods and procedures; d) requirements for records (see 4.2.4); and e) revalidation. |
| | | 7.5.2.1 | Validation of Processes for Production and Service Provision – Supplemental<br>The requirements of 7.5.2 shall apply to all processes for production and service provision. |
| 4.9.b.1 | Cleanliness of Premises<br>The supplier shall maintain premises in a state of order, cleanliness and repair appropriate to the product(s) manufactured. | 6.4.2 | Cleanliness of Premises<br>The organization shall maintain its premises in a state of order, cleanliness and repair consistent with the product and manufacturing process needs. |
| 4.9.b.2 | Contingency Plans<br>The supplier shall prepare contingency plans (e.g. utility interruptions, labor shortage, key equipment failures) to reasonably protect the customer's supply of product in the event of emergency, excluding natural disaster and acts of God. | 6.3.2 | Contingency Plans<br>The organization shall prepare contingency plans to satisfy customer requirements in the event of an emergency such as utility interruptions, labour shortages, key equipment failure and field returns. |

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| 4.9.d.1 | Designation of Special Characteristics<br>The supplier shall comply with all customer requirements for designation, documentation and control of Special Characteristics. The supplier shall provide documentation showing compliance with the customer requirements as requested by any customer. **Note:** All product and process characteristics are important and need to be controlled. However, some characteristics, herein referred to as "special", need extra attention because excessive variation in them might affect a product's safety, compliance with governmental regulations, fit, function, appearance or quality of subsequent manufacturing operations. | 7.2.1.1 | Customer-Designated Special Characteristics<br>The organization shall demonstrate conformity to customer requirements for designation, documentation and control of special characteristics. |
| | | 7.3.2.3 | Special Characteristics<br>The organization shall identify special characteristics (see 7.3.3.d) and * Include All Special Characteristics in the Control Plan, * Comply With Customer-Specified Definitions and Symbols, and * Identify Process Control Documents, including drawings, FMEAs, control plans, and operator instructions with the customer's special characteristic symbol; or the organization's equivalent symbol or notation to include those process steps that affect special characteristics. **Note:** Special characteristic and include product characteristics and process parameters. |
| 4.9.g.1 | Preventive Maintenance<br>The supplier shall identify key process equipment and provide appropriate resources for machined/equipment maintenance and develop an effective planned total preventive maintenance system. At a minimum, this system shall include: * A Procedure That Describes Planned Maintenance Activities * Scheduled Maintenance Activities * Predictive Maintenance Methods, these methods should include a review of appropriate items, such as the manufacture's recommendations, tool wear, optimization of uptime, correlation of SPA data to preventive maintenance activities, correlation of SPC data to preventive maintenance activities, important characteristics of perishable tooling, fluid analysis, infrared monitoring of circuits and vibrations analysis * A Procedure Providing for Packaging and Preservation for Equipment, Tooling and Gauging * Availability of Replacement Parts for Key Manufacturing Equipment * Documenting, Evaluation and improving Maintenance Objectives. | 7.5.1.4 | Preventive and Predictive Maintenance<br>The organization shall identify key process equipment and provide resources for machine/equipment maintenance and develop an effective planned total preventive maintenance system. As a minimum, this system shall include the following: * Planned Maintenance Activities * Packaging and Preservation of Equipment, Tolling and Gauging * Availability of Replacement Parts for Key Manufacturing Equipment * Documenting, Evaluating and Improving Maintenance Objectives. The organization shall utilize predictive maintenance methods to continually improve the effectiveness and the efficiency of production equipment. |

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| **Element** | **Title** | **Element** | **Title** |
| 4.9.1 | Process Monitoring and Operator Instructions<br>The supplier shall prepare documented process monitoring and operator instructions for all employees having responsibilities for operation processes. These instructions shall be accessible at the workstation. **Note:** Job instructions should be available at the time needed without disruption to the job being performed by the operator. These instructions should be derived from the sources listed in the Advanced Product Quality Planning and Control Plan reference manual. Process monitoring and operator instructions may take the form of process sheets, inspections and laboratory test instructions, shop travelers, test procedures, standard operation sheets, or other documents normally used by the supplier to provide the necessary information.<br><br>Process monitoring and operator instructions shall include or reference, as appropriate: * Operation Name and Number Keyed to the Process Flow Diagram * Part Name and Part Number, or Part Family * Current Engineering Level/Date * Required Tolls, Gauges and Other Equipment * Material Identification and Disposition Instructions * Customer and Supplier Designated Special Characteristics * SPC Requirements * Relevant Engineering and Manufacturing Standards * Inspection and Test Instructions (see 4.10.4) * Reaction Plan * Revision Date and Approvals * Visual Aids * Tool Change Intervals and Setup Instructions. | 7.5.1.2 | Work Instructions<br><br>The organization shall prepare documented work instructions for all employees having responsibilities for the operation of processes that impact product quality. These instructions shall be accessible for use at the workstation. These instructions shall be derived from sources such as quality plan, the control plan and the product realization process. |
| | | 8.2.3 | Monitoring and Measurement of Processes<br>The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product. |

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| **Element** | **Title** | **Element** | **Title** |
| 4.9.2 | Maintaining Process Control<br><br>The supplier shall maintain (or exceed) process capability or performance as approved via PPAP. To accomplish this, the supplier shall ensure that the Control Plan and Process Flow Diagram (see Glossary) are implemented, including but not limited to, adherence to the specified: * Measuring Technique * Sampling Plans * Acceptance Criteria (see 4.10.1.1) * Reaction Plans When the Acceptance Criteria is Not Met. See the Advanced Product Quality Planning and Control Plan reference manual. Significant process events (e.g. tool change, machine repair) should be noted on the control charts (see 4.16). When process and/or product data indicate a high degree of capability (e.g. Cpk/Ppk≥3), the supplier may revise the Control Plan, as appropriate (see PPAP, Section II). The supplier shall initiate the appropriate reaction plan from the Control Plan for characteristics which are identified on the Control Plan and are either unstable or non-capable.<br><br>Reaction plans should include containment of process output and 100% inspection. A supplier corrective action plan shall be completed indicating specific timing and assigned responsibilities to assure that the process becomes stable and capable (see 4.10.1.1). The plans are to be reviewed with and approved by the customer when so required. | 8.2.3.1 | Monitoring and Measurement of Manufacturing Processes<br>The organization shall perform process studies on all new manufacturing (including assembly or sequencing) processes to verify process capability and to provide additional input for process control. The results of process studies shall be documented with specifications, where applicable, for means of production, measurement and test, and maintenance instructions. These documents shall include objectives for manufacturing process capability, reliability, maintainability and availability, as well as acceptance criteria. The organization shall maintain manufacturing process capability or performance as specified by the customer part approval process requirements. The organization shall ensure that the control plan and process flow diagram are implemented, including adherence to the specified: * Measurement Techniques * Sampling Plans * Acceptance Criteria * Reaction Plans When Acceptance Criteria Are Not Met.<br><br>Significant process events, such as tool change or machine repair, shall be recorded. The organization shall initiate a reaction plan form the control plan for characteristics that are either not statistically capable or unstable. This reaction plan shall include containment of product and 100% inspection as appropriate. A corrective action plan shall then be completed by the organization, indicating specified timing and assigned responsibilities to assure that the process becomes stable and capable. The plans shall be reviewed with and approved by the customer when so required. The organization shall maintain records of effective dates of process changes. |
| 4.9.3 | Modified Process Control Requirements<br>In some cases, the customer may require either higher or lower capability or performance (see 4.9.2) requirements. In these cases, the Control Plan shall be annotated accordingly (i.e. in the Product/Process Specification/Tolerance column of the suggested APWP Control Plans) | | |

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| 4.9.4 | Verification of Job Set-ups<br>Job set-ups shall be verified whenever a set-up is performed (e.g. initial run of a job, material changeover, job change, significant time periods lapsed between runs, etc…). Job instructions shall be available for set-up personnel. Last-off part comparisons are recommended. The supplier shall use statistical methods of verification where applicable. | 7.5.1.3 | Verification of Job Set-ups<br>Job set-ups shall be verified whenever performed, such as an initial run of a job, material changeover or job change. Work instructions shall be available for set-up personnel. The organization shall use statistical methods of verification where applicable. **Note:** Last-off comparisons are recommended. |
| 4.9.5 | Process Changes<br>The supplier shall maintain records of process change effective dates (see 4.5.3). **Note:** Changes to promote continuous improvement are encouraged. Consult the customer for guidance on approval requirements for such changes. | 7.1.4 | Change Control<br>The organization shall have a process to control and react to changes that impact product realization. The effects of any change, including those changes caused by a supplier, activities shall be assessed, and verification and validation activities shall be defined to ensure compliance with customer requirements. Changes shall be validated before implementation. For proprietary designs, impact on form, fit and function (including performance and/or durability) shall be reviewed with the customer so that all effects can be properly evaluated. Where required by the customer, additional verification/identification requirements, such as those required for new product introduction, shall be met. **Note 1:** Any product realization change affecting customer requirements requires notification to, and agreement from, the customer. **Note 2:** The above requirement applies to product and manufacturing process changes. |
| | | 8.2.3.1 | Monitoring and Measurement of Manufacturing Processes<br>The organization shall maintain records of effective dates of process changes |
| 4.9.6 | Appearance Items<br>For suppliers manufacturing parts designated by the customer as “Appearance Items”, the suppler shall provide: * Appropriate Lighting for Evaluation Areas * Masters For Color, Grain, Gloss, Metallic Brilliance, Texture, Distinctness of Image (DOI), as appropriate * Maintenance and Control of Appearance Masters and Evaluation Equipment * Verification That Personnel Making Appearance Evaluations Are Qualified to Do So | 8.2.4.2 | Appearance Items<br>For organizations manufacturing parts designed by the customer as “appearance items”, the organization shall provide * Appropriate Resources Including Lighting for Evaluation * Masters for Colour, Grain, Gloss, Metallic Brilliance, Texture, Distinctness of Image (DOI), as appropriate * Maintenance and Control of Appearance Masters and Evaluation Equipment * Verification That Personnel Making Appearance Evaluations Are Competent and Qualified to Do So. |
| 4.10 | Inspection and Testing | | |

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| **Element** | **Title** | **Element** | **Title** |
| 4.10.1 | General<br>The suppler shall establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for the product is met. The required inspection and testing, and the records to be established, shall be detailed in the quality plan or document procedures. | 8.2.4 | Monitoring and Measurement of Product<br>The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4). Product release and service delivery shall not proceed until all planned arrangements (see 7.1) have been satisfactory completed, unless otherwise approved by a relevant authority, and where applicable by the customer. **Note:** When selecting product parameters to monitor compliance to specified internal and external requirements, the organization determines the types of product characteristics, leading to: * The Types of Measurement * Suitable Measurement Means * The Capability and Skills Required. |
| 4.10.1.1 | Acceptance Criteria for Attribute Characteristics<br>Acceptance criteria for attribute data sampling plans shall be zero defects. Appropriate acceptance criteria for all other situations (e.g. visual standards) shall be documented by the supplier and approved by the customer. | 7.1.2 | Acceptance Criteria<br>Acceptance criteria shall be defined by the organization and, where required, approved by the customer. For attribute data sampling, the acceptance level shall be zero defects (see 8.2.3.1). |
| 4.10.2 | Receiving Inspection and Testing | | |
| 4.10.2.1 | The supplier shall ensure that incoming product is not used or processed (except in the circumstances described in 4.10.2.3) until it has been inspected or otherwise verified as conforming to specified requirements. Verification of conformance to the specified requirements shall be in accordance with the quality plan (Control Plane) and/or documented procedures. | | |
| 4.10.2.2 | In determining the amount and nature of receiving inspection, consideration shall be given to the amount of control exercised at the subcontractor's premises and the recorded of conformance provided. | | |
| 4.10.2.3 | Where incoming product is released for urgent production purposes prior to verification, it shall be positively identified and recorded (see 4.16) in order to permit immediate recall and replacement in the event of nonconformity to specified requirements. | | |

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| **Element** | **Title** | **Element** | **Title** |
| 4.10.2.4 | Incoming Product Quality<br>The supplier's incoming quality system shall use one or more of the following methods: * Receipt and Evaluation of Statistical Data By the Supplier * Receiving Inspection and/or Testing (e.g., sampling based on performance) * Second or Third Party Assessments or Audits of Subcontractor Sites, When coupled with records of acceptable quality performance * Part Evaluation By Accredited Laboratories | 7.4.3.1 | Incoming Product Quality<br>The organization shall have a process to assure the quality of purchased product (see 7.4.3) utilizing one or more of the following methods: * Receipt Of and Evaluation Of statistical Data By the Organization * Receiving Inspection and/or Testing Such As Sampling Based On Performance * Second or Third-Party Assessments or Audits Of Supplier Sites, when coupled with records of acceptable delivery product quality * Part Evaluation By a Designated Laboratory * Another Method Agreed With the Customer |
| 4.10.3 | In-Process Inspection and Testing<br>The supplier shall; a) inspect the product as required by the quality plan (Control Plan) and/or documented procedures; b) hold product until the required inspection and tests have been received and verified, except when product is released under positive-recall procedures (see 4.10.2.3). Release under positive-recall procedures shall not preclude the activities outlined in 4.10.3a); c) direct process activities toward defect prevention methods, such as statistical process control, mistake-proofing, visual controls, rather than defect detection. | | |
| 4.10.4 | Final Inspection and Testing<br>The supplier shall carry out all final inspection and testing in accordance with the quality plan (Control Plan) and/or documented procedures to complete the evidence of conformance of the finished product to the specified requirements. The quality plan (Control Plan) and/or documented procedures for final inspection and testing shall require tat all specified inspection and tests, including those specified either on receipt of product or in-process, have been carried out and that the results meet specified requirements. Not product shall be dispatched until all the activities specified in the quality plan (Control Plan) and/or documented procedures have been satisfactorily completed and the associated data and documentation are available and authorized. | | |

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| **Element** | **Title** | **Element** | **Title** |
| 4.10.4.1 | Layout Inspection and Functional Testing<br>A layout inspection and a functional verification (to applicable customer engineering material and performance standards) shall be performed for all products at a frequency established by the customer (see Section II). Results shall be available for customer review. | 8.2.4.1 | Layout Inspection and Functional Testing<br>A layout inspection and a functional verification to applicable customer engineering material and performance standards shall be performed for each product as specified in the control plans. Results shall be available for customer review. **Note:** Layout inspection is the complete measurement of all product dimensions shown on the design records. |
| 4.10.4.2 | Final Product Audit<br>The supplier shall conduct audits of packaged final product to verify conformance to all specified requirements (e.g. product, packaging, labeling) at an appropriate frequency. **Note:** This activity, also known as a "dock audit", is based upon sampling and is generally performed after final inspection but prior to shipment. Where customer PPM requirements are met, the frequency of Final Product Audits may be reduced. | | |
| 4.10.5 | Inspection and Test Records<br>The supplier shall establish and maintain records which provide evidence that the product has been inspected and/or tested. These records shall show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria. Where the product fails to pass any inspection and/or test, the procedures for the control of nonconforming product shall apply (see 4.13). Records shall identify the inspection authority responsible for the release of the product (see 4.16). | | |
| 4.10.6 | Supplier Laboratory Requirements<br>**Note:** Element 4.10.6 applies to supplier in-house laboratory facilities, not inspection or testing performed outside of a laboratory facility. | | |

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| **Element** | **Title** | **Element** | **Title** |
| 4.10.6.1 | Laboratory Quality Systems<br>The laboratory (supplier's testing facility – chemical, metallurgical, reliability test validation, e.g., fastener labs) shall have a laboratory scope (see Glossary). The laboratory shall document all its policies, systems, programs, procedures, instructions and findings which enable the laboratory to assure the quality of the tests or calibration results it generates within the scope (see 4.2.1). **Note:** Accreditation of supplier facilities to ISO/IEC Guide 25 or national equivalent is not required by, nor does it satisfy, all QS-9000 requirements for a laboratory. Therefore, the laboratory should be included in the on-site audits. | 7.6.3.1 | Internal Laboratory<br>An organization's internal laboratory facility shall have a defined scope that includes its capability to perform the required inspection, test or calibration services. The laboratory scope shall be included in the quality management system documents. The laboratory shall specify and implement, as a minimum, technical requirements for: * Adequacy of the Laboratory Procedures * Competency of the Laboratory Personnel * Testing of the Product * Capability to Perform These Services Correctly, Traceable to the Relevant Process Standard (such as ASTM, EN, etc…) * Review of the Related Records. **Note:** Accreditation to ISO/IEC 17025 may be used to demonstrate supplier in-house laboratory conformity to this requirement but is not mandatory. |
| 4.10.6.2 | Laboratory Personnel<br>The personnel making professional judgment with reference to testing and/or calibration shall have appropriate background and experience (see 4.1.2.2). **Note:** Such background should include both theoretical and recent practical experience. | | |
| 4.10.6.3 | Laboratory Product Identification and Testing<br>The laboratory shall have procedures for the receipt, identification, handling, protection and retention or disposal of test samples and/or calibration equipment items, including all provisions necessary to protect the integrity of the items (see 4.15). The items shall be retained until final data is complete throughout the life of the item in the laboratory, enabling traceability from final data to raw data (see Glossary and 4.10.1). | | |
| 4.10.6.4 | Laboratory Process Control<br>The laboratory shall monitor, control and record (see 4.16) environmental conditions as required by relevant specifications or where they may influence the quality of results. Requirements for environmental conditions (e.g., biological sterility, dust, electromagnetic interference, radiation, humidity, electrical supply, temperature, and sound and vibration levels) shall be established and maintained as appropriate to the technical activities concerned. | | |

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| 4.10.6.5 | Laboratory Testing and Calibration Methods<br>The laboratory shall use test and/or calibration methods, including those for sampling, which meet the needs of the customer and are appropriate for the tests and/or calibrations it undertakes, preferably the current issue of those published as international, regional, or national standards (see 4.11). The laboratory shall verify its capability to perform to the standard specifications before carrying out such work. When it is necessary to employ methods not covered by standard specifications, these shall be subject to agreement with the customer. | | |
| 4.10.6.6 | Laboratory Statistical Methods<br>Appropriate statistical techniques should be applied to verification activities whose deliverables are data (see 4.20). | | |
| 4.10.7 | Accredited Laboratories<br>Commercial/independent laboratory facilities used by the supplier shall be accredited laboratory facilities. Reference the customer-specific pages of this document and the Glossary. **Note:** Commercial/independent laboratories cannot be registered to QS-9000. **Note:** For further guidance on Element 4.10.7, see ISO/IEC Guide 25 or national equivalent. | 7.6.3.2 | External Laboratory<br>External/commercial/independent laboratory facilities used for inspection, test or calibration services by the organization shall have a defined laboratory scope that includes the capability to perform the required inspection, test or calibration, and either; there shall be evidence that the external laboratory is acceptable to the customer, or the laboratory shall be accredited to ISO/EC 17025 or equivalent. **Note 1:** Such evidence may be demonstrated by customer assessment, for example, or by customer-approved second-party assessment that the laboratory meets the intent of ISC/EC 17025 or national equivalent. **Note 2:** When a qualified laboratory is not available for a given piece of equipment, calibration services may be performed by the equipment manufacturer. In such cases, the organization should ensure that the requirements listed in 7.6.3.1 have been met. |
| 4.11 | Control of Inspection, Measuring and Test Equipment | | |

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| **Element** | **Title** | **Element** | **Title** |
| 4.11.1 | General | 7.6 | Control of Monitoring and Measuring Devices |
| | The supplier shall establish and maintain documented procedures to control, calibrate and maintain inspection, measuring and test equipment (including test software) used by the supplier to demonstrate the conformance of product to the specified requirements. Inspection, measuring and test equipment shall be used in a manner which ensures that the measurement uncertainty is known, and is consistent with the required measurement capability. **Note:** Additional guidance on measurement uncertainty may be found in ISO 10012-1:1992(E). The choice of the specific method to be used should be based upon sound technical knowledge of the complete measurement system, the condition under which it will operate, and the uses for which the data are being produced.<br><br>Where test software of comparative references such as test hardware are used as suitable forms of inspection, they shall be checked to prove that they are capable of verifying the acceptability of product, prior to release for use during production, installation, or servicing, and shall be rechecked at prescribed intervals. The supplier shall establish the extent and frequency of such checks and shall maintain records as evidence of control (see 4.16). Where the availability of technical data pertaining to the inspection, measuring, and test equipment is a specified requirement, such data shall be made available, where required by the customer or customer's representative, for verification that the inspection, measuring, and test equipment is functionally adequate. **Note:** For purposes of this International Standard, the term "measuring equipment" includes "measurement devices". | | The organization shall determine the monitoring and measurement to be taken and the monitoring and measuring devices needed to provide evidence of conformity of product to determine requirements (see 7.2.1). The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements. Where necessary to ensure valid results, measuring equipment shall; a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded; b) be adjusted or re-adjusted as necessary; c) be identified to enable the calibration status to be determined; d) be safeguarded for adjustments that would invalidate the measurement result; e) be protected from damage and deterioration during handling, maintenance and storage. In addition, the organization shall access ad record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4). When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application, shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary. **Note:** See ISO 10012-1 and ISO 10012-2 for guidance. **Note:** A number or other identifier traceable to the device calibration record meets the intent of requirement; c) above. |

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| **Element** | **Title** | **Element** | **Title** |
| 4.11.2 | Control Procedure<br>The supplier shall; a) determine the measurements to be made and the accuracy required, and select the appropriate inspection, measuring and test equipment that is capable of the necessary accuracy and precision; b) identify all inspection, measuring and test equipment that can affect product quality, and calibrate and adjust them at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to internationally or nationally recognized standards. Where no such standards exit, the basis used for calibration shall be documented. **Note:** "Inspection, measuring and test equipment" includes equipment in tooling departments used to qualify or maintain production tools regardless of ownership; c) identify the process employed for the calibration or inspection, measuring and test equipment, including details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria and the action to be taken when results are unsatisfactory; d) identify inspection, measuring and test equipment with a suitable indicator or approved identification record to show the calibration status. **Note:** A serial number traceable to the device calibration record meets the intent of this requirement. E) maintain calibration records for inspection, measuring and test equipment (see 4.16); f) assess and document the validity of previous inspection and test results when inspection, measuring or test equipment is found to be out of calibration; g) ensure that the environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out; h) ensure that the handling, preservation and storage of inspection, measuring and test equipment is such that the accuracy and fitness for use is maintained; i) safeguard inspection, measuring and test facilities, including both test hardware and test software, from adjustments which would invalidate the calibration setting. **Note:** Inspection, measuring and test facilities are generally understood to mean inspection, measuring and test equipment where test results can be invalidated by inappropriate adjustment at the audited site. **Note 18:** The metrological confirmation system for measuring equipment given in ISO 10012 may be used for guidance. | | |

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| 4.11.2.b.1 | Calibration Services<br>Calibration of inspection, measuring or test equipment shall be conducted by a qualified in-house laboratory (see 4.10.6), a qualified commercial/independent laboratory (see 4.10.7), or a customer-recognized government agency. The laboratory scope shall include the calibration of such equipment. Commercial/independent calibration facilities shall be accredited to ISO/IEC Guide 25 or national equivalent, e.g., assessment by and OEM customer or an EM customer-approved second party, that they meet the intent of ISO/IEC Guide 25 or national equivalent. **Note:** Where a qualified laboratory des not exist for a given piece of equipment, calibration services may be performed by original equipment manufacturer. | | |
| 4.11.3 | Inspection, Measuring, and Test Equipment Records<br>Records of calibration (see Glossary) activity for all gages, measuring, test equipment, including those owned by employees, shall include: * Revisions Following Engineering Changes (if appropriate) * Any Out-Of-Specification Reading As Received For Calibration * Statements of Conformance to Specification After Calibration * Notification to the Customer If suspect Material or Product (see Glossary) May Have Been Shipped. | 7.6.2 | Calibration/Verification Records<br>Records of the calibration/verification activity for all gauges, measuring and test equipment, needed to provide evidence of conformity of product to determined requirements, including employee and customer-owned equipment, shall include * Equipment Identification, including the measurement standard against which the equipment is calibrated * Revisions Following Engineering Changes * Any Out-Of-Specification Readings As Received For Calibration/Verification * An Assessment Of the Impact Of Out-Of-Specification Condition * Statements of Conformity to Specification After Calibration/Verification * Notification To the Customer If Suspect Product or Material Has Been Shipped |
| 4.11.4 | Measure System Analysis<br>Appropriate statistical studies shall be conducted to analyze the variation present in the results of each type of measuring and test equipment system. This requirement shall apply to measurement systems referenced in the Control Plan (see 4.2.3.7). The analytical methods and acceptance criteria used should conform to those in the Measurement Systems Analysis reference manual (e.g., bias, linearity, stability, repeatability and reproducibility studies). Other analytical methods and acceptance criteria may be used if approved by the customer. | 7.6.1 | Measurement System Analysis<br>Statistical studies shall be conducted to analyze the variation present in the results of each type of measuring and test equipment system. This requirement shall apply the measurement systems referenced in the Control Plan. The analytical methods and acceptance criteria used shall conform to those in customer reference manuals on measurement systems analysis. Other analytical methods and acceptance criteria may be used if approved by the customer. |

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| 4.12 | Inspection and Test Status<br>The inspection and test status of product shall be identified by suitable means, which indicates the conformance or nonconformance of product with regard to inspection and tests performed. The identification of inspection and test status shall be maintained, as defined in the quality plan (Control plan) and/or documented procedures, throughout production, installation and servicing of the product to ensure that only product that has passed the required inspections and tests (or released under an authorized concession (see 4.13.2) is dispatched, used or installed.<br>**Note:** Location of product in the normal production flow does not constitute suitable indication of inspection and test status unless inherently obvious (e.g., materials in automated production transfer process). Latitude is permitted, beyond automated production transfer processes, if the test status is clearly identified, documented, and achieves the designated purpose. | | |
| 4.12.1 | Supplemental Verification<br>When required by the customer, additional verification/identification requirements shall be met (e.g., new model introduction). | | |
| 4.13 | Control of Nonconforming Material | | |
| 4.13.1 | General<br>The supplier shall establish and maintain documented procedures to ensure that product that does not conform to specified requirements is prevented from unintended use or installation. This control shall provide for identification, documentation, evaluation, segregation (when practical), disposition of nonconforming product, and or notification to the functions concerned. | 8.3 | Control of Nonconforming Product<br>The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure. The organization shall deal with nonconforming product by one or more of the following ways; a) by taking action to eliminate the detected nonconformity; b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; c) by taking action to preclude its original intended use or application. Records of the nature of nonconformities and any subsequent actions take, including concessions obtained, shall be maintained (see 4.2.4). When nonconforming product is corrected is shall be subject to re-verification to demonstrate conformity to the requirements. When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity. |

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| 4.13.1.1 | Suspect Material or Product<br>The element shall apply to suspect material of product (see Glossary) as well as nonconforming product. | 8.3.1 | Control of Nonconforming Product - Supplemental<br>Product with unidentified or suspect status shall be classified as nonconforming product (see 7.5.3). |
| 4.13.1.2 | Visual Identification<br>The supplier shall provide visual identification of any nonconforming or suspect material (see Glossary) or product, and any quarantine areas. | | |
| 4.13.2 | Review and Disposition of Nonconforming Product<br>The responsibility for review and authority for the disposition of nonconforming product shall be defined. Nonconforming product shall be reviewed in accordance with documented procedures. It may be; a) reworked to meet the specified requirements; b) accepted with or without repair by concession; c) regarded for alternative applications; or d) rejected scrapped. Where required by the contract, the proposed use of repair or product (see 4.13.2b), which does not conform to specified requirements shall be reported for concession to the customer or customer's representative. The description of nonconformity that has been accepted, and of repairs, shall be recorded to denote the actual condition (see 4.16). Repaired and/or reworked product shall be re-inspected in accordance with the quality plan (Control Plan) and/or documented procedure. | | |
| 4.13.2.1 | Prioritized Reduction Plans<br>The supplier shall quantify and analyze nonconforming product and establish a prioritized reduction plan. Progress toward the plan should be tracked. | | |
| 4.13.3 | Control of Reworked Product<br>Rework (see Glossary) instructions shall be accessible and utilized by the appropriate personnel in their work areas. There shall be no rework visible on the exterior of the product supplied for service applications without prior approval of the customer's service parts organization. **Note:** Service applications refer to parts and materials provided to dealers and other distribution channels for the purpose of vehicle maintenance and repair. | 8.3.2 | Control of Reworked Product<br>Instructions for rework, including re-inspection requirements, shall be accessible to and utilized by the appropriate personnel. |

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| 4.13.4 | Engineering Approved Product – Authorization<br>The supplier shall obtain prior customer authorization whenever the product or process is different from that currently approved (see Production Part Approval Process manual). This applies equally to products and services purchased from subcontractors. The supplier shall concur with any requests by a subcontractor before submission to the customer. The supplier shall maintain a record of the expiration date of quantity authorized. The supplier shall also ensure compliance with the original or superseding specifications and requirements when the authorization expires. Material shipped on an authorization shall be properly identified on each shipping container. | 8.3.4 | Customer Waiver<br>The organization shall obtain a customer concession or deviation permit prior to further processing whenever the product or manufacturing process is different from that which is currently approved. The organization shall maintain a record of the expiration date or quantity authorized. The organization shall also ensure compliance with the original or superseding specifications and requirements when the authorization expires. Material shipped on an authorization shall be properly identified on each shipping container. This applies equally to purchased product. The organization shall agree wit any requests from suppliers before submission to the customer. |
| 4.14 | Corrective and Preventive Action | | |
| 4.14.1 | General<br>The supplier shall establish and maintain documented procedures for implementing corrective and preventive action. Any corrective or preventive action taken to eliminate the cause of actual or potential nonconformities shall be to a degree appropriate to the magnitude of problems and commensurate with the risks encountered. The supplier shall implement and record any changes to the documented procedures resulting from corrective and preventive actions. | | |
| 4.14.1.1 | Problem Solving Methods<br>A supplier shall use disciplined problem solving methods when an internal or external nonconformance to specification or requirement occur. When external nonconformance occurs, the supplier shall respond in a manner prescribed by the customer. Refer to the customer documents. | 8.5.2.1 | Problem Solving<br>The organization shall have a defined process for problem solving leading to root cause identification and elimination. If a customer-prescribed problem-solving format exists, the organization shall use the prescribed format. |
| 4.14.1.2 | Mistake Proofing<br>The supplier shall use mistake proofing methodology in their corrective and preventive action process to a degree appropriate to the magnitude of the problems and commensurate with the risks encountered. | 8.5.2.2 | Error-Proofing<br>The organization shall use error-proofing methods in their corrective action process. |

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| 4.14.2 | Corrective Actions<br>The procedure for corrective action shall include; a) the effective handling of customer complaints and reports of product nonconformities; b) investigation of the cause of nonconformities relating to product, process and quality system, and recording the results of the in investigation (see 4.16); c) determination of the corrective action needed to eliminate the cause of nonconformities; d) application of controls to ensure that corrective action is taken and that it is effective. | 8.5.2 | Corrective Action<br>The organization shall take action to eliminate the cause of nonconformities in order to prevent reoccurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for; a) reviewing nonconformities (including customer complaints); b) determining the causes of nonconformities; c) evaluating the need for action to ensure that nonconformities do not recur; d) determining and implementing action needed; e) records of the results of action taken (see 4.2.4); and f) reviewing corrective action taken. |
| 4.14.2.1 | Returned Product Test/Analysis<br>The supplier shall analyze parts returned from the customer's manufacturing plants, engineering facilities, and dealerships. Records of these analyses shall be kept and made available upon request. The supplier shall perform effective analysis and where appropriate, initiate corrective action and process changes to prevent reoccurrence. | 8.5.2.4 | Rejected Product Test/Analysis<br>The organization shall analyze parts rejected by the customer's manufacturing plants, engineering facilities and dealerships. The organization shall minimize the cycle time of this process. Records of these analyses shall be kept and made available upon request. The organization shall perform analysis and initiate corrective action to prevent recurrence.<br>**Note:** Cycle time related to rejected product analysis should be consistent with the determination of root cause, corrective action and monitor the effectiveness of implementation. |
| 4.14.2.2 | Corrective Action Impact<br>Where applicable the supplier shall apply the corrective action taken, and controls implemented, to eliminate the cause of nonconformity to other similar processes and products. | 8.5.2.3 | Corrective Action Impact<br>The organization shall apply to other similar processes and products the corrective action, and controls implemented, to eliminate the cause of nonconformity |
| 4.14.3 | Preventive Actions<br>The procedure for preventive action shall include; a) the use of appropriate sources of information such as processes and work operations which affect product quality, concessions, audit results, quality records, service reports and customer complaints to detect, analyze and eliminate potential cause of nonconformities; b) determination of the steps needed to deal with any problems requiring preventive action; c) initiation of preventive action and application of controls to ensure that it is effective; d) ensuring that relevant information on actions taken is submitted for management review (see 4.1.3). | 8.5.3 | Preventive Action<br>The organization shall determine action to eliminate the cause of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. A documented procedure shall be established to define requirements for; a) determining potential nonconformities and their causes; b) evaluating the need for action to prevent occurrence of nonconformities; c) determining and implementing action needed; d) records of results of actions taken (see 4.2.4); and e) reviewing preventive action taken. |

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| 4.15 | Handling, Storage Packaging, Preservation and Delivery | | |
| 4.15.1 | General<br>The supplier shall establish and maintain documented procedures for handling, storage, packaging, preservation and delivery of product. | 7.5.5 | Preservation of Product<br>The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. The preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product. |
| 4.15.2 | Handling<br>The supplier shall provide methods of handling product that prevent damage or deterioration. | | |
| 4.15.3 | Storage<br>The supplier shall use designated storage areas or stock rooms to prevent damage or deterioration of product, pending use or delivery. Appropriate methods for authorizing receipt to and dispatch from such areas shall be stipulated. In order to detect deterioration, the condition of product in stock shall be assessed at appropriate intervals. | 7.5.5.1 | Storage and Inventory<br>In order to detect deterioration, the condition of product in stock shall be assessed at appropriate planned intervals. The organization shall use an inventory management system to optimize inventory turns over time and assure stock rotation, such as "first-in-first-out" (FIFO). Obsolete product shall be controlled in a similar manner to nonconforming product. |
| 4.15.3.1 | Inventory<br>The supplier shall use an inventory management system to optimize inventory turns over time, assure stock rotation and minimize inventory levels. | | |
| 4.15.4 | Packaging<br>The supplier shall control packing, packaging and marking processes (including material used) to the extent necessary to ensure conformance to specified requirements. | | |
| 4.15.4.1 | Customer Packaging Standards<br>The supplier shall comply with all unique customer packaging standards/guidelines, including applicable service part packaging standards. | | |
| 4.15.4.2 | Labeling<br>The supplier shall develop a system to ensure that all materials shipped are labeled according to customer requirements (see Section II). | | |

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| 4.15.5 | Preservation<br>The supplier shall apply appropriate methods for preservation and segregation of products when the product is under the supplier's control. | | |
| 4.15.6 | Delivery<br>The supplier shall arrange for the protection of the quality of product after final inspection and test. Where contractually specified, this protection shall be extended to include delivery to destination. | | |
| 4.15.6.1 | Supplier Delivery Performance Monitoring<br>The supplier shall establish systems to support 100% on-time shipments to meet customer production and service requirements. If 100% on-time shipments are not maintained the supplier shall implement corrective action to improve delivery performance, including communication of delivery problem information to the customer. The supplier shall have a systematic approach to develop, evaluate and monitor adherence to established lead time requirements. The supplier shall implement a system to monitor performance to the customer delivery requirements with corrective actions taken as appropriate. Record of supplier responsible premium freight shall be maintained. The supplier shall ship all materials in conformance with customer requirements, adhering to up-to-date customer-specified transportation mode, routings and containers. | | |
| 4.15.6.2 | Production Scheduling<br>The supplier's production scheduling activity shall be order-driven. **Note:** the use of small lots with a goal of one piece flow is a synchronous manner is encouraged. **Note:** If the supplier's production is scheduled based upon a "forecast", this would not meet the intent of the requirement. A "pull" system (parts/replenishment based upon consumption) utilizing an optimal level of inventory on hand which is commensurate with total process cycle time satisfies the intent of an order-driven system. | 7.5.1.6 | Production Scheduling<br>Production shall be scheduled in order to meet customer requirements, such as just-in-time supported by an information system that permits access to production information at key stages of the process and is order-driven. |

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| 4.15.6.3 | Electronic Communication<br>The supplier shall have a computerized system for receipt of customer planning information and shop schedules, unless waived by the customer. | 7.2.3.1 | Customer Communication - Supplemental<br>The organization shall have the ability to communicate necessary information, including data, in a customer-specified language and format (e.g., compute-aided design data, electronic data exchanges). |
| 4.15.6.4 | Shipment Notification System<br>The supplier shall have a computerized system for on-line transmittal of advance shipment notification (ASNs), transmitted at the time of shipment, unless waived by the customer. The supplier shall have a back-up method in the event that the on-line system fails. The supplier shall verify that all ASNs match shipping documents and labels. | | |
| 4.16 | Control of Quality Records<br>The supplier shall establish and maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance and disposition (DISPOSAL) f quality records. Quality records shall be maintained to demonstrate conformance to specified requirements and the effective operation of the quality system. Pertinent quality records from the subcontractor shall be an element of these data. Al quality records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of quality records shall be established and recorded. Where agreed contractually, quality records shall be made available for evaluation by the customer or the customer's representative. **Note 19:** Records can be in the form of any type of media, such as hard copy or electronic media. | 4.2.4 | Control of Records<br>Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records. **Note 1: "**Disposition" above includes disposal. **Note 2:** "Records" also include customer-specified records. |

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| 4.16.1 | Record Retention<br>Production part approvals, tooling records, purchase orders and amendments shall be maintained for the length of time that the part (or family of parts) is active for production and service requirements plus one calendar year unless otherwise specified by the customer (see Glossary – Active Part). **Note:** All customer purchase order/amendments are included in this requirement. Supplier purchase orders/amendments for customer-owned tooling are included in this requirement. Quality performance records (e.g., control charts, inspection and test results) shall be retained for one calendar year after the year in which they were created. Records of internal quality system audits and management review shall be retained for three years. Retention period longer than those specified above may be specified by a supplier in their procedures. The supplier shall eventually dispose of records. The requirement does not supersede any governmental requirements. All specified retention period shall be considered "minimums". | 4.2.4.1 | Records Retention<br>The control of records shall satisfy regulatory and customer requirements. |
| 4.17 | Internal Quality Audits<br>The supplier shall establish and maintain documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system. Internal quality audits shall be scheduled on the basis of the status and importance of the activity to be audited and shall be carried out by personnel independent of those having direct responsibility for the activity being audited. **Note:** "Activity" can refer to departments, areas, processes, functions, etc…in a company. **Note:** There is no specified checklist that MUST be used for internal auditing purposes. The results of the audits shall be recorded (see 4.16) and brought to the attention of the personnel having responsibility in the area audited. The management personnel responsible for the area shall take timely corrective action on the deficiencies found during the audit. Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken (see 4.16). **Note 20:** The results of internal quality audits form an integral part of the input to management review activities (see 4.1.3) **Note 21:** Guidance on quality system audits is given in ISO 10011. | 8.2.2 | Internal Audit<br>The organization shall conduct internal audits at planned intervals to determine whether the quality management system; a) conforms to the planned arrangements (see 7.1), to the requirements this International Standard and to the quality management system requirements established by the organization; and b) is effectively implemented and maintained. An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. The responsibilities and requirements for planning and conduction of audits, and for reporting results and maintaining records (see 4.2.4) shall defined in a documented procedure. The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes.<br><br>Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2). **Note:** See 10011-1, ISO 10011-2 and ISO 10011-3 for guidance. |

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| | | 8.2.2.1 | Quality Management System Audit<br>The organization shall audit its quality management system to verify compliance with this Technical Specification and any additional quality management system requirements. |
| | | 8.2.2.2 | Manufacturing Process Audit<br>The organization shall audit each manufacturing process to determine its effectiveness. |
| | | 8.2.2.3 | Product Audit<br>The organization shall audit products at appropriate stages of production and delivery to verify conformity to all specified requirements, such as product dimensions, functionality, packaging and labeling, at a defined frequency. |
| | | 8.2.2.5 | Internal Auditor Qualification<br>The organization shall have internal auditors who are qualified to audit the requirements of this Technical Specifications (see 6.2.2.2). |
| 4.17.1 | Internal Audit Schedules<br>Internal auditing should cover all shifts and be conducted according to an audit schedule updated annually. When internal/external nonconformances or customer complaints occur, the planned audit frequency should be increased. | 8.2.2.4 | Internal Audit Plans<br>Internal audits shall cover all quality management related processes, activities and shifts, and shall be scheduled according to an annual plan. When internal/external nonconformities or customer complaints occur, the audit frequency shall be appropriately increased. **Note:** Specific checklists should be used for each audit. |
| 4.18 | Training<br>The supplier shall establish and maintain documented procedures for identifying training needs and provide for the training of all personnel performing activities affecting quality. Personnel performing specific assigned tasks shall be qualified on the basis of appropriate education, training and/or experience, as required. Appropriate records of training shall be maintained (see 4.16). | 6.2.1 | General<br>Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience. |
| | | 6.2.2 | Competence, Awareness and Training<br>The organization shall; a) determine the necessary competence for personnel performing work affecting product quality; b) provide training or take other actions to satisfy these needs; c) evaluate the effectiveness of the actions taken; d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives; and e) maintain appropriate records of education, training, skills and experience (see 4.2.4). |
| | | 6.2.2.1 | Product Design Skills<br>The organization shall ensure that personnel with product design responsibility are competent to achieve design requirements and are skilled in appropriate tools and techniques. Applicable tools and techniques shall be identified by the organization. |

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| | | 6.2.2.2 | Training<br>The organization shall establish and maintain documented procedures for identifying training needs and achieving competence of all personnel performing activities affecting product quality. Personnel performing specific assigned tasks shall be qualified, as required, with particular attention to the satisfaction of customer requirements. **Note 1:** This applies to all employees having an effect on quality at all levels of the organization. **Note 2:** An example of the customer specific requirements is the application of digitized mathematically based data. |
| 4.18.1 | Training Effectiveness<br>Training effectiveness shall be periodically reviewed. **Note:** Training effectiveness may be practically reviewed by various methods, such as pre- and post- testing and audits/appraisals of performance. | 6.2.2.3 | Training on the Job<br>The organization shall provide on-the-job training for personnel in any new or modified job affecting product quality, including contract or agency personnel. Personnel whose work can affect quality shall be informed about the consequences to the customer of nonconformity to quality requirements. |
| 4.19 | Servicing<br>Where servicing is a specified requirement, the supplier shall establish and maintain documented procedures for performing, verifying and reporting that the servicing meets the specified requirements. **Note:** Any after-sales product servicing provided as part of the OEM contract or Purchase Order would fall under Element 4.19. | 7.5.1.8 | Service Agreement with Customer<br>Where there is a service agreement with the customer, the organization shall verify the effectiveness of: * Any Organization Service Centres * Any Special-Purpose Tools or Measurement Equipment * The Training of Service Personnel. |
| 4.19.1 | Feedback of Information From Service<br>A procedure for communication of information on service concerns to manufacturing, engineering and design activities shall be established and maintained. **Note:** The intent of the addition of "service concerns" to Element 4.19 is to ensure that the supplier's organization is aware of nonconformities that occur external to the supplier's own organization (see 4.14). | 7.5.1.7 | Feedback of Information From Service<br>A process for communication of information on service concerns to manufacturing, engineering and design activities shall be established and maintained. **Note:** The intent of the addition of "service concerns" to this subclause is to ensure that the organization is aware of noncomformities that occur external to its organization. |
| 4.20 | Statistical Techniques | | |
| 4.20.1 | Identification of Need<br>The supplier shall identify the need for statistical techniques required for establishing, controlling and verifying process capability and product characteristics. | 8.1.1 | Identification of Statistical Tools<br>Appropriate statistical tools for each process shall be determined during advance quality planning and in the Control Plan. |

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| 4.20.2 | Procedures<br>The supplier shall establish and maintain documented procedures to implement and control the application of the statistical techniques identified in 4.20.1. | | |
| 4.20.3 | Selection of Statistical Tools<br>Statistical tools, if applicable, for each process should be determined during advanced quality planning and shall be included in the Control Plan. | | |
| 4.20.4 | Knowledge of Basic Statistical Concepts<br>Basic concepts such as variation, control (stability), capability and over-adjustment should be understood throughout the supplier's organization as appropriate. Consult the Statistical Process Control reference manual. | 8.1.2 | Knowledge of Basic Statistical Concepts<br>Basic statistical concepts, such as variation, control (stability), process capability and over-adjustment shall be understood and utilized throughout the organization. |
| | | ISO/TS 16949:2002 New Requirements | |
| | | 5.1 | Management Commitment<br>Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improve its effectiveness by; a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements; b) establishing the quality policy; c) ensuring that quality objectives are established; d) conducting management reviews; and e) ensuring the availability of resources. |
| | | 5.1.1 | Process Efficiency<br>Top management shall review the product realization processes and the support processes to assure their effectiveness and efficiency. |
| | | 5.4.1 | Quality Objectives<br>Top management shall ensure that quality objectives, including those needed to meet requirements for product (see 7.1.a) are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy. |

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| | | 5.5.2.1 | Customer Representative<br>Top management shall designate personnel with responsibility and authority to ensure that customer requirements are addressed. This includes selection of special characteristics, setting quality objectives and related training, corrective and preventive actions, product design and development. |
| | | 5.5.3 | Internal Communication<br>Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system. |
| | | 6.2.2.4 | Employee Motivation and Empowerment<br>The organization shall have a process to motivate employees to achieve quality objectives, to make continual improvements, and to create an environment to promote innovation. The process shall include the promotion of quality and technological awareness throughout the whole organization. The organization shall have a process to measure the extent to which its personnel are aware of the relevance and importance of their activities and how they contributed to the achievement of the quality objectives (see 6.2.2.d). |
| | | 6.3 | Infrastructure<br>The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirement. Infrastructure includes, as applicable; a) buildings, workspace and associated utilities; b) process equipment (both hardware and software); and c) support services (such as transport or communication). |
| | | 7.2.3 | Customer Communication<br>The organization shall determine and implement effective arrangements for communicating with customers in relation to; a) product information; b) enquiries, contracts or order handling, including amendments; and c) customer feedback, including customer complaints. |

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| | | 7.3.2.1 | Product Design Input<br>The organization shall identify, document and review the product design inputs requirements, including the following: * Customer Requirements (contract review) Such as Special Characteristics (see 7.3.2.3), Identification, Traceability and Packaging * Use of Information, the organization shall have a process to deploy information gained from previous design projects, competitor analysis, supplier feedback, internal input, field data, and other relevant sources, for current and future projects of a similar nature * Targets For Product Quality, Life, Reliability, Durability, Maintainability, Timing and Cost. |
| | | 7.3.2.2 | Manufacturing Process Design Input<br>The organization shall identify, document and review the manufacturing process design input requirements, including: * Product Design Output Data * Targets For Productivity, Process Capability and Cost * Customer Requirements If Any and * Experience From Previous Developments. |
| | | 7.3.3.2 | Manufacturing Process Design Output<br>The manufacturing process design output shall be expressed in terms that can be verified against manufacturing process design input requirements and validated. The manufacturing process design output shall include * Specifications and Drawings * Manufacturing Process Flow Chart/Layout * Manufacturing Process FMEAs * Control Plan (see 7.5.1.1) * Work Instructions * Process Approval Acceptance Criteria * Data for Quality, Reliability, Maintainability and Measurability * Results of Error-Proofing Activities As Appropriate * Methods of Rapid Detection and Feedback of Product/Manufacturing Process Nonconformities |
| | | 7.4.3.2 | Supplier Monitoring<br>Supplier performance shall be monitored through the following indicators: * Delivered product Quality * Customer Disruptions Including Field Returns * Delivery Schedule Performance (including incidents of premium freight) * Special Status Customer Notifications Related to Quality or Delivery Issues. The organization shall promote supplier monitoring of the performance of their manufacturing processes. |

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| **Element** | **Title** | **Element** | **Title** |
| | | 8.1 | Measurement, Analysis and Improvement – General<br>The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed; a) to demonstrate conformity of the product; b) to ensure conformity of the quality management system; and c) to continually improve the effectiveness of the quality management system. This shall include determination of applicable methods, including statistical techniques, and the extent of their use. |
| | | 8.2.2.5 | Internal Auditor Qualifications<br>The organization shall have internal auditors who are qualified to audit the requirements of the Technical Specification (see 6.2.2.2). |
| | | 8.5.1.2 | Manufacturing Process Improvement<br>Manufacturing process improvement shall continually focus upon control and reduction of variation in product characteristics and manufacturing process parameters. **Note 1:** Controlled characteristics are documented in the Control Plan. **Note 2:** Continual improvement is implemented once manufacturing processes are capable, stable, and product characteristics are predictable and meet customer requirements. |

# APPENDIX B – CROSSOVER MATRIX ISO/TS 16949:2002 TO QS-9000 3RD

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| **Element** | **Title** | **Element** | **Title** |
| **4** | **Quality Management System** | | |
| 4.1 | General Requirements<br>The organization shall establish, document, implement a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard. The organization shall; a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2); b) determine the sequence and interaction of these processes, c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective; d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes, e) monitor, measure and analyze these processes; and f) implement actions necessary to achieve planned results and continual improvement of these processes. These processes shall be managed by the organization in accordance with the requirements of this International Standard.<br>Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system. **Note:** Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement. | 4.2.1 | General<br>The supplier shall establish, document and maintain quality system as a means of ensuring that product conforms to specified requirements. The supplier shall prepare a quality manual covering the requirements of this International Standard. The quality manual shall include or make reference to the quality system procedures and outline the structure to the documentation used in the quality system. **Note:** Guidance on quality manuals is given in ISO 10013. |

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| **Element** | **Title** | **Element** | **Title** |
| 4.1.1 | General Requirements - Supplemental<br>Ensuring control over outsourced processes shall not absolve the organization of the responsibility of conformity to all customer requirements. **Note:** see also 7.4.1 and 7.4.1.3 | | |
| 4.2 | Documentation Requirements | | |
| 4.2.1 | General<br>The quality management system documentation shall include: a) documented statements of a quality policy and quality objectives, b) a quality manual, c) documented procedures required by this International Standard d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and e) records required by this International Standard (see 4.2.4). **Note 1:** Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. **Note 2:** The extent of the quality management system documentation can differ from one organization to another due to a) the size of organization and type of activities, b) the complexity of processes and their interactions, and c) the competence of personnel. **Note 3:** The documentation can be in any form or type of medium. | 4.2.2 | Quality Systems Procedures<br>The supplier shall: a) prepare documented procedures consistent with requirements of this International Standard and the supplier's stated quality policy, and b) effectively implement the quality system and its documented procedures. For the purposes of this International Standard, the range and detail of the procedures that form part of the quality system shall be dependent upon the complexity of the work, the methods used, and the skills and training needed by personnel involved in carrying out the activity. **Note 7:** Documented procedures may make reference to work instructions that define how an activity is performed. |
| 4.2.2 | Quality Manual<br>The organization shall establish and maintain a quality manual that includes: a) the scope of the quality management system, including details of and justification for any exclusion (see 1.2) b) the documented procedures established for the quality management system, or referenced to them, and c) a description of the interaction between the processes of the quality management system. | | |
| 4.2.3 | Control of Documents<br>Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4. A documented procedure shall be established to define the controls needed: a) to approve documents for adequacy prior to issue, b) to review and update as necessary and re-approve documents, c) to ensure that changes and the current revision status of documents are identified, d) to ensure that relevant versions of applicable documents are available at point of use, e) ensure that documents remain legible and readily identifiable, f) to ensure that documents of external origin are identified and their distribution controlled, and g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose. | 4.5.1 | General<br>The supplier shall establish and maintain documented procedures to control all documents and data that relate to the requirements of this International Standard including, to the extent applicable, documents of external origin such as standards and customer drawings. **Note 15:** Documents and data can be in the form of any type of media, such as hard copy or electronic media. |

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| **Element** | **Title** | **Element** | **Title** |
| | | 4.5.2 | Document and Data Approval and Issue- |
| | | | The documents and data shall be reviewed and approve for adequacy by authorized personnel prior to issue. A master list of equivalent document control procedure identifying the current revision status of documents shall be established and be readily available to preclude the use of invalid and/or obsolete documents. This control shall ensure that: a) the pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed;<br><br>**Note:** Examples of appropriate documents include: * Engineering drawings * Engineering standards * Math (CAD) data * Inspection Instructions * Test procedures * Work Instructions * Operations sheets * Quality manual * Operational procedures * Quality assurance procedures * Material specifications, b) invalid and/or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use; c) any obsolete documents retained for legal and/or knowledge preservation purposes are suitably identified. |
| 4.2.3.1 | Engineering Specifications<br>The organization shall have a process to assure the timely review, distribution and implementation of all customer engineering standards/specifications and changes based on customer-required schedule. Timely review should be as soon as possible, and shall not exceed two working weeks. The organization shall maintain a record of the date on which each change is implemented in production. Implementation shall include updated documents. **Note:** A change in these standards/specifications requires an updated record of customer production part approval when these specifications are referenced on the design records or if they affect documents of production part approval process, such as control plan, FMEA, etc.... | 4.5.2.1 | Engineering Specifications<br>The supplier shall establish a procedure to assure the timely review (e.g. business "days", not weeks or months), distribution and implementation of all customer engineering standards/specifications and changes. The supplier shall maintain a record of the date on which each change is implemented in production (subject to record control, see 4.16). Implementation shall include updates to all appropriate documents. **Note:** A change in these specifications should require an updated PPAP record when these specifications are referenced on the design record (see Glossary) or if they affect PPAP documents (e.g. Control Plan, FMEAs, etc.) See PPAP. |
| 4.2.4 | Control of Records<br>Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records. **Note 1:** "Disposition" above includes disposal. **Note 2:** "Records" also include customer-specified records. | 4.16 | Control of Quality Records<br>The supplier shall establish and maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance and disposition (DISPOSAL) of quality records. Quality records shall be maintained to demonstrate conformance to specified requirements and the effective operation of the quality system. Pertinent quality records from the subcontractor shall be an element of these data. All quality records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of quality records shall be established and recorded. Where agreed contractually, quality records shall be made available for evaluation by the customer or the customer's representative. **Note 19:** Records can be in the form of any type of media, such as hard copy or electronic media. |

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| **Element** | **Title** | **Element** | **Title** |
| 4.2.4.1 | Records Retention | 4.16.1 | Record Retention |
| | The control of records shall satisfy regulatory and customer requirements. | | Production part approvals, tooling records, purchase orders and amendments shall be maintained for the length of time that the part (or family of parts) is active for production and service requirements plus one calendar year unless otherwise specified by the customer (see Glossary - Active Part). **Note:** All customer purchase orders/amendments are included in this requirement. Supplier purchase orders/amendments for customer-owned tooling are included in this requirement. Quality performance records (e.g. control charts, inspection and test results) shall be retained for one calendar year after the year in which they were created. Records of internal quality system audits and management review shall be retained for three years. Retention periods longer than those specified above may be specified by a supplier in their procedures. The supplier shall eventually dispose of records. The requirement does not supersede any governmental requirements. All specified retention periods shall be considered "minimums". |
| **5** | **Management Responsibility** | | |
| 5.1 | Management Commitment<br>Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improve its effectiveness by: a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, b) establishing the quality policy, c) ensuring that quality objectives are established, d) conducting management reviews, and) ensuring the availability of resources. | | |
| 5.1.1 | Process Efficiency<br>Top management shall review the product realization processes and the support processes to assure their effectiveness and efficiency. | | |
| 5.2 | Customer Focus<br>Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1) | 4.1.6 | Customer Satisfaction<br>The supplier shall have a documented process for determining customer satisfaction, including frequency of determination, and how objectivity and validity are assured. Trends in customer satisfaction and key indicators of customer dissatisfaction shall be documented and supported by objective information. These trends should be compared to those of competitors, or appropriate benchmarks, and reviewed by senior management. **Note:** Considerations should be given to internal, external and final customers. |

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| **Element** | **Title** | **Element** | **Title** |
| 5.3 | Quality Policy<br>Top management shall ensure that the quality policy: a) is appropriate to the purpose of the organization, b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system, c) provides a framework for establishing and reviewing quality objectives, d) is communicated and understood within the organization, and e) is reviewed for continuing suitability | 4.1.1 | Quality Policy<br>The supplier's management with executive responsibility shall define and document its policy for quality, including objectives for quality and its commitment to quality. The quality policy shall be relevant to the supplier's organizational goals and the expectations and needs of its customers. The supplier shall ensure that this policy is understood, implemented and maintained at all levels of the organization. |
| 5.4 | Planning | | |
| 5.4.1 | Quality Objectives<br>Top management shall ensure that quality objectives, including those needed to meet requirements for product (see 7.1.a) are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy. | | |
| 5.4.1.1 | Quality Objectives - Supplemental<br>Top management shall define quality objectives and measurements that shall be included in the business plan and used to deploy the quality policy. **Note:** Quality objectives should address customer expectations and be achievable within a defined time period. | 4.1.4 | Business Plan<br>The supplier shall utilize a formal, documented, comprehensive business plan. The Business Plan shall be a controlled document. The content of the Business Plan is not subject to third party audit. This plan may typically include as applicable: * Market-related issues * Financial planning and cost * Growth projections * Plant/facilities plan * Cost objectives * Human resource development * R & D plans, projections, and projects with appropriate funding * Projected sales figures * Quality objectives * Customer satisfaction plans * Key internal quality and operational performance measurables * Health, Safety and Environmental issues. Goals and plans shall cover short-term (1-2 years) and longer-term (3 years or more). The goals and plans should be based on analysis of competitive products and on benchmarking inside and outside the automotive industry and the supplier's commodity. Methods to determine current and future customer expectations shall be in place.<br>An objective process shall be used to define the scope and collection of information, including the frequency and methods of collection. Methods to track, update, revise, and review the plan shall be documented to ensure that the plan is followed and communicated throughout the organization as appropriate. **Note:** Data and information should drive process improvement plans. **Note:** The supplier should provide means for employee empowerment in meeting business goals. |

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| **Element** | **Title** | **Element** | **Title** |
| 5.4.2 | Quality Management Systems Planning | 4.2.3 | Quality Planning |
| | Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented. | | The supplier shall define and document how the requirements for quality will be met. Quality planning shall be consistent with all other requirements of a supplier's quality system and shall be documented in a format to suit the supplier's method of operation. The supplier shall give consideration to the following activities, as appropriate, in meeting the specified requirements for products, projects or contracts: a) the preparation of quality plans; b) the identification and acquisition of any controls, processes, equipment (including inspection and test equipment), fixtures, resources and skills that may be needed to achieve the required quality; c) ensuring the compatibility of the design, the production process, installation, servicing, inspection and test procedures and the applicable documentation; d) the updating, as necessary, of quality control, inspection and testing techniques, including the development of new instrumentation; e) the identification of any measurement requirement involving capability that exceeds the known state of art, in sufficient time for the needed capability to be developed; f) the identification of suitable verification at appropriate stages in the realization of product; g) the clarification of standards of acceptability for all features and requirements, including those which contain a subjective element; h) the identification and preparation of quality records (see 4.16) **Note:** The quality plans referred to (see 4.2.3.a) may be in the form of a reference to the appropriate documented procedures that form an integral part of the supplier's quality system. |
| 5.5 | Responsibility, Authority and Communication | | |
| 5.5.1 | Responsibility and Authority<br>Top management shall ensure that the responsibilities and authorities are defined and communicated within the organization. | 4.1.2.1 | Responsibility and Authority<br>The responsibility, authority and the interrelation of personnel who manage, perform and verify work effecting quality shall be defined and documented, particularly for personnel who need the organizational freedom and authority to; a) initiate action to prevent the occurrence of any nonconformities relating to product, process and quality system **Note:** It is recommended that the personnel responsible for quality have the authority to stop production, if necessary to correct quality problems. b) identify and record any problems relating to the product, process and quality system; c) initiate, recommend or provide solutions through designated channels; d) verify the implementation of solutions; e) control further processing, delivery or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected. f) represent the needs of the customer in internal functions in addressing QS-9000 requirements (e.g. selection of special characteristics, setting quality objectives, training, corrective & preventive actions, product design and development). |

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| **Element** | **Title** | **Element** | **Title** |
| 5.5.1.1 | Responsibility for Quality<br>Managers with responsibility and authority for corrective actions shall be promptly informed of products or processes which do not conform to requirements. Personnel responsible for product quality shall have the authority to stop production to correct quality problems. Production operations across all shifts shall be staffed with personnel in charge of, or delegated responsibility for, ensuring product quality. | 4.1.2.5 | Information to Management<br>Management with responsibility and authority for corrective actions shall be promptly informed of products or processes which become noncompliant with specified requirements. |
| 5.5.2 | Management Representative<br>Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes: a) ensuring that processes needed for the quality management system are established, implemented and maintained, b) reporting to top management on the performance of the quality management system and any need for improvement, and c) ensuring that promotion of awareness of customer requirements throughout the organization. **Note:** The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system. | 4.1.2.3 | Management Representative<br>The supplier's management with executive responsibility shall appoint a member of the supplier's own management who, irrespective of other responsibilities, shall have defined authority for: a) ensuring that a quality system is established, implemented and maintained in accordance with this International Standard, and b) reporting on the performance of the quality system to the supplier's management for review and as a basis for improvement of the quality system. NOTE 5: The responsibility of a management representative may also include liaison with external parties on matters relating to the supplier's quality system. |
| 5.5.2.1 | Customer Representative<br>Top management shall designate personnel with responsibility and authority to ensure that customer requirements are addressed. This includes selection of special characteristics, setting quality objectives and related training, corrective and preventive actions, product design and development. | | |
| 5.5.3 | Internal Communication<br>Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system. | | |
| 5.6 | Management Review | | |
| 5.6.1 | Management Review - General<br>The management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained (see 4.2.4) | 4.1.3 | Management Review<br>The supplier's management with executive responsibility shall review the quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of this International Standard and the supplier's stated quality policy and objectives (see 4.1.1). Records of such reviews shall be maintained (see 4.16). |

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| **Element** | **Title** | **Element** | **Title** |
| 5.6.1.1 | Quality Management System Performance<br>These reviews shall include all requirements of the quality management system and its performance trends as an essential part of the continual improvement process. Part of the management review shall be the monitoring of quality objectives, and the regular reporting and evaluation of the cost of poor quality (see 8.4.1. and 8.5.1). These results shall be recorded to provide, as a minimum, evidence of the achievement of * the quality objectives specified in the business plan, and * customer satisfaction with product supplied. | | |
| 5.6.2 | Review Input<br>The input to management review shall include information on: a) results of audits, b) customer feedback, c) process performance and product conformity, d) status of preventive and corrective actions, e) follow-up actions from previous management reviews, f) changes that could affect the quality management system, and g) recommendations for improvement. | | |
| 5.6.2.1 | Review Input - Supplemental<br>Input to management review shall include an analysis of actual and potential field-failures and their impact on quality, safety or the environment. | | |
| 5.6.3 | Review Output<br>The output from the management review shall include any decision and actions related to a) improvement of the effectiveness of the quality management system and its processes, b) improvement of product related to customer requirements, and c) resource needs. | | |
| | | 4.1.3.1 | Management Review<br>This Management Review requirement shall include all elements of the entire quality system, not only those specifically required in other elements (e.g. 4.14.3.d). **Note:** Management Review should be conducted with a multidisciplinary approach (see Glossary). |
| **6** | **Resource Management** | | |
| 6.1 | Provision of Resources<br>The organization shall determine and provide the resources needed: a) to implement and maintain the quality management system and continually improve its effectiveness, and b) to enhance customer satisfaction by meeting customer requirements. | 4.1.2.2 | Resources<br>The supplier shall identify resource requirements and provide adequate resources, including the assignment of trained personnel (see 4.18), for management, performance of work and verification activities, including internal quality audits. |

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| **Element** | **Title** | **Element** | **Title** |
| 6.2 | Human Resources | | |
| 6.2.1 | General<br>Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience. | 4.18 | Training<br>The supplier shall establish and maintain documented procedures for identifying training needs and provide for the training of all personnel performing activities affecting quality. Personnel performing specific assigned tasks shall be qualified on the basis of appropriate education, training and/or experience, as required. Appropriate records of training shall be maintained (see 4.16). |
| 6.2.2 | Competence, Awareness and Training<br>The organization shall; a) determine the necessary competence for personnel performing work affecting product quality, b) provide training or take other actions to satisfy these needs, c) evaluate the effectiveness of the actions taken, d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and e) maintain appropriate records of education, training, skills and experience. (see 4.2.4) | | |
| 6.2.2.1 | Product Design Skills<br>The organization shall ensure that personnel with product design responsibility are competent to achieve design requirements and are skilled in appropriate tools and techniques. Applicable tools and techniques shall be identified by the organization. | 4.4.2.1 | Required Skills<br>The supplier's design activity should be qualified in the following skills as appropriate: * Geometric dimensioning and tolerancing (GD&T) * Quality function deployment (QFD) * Design for manufacturing (DFM)/Design for assembly (DFA) * Value engineering (VE) * Design of experiments (DOE) * Failure mode and effects analysis (DFMEA/PFMEA, etc.) * Finite element analysis (FEA) * Solid modeling * Simulation techniques * Computer aided design (CAD)/Computer aided engineering (CAE) * Reliability engineering plans |
| 6.2.2.2 | Training<br>The organization shall establish and maintain documented procedures for identifying training needs and achieving competence of all personnel performing activities affecting product quality. Personnel performing specific assigned tasks shall be qualified, as required, with particular attention to the satisfaction of customer requirements. **Note 1:** This applies to all employees having an effect on quality at all levels of the organization. **Note 2:** An example of the customer specific requirements is the application of digitized mathematically based data. | | |

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| **Element** | **Title** | **Element** | **Title** |
| 6.2.2.3 | Training on the Job<br>The organization shall provide on-the-job training for personnel in any new or modified job affecting product quality, including contract or agency personnel. Personnel whose work can affect quality shall be informed about the consequences to the customer of nonconformity to quality requirements. | | |
| | | 4.18.1 | Training Effectiveness<br>Training effectiveness shall be periodically reviewed. **Note:** Training effectiveness may be practically reviewed by various methods, such as pre- and post-testing and audits/appraisals of performance. |
| 6.2.2.4 | Employee Motivation and Empowerment<br>The organization shall have a process to motivate employees to achieve quality objectives, to make continual improvements, and to create an environment to promote innovation. The process shall include the promotion of quality and technological awareness throughout the whole organization. The organization shall have a process to measure the extent to which its personnel are aware of the relevance and importance of their activities and how they contributed to the achievement of the quality objectives (see 6.2.2 d). | | |
| 6.3 | Infrastructure | | |
| | The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable: a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) support services (such as transport or communication). | | |
| 6.3.1 | Plant, Facility and Equipment Planning<br>The organization shall use a multidisciplinary approach (see 7.3.1.1) for developing plant, facility and equipment plans. Plant layouts shall optimize material travel, handling and value-added use of floor space, and shall facilitate synchronous material flow. Methods shall be developed and implemented to evaluate and monitor the effectiveness of existing operations. **Note:** These requirements should focus on lean manufacturing principles and the link to the effectiveness of the quality management system. | 4.2.6.1 | Facilities, Equipment, and Process Planning Effectiveness<br>The supplier shall use a multi-disciplinary approach for developing facilities, processes and equipment plans in conjunction with the advanced quality planning process. Plant layout should minimize material travel and handling, facilitate synchronous material flow, and maximize value-added use of floor space. Methods shall be developed for evaluating the effectiveness of existing operations and processes considering the following factors: overall work plan, appropriate automation, ergonomics and human factors, operator and line balance, storage and buffer inventory levels, value-added labor content. **Note:** The supplier should identify and define appropriate metrics and monitor the effectiveness of existing operations. |

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| **Element** | **Title** | **Element** | **Title** |
| 6.3.2 | Contingency Plans<br>The organization shall prepare contingency plans to satisfy customer requirements in the event of an emergency such as utility interruptions, labour shortages, key equipment failure and field returns. | 4.9.b.2 | Contingency Plans<br>The supplier shall prepare contingency plans (e.g. utility interruptions, labor shortages, key equipment failures) to reasonably protect the customer's supply of product in the event of emergency, excluding natural disaster and acts of God. |
| 6.4 | Work Environment<br>The organization shall determine and manage the work environment needed to achieve conformity to product requirements. | 4.9 | Process Control<br>The supplier shall identify and plan the production, installation and servicing processes which directly affect quality and shall ensure that these processes are carried out under controlled conditions. Controlled conditions shall include the following: a) documented procedures defining the manner of production, installation and servicing, where the absence of such procedures could adversely affect quality; b) use of suitable production, installation and servicing equipment, and a suitable working environment (see Glossary) c) compliance with reference standards/codes, quality plans and/or documented procedures; d) monitoring and control of suitable process parameters and product characteristics. e) the approval of processes and equipment, as appropriate: f) criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g. written standards, representative samples or illustrations; g) suitable maintenance of equipment to ensure continuing process capability.<br>Where the results of processes cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use, the processes shall be carried out by qualified operators and/or shall require continuous monitoring and control of process parameters to ensure that the specified requirements are met. The requirements for any qualification of process operations, including associated equipment and personnel (see 4.18), shall be specified. **Note 16:** Such processes requiring pre-qualification of their process capability are frequently referred to as special processes. Records shall be maintained for qualified processes, equipment and personnel, as appropriate. (see 4.16) |
| 6.4.1 | Personal Safety to Achieve Product Quality<br>Product safety and means to minimize potential risks to employees shall be addressed by the organization, especially in the design and development process and in manufacturing process activities. | 4.2.3.4 | Product Safety<br>Due care and product safety shall be considered in the supplier's design control (element 4.4) and process control (element 4.9) policies and practices. The supplier should promote internal awareness of safety considerations relative to the supplier's product. |
| 6.4.2 | Cleanliness of Premises<br>The organization shall maintain its premises in a state of order, cleanliness and repair consistent with the product and manufacturing process needs. | 4.9.b.1 | Cleanliness of Premises<br>The supplier shall maintain premises in a state of order, cleanliness and repair appropriate to the product(s) manufactured. |

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| **Element** | **Title** | **Element** | **Title** |
| **7** | **Product Realization** | | |
| 7.1 | Planning of Product Realization<br>The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4) The output of this planning shall be in a form suitable for the organization's methods of operation. **Note 1:** A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan. **Note 2:** The organization may also apply the requirements given in 7.3 to the development of product realization processes. **Note:** Some customers refer to project management or advanced product quality planning as a means to achieve product realization. Advanced product planning embodies the concepts of error prevention and continual improvement as contrasted with error detection, and is based on a multidisciplinary approach. | 4.2.3.1 | Advanced Quality Planning<br>The supplier shall establish and implement an advanced product quality planning process. The supplier should convene internal multidisciplinary teams to prepare for production of new or changed products. These teams should use appropriate techniques identified in the Advanced Product Quality Planning and Control Plan reference manual. Similar techniques that accomplish the intent are acceptable. Team actions should include: * Development/finalization of special characteristics * Development and review of FMEAs * Establish of actions to reduce the potential failure modes with high risk priority numbers * Development or review of Control Plans |
| 7.1.1 | Planning of Product Realization - Supplemental<br>Customer requirements and references to its technical specifications shall be included in the planning of product realization as a component of the quality plan. | 4.1.2.4 | Organizational Interfaces<br>The supplier shall have systems in place to ensure management of appropriate activities during concept development through production (refer to Advanced Product Quality Planning and Control Plan reference manual). The supplier shall use a multi-disciplinary approach for decision-making and have the ability to communicate necessary information and data in the customer-prescribed format. **Note:** Typical functions to be included are: * Engineering/Technical * Manufacturing/Production * Industrial Engineering * Purchasing/Materials Management * Quality/Reliability * Cost Estimating * Product Service * Management Information Systems/Data Processing * Packaging Engineering * Tooling Engineering/Maintenance * Marketing and Sales * Subcontractors, as necessary |

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| **Element** | **Title** | **Element** | **Title** |
| 7.1.2 | Acceptance Criteria<br>Acceptance criteria shall be defined by the organization and, where required, approved by the customer. For attribute data sampling, the acceptance level shall be zero defects (see 8.2.3.1). | 4.10.1.1 | Acceptance Criteria for Attribute Characteristics<br>Acceptance criteria for attribute data sampling plans shall be zero defects. Appropriate acceptance criteria for all other situations (e.g. visual standards) shall be documented by the supplier and approved by the customer. |
| | | 4.10.2 | Receiving Inspection and Testing |
| | | 4.10.2.1 | The supplier shall ensure that incoming product is not used or processed (except in the circumstances described in 4.10.2.3) until it has been inspected or otherwise verified as conforming to specified requirements. Verification of conformance to the specified requirements shall be in accordance with the quality plan (Control Plan) and/or documented procedures |
| | | 4.10.2.2 | In determining the amount and nature of receiving inspection, consideration shall be given to the amount of control exercised at the subcontractor's premises and the recorded evidence of conformance provided. |
| | | 4.10.2.3 | Where incoming product is released for urgent production purposes prior to verification, it shall be positively identified and recorded (see 4.16) in order to permit immediate recall and replacement in the event of nonconformity to specified requirements. |
| 7.1.3 | Confidentiality<br>The organization shall ensure the confidentiality of customer-contracted products and projects under development, and related product information. | 4.4.11 | Confidentiality<br>The supplier shall ensure the confidentiality of customer-contracted products under development and related product information. |
| 7.1.4 | Change Control<br>The organization shall have a process to control and react to changes that impact product realization. The effects of any change, including those changes caused by any supplier, activities shall be assessed, and verification and validation activities shall be defined, to ensure compliance with customer requirements. Changes shall be validated before implementation. For proprietary designs, impact on form, fit and function (including performance and/or durability) shall be reviewed with the customer so that all effects can be properly evaluated. Where required by the customer, additional verification/identification requirements, such as those required for new product introduction, shall be met. **Note 1:** Any product realization change affecting customer requirements requires notification to, and agreement from, the customer. **Note 2:** The above requirement applies to product and manufacturing process changes. | 4.9.5 | Process Changes<br>The supplier shall maintain records of process change effective dates. (see 4.5.3) **Note:** Changes to promote continuous improvement are encouraged. Consult the customer for guidance on approval requirements for such changes. |

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| 7.2 | Customer-Related Processes | | |
| 7.2.1 | Determination of Requirements Related to the Product<br>The organization shall determine: a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements related to the product, and d) any additional requirements determined by the organization. **Note 1:** Post-delivery activities include any after-sales product service provided as part of the customer contract or purchase order. **Note 2:** The requirement includes recycling, environmental impact and characteristics identified as a result of the organization's knowledge of the product and manufacturing processes (see 7.3.2.3). **Note 3:** Compliance to item c) includes all applicable governmental regulations, applies to acquisition, storage, handling, recycling, elimination or disposal of materials. | 4.3.1 | General<br>The supplier shall establish and maintain documented procedures for contact review and for the coordination of these activates. **Note:** The supplier is not required to return signed Purchase Order Acknowledgements unless otherwise specified by the customer. |
| 7.2.1.1 | Customer-Designated Special Characteristics<br>The organization shall demonstrate conformity to customer requirements for designation, documentation and control of special characteristics. | 4.2.3.2 | Special Characteristics<br>The suppliers process control guidelines and similar documents (e.g. FMEA's, Control Plans, Operator Instructions) shall be marked with the customer's special characteristics symbol (or the supplier's equivalent symbol or notation) to indicate those process steps that affect Special Characteristics, when Special Characteristics are identified on the customer design record (see Glossary) (see Appendix C) **Note:** Initially, the customer may determine Special Characteristics and identify them. Special Characteristics may be identified from any product characteristic category, e.g. dimensional, material, appearance, performance. |
| | | 4.9.d.1 | Designation of Special Characteristics<br>The supplier shall comply with all customer requirements for designation, documentation and control of Special Characteristics. The supplier shall provide documentation showing compliance with the customer requirements as requested by any customer. **Note:** All product and process characteristics are important and need to be controlled. However, some characteristics, herein referred to as "special", need extra attention because excessive variation in them might affect a product's safely, compliance with governmental regulations, fit, function, appearance or quality of subsequent manufacturing operations. |

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| 7.2.2 | Review of Requirements Related to the Product<br>The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or order, acceptance of changes to contracts or orders) and shall ensure that; a) product requirements are defined b) contract or order requirements differing from those previously expressed are resolved, and c) the organization has the ability to meet the defined requirements. Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4). Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance. Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.<br>**Note:** In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material. | 4.3.2 | Review<br>Before the submission of a tender, or the acceptance of a contract or order (statement of requirement), the tender, contract or order shall be reviewed by the supplier to ensure that: a) the requirements are adequately defined and documented; where no written statement of requirement is available for an order received by verbal means, the supplier shall ensure that the order requirements are agreed before their acceptance; b) any difference between the contract or order requirements and those in the tender are resolved; c) The supplier has the capability to meet contract or order requirements; d) all customer requirements, including those in Section II of this document, shall be met. |
| | | 4.3.3 | Amendment to Contract<br>The supplier shall identify how an amendment to a contract is made and correctly transferred to the functions concerned within the supplier's organization. |
| | | 4.3.4 | Records<br>Records of contract reviews shall be maintained (see 4.16) **Note:** Channels for communication and interfaces with the customer's organization is these contract matters should be established. |
| 7.2.2.2 | Organization Manufacturing Feasibility<br>The organization shall investigate, confirm and document the manufacturing feasibility of the proposed products in the contract review process, including risk analysis. | 4.2.3.3 | Feasibility Reviews<br>The supplier shall investigate and confirm the manufacturing feasibility of proposed products prior to contracting to produce those products. Feasibility is an assessment of the suitability of a particular design, material, or process for production, while conforming to all engineering requirements at the required statistical process capability and at specified volumes. Feasibility reviews should be documented using the Team Feasibility Commitment in the Advanced Product Quality Planning and Control Plan reference manual. |

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| 7.2.3 | Customer Communication<br>The organization shall determine and implement effective arrangements for communicating with customers in relation to; a) product information, b) enquiries, contracts or order handling, including amendments, and c) customer feedback, including customer complaints. | | |
| 7.2.3.1 | Customer Communication - Supplemental<br>The organization shall have the ability to communicate necessary information, including data, in a customer-specified language and format (e.g. computer-aided design data, electronic data exchanges). | 4.15.6.3 | Electronic Communication<br>The supplier shall have a computerized system for receipt of customer planning information and ship schedules, unless waived by the customer. |
| | | 4.15.6.4 | Shipment Notification System<br>The supplier shall have a computerized system for on-line transmittal of advance shipment notification (ASNs), transmitted at the time of shipment, unless waived by the customer. The supplier shall have a back-up method in the event that the on-line system fails. The supplier shall verify that all ASNs match shipping documents and labels. |
| 7.3 | Design and Development<br>**Note:** The requirements of 7.3 include product and manufacturing process design and development, and focus on error prevention rather on detection. | 4.2.3.5 | Failure Mode and Effects Analysis<br>Process FMEAs shall consider all Special Characteristics. Efforts shall be taken to improve the process to achieve defect prevention rather than defect detection. Certain customers have FMEA review and approval requirements that shall be met prior to production part approval (see Section II). Refer to the Potential Failure Mode and Effects Analysis reference manual. |
| 7.3.1 | Design and Development Planning<br>The organization shall plan and control the design and development of product. During the design and development planning, the organization shall determine: a) the design and development stages, b) the review, verification and validation that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development. The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output shall be updated, as appropriate, as the design and development progresses. | 4.4 | Design Control<br>**Note:** THIS ELEMENT APPLIES TO DESIGN RESPONSIBLE SUPPLIERS ONLY. A supplier is defined as design-responsible if it has the authority to establish a new, or change an existing product specification for any product shipped to a customer. Customer approval of a design responsible supplier's product does not waive the supplier's design responsible status. Consult your customer for further clarification if needed. |
| | | 4.4.1 | General<br>The supplier shall establish and maintain documented procedures to control and verify the design of the product in order to ensure that the specified requirements are met. |

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| | | 4.4.1.1 | Use of Design Data<br>The supplier shall have a process to deploy information gained from previous design projects to current and future projects of a similar nature**.** |
| | | 4.4.2 | Design and Development Planning<br>The supplier shall prepare plans for each design and development activity. The plans shall describe or reference those activities, and define responsibility for their implementation. The design and development activities shall be assigned to qualified personnel equipped with adequate resources. The plans shall be updated, as the design evolves. |
| 7.3.1.1. | Multidisciplinary Approach<br>The organization shall use a multidisciplinary approach to prepare for product realization, including * development/finalization and monitoring of special characteristics, * development and review of FMEAs, including actions to reduce potential risks, and * development and review of control plans. **Note:** A multidisciplinary approach typically includes the organization's design, manufacturing, engineering, quality, production and other appropriate personnel. | 4.4.3 | Organization and Technical Interfaces<br>Organization and technical Interfaces between different groups which input to the design process shall be defined and the necessary information documented, transmitted and regularly reviewed. |
| 7.3.2 | Design and Development Inputs<br>Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include: a) functional and performance requirements, b) applicable statutory and regulatory requirements, c) where applicable, information derived from previous similar designs, and d) other requirements essential for design and development. These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other. **Note:** special characteristics see (7.2.1.1) are included in this requirement. | 4.4.4 | Design Input<br>Design input requirements relating to the product, including applicable statutory and regulatory requirements, shall be identified, documented and their selection reviewed by the supplier for adequacy. Incomplete, ambiguous or conflicting requirements shall be resolved with those responsible for imposing these requirements. Design input shall take into consideration the results of any contract review activities. |
| 7.3.2.1 | Product Design Input<br>The organization shall identify, document and review the product design inputs requirements, including the following; * customer requirements (contract review) such as special characteristics (see 7.3.2.3), identification, traceability and packaging; * use of information: the organization shall have a process to deploy information gained from previous design projects, competitor analysis, supplier feedback, internal input, field data, and other relevant sources, for current and future projects of a similar nature; * targets for product quality, life, reliability, durability, maintainability, timing and cost. | | |

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| | | 4.4.4.1 | Design Input - Supplemental<br>The supplier shall have appropriate resources and facilities to utilize computer-aided product design, engineering and analysis. If these functions are subcontracted, the suppliers shall provide technical leadership. The CAD/CAE systems shall be capable of two way interface with customer systems. The requirement for computer-aided systems can be waived by the customer. |
| 7.3.2.2 | Manufacturing Process Design Input<br>The organization shall identify, document and review the manufacturing process design input requirements, including * product design output data * targets for productivity, process capability and cost, * customers requirements, if any and * experience from previous developments. | | |
| 7.3.2.3 | Special Characteristics<br>The organization shall identify special characteristics (see 7.3.3 d) and * include all special characteristics in the control plan, * comply with customer-specified definitions and symbols, and * identify process control documents including drawings, FMEAs, control plans, and operator instructions with the customer's special characteristic symbol or the organization's equivalent symbol or notation to include those process steps that affect special characteristics. **Note:** Special characteristic can include product characteristics and process parameters. | 4.2.3.2 | Special Characteristics<br>The suppliers process control guidelines and similar documents (e.g. FMEA's, Control Plans, Operator Instructions) shall be marked with the customer's special characteristics symbol (or the supplier's equivalent symbol or notation) to indicate those process steps that affect Special Characteristics, when Special Characteristics are identified on the customer design record (see Glossary) (see Appendix C) **Note:** Initially, the customer may determine Special Characteristics and identify them. Special Characteristics may be identified from any product characteristic category, e.g. dimensional, material, appearance, performance. |
| | | 4.9.d.1 | Designation of Special Characteristics<br>The supplier shall comply with all customer requirements for designation, documentation and control of Special Characteristics. The supplier shall provide documentation showing compliance with the customer requirements as requested by any customer. **Note:** All product and process characteristics are important and need to be controlled. However, some characteristics, herein referred to as "special", need extra attention because excessive variation in them might affect a product's safely, compliance with governmental regulations, fit, function, appearance or quality of subsequent manufacturing operations. |

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| 7.3.3 | Design and Development Outputs<br>The output of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release. Design and development outputs shall: a) meet the input requirements for design and development b) provide appropriate information for purchasing, production and for service provision, c) contain or reference product acceptance criteria, and d) specify the characteristics of the product that are essential for its safe and proper use. | 4.4.5 | Design Output<br>Design output shall be documented and expressed in terms that can be verified and validated against design input requirements. Design output shall: a) meet the design input requirements; b) contain or make reference to acceptance criteria; c) identify those characteristics of the design that are crucial ("Special Characteristics" - see Appendix C) to the safe and proper functioning of the product (e.g. operating, storage, handling, maintenance and disposal requirements). Design output documents shall be reviewed before release. |
| 7.3.3.1 | Product Design Output- Supplemental<br>The product design output shall be expressed in terms that can be verified and validated against product design input requirements. The product design output shall include; * design FMEA, reliability results * product special characteristics and specifications * product error-proofing, as appropriate * product definition including drawings or mathematically based data * product design reviews results, and * diagnostic guidelines where applicable. | 4.4.5.1 | Design Output - Supplemental<br>The supplier's design output shall be the result of a process that includes: * Efforts to simplify, optimize, innovate, and reduce waste (e.g. QFD, DFM/DFA, VE, DOE, tolerance studies, response surface methodology, or appropriate alternatives) * Utilization of geometric dimensioning and tolerancing as applicable * Analysis of cost/performance/risk trade-offs * Use of feedback from testing, production, and the field * Use of design FMEAs |
| 7.3.3.2 | Manufacturing Process Design Output<br>The manufacturing process design output shall be expressed in terms that can be verified against manufacturing process design input requirements and validated. The manufacturing process design output shall include * specifications and drawings * manufacturing process flow chart/layout, * manufacturing process FMEAs, * control plan (see 7.5.1.1), * work instructions, * process approval acceptance criteria, * data for quality, reliability, maintainability and measurability, * results of error-proofing activities, as appropriate, and * methods of rapid detection and feedback of product/manufacturing process nonconformities. | | |
| 7.3.4 | Design and Development Review<br>At suitable stages, systematic reviews and design and development shall be performed in accordance with planned arrangements (see 7.3.1); a) to evaluate the ability of the results of design and development to meet requirements, and b) to identify any problems and propose necessary actions. Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).<br>**Note:** These reviews are normally coordinated with the design phase and include manufacturing process design and development. | 4.4.6 | Design Review<br>At appropriate stages of design, formal documented reviews of the design results shall be planned and conducted. Participants at each design review shall include representatives of all functions concerned with the design stage being reviewed, as well as other specialist personnel, as required. Records of such reviews shall be maintained (see 4.16). |

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| 7.3.4.1 | Monitoring<br>Measurements at specified stages of design and development shall be defined, analyzed and reported with summary results as an input to management review. **Note:** These measurements include quality risks, costs, lead-times, critical paths and others, as appropriate. | | |
| 7.3.5 | Design and Development Verification<br>Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4). | 4.4.7 | Design Verification<br>At appropriate stages of design, design verification shall be performed to ensure that the design stage output meets the design stage input requirements. The design verification measures shall be recorded (see 4.16) **Note 10:** In addition to conducting design reviews (see 4.4.6) design verification may include activities such as the following: * performing alternative calculations, * comparing the new design with a similar proven design, if available, * undertaking tests and demonstrations, and * reviewing the design stage documents before release. |
| 7.3.6 | Design and Development Validation<br>Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (se 4.2.4). **Note 1:** The validation process normally includes an analysis of field reports for similar products. **Note 2:** The requirements of 7.3.5 and 7.3.6 above apply to both product and manufacturing processes. | 4.4.8 | Design Validation<br>Design validation shall be performed to ensure that product conforms to define user needs and/or requirements. |
| 7.3.6.1 | Design and Development Validation – Supplemental<br>Design and development validation shall be performed in accordance with customer requirements including programme timing. | 4.4.8.1 | Design Validation – Supplemental<br>Design validation shall be performed in conjunction with customer programming timing requirements. Validation results shall be recorded (see 4.16). Design failures shall be documented in the validation records. Procedures for corrective and preventive action shall be followed in addressing such design failures. **Notes 11:** Design validation follows successful design verification (see 4.4.7) **12.** Validation is normally performed under defined operating conditions. **13.** Validation is normally performed on the final product, but may be necessary in earlier stages prior to product completion. **14.** Multiple validations may be performed if there are different intended uses. |

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| 7.3.6.2 | Prototype Programme<br>When required by the customer, the organization shall have a prototype programme and control plan. The organization shall use, wherever possible, the same suppliers, tooling and manufacturing processes as will be used in production. All performance-testing activities shall be monitored for timely completion and conformity to requirements. While services may be outsourced, the organization shall be responsible for the outsourced services, including technical leadership. | 4.4.10 | Customer Prototype Support<br>When required by the customer, the supplier shall have a comprehensive prototype program. The supplier shall use the same subcontractors, tooling and processes, as will be used in production wherever possible. Performance tests shall consider and include as appropriate product life, reliability and durability. All performance testing activities shall be tracked to monitor timely completion and conformance to requirements. While these services may be contracted, the supplier shall provide technical leadership. |
| 7.3.6.3 | Product Approval Process<br>The organization shall conform to a product and manufacturing process approval procedure recognized by the customer. **Note:** Product approval should be subsequent to the verification of the manufacturing process. The product and manufacturing process approval procedure shall also be applied to suppliers. | 4.2.4.1 | General<br>The supplier shall fully comply with all requirements set forth in the Production Part Approval Process (PPAP) manual. |
| | | 4.2.4.2 | Subcontractor Requirements<br>Suppliers should utilize a part approval process (e.g. PPAP) for subcontractors (see Glossary). **Note:** Certain customers require that their suppliers use PPAP with their subcontractors (See Section II). |
| | | 4.2.4.3 | Engineering Change Validation<br>The supplier shall verify that changes are properly validated. See 4.12, 4.16 and PPAP. **Note:** This applies equally to suppliers and subcontractors. |
| | | 4.4.9.1 | Design Changes - Supplemental<br>All design changes, including those proposed by subcontractors, shall have written customer approval, or waiver of such approval, prior to production implementation. See the Productions Part Approval Process manual and the customer-specific pages of this document. For proprietary designs, impact on form, fit, function, performance, and/or durability shall be determined with the customer so that all effects can be properly evaluated. |

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| 7.3.7 | Control of Design and Development Changes<br>Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the change on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4). **Note:** Design and development changes include all changes during the product programme life (see 7.1.4). | 4.4.9 | Design Changes<br>All design changes and modifications shall be identified, documented, reviewed and approved by authorized personnel before their implementation. |
| | | 4.4.9.2 | Design Change Impact<br>The supplier shall consider the impact of a design change on the system in which the product is used. |
| | | 4.5.3 | Document and Data Changes<br>Changes to documents and data shall be reviewed and approved by the same functions/organizations that performed the original review and approval, unless specifically designated otherwise. The designated functions/organizations shall have access to pertinent background information upon which to base their review and approval. Where practicable, the nature of the change shall be identified in the document or the appropriate attachments. |
| 7.4 | Purchasing | | |
| 7.4.1 | Purchasing Process<br>The organization shall ensure that purchased products conform to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. The organization shall evaluate and select suppliers based on their ability to supply products in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluation and any necessary actions arising from the evaluation shall be maintained (see 4.2.4). **Note 1:** Purchased products above include all products and services that affect customer requirements such as subassembly, sequencing, sorting, rework and calibration services. **Note 2:** When there are mergers, acquisitions or affiliations associated with suppliers, the organization should verify the continuity of the supplier's quality management system and its effectiveness. | 4.6.1 | General<br>The supplier shall establish and maintain documented procedures to ensure that purchased products (see 3.1) conform to specified requirements. **Note:** The reference above, "see 3.1" is to Section 3.1 in ISO 9001 or 9002 where "product" is defined. |

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| 7.4.1.1 | Regulatory Conformity<br>All purchased products or materials use in product shall conform to applicable regulatory requirements. | 4.6.1.2 | Government, Safety and Environmental Regulations<br>All purchased materials used in part manufacture shall satisfy current governmental and safety constraints on restricted, toxic and hazardous materials; as well as environmental, electrical and electromagnetic considerations applicable to the country of manufacture and sale (see Glossary - Approved Materials). |
| | | 4.6.2 | Evaluations of Subcontractors<br>The supplier shall: a) evaluate and select subcontractor on the basis of their ability to meet subcontract requirements including the quality system and any specific quality assurance requirements; b) define the type and extent of control exercised by the supplier over subcontractors. This shall be dependent upon the type of product, the impact of subcontracted product on the quality of final product and, where applicable, on the quality audit reports and/or quality records of the previously demonstrated capability and performance of subcontractors; c) establish and maintain quality records of acceptable subcontractors (see 4.16). **Note:** Methods other than an "Approved subcontractors list" may be utilized to meet this requirement. |
| 7.4.1.2 | Supplier Quality Management System Development<br>The organization shall perform supplier quality management system development with the goal of supplier conformity with this Technical Specification. Conformity with ISO 9001:2000 is the first step in achieving this goal. **Note:** The prioritization of suppliers for development depends upon, for example, the supplier's quality performance and the importance of the product supplied. Unless otherwise specified by the customer, suppliers to the organization shall be third party registered to ISO9001:2000 by an accredited third-party certification body. | 4.6.2.1 | Subcontractor Development<br>The supplier shall perform subcontractor (see Glossary) quality system development with the goal of subcontractor compliance to QS-9000 using section I of QS-9000 as their fundamental quality system requirement. Assessments, if part of subcontractor development, should occur at supplier specified frequency. Subcontractor assessments to QS-9000 by the OEM customer, an OEM customer-approved second party, or an accredited third party certification body/registrar will be recognized in lieu of audits by the supplier. **Note:** Acceptance of the above audits or ISO 9001/9002 registration is not intended to limit more specific supplier/subcontractor quality system and product development. **Note:** The prioritization of subcontractors for development is dependent upon the needs of the subcontractor relative to the requirements of QS-9000 and the importance of the product or service they supply. The use of customer-designated subcontractors does not relieve the supplier of the responsibility for ensuring the quality of subcontracted parts, materials and services. |

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| | | 4.6.2.2 | Scheduling Subcontractors<br>The supplier shall require 100% on time delivery performance from subcontractors. The supplier shall provide appropriate planning information and purchase commitments to enable subcontractors to meet this expectation. The supplier shall implement a system to monitor the delivery performance of subcontractors with corrective actions taken as appropriate. Records of premium freight shall include both supplier and subcontractor paid charges. |
| 7.4.1.3 | Customer-Approved Sources<br>Where specified by the contract (e.g. customer engineering drawing, specification), the organization shall purchase products, materials or services from approved sources. The use of customer-designated sources, including tool/gauge suppliers, does not relieve the organization of the responsibility for ensuring the quality of purchased products. | 4.6.1.1 | Approved Materials for Ongoing Production<br>Where the customer has an approved subcontractor list, the supplier shall purchase the relevant materials from subcontractors on the list. Any additional subcontractors may only be used after they have been added to the list by the customer's Materials Engineering activity. **Note:** To be added to any existing customer "approved subcontractor list", a company should contact the appropriate customer engineering function to be considered. These lists exist only for certain commodities and, where they do exist, they may be found in the customer design record. (see Glossary) |
| 7.4.2 | Purchasing Information<br>Purchasing information shall describe the product to be purchased, including where appropriate: a) requirements for approval of product, procedures, processes and equipment, b) requirements for qualification of personnel, and c) quality management system requirements. The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier. | 4.6.3 | Purchasing Data<br>Purchasing documents shall contain data clearly describing the product ordered, including where applicable: a) the type, class, grade or other precise identification; b) the title or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data, including requirements for approval or qualification of product, procedures, process equipment and personnel; c) the title, number and issue of the quality system standard to be applied. The supplier shall review and approve purchasing documents for adequacy of specified requirements prior to release. |
| 7.4.3 | Verification of Purchased Product<br>The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information. | 4.6.4.1 | Supplier Verification at Subcontractor's Premises<br>Where the supplier proposes to verify purchased product at the subcontractor's premises, the supplier shall specify verification arrangements and the method of product release in the purchasing documents. |

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| | | 4.6.4.2 | Customer Verification of Subcontracted Product<br>Where specified in the contract, the supplier's customer or the customer's representative shall be afforded the right to verify at the subcontractor's premises and the supplier's premises that subcontracted product conforms to specified requirements. Such verification shall not be used by the supplier as evidence of effective control of quality by the subcontractor. Verification by the customer shall not absolve the supplier of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer. |
| 7.4.3.1 | Incoming Product Quality<br>The organization shall have a process to assure the quality of purchased product (see 7.4.3) utilizing one or more of the following methods: * receipt of, and evaluation of, statistical data by the organization; * receiving inspection and/or testing such as sampling based on performance; * second- or third-party assessments or audits of supplier sites, when coupled with records of acceptable delivery product quality; * part evaluation by a designated laboratory * another method agreed with the customer. | 4.10.2.4 | Incoming Product Quality<br>The supplier's incoming quality system shall use one or more of the following methods: * Receipt and evaluation of statistical data by the supplier * Receiving inspection and/or testing (e.g., sampling based on performance) * Second or third party assessments or audits of subcontractor sites, when coupled with records of acceptable quality performance * Part evaluation by accredited laboratories |
| 7.4.3.2 | Supplier Monitoring<br>Supplier performance shall be monitored through the following indicators: * delivered product quality; * customer disruptions including field returns; * delivery schedule performance (including incidents of premium freight); * special status customer notifications related to quality or delivery issues. The organization shall promote supplier monitoring of the performance of their manufacturing processes. | | |

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| 7.5 | Production and Service Provision | | |
| 7.5.1 | Control of Production and Service Provision<br>The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable: a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, and f) the implementation of release, delivery and post-delivery activities. | 4.9 | Process Control<br>The supplier shall identify and plan the production; installation and servicing processes which directly affect quality and shall ensure that these processes are carried out under controlled conditions. Controlled conditions shall include the following: a) documented procedures defining the manner of production, installation and servicing, where the absence of such procedures could adversely affect quality; b) use of suitable production, installation and servicing equipment, and a suitable working environment (see Glossary) c) compliance with reference standards/codes, quality plans and/or documented procedures; d) monitoring and control of suitable process parameters and product characteristics. e) the approval of processes and equipment, as appropriate: f) criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g. written standards, representative samples or illustrations; g) suitable maintenance of equipment to ensure continuing process capability.<br>Where the results of processes cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use, the processes shall be carried out by qualified operators and/or shall require continuous monitoring and control of process parameters to ensure that the specified requirements are met. The requirements for any qualification of process operations, including associated equipment and personnel (see 4.18), shall be specified. **Note 16:** Such processes requiring pre-qualification of their process capability are frequently referred to as special processes. Records shall maintain for qualified processes, equipment and personnel, as appropriate. (see 4.16) |

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| 7.5.1.1 | Control Plan<br>The organization shall * develop control plans (see Annex A) at the system, subsystem, component and/or material level for the product supplied, including those for processes producing bulk materials as well as parts, and * have a control plan for pre-launch and production that takes into account the design FMEA and manufacturing process FMEA outputs. The control plan shall * list the controls used for the manufacturing process control, * include methods for monitoring of control exercised over special characteristics (see 7.3.2.3) defined by both the customer and the organization, * include the customer-required information, if any, and *initiate the specified reaction plan (see 8.2.3.1) when the process becomes unstable or not statistically capable. Control plans shall be reviewed and updated when any change occurs affecting product, manufacturing process, measurement, logistics, supply resources or FMEA (see 7.1.4). **Note:** Customer approval may be required after review or update of the control plan. | 4.2.3.7 | The Control Plan<br>The supplier shall develop Control Plans at the system, subsystem, component and/or material level, as appropriate for the product supplied. The Control Plan shall include the information required in the Control Plan form in Appendix J. The Control Plan requirement encompasses processes producing bulk materials (e.g. steel, plastic resin, paint) as well as those producing parts. The output of the advanced quality planning process, beyond the development of robust processes, is a Control Plan. Control Plan shall be revised or updated when products or processes differ significantly from those in current production. The Control Plan should list the controls used for process control (see 4.9). The Control Plan shall cover three distinct phased as appropriate: * Prototype * Prelaunch * Production. **Note:** A multi-disciplinary approach typically includes the supplier's design, manufacturing, engineering, quality, production, and other appropriate personnel. For external suppliers, it may include the customer's Purchasing, Quality, Product Engineering, customer plant personnel as well as subcontractors. Control Plans shall be reviewed and updated as appropriate when any of the following occur: * The product is changed * The processes are changed * The processes become unstable * The processes become non-capable * Inspection method, frequency, etc. is revised. |
| 7.5.1.2 | Work Instructions<br>The organization shall prepare documented work instructions for all employees having responsibilities for the operation of processes that impact product quality. These instructions shall be accessible for use at the workstation. These instructions shall be derived from sources such as quality plan, the control plan and the product realization process. | 4.9.1 | Process Monitoring and Operator Instructions<br>The supplier shall prepare documented process monitoring and operator instructions for all employees having responsibilities for operation of processes. These instructions shall be accessible at the workstation. Note: Job instructions should be available at the time needed without disruption to the job being performed by the operator. These instructions should be derived from the sources listed in the Advanced Product Quality Planning and Control Plan reference manual. Process monitoring and operator instructions may take the form of process sheets, inspections and laboratory test instructions, shop travelers, test procedures, standard operation sheets, or other documents normally used by the supplier to provide the necessary information.<br>Process monitoring and operator instructions shall include or reference, as appropriate: * Operation name and number keyed to the process flow diagram * Part name and part number, or part family * Current engineering level/date * Required tools, gages and other equipment * Material identification and disposition instructions * Customer and supplier designated special characteristics * SPC requirements * Relevant engineering and manufacturing standards * Inspection and test instructions (see 4.10.4) * Reaction plan * Revision date and approvals * Visual aids * Tool change intervals and setup instructions |

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| 7.5.1.3 | Verification of Job Set-ups<br>Job set-ups shall be verified whenever performed, such as an initial run of a job, material changeover or job change. Work instructions shall be available for set-up personnel. The organization shall use statistical methods of verification where applicable. **Note:** Last-off comparisons are recommended. | 4.9.4 | Verification of Job Set-ups<br>Job set-ups shall be verified whenever a set-up is performed (e.g. initial run of a job, material changeover, job change, significant time periods lapsed between runs, etc.). Job instructions shall be available for setup personnel. Last-off part comparisons are recommended. The supplier shall use statistical methods of verification where applicable. |
| 7.5.1.4 | Preventive and Predictive Maintenance<br>The organization shall identify key process equipment and provide resources for machine/equipment maintenance and develop an effective planned total preventive maintenance system. As a minimum, this system shall include the following; * planned maintenance activities * packaging and preservation of equipment, tooling and gauging; * availability of replacement parts for key manufacturing equipment; * documenting, evaluating and improving maintenance objectives. The organization shall utilize predictive maintenance methods to continually improve the effectiveness and the efficiency of production equipment. | 4.9.g.1 | Preventive Maintenance<br>The supplier shall identify key process equipment and provide appropriate resources for machined/equipment maintenance and develop an effective planned total preventive maintenance system. At a minimum, this system shall include; * A procedure that describes planned maintenance activities * Scheduled maintenance activities * Predictive maintenance methods - These methods should include a review of appropriate items such as the manufacture's recommendations, tool wear, optimization of uptime, correlation of SPA data to preventive maintenance activities, correlation of SPC data to preventive maintenance activities, important characteristics of perishable tooling, fluid analysis, infrared monitoring of circuits and vibrations analysis * A procedure providing for packaging and preservation of equipment, tooling and gaging * Availability of replacement parts for key manufacturing equipment * Documenting, evaluating and improving maintenance objectives. |
| 7.5.1.5 | Management of Production Tooling<br>The organization shall provide resources for tool and gage design, fabrication and verification activities. The organization shall establish and implement a system for production tooling management including; * maintenance and repair facilities and personnel * storage and recovery * set-up * tool-change programs for perishable tools * tool design modification documentation, including engineering change level * tool modification and revision to documentation * tool identification, defining the status, such as production, repair or disposal. The organization shall implement a system to monitor these activities if any work is outsourced. **Note:** This requirement also applies to the availability of tools for vehicle service parts. | 4.2.6.2 | Tooling Management<br>The supplier shall establish and implement a system for tooling management including: * Maintenance and repair facilities and personnel * Storage and recovery * Setup * Tool change programs for perishable tools * Tool modification, including tool design documentation. The supplier shall provide appropriate technical resources for tool (see Glossary) and gages design, fabrication and full dimensional inspection. The supplier shall implement a system to track and follow-up on these activities if any of this work is subcontracted. **Note:** Tooling Management (4.2.6.2) is not required of warehouses of distributors. |
| 7.5.1.6 | Production Scheduling<br>Production shall be scheduled in order to meet customer requirements, such as just-in-time supported by an information system that permits access to production information at key stages of the process and is order driven. | 4.15.6.2 | Production Scheduling<br>The supplier's production scheduling activity shall be order-driven. **Note:** The use of small lots with a goal of one piece flow is a synchronous manner is encouraged. **Note:** If the supplier's production is scheduled based upon a "forecast", this would not meet the intent of the requirement. A "pull" system (parts/replenishment based upon consumption) utilizing an optimal level of inventory on hand which is commensurate with total process cycle time satisfies the intent of an order-driven system. |

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| 7.5.1.7 | Feedback of Information From Service<br>A process for communication of information on service concerns to manufacturing, engineering and design actives shall be established and maintained. **Note:** The intent of the addition of "service concerns" to this subclause is to ensure that the organization is aware of nonconformities that occur external to its organization. | 4.19.1 | Feedback of Information From Service<br>A procedure for communication of information on service concerns to manufacturing, engineering and design activities shall be established and maintained. **Note:** The intent of the addition of "service concerns" to Element 4.19 is to ensure that the supplier's organization is aware of nonconformities that occur external to the supplier's own organization. (see 4.14) |
| 7.5.1.8 | Service Agreement With Customer<br>Where there is a service agreement with the customer, the organization shall verify the effectiveness of; * any organization service centres, * any special-purpose tools or measurement equipment, and * the training of service personnel. | 4.19 | Servicing<br>Where servicing is a specified requirement, the supplier shall establish and maintain documented procedures for performing, verifying and reporting that the servicing meets the specified requirements. **Note:** Any after-sales product servicing provided as part of the OEM contract or Purchase Order would fall under Element 4.19. |
| 7.5.2 | Validation of Processes for Production and Service Provision.<br>The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes including, as applicable: a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records (see 4.2.4), and e) revalidation. | | |
| 7.5.2.1 | Validation of Processes for Production and Service Provision - Supplemental<br>The requirements of 7.5.2 shall apply to all processes for production and service provision. | | |
| 7.5.3 | Identification and Traceability<br>Where appropriate, the organization shall identify the product by suitable means throughout product realization. The organization shall identify the product status with respect to monitoring and measurement requirements. Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4). **Note:** In some industry sectors, configuration management is a means by which identification and traceability are maintained. **Note:** Inspection and test status is not indicated by the location of product in the production flow unless inherently obvious, such as material in an automated production transfer process. Alternatives are permitted, if the status is clearly identified, documented and achieves the designated purpose. | 4.8 | Product Identification and Traceability<br>Where appropriate, the supplier shall establish and maintain documented procedures for identifying the product by suitable means from receipt and during all staged of production, delivery and installation. **Note:** for QS-9000, the words "where appropriate" above are not applicable. Where and to the extent that traceability is a specified requirement, the supplier shall establish and maintained documented procedures for unique identification of individual product or batches. This identification shall be recorded (see 4.16). |

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| 7.5.3.1 | Identification and Traceability - Supplemental<br>The words "Where appropriate" in 7.5.3 shall not apply. | | |
| 7.5.4 | Customer Property<br>The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. In any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4). **Note:** Customer property can include intellectual property. **Note:** Customer-owned returnable packaging is included in this clause. | 4.7 | Control of Customer Supplier Product<br>The supplier shall establish and maintain documented procedures for the control of verification, storage and maintenance of customer-supplied product provided for incorporation into the supplies or for related activities. Any such product that is lost, damaged or is otherwise unsuitable for use shall be recorded and reported to the customer (see 4.16). Verification by the supplier does not absolve the customer of the responsibility to provide acceptable product. **Note:** Customer-owned returnable packaging is included in this element (see 4.15.4) |
| 7.5.4.1 | Customer-Owned Production Tooling<br>Customer-owned tools, manufacturing, test, inspection tooling and equipment shall be permanently marked so that the ownership of each item is visible, and can be determined. | 4.7.1 | Customer-Owned Tooling<br>Customer-owned tools and equipment shall be permanently marked so that the ownership of each item is visually apparent. **Note:** An affixed tag specifically containing the part number and/or customer name to identify ownership is the preferred approach. However, this requirement may be met by using a supplier designated number cross-referenced with clear traceability back to the customer. |
| 7.5.5 | Preservation of Product<br>The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. The preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product. | 4.15.1 | General<br>The supplier shall establish and maintain documented procedures for handling, storage, packaging, preservation and delivery of product. |
| | | 4.15.2 | Handling<br>The supplier shall provide methods of handling product that prevent damage or deterioration. |
| 7.5.5.1 | Storage and Inventory<br>In order to detect deterioration, the condition of product in stock shall be assessed at appropriate planned intervals. The organization shall use an inventory management system to optimize inventory turns over time and assure stock rotation, such as "first-in-first-out" (FIFO). Obsolete product shall be controlled in a similar manner to nonconforming product. | 4.15.3 | Storage<br>The supplier shall use designated storage areas or stock rooms to prevent damage or deterioration or product, pending use or delivery. Appropriate methods for authorizing receipt to and dispatch from such area shall be stipulated. In order to detect deterioration, the condition of product in stock shall be assessed at appropriate intervals. |
| | | 4.15.3.1 | Inventory<br>The supplier shall use an inventory management system to optimize inventory turns over time, assure stock rotation and minimize inventory levels. |

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| | | 4.15.4 | Packaging<br>The supplier shall control packing, packaging and marking processes (including material used) to the extent necessary to ensure conformance to specified requirements. |
| | | 4.15.4.1 | Customer Packaging Standards<br>The supplier shall comply with all unique customer packaging standards/guidelines, including applicable service part packaging standards. |
| | | 4.15.4.2 | Labeling<br>The supplier shall develop a system to ensure that all materials shipped are labeled according to customer requirements (see section II). |
| | | 4.15.5 | Preservation<br>The supplier shall apply appropriate methods for preservation and segregation of products when the product is under the supplier's control. |
| | | 4.15.6 | Delivery<br>The supplier shall arrange for the protection of the quality of product after final inspection and test. Where contractually specified, this protection shall be extended to include delivery to destination. |
| | | 4.15.6.1 | Supplier Delivery Performance Monitoring<br>The supplier shall establish systems to support 100% on-time shipments to meet customer production and service requirements. If 100% on-time shipments are not maintained the supplier shall implement corrective action to improve delivery performance, including communication of delivery problem information to the customer. The supplier shall have a systematic approach to develop, evaluate and monitor adherence to established lead time requirements. The supplier shall implement a system to monitor performance to the customer delivery requirements with corrective actions taken as appropriate. Record of supplier responsible premium freight shall be maintained. The supplier shall ship all materials in conformance with customer requirements, adhering to up-to-date customer-specified transportation mode, routings and containers. |

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| 7.6 | Control of Monitoring and Measuring Devices<br>The organization shall determine the monitoring and measurement to be taken and the monitoring and measuring devices needed to provide evidence of conformity of product to determine requirements (see 7.2.1). The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements. Where necessary to ensure valid results, measuring equipment shall: a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded; b) be adjusted or re-adjusted as necessary; c) be identified to enable the calibration status to be determined; d) be safeguarded for adjustments that would invalidate the measurement result; e) be protected from damage and deterioration during handling, maintenance and storage. In addition, the organization shall access and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4). When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application, shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary. **Note:** See ISO 10012-1 and ISO 10012-2 for guidance. **Note:** A number or other identifier traceable to the device calibration record meets the intent of requirement c) above. | 4.11.1 | General<br>The supplier shall establish and maintain documented procedures to control, calibrate and maintain inspection, measuring and test equipment (including test software) used by the supplier to demonstrate the conformance of product to the specified requirements. Inspection, measuring and test equipment shall be used in a manner which ensures that the measurement uncertainty is known and is consistent with the required measurement capability. **Note:** Additional guidance on measurement uncertainty may be found in ISO 10012-1:1992 (E). The choice of the specific method to be used should be based upon sound technical knowledge of the complete measurement system, the conditions under which it will operate, and the uses for which the data are being produced. Where test software of comparative references such as test hardware are used as suitable forms of inspection, they shall be checked to prove that they are capable of verifying the acceptability of product, prior to release for use during production, installation, or servicing, and shall be rechecked at prescribed intervals. The supplier shall establish the extent and frequency of such checks and shall maintain records as evidence of control (see 4.16). Where the availability of technical data pertaining to the inspection, measuring, and test equipment is a specified requirement, such data shall be made available, when required by the customer or customer's representative, for verification that the inspection, measuring, and test equipment is functionally adequate. **Note:** For purposes of this International Standard, the term "measuring equipment" includes "measurement devices". |

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| | | 4.11.2 | Control Procedure<br>The supplier shall: a) determine the measurements to be made and the accuracy required, and select the appropriate inspection, measuring and test equipment that is capable of the necessary accuracy and precision; b) identify all inspection, measuring and test equipment that can affect product quality, and calibrate and adjust them at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to internationally or nationally recognized standards. Where no such standards exit, the basis used for calibration shall be documented; **Note:** "inspection, measuring and test equipment" includes equipment in tooling departments used to qualify or maintain production tools regardless of ownership, c) identify the process employed for the calibration or inspection, measuring and test equipment, including details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria and the action to be taken when results are unsatisfactory; d) identify inspection, measuring and test equipment with a suitable indicator or approved identification record to show the calibration status: **Note:** a serial number traceable to the device calibration record meets the intent of this requirement, e) maintain calibration records for inspection, measuring and test equipment (see 4.16); f) assess and document the validity of previous inspection and test results when inspection, measuring or test equipment is found to be out of calibration; g) ensure that the environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out; h) ensure that the handling, preservation and storage of inspection, measuring and test equipment is such that the accuracy and fitness for use is maintained; i) safeguard inspection, measuring and test facilities, including both test hardware and test software, from adjustments which would invalidate the calibration setting.<br>**Note:** Inspection, measuring and test facilities are generally understood to mean inspection, measuring and test equipment where test results can be invalidated by inappropriate adjustment at the audited site. **Note 18:** The metrological confirmation system for measuring equipment given in ISO 10012 may be used for guidance. |
| | | 4.11.2.b.1 | Calibration Services<br>Calibration of inspection, measuring or test equipment shall be conducted by a qualified in-house laboratory (see 4.10.6), a qualified commercial/independent laboratory (see 4.10.7), or a customer-recognized government agency. The laboratory scope shall include the calibration of such equipment. Commercial /independent calibration facilities shall be accredited to ISO/IEC Guide 25 or national equivalent, e.g. assessment by an OEM customer or an OEM customer-approved second party, that they meet the intent of ISO/IEC Guide 25 or national equivalent. **Note:** Where a qualified laboratory does not exist for a given piece of equipment, calibration services may be performed by original equipment manufacturer. |

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| 7.6.1 | Measurement System Analysis<br>Statistical studies shall be conducted to analyze the variation present in the results of each type of measuring and test equipment system. This requirement shall apply the measurement systems referenced in the control plan. The analytical methods and acceptance criteria used shall conform to those in customer reference manuals on measurement systems analysis. Other analytical methods and acceptance criteria may be used if approved by the customer. | 4.11.4 | Measure System Analysis<br>Appropriate statistical studies shall be conducted to analyze the variation present in the results of each type of measuring and test equipment system. This requirement shall apply to measurement systems referenced in the Control Plan (see 4.2.3.7). The analytical methods and acceptance criteria used should conform to those in the Measurement Systems Analysis reference manual (e.g. bias, linearity, stability, repeatability and reproducibility studies). Other analytical methods and acceptance criteria may be used if approved by the customer. |
| | | 4.12 | Inspection and Test Status<br>The inspection and test status of product shall be identified by suitable means, which indicates the conformance or nonconformance of product with regard to inspection and tests performed. The identification of inspection and test status shall be maintained, as defined in the quality plan (Control Plan) and/or documented procedures, throughout production, installation and servicing of the product to ensure that only product that has passed the required inspections and tests (or released under an authorized concession (see 4.13.2) (is dispatched, used or installed. **Note:** Location of product in the normal production flow does not constitute suitable indication of inspection and test status unless inherently obvious (e.g. material in automated production transfer process). Latitude is permitted, beyond automated production transfer processes, if the test status is clearly identified, documented, and achieves the designated purpose. |
| | | 4.12.1 | Supplemental Verification<br>When required by the customer, additional verification/identification requirements shall be met (e.g. new model introduction). |
| 7.6.2 | Calibration/Verification Records<br>Records of the calibration/verification activity for all gauges, measuring and test equipment, needed to provide evidence of conformity of product to determined requirements, including employee and customer-owned equipment, shall include; * equipment identification, including the measurement standard against which the equipment is calibrated, * revisions following engineering changes, * any out-of-specification readings as received for calibration/verification, * an assessment of the impact of out-of-specification condition, * statements of conformity to specification after calibration/verification, and * notification to the customer if suspect product or material has been shipped. | 4.11.3 | Inspection, Measuring, and Test Equipment Records<br>Records of calibration (see Glossary) activity for all gages, measuring, test equipment, including those owned by employees, shall include * Revisions following engineering changes (if appropriate); * Any out of specification reading as received for calibration; * Statements of conformance to specification after calibration; * Notification to the customer if suspect material or product (see Glossary) may have been shipped. |

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| 7.6.3 | Laboratory Requirements | | |
| 7.6.3.1 | Internal Laboratory<br>An organization's internal laboratory facility shall have a defined scope that includes its capability to perform the required inspection, test or calibration services. The laboratory scope shall be included in the quality management system documentation. The laboratory shall specify and implement, as a minimum, technical requirements for * adequacy of the laboratory procedures, * competency of the laboratory personnel, * testing of the product, * capability to perform these services correctly, traceable to the relevant process standard (such as ASTM, EN, etc.) and * review of the related records. **Note:** Accreditation to ISO/IEC 17025 may be used to demonstrate supplier in-house laboratory conformity to this requirement but is not mandatory. | 4.10.6.1 | Laboratory Quality Systems<br>The laboratory (supplier's testing facility - chemical, metallurgical, reliability, test validation, e.g. fastener labs) shall have a laboratory scope (see Glossary). The laboratory shall document all its policies, systems, programs, procedures, instructions and findings which enable the laboratory to assure the quality of the tests or calibration results it generates within the scope (see 4.2.1). **Note:** Accreditation of supplier facilities to ISO/IEC Guide 25 or national equivalent is not required by, nor does it satisfy, all QS-9000 requirements for a laboratory. Therefore, the laboratory should be included in the on-site audits. |
| | | 4.10.6.2 | Laboratory Personnel<br>The personnel making professional judgment with reference to testing and/or calibration shall have appropriate background and experience (see 4.1.2.2). **Note:** Such background should include both theoretical and recent practical experience. |
| | | 4.10.6.3 | Laboratory Product Identification and Testing<br>The laboratory shall have procedures for the receipt, identification, handling, protection and retention or disposal of test samples and/or calibration equipment items, including all provisions necessary to protect the integrity of the items (see 4.15). The items shall be retained until final data is complete throughout the life of the item in the laboratory, enabling traceability from final data to raw data (see Glossary and 4.10.1). |
| | | 4.10.6.4 | Laboratory Process Control<br>The laboratory shall monitor, control and record (see 4.16) environmental conditions as required by relevant specifications or where they may influence the quality of results. Requirements for environmental conditions (e.g. biological sterility, dust, electromagnetic interference, radiation, humidity, electrical supply, temperature, and sound and vibration levels) shall be established and maintained as appropriate to the technical activities concerned. |

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| | | 4.10.6.5 | Laboratory Testing and Calibration Methods<br>The laboratory shall use test and/or calibration methods, including those for sampling, which meet the needs of the customer and are appropriate for the tests and/or calibrations it undertakes, preferably the current issue of those published as international, regional, or national standards (see 4.11). The laboratory shall verify its capability to perform to the standard specifications before carrying out such work. When it is necessary to employ methods not covered by standard specifications, these shall be subject to agreement with the customer. |
| | | 4.10.6.6 | Laboratory Statistical Methods<br>Appropriate statistical techniques should be applied to verification activities whose deliverables are data (see 4.20). |
| 7.6.3.2 | External Laboratory<br>External/commercial/independent laboratory facilities used for inspection, test or calibration services by the organization shall have a defined laboratory scope that includes the capability to perform the required inspection, test or calibration, and either; * there shall be evidence that the external laboratory is acceptable to the customer, or * the laboratory shall be accredited to ISO/EC 17025 or equivalent. **Note 1:** Such evidence may be demonstrated by customer assessment, for example, or by customer-approved second-party assessment that the laboratory meets the intent of ISC/EC 17025 or national equivalent. **Note 2:** When a qualified laboratory is not available for a given piece of equipment, calibration services may be performed by the equipment manufacturer. In such cases, the organization should ensure that the requirements listed in 7.6.3.1 have been met. | 4.10.7 | Accredited Laboratories<br>Commercial/independent laboratory facilities used by the supplier shall be accredited laboratory facilities. Reference the customer-specific pages of this document and the Glossary. **Note:** Commercial/independent laboratories cannot be registered to QS-9000. **Note:** For further guidance on Element 4.10.7, see ISO/IEC Guide 25 or national equivalent. |
| **8** | **Measurement, Analysis and Improvement** | | |
| 8.1 | General<br>The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed: a) to demonstrate conformity of the product, b) to ensure conformity of the quality management system, and c) to continually improve the effectiveness of the quality management system. This shall include determination of applicable methods, including statistical techniques, and the extent of their use. | | |

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| 8.1.1 | Identification of Statistical Tools<br>Appropriate statistical tools for each process shall be determined during advance quality planning and included in the control plan. | 4.20.1 | Identification of Need<br>The supplier shall identify the need for statistical techniques required for establishing, controlling and verifying process capability and product characteristics. |
| | | 4.20.2 | Procedures<br>The supplier shall establish and maintain documented procedures to implement and control the application of the statistical techniques identified in 4.20.1. |
| | | 4.20.3 | Selection of Statistical Tools<br>Statistical tools, if applicable, for each process should be determined during advanced quality planning and shall be included in the Control Plan. |
| 8.1.2 | Knowledge of Basic Statistical Concepts<br>Basic statistical concepts, such as variation, control (stability), process capability and over-adjustment shall be understood and utilized throughout the organization. | 4.20.4 | Knowledge of Basic Statistical Concepts<br>Basics concepts such as variation, control (stability), capability, and over adjustment should be understood throughout the supplier's organization as appropriate. Consult the Statistical Process Control reference manual. |
| 8.2 | Monitoring and Measurement | | |
| 8.2.1 | Customer Satisfaction<br>As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined. **Note:** Consideration should be given to both internal and external customers. | | |
| 8.2.1.1 | Customer Satisfaction - Supplemental<br>Customer satisfaction with the organization shall be monitored through continual evaluation of performance to the realization processes. Performance indicators shall be based on objective data and include, but not limited to: - delivered part quality performance - customer disruptions including field actions - delivery schedule performance (including incidents of premium freight), and - customer notification related to quality or delivery issues. The organization shall monitor the performance of manufacturing processes to demonstrate compliance with customer requirements for product quality and efficiency of the process. | | |

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| **Element** | **Title** | **Element** | **Title** |
| 8.2.2 | Internal Audit<br>The organization shall conduct internal audits at planned intervals to determine whether the quality management system a) conforms to the planned arrangements (see 7.1), to the requirements this International Standard and to the quality management system requirements established by the organization, and b) is effectively implemented and maintained. An audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. The responsibilities and requirements for planning and conduction audits, and for reporting results and maintaining records (see 4.2.4) shall defined in a documented procedure. The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes.<br>Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2). **Note:** See 10011-1, ISO 10011-2 and ISO 10011-3 for guidance. | 4.17 | Internal Quality Audits<br>The supplier shall establish and maintain documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system. Internal quality audits shall be scheduled on the basis of the status and importance of the activity to be audited and shall be carried out by personnel independent of those having direct responsibility for the activity being audited. **Note:** "Activity" can refer to departments, areas, processes, functions, etc. in a company. **Note:** There is no specified checklist that MUST be used for internal auditing purposes. The results of the audits shall be recorded (see 4.16) and brought to the attention of the personnel having responsibility in the area audited. The management personnel responsible for the area shall take timely corrective action on the deficiencies found during the audit. Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken (see 4.16).<br>**Note 20:** The results of internal quality audits form an integral part of the input to management review activities (see 4.1.3). **Note 21:**Guidance on quality system audits is given in ISO 10011. |
| 8.2.2.1 | Quality Management System Audit<br>The organization shall audit its quality management system to verify compliance with this Technical Specification and any additional quality management system requirements. | | |
| 8.2.2.2 | Manufacturing Process Audit<br>The organization shall audit each manufacturing process to determine its effectiveness. | | |
| 8.2.2.3 | Product Audit<br>The organization shall audit products at appropriate stages of production and delivery to verify conformity to all specified requirements, such as product dimensions, functionality, packaging and labeling, at a defined frequency. | | |
| 8.2.2.4 | Internal Audit Plans<br>Internal audits shall cover all quality management related processes, activities and shifts, and shall be scheduled according to an annual plan. When internal/external nonconformities or customer complaints occur, the audit frequency shall be appropriately increased. **Note:** Specific checklists should be used for each audit. | 4.17.1 | Internal Audit Schedules<br>Internal auditing should cover all shifts and be conducted according to an audit schedule updated annually. When internal/external nonconformance or customer complaints occur, the planned audit frequency should be increased. |

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| **Element** | **Title** | **Element** | **Title** |
| 8.2.2.5 | Internal Auditor Qualification<br>The organization shall have internal auditors who are qualified to audit the requirements of this Technical Specifications (see 6.2.2.2). | | |
| 8.2.3 | Monitoring and Measurement of Processes<br>The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product. | | |
| 8.2.3.1 | Monitoring and Measurement of Manufacturing Processes<br>The organization shall perform process studies on all new manufacturing (including assembly or sequencing) processes to verify process capability and to provide additional input for process control. The results of process studies shall be documented with specifications, where applicable, for means of production, measurement and test, and maintenance instructions. These documents shall include objectives for manufacturing process capability, reliability, maintainability and availability, as well as acceptance criteria. The organization shall maintain manufacturing process capability or performance as specified by the customer part approval process requirements. The organization shall ensure that the control plan and process flow diagram are implemented, including adherence to the specified; * measurement techniques, * sampling plans, * acceptance criteria, * reaction plans when acceptance criteria are not met. Significant process events, such as tool change or machine repair, shall be recorded.<br>The organization shall initiate a reaction plan from the control plan for characteristics that are either not statistically capable or unstable. This reaction plan shall include containment of product and 100% inspection as appropriate. A corrective action plan shall then be completed by the organization, indicating specified timing and assigned responsibilities to assure that the process becomes stable and capable. The plans shall be reviewed with and approved by the customer when so required. The organization shall maintain records of effective dates of process changes. | 4.9.2 | Maintaining Process Control<br>The supplier shall maintain (or exceed) process capability or performance as approved via PPAP. To accomplish this, the supplier shall ensure that the Control Plan and Process Flow Diagram (see Glossary) are implemented, including but not limited to, adherence to the specified: * Measuring technique * Sampling plans * Acceptance criteria (see 4.10.1.1) * Reaction plans when the acceptance criteria is not met See the Advanced Product Quality Planning and Control Plan reference manual. Significant process events (e.g. tool change, machine repair) should be noted on the control charts (see 4.16) When process and/or product data indicate a high degree of capability (e.g. Cpk/Ppk > 3), the supplier may revise the Control Plan, as appropriate (See PPAP section II). The supplier shall initiate the appropriate reaction plan from the Control Plan for characteristics which are identified on the Control Plan and are either unstable or non-capable. Reaction plans should include containment of process output and 100% inspection.<br>A supplier corrective action plan shall then be completed indicating specific timing and assigned responsibilities to assure that the process becomes stable and capable (see 4.10.1.1). The plans are to be reviewed with and approved by the customer when so required. |

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| **Element** | **Title** | **Element** | **Title** |
| | | 4.9.3 | Modified Process Control Requirements<br>In some cases, the customer may require either higher or lower capability or performance (see 4.9.2) requirements. In these cases, the Control Plan shall be annotated accordingly (i.e. in the Product/Process Specification/Tolerance column of the suggested APQP Control Plans). |
| 8.2.4 | Monitoring and Measurement of Product<br>The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4). Product release and service delivery shall not proceed until all planned arrangements (see 7.1) have been satisfactory completed, unless otherwise approved by a relevant authority, and where applicable by the customer. **Note:** When selecting product parameters to monitor compliance to specified internal and external requirements, the organization determines the types of product characteristics, leading to; * the types of measurement, * suitable measurement means, and * the capability and skills required. | 4.10.1 | General<br>The suppler shall establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for the product is met. The required inspection and testing, and the records to be established, shall be detailed in the quality plan or documented procedures. |
| 8.2.4.1 | Layout Inspection and Functional Testing<br>A layout inspection and a functional verification to applicable customer engineering material and performance standards shall be performed for each product as specified in the control plans. Results shall be available for customer review. **Note:** Layout inspection is the complete measurement of all product dimensions shown on the design records. | 4.10.4.1 | Layout Inspection and Functional Testing<br>A layout inspection and a functional verification (to applicable customer engineering material and performance standard(s) shall be performed for all products at a frequency established by the customer (see Section II). Results shall be available for customer review. |
| | | 4.10.4.2 | Final Product Audit<br>The supplier shall conduct audits of packaged final product to verify conformance to all specified requirements (e.g. product, packaging, labeling) at an appropriate frequency. **Note:** This activity, also known as a "dock audit", is based upon sampling and is generally performed after final inspection but prior to shipment. Where customer PPM requirements are met, the frequency of Final Product Audits may be reduced. |

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| **Element** | **Title** | **Element** | **Title** |
| | | 4.10.5 | Inspection and Test Records<br>The supplier shall establish and maintain records which provide evidence that the product has been inspected and/or tested. These records shall show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria. Where the product fails to pass any inspection and/or test, the procedures for the control of nonconforming product shall apply (See 4.13). Records shall identify the inspection authority responsible for the release of the product (see 4.16). |
| | | 4.10.6 | Supplier Laboratory Requirements<br>**Note:** Element 4.10.6 applies to supplier in-house laboratory facilities, not inspection or testing performed outside of a laboratory facility. |
| 8.2.4.2 | Appearance Items<br>For organizations manufacturing parts designed by the customer as "appearance items", the organization shall provide * Appropriate resources including lighting for evaluation * masters for colour, grain, gloss, metallic brilliance, texture, distinctness of image (DOI), as appropriate * maintenance and control of appearance masters and evaluation equipment, and * verification that personnel that personnel making appearance evaluations are competent and qualified to do so. | 4.9.6 | Appearance Items<br>For suppliers manufacturing parts designated by the customer as "Appearance Items", the suppler shall provide: * Appropriate lighting for evaluation areas * Masters for color, grain, gloss, metallic brilliance, texture, distinctness of image (DOI) as appropriate * Maintenance and control of appearance masters and evaluation equipment * Verification that personnel making appearance evaluations are qualified to do so. |
| 8.3 | Control of Nonconforming Product<br>The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure. The organization shall deal with nonconforming product by one or more of the following ways; a) by taking action to eliminate the detected nonconformity; b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; c) by taking action to preclude its original intended use or application. Records of the nature of nonconformities and any subsequent actions take, including concessions obtained, shall be maintained (see 4.2.4). When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements. When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effect. Of the nonconformity. | 4.13.1 | General<br>The supplier shall establish and maintain documented procedures to ensure that product that does not conform to specified requirements is prevented from unintended use or installation. This control shall provide for identification, documentation, evaluation, segregation (when practical), disposition of nonconforming product, and or notification to the functions concerned. |

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| **Element** | **Title** | **Element** | **Title** |
| 8.3.1 | Control of Nonconforming Product – Supplemental<br>Product with unidentified or suspect status shall be classified as nonconforming product (see 7.5.3). | 4.13.1.1 | Suspect Material or Product<br>The element shall apply to suspect material of product (see Glossary) as well as nonconforming product. |
| | | 4.13.1.2 | Visual Identification<br>The supplier shall provide visual identification of any nonconforming or suspect material (see Glossary) or product, and any quarantine areas. |
| | | 4.13.2 | Review and Disposition of Nonconforming Product<br>The responsibility for review and authority for the disposition of nonconforming product shall be defined. Nonconforming product shall be reviewed in accordance with documented procedures. It may be: a) reworked to meet the specified requirements, b) accepted with or without repair by concession, c) re-graded for alternative applications, or d) rejected scrapped. Where required by the contract, the proposed use of repair or product (see 4.13.2b), which does not conform to specified requirements shall be reported for concession to the customer or customer's representative. The description of nonconformity that has been accepted, and of repairs, shall be recorded to denote the actual condition. (see 4.16). Repaired and/or reworked product shall be reinspected in accordance with the quality plan (Control Plan) and/or documented procedure. |
| | | 4.13.2.1 | Prioritized Reduction Plans<br>The supplier shall quantify and analyze nonconforming product and establish a prioritized reduction plan. Progress toward the plan should be tracked. |
| 8.3.2 | Control of Reworked Product<br>Instructions for rework, including re-inspection requirements, shall be accessible to and utilized by the appropriate personnel. | 4.13.3 | Control of Reworked Product<br>Rework (see Glossary) instructions shall be accessible and utilized by the appropriate personnel in their work areas. There shall be no rework visible on the exterior of the products supplied for service applications without prior approval of the customer's service parts organization. **Note:** A Service application refers to parts and materials provided to dealers and other distribution channels for the purpose of vehicle maintenance and repair. |
| 8.3.3 | Customer Information<br>Customers shall be informed promptly in the event that nonconforming product has been shipped. | 4.1.2.5 | Information to Management<br>Management with responsibility and authority for corrective actions shall be promptly informed of products or processes which become noncompliant with specified requirements. |

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| **Element** | **Title** | **Element** | **Title** |
| 8.3.4 | Customer Waiver<br>The organization shall obtain a customer concession or deviation permit prior to further processing whenever the product or manufacturing process is different from that which is currently approved. The organization shall maintain a record of the expiration date or quantity authorized. The organization shall also ensure compliance with the original or superseding specifications and requirements when the authorization expires. Material shipped on an authorization shall be properly identified on each shipping container. This applies equally to purchase product. The organization shall agree with any requests from suppliers before submission to the customer. | 4.13.4 | Engineering Approved Product - Authorization<br>The supplier shall obtain prior customer authorization whenever the product or process is different from that currently approved (see Production Part Approval Process manual). This applies equally to products and services purchased from subcontractors. The supplier shall concur with any requests by a subcontractor before submission to the customer. The supplier shall maintain a record of the expiration date or quantity authorized. The supplier shall also ensure compliance with the original or superseding specifications and requirements when the authorization expires. Material shipped on an authorization shall be properly identified on each shipping container. |
| 8.4 | Analysis of Data<br>The organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data shall provide information relating to; a) customer satisfaction (see 8.2.1; b) conformity to product requirement (see 7.2.1); c) characteristics and trends of processes and products including opportunities for preventive action; and d) suppliers. | 4.1.5 | Analysis and Use of Company Level Data<br>The supplier shall document trends in quality, operational performance (productivity, efficiency, effectiveness, cost of poor quality) and current quality levels for key product and service features. These should be compared with those of competitors and/or appropriate benchmarks. Trends in data and information should be compared with progress toward overall business objectives and lead to action to support: 1) Development of priorities for prompt solutions to customer-related problems, 2) Determination of key customer-related trends and correlations to support status review, decision-making and longer-term planning. |
| 8.4.1 | Analysis and Use of Data<br>Trends in quality and operational performance shall be compared with progress toward objectives and lead to action to support the following: * development of priorities for prompt solutions to customer-related problems; * determination of key customer-related trends and correlation for status review, decision-making and longer term planning; * an information system for the timely reporting of product information arising from usage. **Note:** Data should be compared with those of competitors and/or appropriate benchmarks. | | |

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| **Element** | **Title** | **Element** | **Title** |
| 8.5 | Improvement | | |
| 8.5.1 | Continual Improvement<br>The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. | 4.2.5.1 | General<br>The supplier shall continuously improve in quality, service (including timing delivery) and price that benefit all customers. This requirement does not replace the need for innovative improvements. **Note:** A continuous improvement philosophy should be fully deployed throughout the supplier's organization. Continuous improvement shall extend to product characteristics with the highest priority on special characteristics. **Note:** Cost elements or price should be one of the key indicators within a continuous improvement system. **Note:** For those product characteristics and process parameters that can be evaluated using variable data, continuous improvement means optimizing the characteristics and parameters at a target value and reducing variation around that value. For those product characteristics and process parameters that can only be evaluated using attribute data, continuous improvement is not possible until characteristics are conforming. If attribute data results do not equal zero defects, it is by definition nonconforming product (see 4.10.1.1, 4.13, 4.14). Improvements made in these situations are by definition corrective actions, not continuous improvement. The supplier shall develop a prioritized action plan for continuous improvement in processes that have demonstrated stability, acceptable capability and performance. **Note:** Processes with unacceptable capability/performance require corrective action (see 4.14.2). |
| 8.5.1.1 | Continual Improvement of the Organization<br>The organization shall define a process for continual improvement (see examples in Appendix B of ISO 9004:2000). | | |
| 8.5.1.2 | Manufacturing Process Improvement<br>Manufacturing process improvement shall continually focus upon control and reduction of variation in product characteristics and manufacturing process parameters. **Note:** Controlled characteristics are documented in the control plan. **Note 2:** Continual improvement is implemented once manufacturing processes are capable and stable, or product characteristics are predictable and meet customer requirements. | 4.2.5.2 | Quality and Productivity Improvements<br>The supplier shall identify opportunities for quality and productivity improvement and implement appropriate improvement projects. **Note:** Examples of situations which might lead to improvement projects are: * Unscheduled machine downtime * Machine setup, die change and machine changeover times * Excessive cycle time * Scrap, rework and repair * Non value-added use of floor space * Excessive variation * Less than 100% first run capability * Process averages not centered on target values (bilateral tolerance) * Testing requirements not justified by accumulated results * Waste of labor and materials * Cost of poor quality * Difficult assembly or installation of the product * Excessive handling and storage * New target values to optimize customer processes * Marginal measurement system capability (See MSA and ISO 10012-1) * Customer dissatisfaction, e.g. complaints, repairs, returns, mis-shipments, incomplete orders, customer plant concerns, warranty, etc. |

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| **Element** | **Title** | **Element** | **Title** |
| | | 4.2.5.3 | Techniques for Continuous Improvement<br>The supplier shall demonstrate knowledge of appropriate continuous improvement measures and methodologies and shall use those that are appropriate. **Note:** The following list shows examples of possible techniques which might be used. There may be many other methods which meet specific supplier needs more appropriately. |
| 8.5.2 | Corrective Action<br>The organization shall take action to eliminate the cause of nonconformities in order to prevent reoccurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for; a) reviewing nonconformities (including customer complaints); b) determining the causes of nonconformities; c) evaluating the need for action to ensure tat nonconformities do no recur; d) determining and implementing action needed; e) records of the results of action taken (see 4.2.4); and f) reviewing corrective action taken. | 4.14.2 | Corrective Actions<br>The procedure for corrective action shall include; a) the effective handling of customer complaints and reports of product nonconformities; b) investigation of the cause of nonconformities relating to product, process and quality system, and recording the results of the investigation (see 4.16); c) determination of the corrective action needed to eliminate the cause of nonconformities; d) application of controls to ensure that corrective action is taken and that it is effective. |
| 8.5.2.1 | Problem Solving<br>The organization shall have a defined process for problem solving leading to root cause identification and elimination. If a customer-prescribed problem-solving format exists, the organization shall use the prescribed format. | 4.14.1.1 | Problem Solving Methods<br>A supplier shall use disciplined problem solving methods when an internal or external nonconformance to specification or requirement occurs. When external nonconformances occur, the supplier shall respond in a manner prescribed by the customer. Refer to the customer documents. |
| | | 4.14.1 | General<br>The supplier shall establish and maintain documented procedures for implementing corrective and preventive action. Any corrective or preventive action taken to eliminate the cause of actual or potential nonconformities shall be to a degree appropriate to the magnitude of problems and commensurate with the risks encountered. The supplier shall implement and record any changes to the documented procedures resulting from corrective and preventive actions. |
| 8.5.2.2 | Error-proofing<br>The organization shall use error—proofing methods in their corrective action process. | 4.2.3.6 | Mistake Proofing<br>The supplier shall utilize appropriate mistake proofing methodologies during the planning of processes, facilities, equipment and tooling. |
| | | 4.14.1.2 | Mistake Proofing<br>The supplier shall use mistake-proofing methodology in their corrective and preventive action process to a degree appropriate to the magnitude of the problems and commensurate with the risks encountered. |

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| **Element** | **Title** | **Element** | **Title** |
| 8.5.2.3 | Corrective Action Impact<br>The organization shall apply to other similar processes and products the corrective actions, and controls implemented, to eliminate the cause of nonconformity. | 4.14.2.2 | Corrective Action Impact<br>Where applicable the supplier shall apply the corrective action taken, and controls implemented, to eliminate the cause of nonconformity to other similar processes and products. |
| 8.5.2.4 | Rejected Product Test/Analysis<br>The organization shall analyze parts rejected by the customer's manufacturing plants, engineering facilities and dealerships. The organization shall minimize the cycle time of this process. Records of these analyses shall be kept and made available upon request. The organization shall perform analysis and initiate corrective action to prevent recurrence. **Note:** Cycle time related to rejected product analysis should be consistent with the determination of root cause, corrective action and monitoring the effectiveness of implementation. | 4.14.2.1 | Returned Product Test/Analysis<br>The supplier shall analyze parts returned from the customer's manufacturing plants, engineering facilities, and dealerships. Records of these analyses shall be kept and made available upon request. The supplier shall perform effective analysis and where appropriate, initiate corrective action and process changes to prevent reoccurrence. |
| 8.5.3 | Preventive Action<br>The organization shall determine action to eliminate the cause of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. A documented procedure shall be established to define requirements for; a) determining potential nonconformities and their causes; b) evaluate the need for action to prevent occurrence of nonconformities; c) determining and implementing action needed; d) records of results of actions taken (see 4.2.4); and e) reviewing preventive action taken. | 4.14.3 | Preventive Actions<br>The procedure for preventive action shall include: a) the use of appropriate sources of information such as processes and work operations which affect product quality, concessions, audit results, quality records, service reports and customer complaints to detect, analyze and eliminate potential causes of nonconformities; b) determination of the steps needed to deal with any problems requiring preventive action; c) initiation of preventive action and application of controls to ensure that it is effective; d) ensuring that relevant information on actions taken is submitted for management review (see 4.1.3). |
| | | 4.1 | Management Responsibility |
| | | 4.1.2<br>4.1.6.1 | Organization<br>A supplier shall notify their certification body/registrar in writing within five (5) working days when a customer places the site in any of the following statuses; * Chrysler "Needs Improvement" * Ford Q-1 Revocation * General Motors Level II Containment. |
| | | 4.2 | Quality Systems |
| | | 4.2.4 | Product Approval Process |
| | | 4.2.5 | Continuous Improvement |
| | | 4.2.6 | Facility and Tooling Management |

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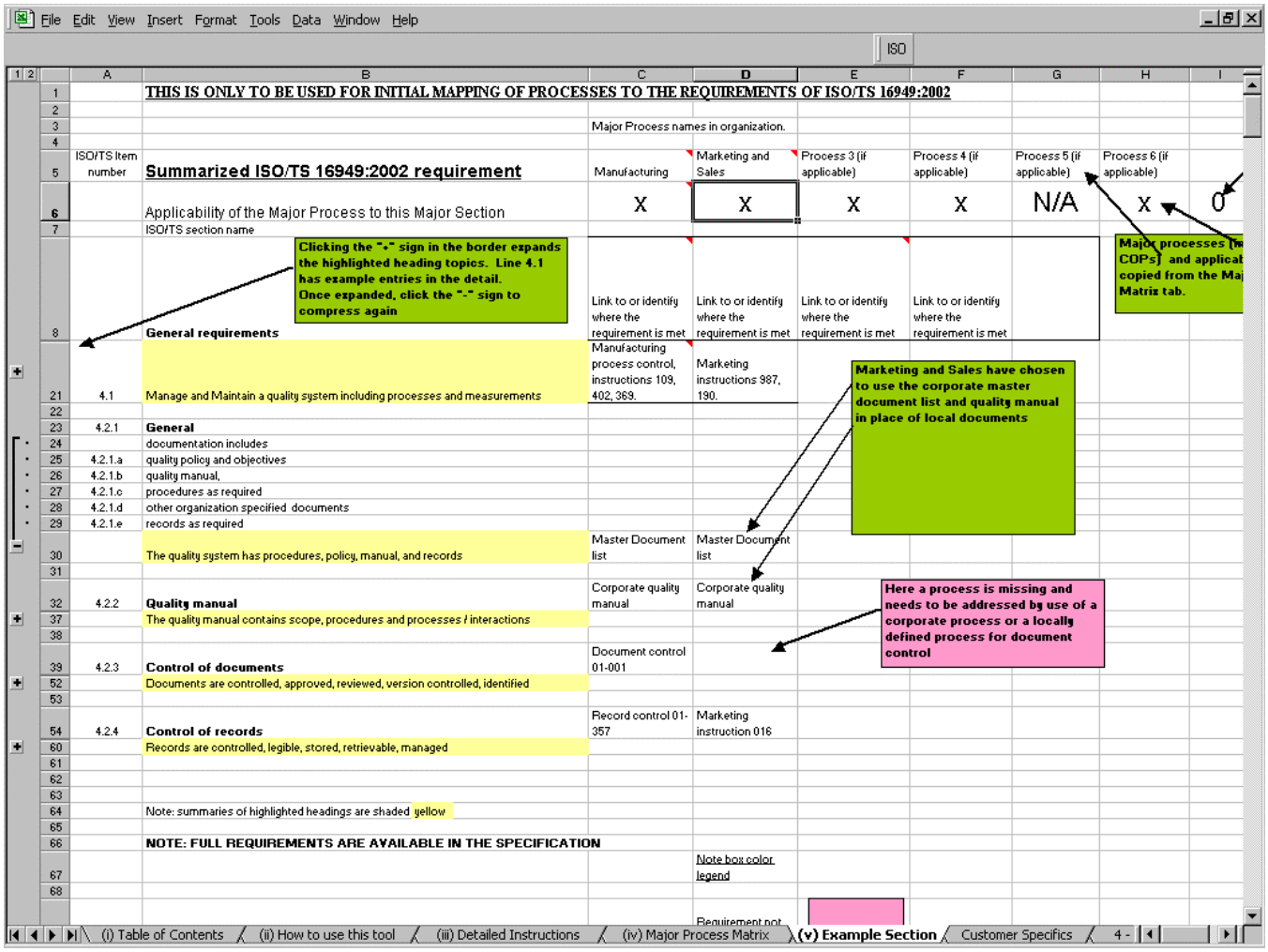
| **Element** | **Title** | **Element** | **Title** |
| | | 4.6 | Purchasing<br><br>The supplier shall; a) inspect the product as required by the quality plan (Control Plan) and/or document procedures; b) hold product until the required inspection and tests have been received and verified, except when product is release under positive-recall procedures (see 4.10.2.3). Release under positive-recall procedures shall not preclude the activities outlined in 4.10.3a); c) direct process activities toward defect prevention methods, such as statistical process control, mistake proofing, visual controls, rather than defect detection. |
| | | 4.13 | Control of Nonconforming Material |
| | | 4.14 | Corrective and Preventive Action |
| | | 4.15 | Handling, Storage Packaging, Preservation and Delivery |
| | | 4.20 | Statistical Techniques |
| | | 4.1.6.1 | Certification Body/Registrar Notification |
| | | 4.3 | Contact Review |
| | | 4.10 | Inspection and Test |
| | | 4.11 | Control of Inspection, Measuring and Test Equipment |

# APPENDIX C – PROCESS IDENTIFICATION TOOL




ISO/TS 16949:2002 clause 4.1a states, "The organization shall identify 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 16949:2002 are met.

The *Process Identification Tool* (a Microsoft Excel-based mapping tool) provides step-by-step instructions on how to identify the processes in an organization and how to map those internal processes to the requirements of ISO/TS 16949:2002.

The Process Identification Tool is located on the AIAG Web site:
http://www.aiag.org/isots_tool/isots_tool.asp

# APPENDIX D – RECOMMENDED TRAINING

ISO/TS 16949:2002 Recommended Training offered through AIAG:

### Understanding ISO/TS 16949:2002

This course will provide the best overview for all personnel directly involved in the implementation process. Through individual participation and group activities, learn the requirements of ISO/TS 16949:2002, including the process approach to management. Participate in activities that create an understanding of how the process approach, in conjunction with the intents and requirements, can provide benefits for your organization and, most importantly, for your customers.

### How to Transition to ISO/TS 16949:2002

This course will provide you with a basic understanding of ISO/TS 16949:2002, including the process approach to quality system management. You will identify the core support and management processes of your own organization, plus the processes' sequence, interaction and measurement needs (ISO/TS requirements). In conjunction with process identification, you will complete a gap analysis to indicate your present system's status in relationship to a compliant ISO/TS 16949:2002 quality management system.

### Fundamentals of ISO/TS 16949:2002 Internal Quality Auditing

Through individual participation and group activities, acquire the necessary skills to conduct successful process approach internal quality system audits for ISO/TS 16949:2002. This course includes a simulated process approach audit, based on an actual organization that has implemented a process-based management system, as required by ISO/TS 16949:2002.

### Transitioning Internal Auditors to ISO/TS 16949:2002

For internal auditors transitioning from QS-9000 or ISO/TS 16949:1999 to ISO/TS 16949:2002, this course focuses on the skills necessary to conduct successful internal quality system audits for ISO/TS 16949:2002, including the process approach to management and the process approach to auditing. This course also includes a brief overview of the ISO/TS 16949:2002.

### ISO/TS 16949:2002 Supplier Auditor Certification

This intensive four-day course and certification exam is the "supplier version" of the official ISO/TS 16949 third-party auditor certification course. You will gain knowledge of ISO/TS 16949:2002 by focusing on the differences between this standard and ISO 9001/QS-9000. ISO/TS 16949:2002 knowledge is linked to the appropriate use of the core tools (i.e., APQP, FMEA, PPAP, MSA, and SPC) in an ISO/TS 16949 quality system. You will be evaluated through an oral examination, written examination, and a performance assessment; however, the supplier course evaluations have been modified to meet the particular needs of an internal or second-party auditor.

**RAB-Accredited ISO 9001:2000 Lead auditor Training with AIAG ISO/TS 16949:2002 supplier Auditor Certification**

The only ISO/TS 16949:2002 training course that combines the AIAG's Supplier Auditor Certification Training with Plexus Corporation's RAB-Accredited ISO 9001:2000 Lead Auditor Training, allowing you to attain two certificates in one course. Included in the course is detailed instruction on the customer-oriented processes (COPs), a review of the new process-approach auditing methodology that is utilized in the Certification Body auditor training, and a simulated audit. This course also includes a written examination and performance evaluation.

# APPENDIX E – IATF CONTACT INFORMATION

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# APPENDIX F – ISO/TS 16949:2002 MANUALS

The ISO/TS 16949:2002 4 Pack is comprised of the following documents:

### ISO/TS 16949:2002 Quality Management Systems - Particular requirements for the application of ISO 9001:2000 for automotive production and relevant service part organizations

The ISO/TS 16949:2002 aligns with ISO 9001:2000 (released December 2000). Subscribing members to the International Automotive Task Force (IATF) will recognize certification to ISO/TS 16949:2002, in accordance with the IATF registration scheme and customer-specific requirements. The IATF is the recognizing body for the ISO/TS 16949:2002 requirements document and registration scheme.

This document should be used as a resource to identify the requirements of ISO/TS 16949:2002 to be complied with for certification.

### IATF Quality System Assessment Checklist – Checklist to ISO/TS 16949:2002

The Quality System Assessment checklist to ISO/TS 16949:2002 is to be used as a guide in auditing the requirements of ISO/TS 16949:2002. Clauses in ISO/TS 16949:2002 are referenced in the requirements column. Automotive requirements are italicized.

The intent of the Automotive Process Approach to auditing for ISO/TS 16949:2002 is that the audit not be conducted using an element by element or section driven checklist. Therefore, the checklist should be used as a tool to identify the completeness of the audit; and may be used after the audit, but not during the audit. In other words, all applicable requirements of ISO/TS 16949:2002 are to be audited to an identified process as explained in the manual.

This document also identifies the activities that must be included in audit planning during audit preparation.

### Automotive Certification Scheme for ISO/TS 16949:2002 - Rules for Achieving IATF Recognition, First Edition

This document contains the rules for IATF recognized ISO/TS 16949:2002 certification bodies. The document identifies IATF requirements for: certification body recognition, certification body audit process, certification body auditor qualifications, certificate content, and other requirements. All requirements are binding on IATF recognized certification bodies for the ISO/TS 16949:2002 certification scheme.

This document will be useful in understanding the IATF's automotive certification scheme for ISO/TS 16949:2002 and should be considered when an organization selects its certification body.

### IATF Guidance to ISO/TS 16949:2002

The IATF Guidance is to be used for reference only. It is not intended to be a requirement for certification. It supports ISO/TS 16949:2002, with examples, applications, practices, or explanation.

# APPENDIX G – HEAT TREAT PROCESS EXAMPLE

The purpose of this Appendix is to provide an example of the four attributes of a process in the case of the development of the re-arrangement of a heat treat process in an existing manufacturing line:

- Management Responsibility
- Resource Management
- Product Realization
- Measurement, Analysis and Improvement

Process: Designing a heat treat sequence.

Product: New design of a manufacturing line.

Customer requirement: All parts made by the line meet print specifications at a specified capability.

Customer: The manufacturing facility.

### Management Responsibility

*Definition: represents the action of management oversight to ensure that all process steps contribute to the fulfillment of customer requirements.*

ABC's management realizes that although they have the necessary equipment at the site, they will need to rearrange their manufacturing sequence to meet customer XYZ's requirements by moving the heat treat process to after the coating operation. Currently, the heat treat process is before the plating operation.

Customer XYZ approves the re-arrangement of a manufacturing process at supplier organization ABC.

Customer build timing demands that the change be implemented within 10 days to meet the plant requirements and have no negative cost implications.

ABC management engages the employees to design the process change while meeting the following:

- statutory and regulatory requirements
- alignment with the organization's quality policy
- ensuring that all quality objectives are met when this change is implemented (individual process, customer, entire supplier organization)
- management review of the success or failure of the process change and incorporating lessons learned for similar future changes

## Resource Management

*Definition: the provision to the process of appropriate and sufficient resources (skills, personnel, equipment, and infrastructure) to permit fulfillment of customer satisfaction.*

Management assembles and authorizes a team to develop the modified manufacturing process. Members are selected from internal departments based on their knowledge of the equipment, process flows, design techniques and familiarity with customer requirements. The team selects appropriate tools for this design project (e.g., CAD and computer resources). No external resources were necessary for this project.

In meeting customer requirements, the team must also consider contingencies and the work environment (as outlined by section 6 of ISO/TS 16949:2002). On the first day, a key team member is pulled away to work on another project. The team replaces the missing person by pulling someone off of another project.

**Note:** Knowledge may be developed by either training or experience.

## Product Realization

*Definition: includes the steps for planning, understanding customer requirements, design, procurement, production quality control, and logistics necessary to produce the intended product.*

In order to meet customer requirements, the expected output must be clearly defined.

In this example, the product is a modified manufacturing process flow, which meets or exceeds customer requirements.

The team defines a plan to meet customer quality requirements within the timing specified by management.

Interactions with related processes are reviewed, since the production line to be redesigned is used by two other products. The team brings in people to represent the other products using the line to ensure that the other products are not affected by the final changes.

In planning for the change of the process design, at least the following are considered by the team: customer and locally defined special characteristics, update of control plans and FMEAs, and other appropriate documentation. In particular, previous, similar design projects should be reviewed for lessons learned.

Once the design work is started, the design progress is reviewed at appropriate stages per the design plan.

The methodologies used to design the prototype line are based on technical specification process optimization tools and technical specification procedures.

In order to reduce the impact on current production of the three parts using the line, a pilot line is developed to represent the prototype manufacturing process. All three parts are run on the prototype line, with full part validation and engineering specification testing completed.

Once the customer specifications are met for all three parts run off the prototype line for all expected ranges of input, including material, operator, tool wear, environment, demand fluctuation, etc., the design of the modified line must include establishment of the following to meet capability requirements:

- preventive maintenance
- tooling management
- production scheduling
- contingency plans
- preservation and handling and traceability
- inline monitoring

**Measurement, Analysis and Improvement**:

*Definition: validation of conformity of the process and of the final product to customer requirements, and continuous improvement through corrective and preventive actions.*

Measurement covers all phases of the process. Additionally, appropriate measurement and data analysis techniques must also be used.

In the example of the modified manufacturing line, several phases exist where measurement can be applied:

- where the specifications for the modified process are received
  - The control plan or other indicator of process measurements
  - Final inspection showing part or sample compliance to requirements
- validation checkpoints for the development of the new line
- compliance of the manufacturing line design process to all corporate and customer requirements, including lessons learned for continual improvement
- Sign-off validation check for prototype parts prior to production volumes and postproduction performance verification

Not all requirements in the ISO/TS 16949:2002 requirements manual Clause 8 (Measurement, analysis and improvement) need to be met everywhere a measurement is made. They must be met, however as appropriate. The following example should help to explain the applicability of each requirement.

In general, where measurements are made, the following apply in every case:

- appropriate statistical tools must be used
- customer metrics must be known to determine level of customer satisfaction
- type of measurement technique to be employed (e.g. audits, product measurements, management reviews)
- skills or capability required by personnel or measurement equipment
- customer review and waiver / acceptance process as appropriate
- means to manage corrective actions where performance does not meet customer expectations
- lessons learned to ensure continual improvement, or corrective actions

In addition to the above generally applied requirements:

For this example of the process of designing a change in a manufacturing process, measurements may not be as straightforward as measurements on an actual manufacturing line where the product is a component. In this case, the product is the manufacturing line and its capability. The process for generating the modified production line is what is measured. The components coming off the line give an indication of the capability of the line, but are not the product of this example process.

The following shows the application of the measurement requirements to the measurement phases listed above at the beginning of this measurement and continual improvement section.

Where the specifications are received

- The new line must meet all product specification requirements
  - In building and testing the line, the team must know that it has the capability to measure the required characteristics on the new line to ensure long-term line performance capability. This is especially true for a product different from that being produced elsewhere in the plant.
  - The type of measurements here are typically of the physical product measurement. However, to measure line development performance, the measurement might be attribute – the line was capable of measuring to customer requirements or not.

Validation checkpoints for the development of the new line.

- This is typically a management tool, much like APQP, with deadlines and target dates and deliverables.
  - The measurements might be time based or attribute based where management reviews the progress vs. the plan and approves or rejects the progress so far.
  - These metrics are often reviewed in Management Review as part of monitoring the effectiveness of the line development process.
  - These deadlines are also often developed internally to meet the customer delivery date requirement. The customer may not specify or be concerned with these intermediate checkpoints. Although the customer (the manufacturing organization) may require progress reports to assess likelihood of meeting the final deadline.

The compliance of the manufacturing line design process to all corporate and customer requirements, including lessons learned for continual improvement.

- The organization may have specific internal processes it is required to follow in developing the new line.
  - These processes might include business planning, documentation and approval of projects, record retention, health and safety, personnel training, environmental, equipment calibration, machine set up, etc.
  - Compliance to these processes is typically assessed by internal audit of the new line development process. As explained in the process auditing section of this part of the Implementation Guide, this modified line development process might be audited, choosing this particular line as the example.
  - The internal audit results are typically reviewed as part of Management Review where any issues discovered are analyzed to determine applicability to other similar line development processes. If the corrective actions are applied to the lines where the issues have not yet appeared, then preventive action has been taken – leading to continual improvement and application of lessons learned in the process of designing modified manufacturing lines.

Sign-off validation check for prototype parts prior to production volumes and postproduction performance verification.

- This is proof that the new line meets the customer.
  - This type of measurement may include both manufacturing process and product types of measurement.
  - Management will need to see evidence that Manufacturing has signed off that all line performance and part specifications have been met for both demonstration and longer term product runs, as required.
    - Approval protocols will have to be followed, including application of appropriate problem solving / prevention of recurrence tools to correct any issues discovered (reviewed by process audit)
    - Product compliance must be met (measurement capability, statistical methods, layout, potential for process variability reduction, error proofing, product testing, etc.)
    - Other measurements or demonstrations as required by Manufacturing.

# APPENDIX H – THE QUALITY MANAGEMENT SYSTEM AUDIT

This Appendix gives some examples and guidance on how to conduct a Quality Management System Audit by using the process approach.

Preparation for the Quality Management System Audit:

- Verify that the organization's quality management system is in compliance with the ISO/TS 16949:2002. During the implementation phase, compliance is initially determined during document review. Ongoing, the auditor reviews any changes to the QMS since last audit (refer to ISO/TS 16949:2002, paragraph 5.4.2).
- Prior to "walking the process", review the metrics and objectives associated with that process – however, not all processes have direct metrics. You may need to identify metrics that are broad indicators of the "health" of the process. For example, a machining process may be measured by end-of-line PPM (parts defective per million parts produced) that is related to machine part characteristics.
- It is important to use the data collected to identify areas of the process that may be leading to poor performance in the metrics. If the audit is going to address machining, and three product lines are within specification, but one line is not, audit the line not to specification. Use the audit as an opportunity to improve the product. This is the very basis of process auditing. It becomes value-added.
- Where metrics indicate the organization is meeting its goals, the audit can shift to preventive action. Focus on the organization's processes for reviewing and reducing sources of variation as it relates to their continual improvement process.
- To measure the effectiveness of the quality management system, verify conformance of the organization's metrics to customer expectations. Take sample data from product made on each line for each shift of operations, before and after maintenance, etc., to include typical sources of process variation.
- Obtain a list of the customer requirements (internal or external) for each process.

## Conducting the Process Audit

A process audit approach follows the organization's system through its natural flow. Choose the areas based on the data for those processes that are not performing to customer requirements. By reviewing the different areas of the process, it is likely that the source of the poor customer satisfaction will be found. When all products meet customer requirements, ask about continual improvement efforts using measurements and objectives.

The auditor should get an overview of the process to be audited from the process owner (e.g. top management responsible for that process) so that the process, its inputs, supporting processes, measurements, etc., can be established to ensure an effective audit.

The basic steps in a process approach are:

- **What are the inputs to the processes** - Who is the customer of the process?
- **Management Responsibility** - How are the processes assigned and under what authority?
- **Resource Management** - How are resource requirements met?
- **Product Realization** - What are the interfaces (function to function) and how is it ensured that those responsibilities (hand offs) from one function to another are executed throughout the product realization process to meet customer requirements? What steps are required to be performed to make the product and are these steps completed to specification? What was done in the event the product does not meet customer requirements?
- **Measurement, analysis and improvement** - How is the process measured, analyzed and improved – what is the progress towards the objectives?
- What are the outputs?
- These basic steps are followed for any process to determine if the process is effective.

## Reviewing Metrics During the Audit

The audit continues by reviewing the metrics.

- Are the metrics (goals and targets) being met? Ask about the particular metrics determined during the audit planning.
- Are there areas defined by the customer that need improvement? Ask about the ones found in the audit planning.
- During the audit, focus on those areas that need improvement.
- What is the organization doing to meet their goals?
- If the organization is not meeting their goals and targets, what corrective action activities are being performed?
- If they are meeting the goals and targets, what steps are they taking to improve (continual improvement)?

The right focus will lead the organization to improvement in areas most important to the customer.

Next, the processes contained within the organization are checked to see that they are assigned, executed and are effective. Effectiveness is judged by verifying compliance to customer requirements as well as internal requirements. Organizational metrics must incorporate customer expectations at a minimum. Follow the process flow within the organization.

- Each functional area introduced in the process needs to know the inputs (including noise) and outputs of their process steps. Is the process hand-offs understood and implemented?
- How does the employee know when to accomplish his/her task?
- Does the employee know where the process leads from his/her responsibility to the next step or process?
- In other words, are the interfaces and linkages understood?

The process audit approach reaches beyond the traditional "within four walls" or "site" audits. The process needs to be followed throughout the organization to be sure the linkages are working. The focus is not on performance within each functional silo, but on whether the linkages among those functions produce the desired result.

Under the elemental approach, each function may be performing well, but not working together as an organization toward common goals. It is not uncommon for a functional area to believe that it is contributing; only to find out that what they thought was valuable was actually creating confusion, inconsistencies, or contradictions to the next step in the process. Here is an example of what might happen in an organization:

A manufacturing quality department for one area was monitoring nonconformities, including scrap, in one database. The metric for improvement in that department was a reduction in scrap. Use of a certain hard material resulted in a 20% scrap rate. An analysis of the data led the department to use softer material that was more easily machined and reduced scrap and therefore, drove local improvement.

At the same time, the customer, the manufacturing department that was using the product, experienced 80% failure rate, since the part was no longer meeting durability requirements. The part was too soft.

As you can see from the above example, sub-optimization without full understanding of customer requirements can lead to greater inefficiency and loss.

**Note:** Results of the audit are forwarded for management review.

# APPENDIX I – THE MANUFACTURING PROCESS AUDIT

This Appendix gives examples or suggestions on how to conduct a Manufacturing Process Audit.

Determine the manufacturing processes within the organization (such as product lines, similar processes within locations).

- What are the inputs to the manufacturing processes? An effective way to audit a manufacturing process is to verify conformance to the organization's processes and applicable customer specified requirements.
- Within the manufacturing process, do the manufacturing steps flow naturally and effectively from task to task?
- What is the output of the process? Who is the customer and what are their requirements?
- Determine how the site ensures the manufacturing portion of product realization is effective. What are the measurements of the process?

Useful tools: The process specification as defined in the output from the process design in ISO/TS 16949:2002 paragraph 7.3.3.2 may be used in determining the scope of the audit. Compare the PFD (Process Flow Diagram), PFMEA, control plan and work instructions. Initially, make sure the documentation has been updated to address all internal and external concerns – ask for recent customer concerns and ask to be shown where those concerns were addressed by updates to the processes.

- Select a sample of steps in the control plan. Internal and external concerns and quality concerns should be used as input in selecting the appropriate steps. Follow execution of these steps on the manufacturing floor to see if the steps in the control plan match actual practice.
- Within the sample, it is helpful to select steps near the beginning, in the middle and at the end.
- It is also helpful to include a step involving inspection.
- When reviewing execution to the control plan and corresponding work instructions, determine if the inspection and test status is clearly defined so that quality is ensured through each operator hand-off (shift to shift as well as operation to operation on the same shift). Does each operator know when to start and when to stop their process? Does the operator know how to communicate status clearly to the next operation?

Another helpful tool during the manufacturing process audit is the PFMEA. Look at linkages/interfaces with the PFMEA to the Control Plan.

Section 6.2.2.4 of ISO/TS 16949:2002 "Employee motivation and empowerment" states: "The organization shall have a process to measure the extent to which its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives.

- Ask employees at all levels how their tasks contribute to the quality of the product, not just the direct operator, e.g., the process owner, the manager, the supervisor, the support personnel.
- What is the impact to the customer if they do it wrong? (Refer to the PFMEA for the potential causes of failure)

Other key steps in reviewing the manufacturing process include the interfaces/linkages between customer complaints and internal nonconformities with flow charts, PFMEAs and control plans, work instructions and training.

- Are failures identified in these reports of nonconformities reviewed and included in the PFMEA?
- Does the control plan identify these failures and provide error proofing or containment?
- Where changes to the PFMEA and control plan are made, what is the linkage between these changes and associated changes to work instructions?
- Are the employees advised of customer complaint issues?
- How is this linked to training?

Review the part certification requirements within the manufacturing process for continued effectiveness.

- Are the capability requirements for significant characteristics still being met?
- Is the manufacturing plant still meeting the print tolerance?
- Are the run-at-rate / capacity requirements still being met?

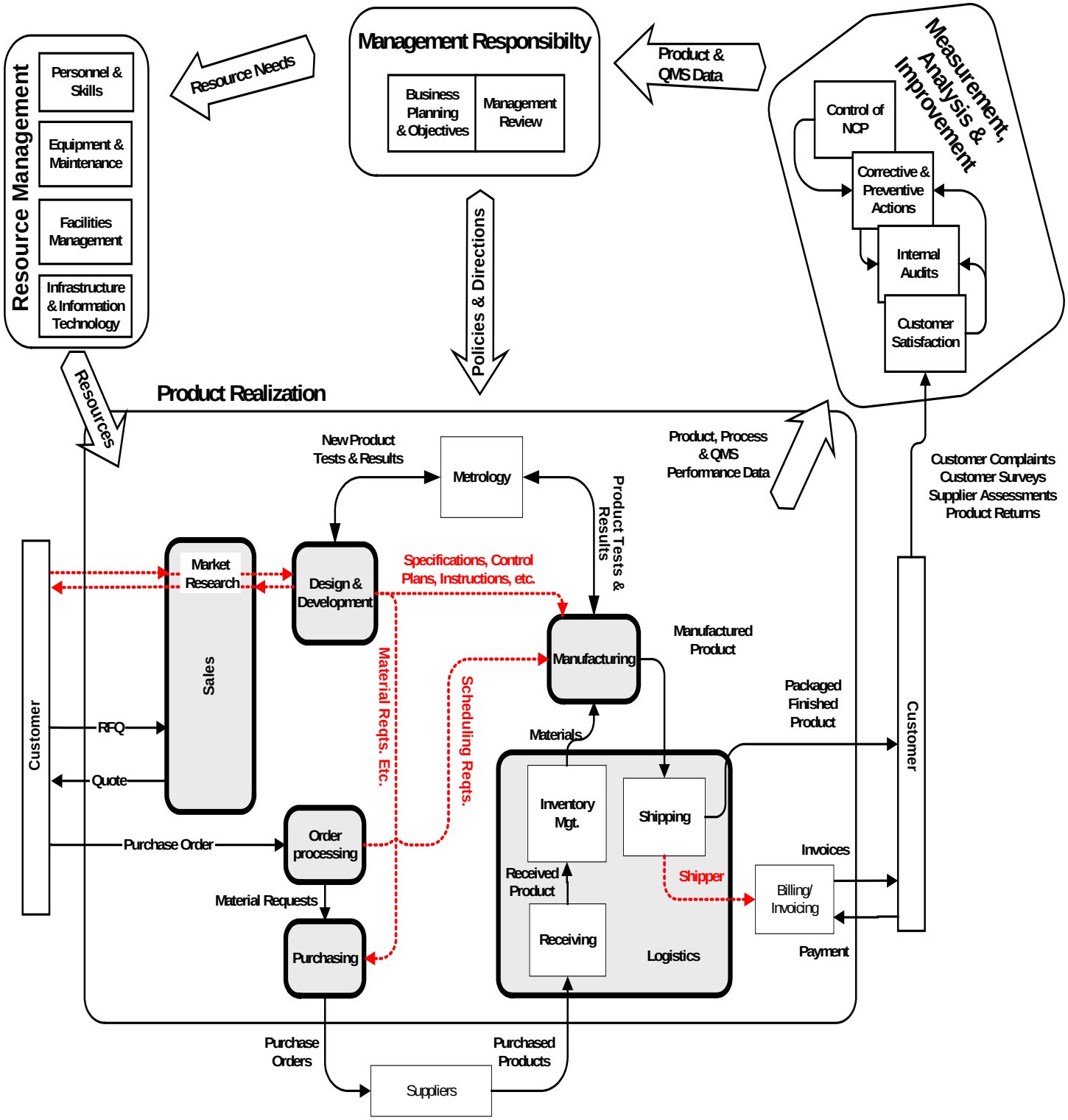
# APPENDIX J – PROCESS MAPPING EXAMPLES

**Objective:** The objective of this section is to provide organizations with some examples of how process mapping can be used to help organizations understand their quality management system and their processes in order to meet the requirements of ISO/TS 16949:2002.

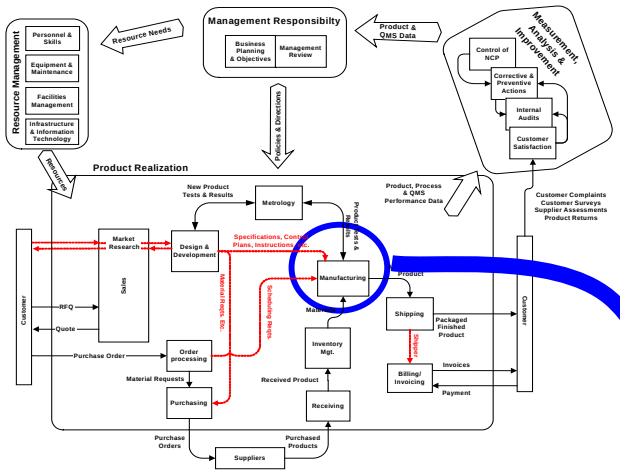
**Mapping the system versus mapping a process:** When considering using process mapping as a tool to meet the requirements of ISO/TS 16949:2002 organizations should understand that process mapping should be viewed on two different levels. One level is mapping the quality management system's key processes and the second level is then using process mapping the key processes themselves and their sub-processes if necessary.

Mapping the QMS: Clause Requirement 4.1.a) states that organizations shall identify the processes needed for their QMS and their application throughout the organization. Requirement Clause 4.1.b) states that organizations shall also determine the sequence and interaction of these processes. Requirement Clause 4.2.2.c) states that organizations shall include a description of the interaction between the processes of the QMS in the quality manual. Process mapping the QMS illustrating the sequence and the key inputs (customer requirements) and outputs (input to the next process) of each process is an excellent way for organizations to meet the requirements. Additionally, this allows the organization to gain an understanding of how their processes work together with other processes (interact) to produce a product that meets customer requirements.

**Note:** Complete process definition should consider: management responsibility, resource management, process realization steps, metrics and measurements. Each organization's QMS is unique and therefore there can be no "one right way" for organizations to do process mapping. A QMS from a macro perspective is provided as a framework to consider when deciding how best to meet the ISO/TS 16949:2002 requirements stated above.




**Note:** Bolded and shaded processes represent key product realization processes




**Manufacturing Process**

Management Responsibility

- Process Owner: Manufacturing Manager
- Provides:
  - Polices & Directives
  - Objectives & Targets
  - Resources
- Monitors:
  - QMS performance
  - Progress toward objectives & targets
  - Product conformity
  - Cost of quality indicators
  - Customer satisfaction indicators

Monitoring & Measurement

- Process Performance / Capability
- Product Conformity (PPMs)
- In-Process / Final Inspection & Test

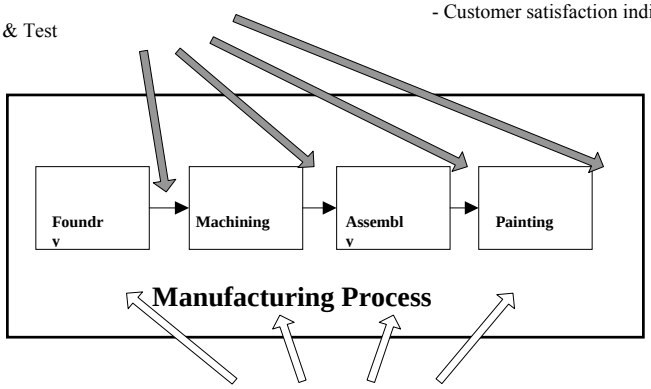
**Process Inputs**

Resource Inputs:

- Competent Personnel
- Materials
- Equipment / Tooling
- Funding

Other Inputs

- Scheduling Requirements
- Specifications
- Control Plans
- Acceptance Criteria
- Customer Requirements
- Product Test Results

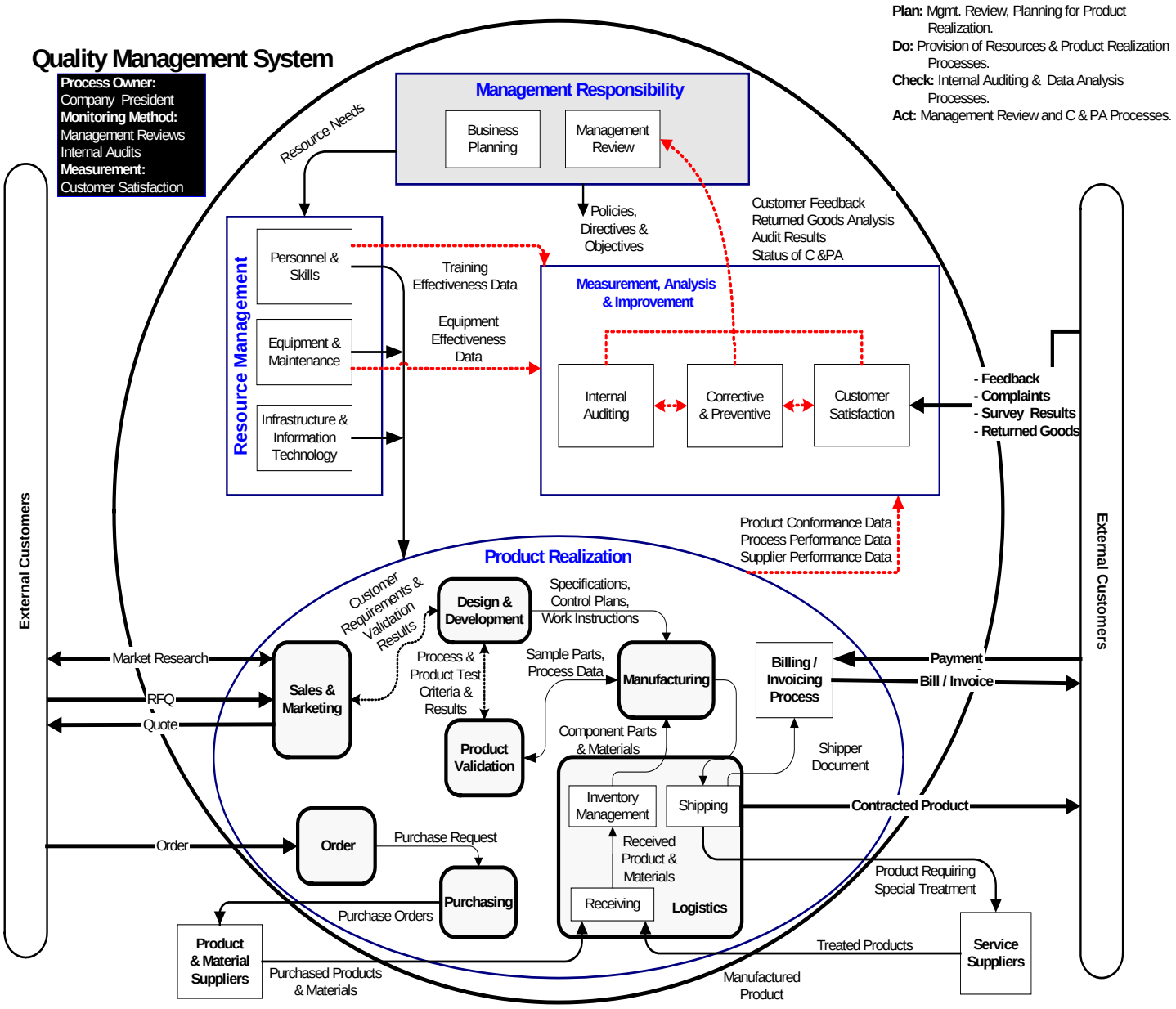



**Process Realization Steps**

**(Or Sub-Processes)**

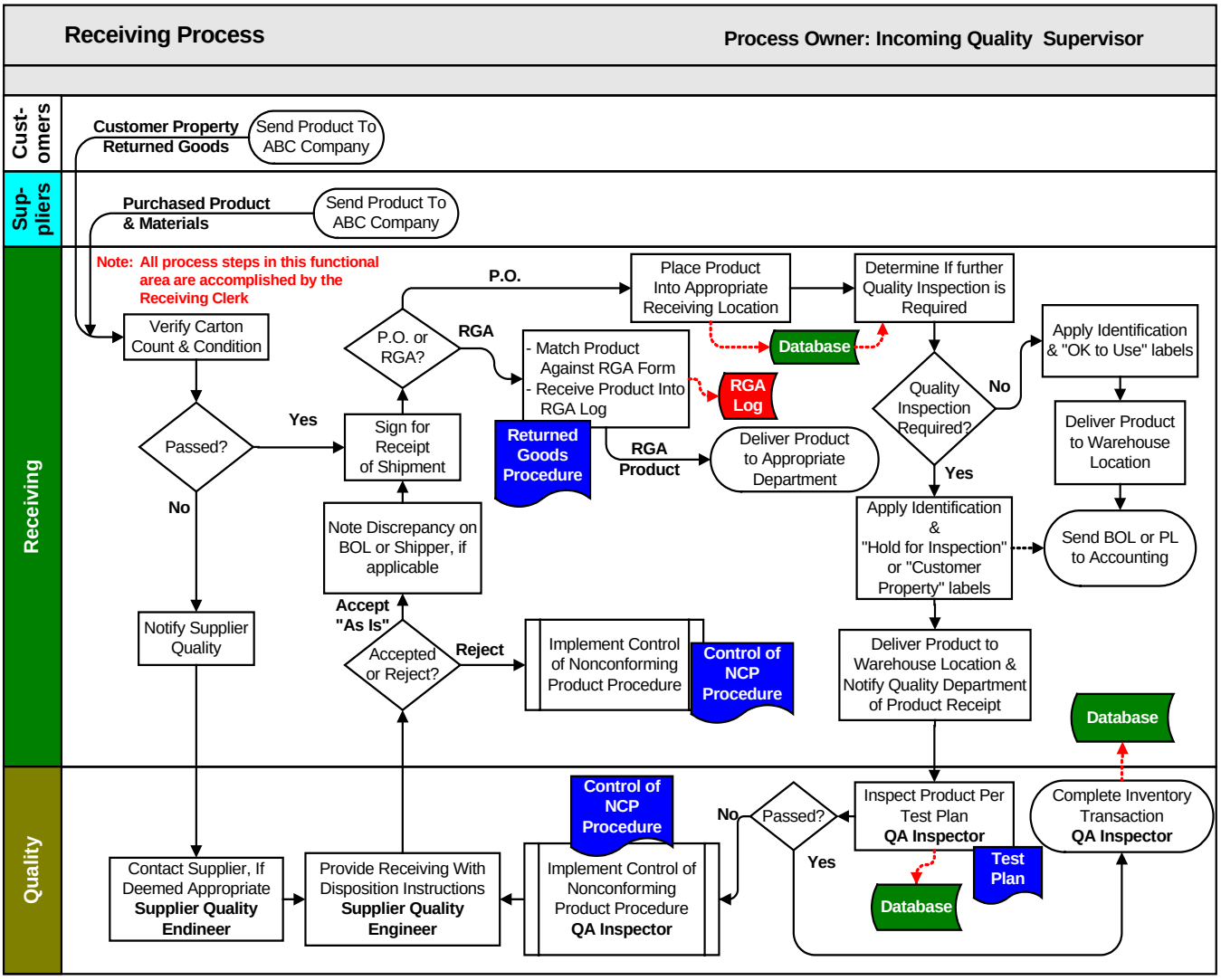
**Process Output**

**Manufactured Product**



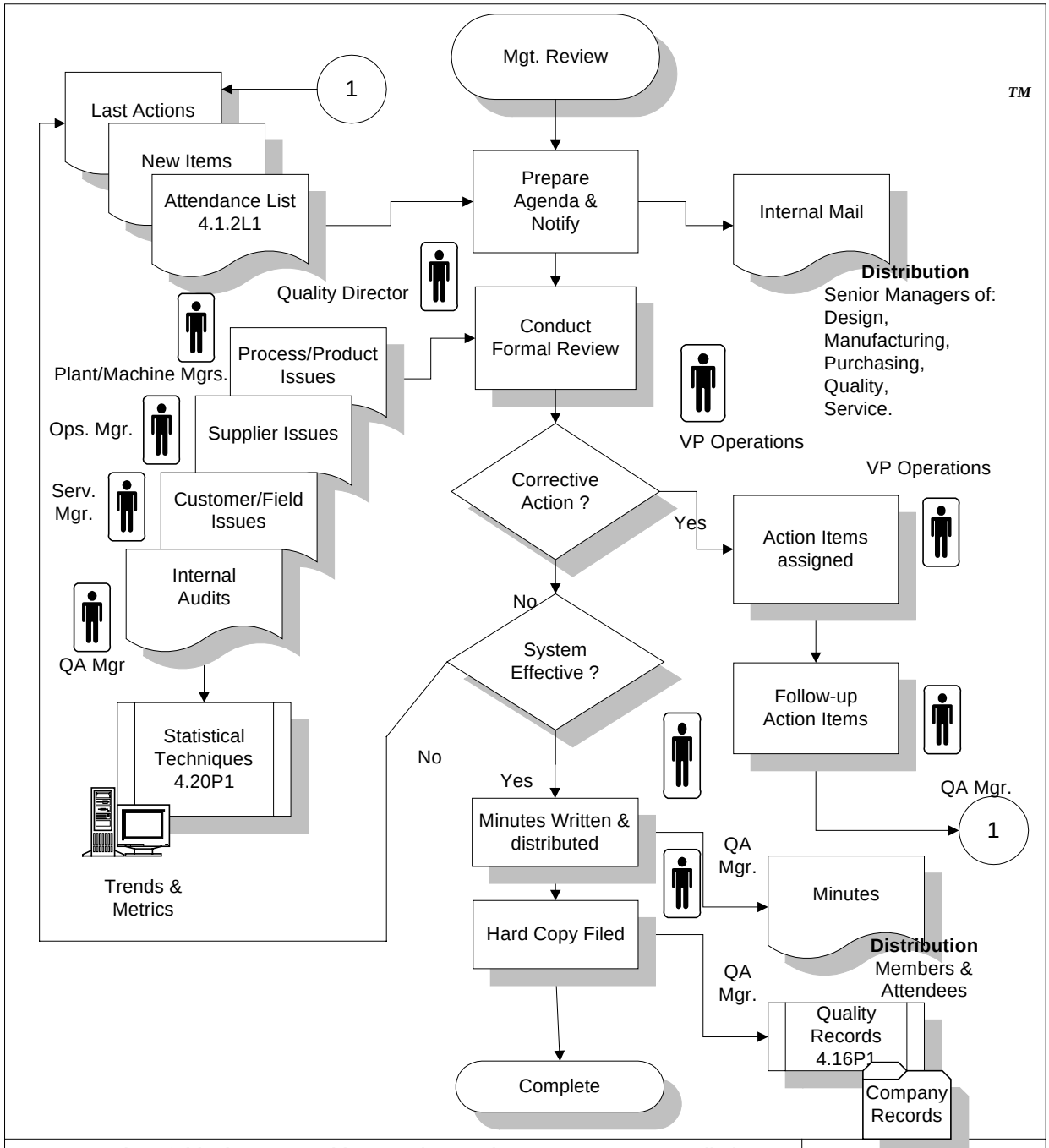

**Note**: Bolded and shaded processes represent key product realization processes

Mapping individual processes: Mapping processes can help organizations understand the activities within a process as well as its linkages (inputs and outputs) with other processes. Looking at the process steps graphically often helps organizations identify redundant steps and other inefficiencies that can be opportunities for process improvements and cost reduction. Below is an example of a map at the process level.



**Key Considerations:** There are many different ways to do process mapping and it is up to each organization to determine the appropriate method for their organization and QMS. If graphical flowcharts are used, it is recommended that a standard symbolism be used. It is recommended that organizations define a standard set of symbols to be used by the organization in all process maps. This will ensure that everyone can understand the process maps created throughout the organization. The nature of the process itself may help determine which process mapping methodology is best.

Processes can be defined by a series of procedures, which together meet all the requirements of having all attributes of a process.

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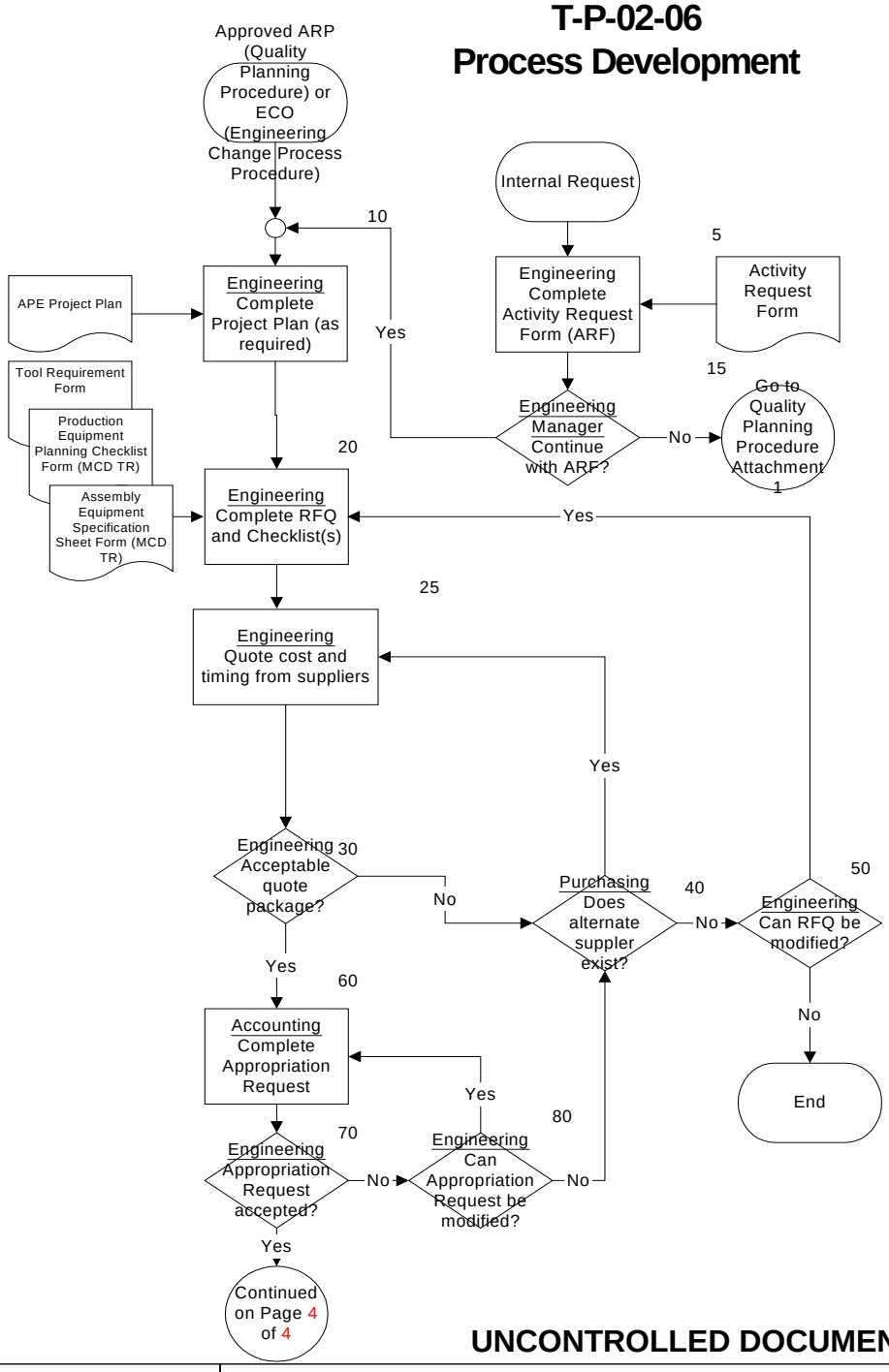
Page 1 of 1

**Management Review**
Process Owner: John Doe

Doc: 4.1 P1
Rev: 1
Date: 9/14/98

# T-P-02-06
# Process Development




10 Engineering to establish a Project Plan and update as required.

20 RFQ to include Project Plan information as well as requirements as outlined in:
- Tool Requirement Form;
- Production Equipment Planning Checklist Form
- Assembly Equipment Spec. Sheet Form

Note

70 and 80 Not applicable for spare parts or capital less than $1,500.00.

**UNCONTROLLED DOCUMENT WHEN PRINTED**

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| | **Common Element Champion**<br>N/A | **Non-Common Element Champion** | **Revision:**<br>10<br>**Approval Route:**<br>T-02 | **Revision Date**<br>Febuary 7, 2003 | **Reference** |

## Process Approach Analysis

Includes information about the following:

- "Turtle" process analysis tool
- Basic definitions of processes
- Audit Planning Matrix

## Explanation

This analysis addresses three important facets of understanding and applying the Process Approach to Management. They include the following:

- The need to understand the basic elements of a process
- The need for a tool to assist in analyzing processes
- The need for a tool to assist in summarizing the organization's processes into a form that can support the planning and executions of audits and other reviews

The sequence of, and the reasons for, the inclusion of the information provided are as follows:

1) Page 2 displays a brief explanation/definition of a process, which leads to a brief description of how the understanding of a generic process, the Process Model for quality systems, and customer focus of an organization's processes can be brought together into a single concept; the first step in understanding processes.

2) Page 3 briefly lists the ten, generic (suggested) Customer Oriented Processes (COP) *(COPs are those processes directly connected to and/or focused on an external customer)*. A graphic illustration is provided to present a model of how the ten COPs would look conceptually. Pages 2 and 3 are in place to give the reader a mental picture of how each of the concepts described could be viewed separately and together. It is intended to help the reader form a kind of benchmark mental picture of the concepts.

3) Page 4 applies the Process Approach concept to a generic organization. Because it is a service organization that is not in the direct supply chain to the automotive industry, the ten COPs are not utilized completely. This illustration was chosen to give the reader an idea of how the "octopus" model could be applied to any organization, and to be careful not to prescribe the way it must be applied in an automotive organization *[ORGANIZATIONS NEED TO DECIDE WHAT MODEL WORKS BEST FOR THEM, KEEPING IN MIND IN THE AUTOMOTIVE SUPPLY CHAIN, THE FOCUS ON CUSTOMER ORIENTATION IS A PRIMARY CONSIDERATION --- NOT A RULE, BUT A CONSIDERATION]*

4) Pages 5-7 introduce, explain and apply the "turtle" tool. The turtle tool is a simple, yet powerful, tool used to analyze processes. Page 5 introduces the elements of the tool. Page 6 applies the tool to the Car Dealer example from Page 4. Page 7 reasserts the tool in a template form, along with a simple set of directions.

5) Page 8 is an illustration of a process approach audit, planning tool called the Process Approach Audit Worksheet.

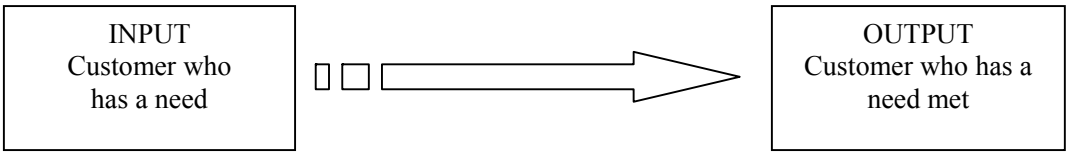
6) Page 9 is a Process Approach Audit Worksheet, which has been completed (to the extent possible, without having an actual organization from which to base the completion of each column) for the Car Dealership example. It is provided to give implementers and auditors an idea of how this type of analysis can be supported. The example Process Approach Audit Worksheet is completed for the

COP – Finance. The other COPs (1-5) would require additional matrix sheets. *Note: This is an ISO 9001 example, as the Car Dealer is not eligible for TS certification. However, a TS Worksheet would be completed the same way.*

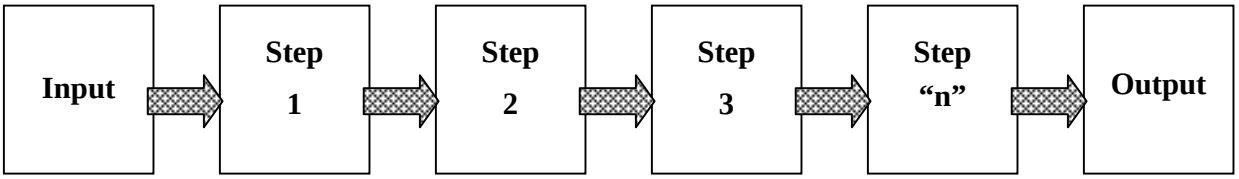
## Process Defined

A process is a chain of added value activities delivering a product or a service to a customer (internal or external) of the process.

A process has a start and an end defined by two limits as shown by the diagram below

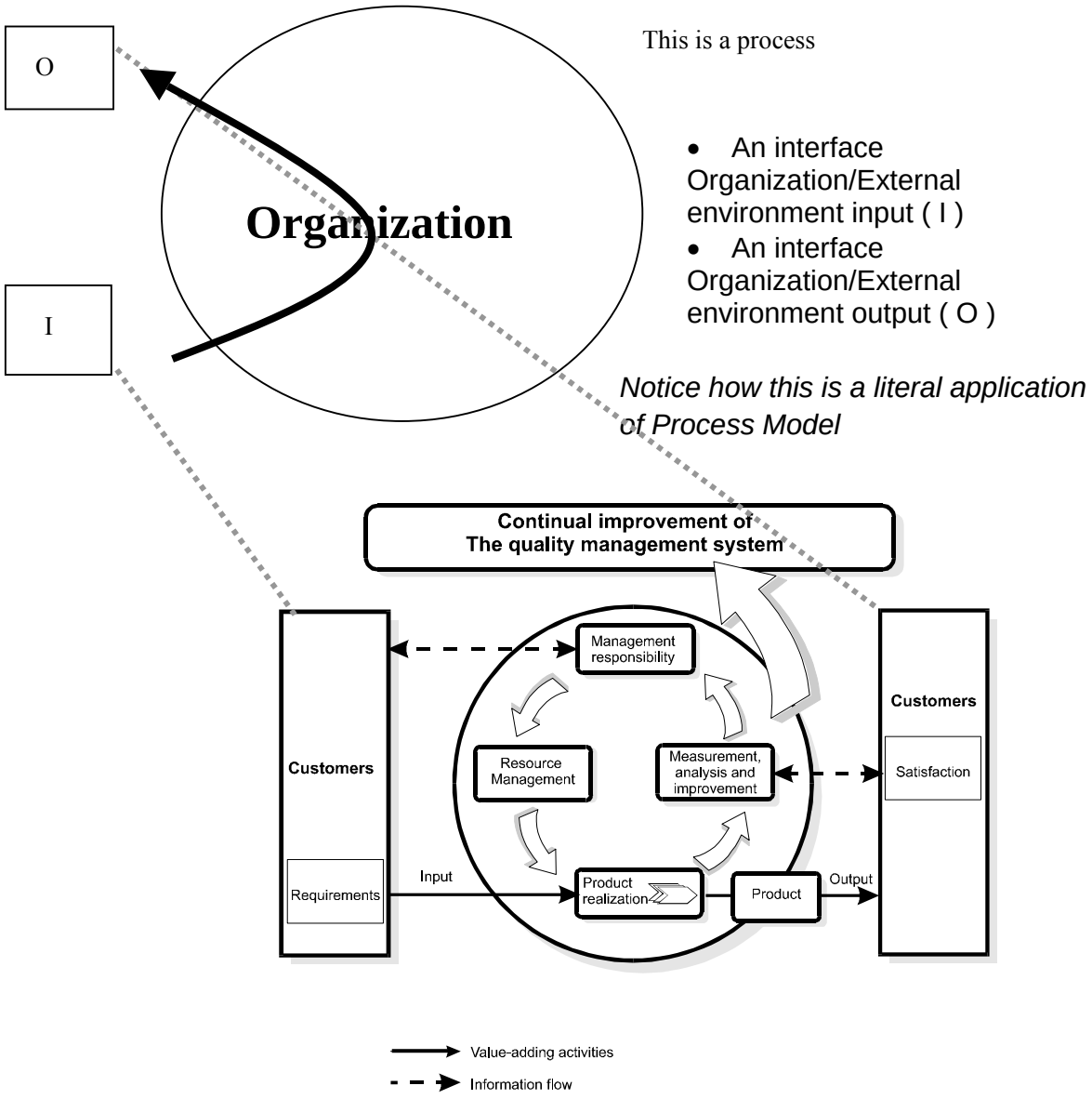



And a chain of activities between these two limits as shown by the diagram below



## Customer Oriented Process Defined

Internal/external interface between an organization and a customer



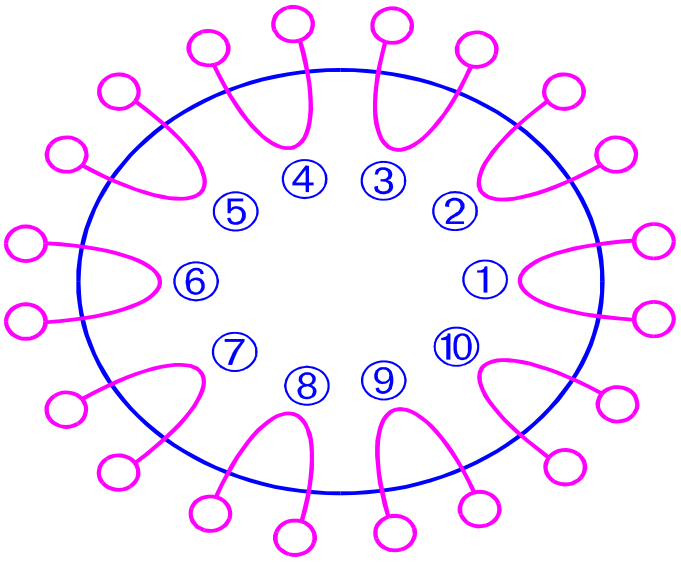
## List of Customer Oriented Processes for the Automotive Industry

### Suggested COPs:

**The following ten COPs are certainly not the only ones an observer would find in an automotive organization** but they are universal enough to be a good benchmark from which to begin an identification process, with others added as required based on the organization and its operations. These would apply to electrical, chemical and mechanical organizations and/or suppliers. **Note:** COPs 4 – 7 hold the highest interest for most OEMs.

1. Market Analysis/Customer Requirements
2. Bid/Tender
3. Order/Request
4. Product and Process Design
5. Product and Process Verification/Validation
6. Product Production
7. Delivery
8. Payment
9. Warranty/Service
10. Post Sales/Customer Feedback

## Customer Oriented Processes form an organizational "Octopus"



The "Octopus" graphically illustrates the direct **inputs** from the customer to the organization and the resultant direct **outputs** from the organization to the customer. The number (ten) of customer-oriented processes **(COPs)** depicted in the above diagram is not intended to indicate a recommended or total number of COPs. The number is used to illustrate the multiple nature of customer/organization interactions. Nor does the model ultimately used by the organization to describe its system need to look like this model; it is provided to help implementing organizations visualize one model that could be used to portray the "sequence and interaction" within their quality management systems.

> **Note**: To avoid prescription an automotive-related organization is used for the example. The Dealer is not TS eligible, but may certify to ISO 9001:2000. The documents provided support an ISO 9001:2000 registration for this example.

## COP Analysis

## Example: A Car Dealer and Service Center

*The following example is provided so that implementers of the automotive process approach can obtain a sense of what an application of the process approach might look like.*

Mr. Smith is not pleased with the performance of his car; he decides that he will take the time to go to a car dealership and service center near him to have his automobile diagnosed. He is new to the area, so he is not familiar with all the services offered by the Service Center. Mr. Smith hopes the car can be diagnosed and the repairs made, but he is prepared to negotiate the purchase of a new or used car, if the diagnosis and repair do not appear to be cost effective.

On arriving at the car dealer, he sees the signs, which indicate the entrances for the Sales Department and the Service Center. He enters the Service Center entrance to ask the service center manager about having his car diagnosed. Mr. Smith is informed that the service center can do the diagnosis immediately.

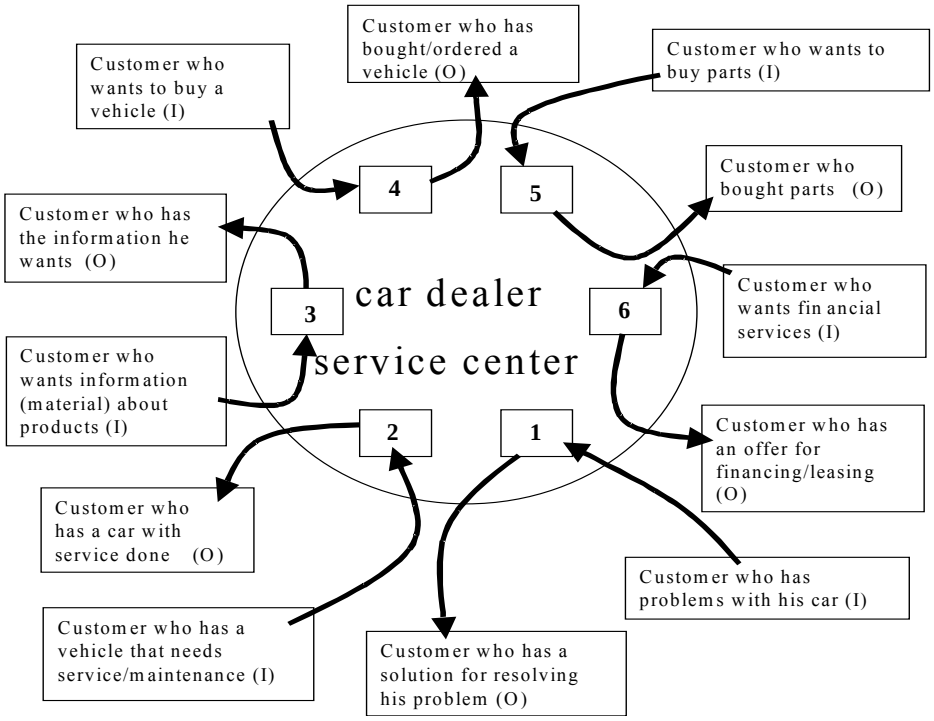
Following the diagnosis the service center manager explains the findings to Mr. Smith. The problems are extensive and Mr. Smith decides that perhaps his best plan of action may be to purchase a new or used car.

Mr. Smith is introduced to a car salesperson, Ms. Jones, who interviews Mr. Smith regarding what he might be considering in regard to a car. Things like the size of the car, the options included the color and, of course, the prices are discussed between Mr. Smith and Ms. Jones. Ms. Jones shows him a number of cars.

Mr. Smith decides his best course of action is to repair his old car and purchase a used car. His old car will be given to his daughter, who is in college, and the used car he has selected fits his present needs quite nicely.

After completing his negotiations, he would now like to pay for the repairs and the used car he has purchased. Mr. Smith is introduced to the business manager, Mr. Frugle, who is prepared to explain to him the payment and leasing options. Mr. Smith makes his selections. Everything is now in order. He drives away in his new "used" car and with a time and date of when he can pick up his repaired, old car. Mr. Smith is one happy guy.

## Process Approach Octopus for example Car Dealer and Service Center

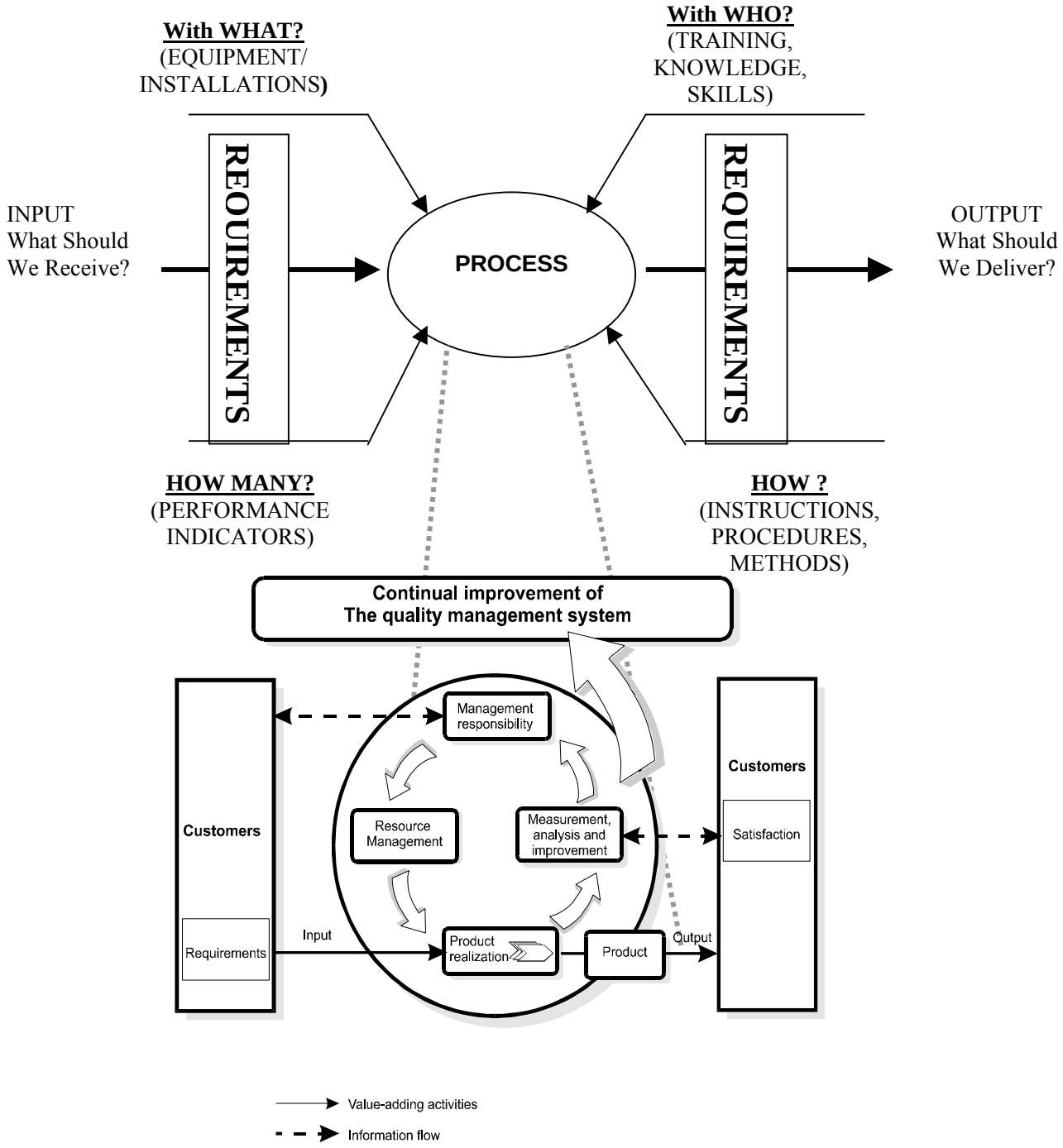



**COP List for the example Car Dealer and Service Center**

1. Customer Service
2. Car Service
3. Sales Support
4. Car Sales
5. Parts Sales
6. Finance

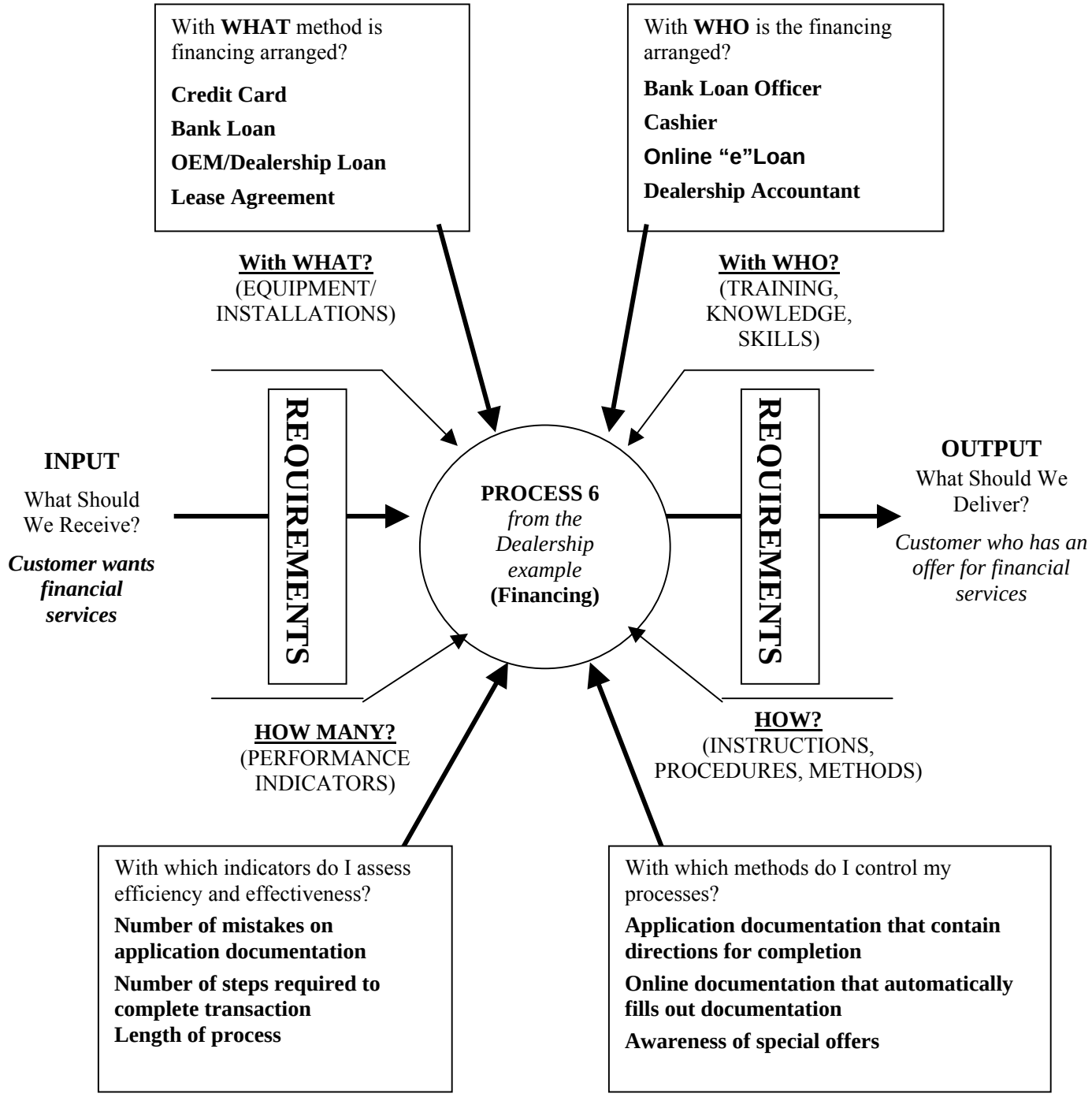
## Four Questions About a Process

A useful tool for analyzing processes is displayed below. The tool is often referred to as the "turtle." As can be seen below, the tool is comprised of four questions about the process (comprising the legs) and two questions related to the input and output (head and tail). For reinforcement and clarification, the relationship with the Process Model is also shown. The tool is helpful for both implementation and auditing.



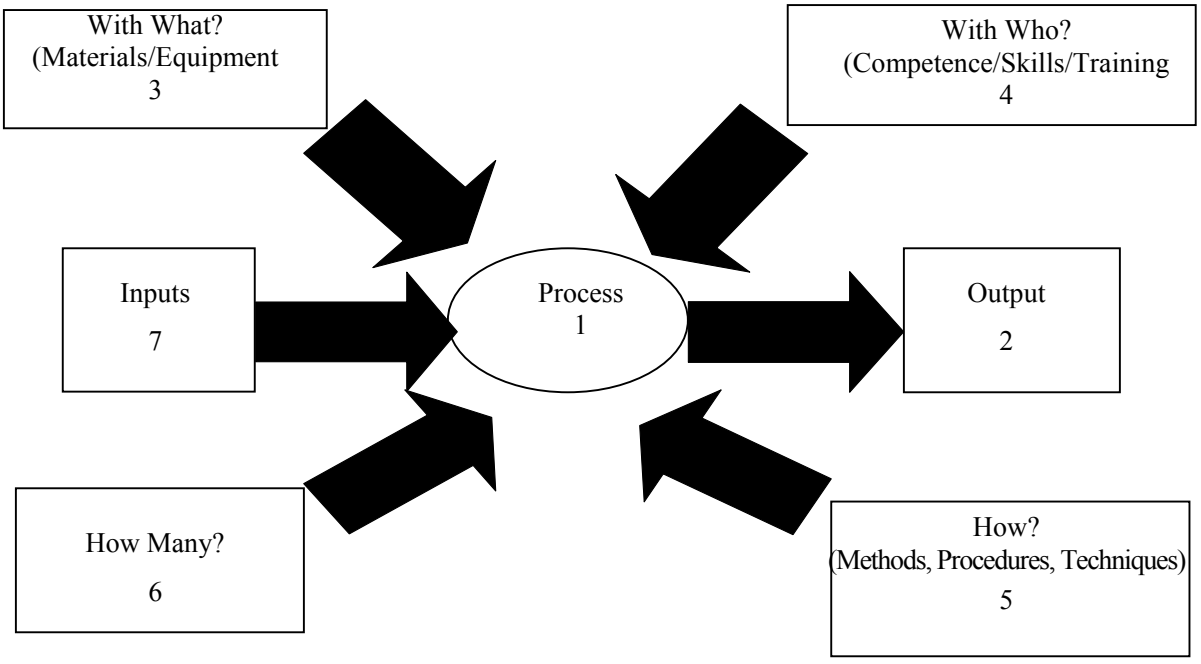
## Four Questions About a Process

Depicted below are the four questions applied to one of the COPs – Process 6 Finance from the Car Dealer example organization. The two questions pertaining input and output are also summarized.



## Process Approach "Turtle" Diagram: A Powerful Analytic Tool for Auditing and Implementation

Below is a simplified version of the tool, which indicates the order that many practitioners have found most helpful when using the tool (particularly when using the tool for auditing). The boxes invite note- taking by the user, particularly, if used as an audit tool on-site. The matrix at the bottom of the page gives a brief explanation of what is intended for each box.




| Section | Details |
|---|---|
| 1 | Enter COP or Support Process name. |
| 2 | Enter details of the actual output this may be a product, document, and should be to actual measure of effectiveness |
| 3 | Enter details of the machine, materials( including test equipment), computer systems, software used in the process |
| 4 | Enter resource requirements, pay particular attention to required skills and competence criteria, safety equipment etc. |
| 5 | Enter details of linked process controls, support process, procedures, methods etc. |
| 6 | Enter the measures of process effectiveness i.e. matrix and target. |
| 7 | Enter details of the actual input this may be a document, materials, tooling, schedule etc. |

## Process Approach Audit Worksheet

Below is an explanatory version of the Process Approach Audit Worksheet, which includes a set of directions. Also, note that a reminder of Process Characteristics and the Four Questions for process analysis are provided in two boxes at the top of the worksheet.

**A "Process Approach" Audit Worksheet**
**to assist in**
**Audit Scheduling and Evaluation Tool Creation/Completion**

| Column Identification Number | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| *Six Process Characteristics:*<br>❑ *Has an owner*<br>❑ *Is defined*<br>❑ *Is documented*<br>❑ *Linkages are established*<br>❑ *Is monitored*<br>❑ *Has records maintained* | | | *Four Support Process Questions (related to risk):*<br>❑ *With What? (Materials, Equipment)*<br>❑ *With Who? (Skills, Training)*<br>❑ *With What Key Criteria? ( Measurement, Assessment)*<br>❑ *How? (Methods, Techniques)* | | | | | |
| **Customer Oriented Process (COP)** | **Support Processes for COP** | **Management Processes** | **Organization Location *(Physical and Organizational)*** | **Expected or Required Key Indicators, Measurements** | **Applicable Requirements** | **Applicable References** | **Descriptions of Audit Observations, Evidence, Potential and Actual Findings** | **Classification:**<br>❑ **Needs Further Research (NR)**<br>❑ **Opportunities for Improvement (OI)**<br>❑ **Non – Conformance (NC)** |
| *(row 1 is to be used for the COP identified in this box)* | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |

**Comments about the intent of the Worksheet**

- Columns 1-7 are to be completed prior to the planned audit (by the auditor or personnel designated by the organization)
- Column 1 list the COPs (row 1 should be used to detail the information needed to audit the COP)
- Column 2 lists the direct Support Processes (these occur on three levels – Mgmt, System, Operation – individually or in combination)
- Column 3 lists the Management Processes, which are those processes that assess the performance of the COPs and Support Processes, and which produce organization wide decisions, objectives, changes, etc.
- Column 4 lists where one would expect to find the process in whole or part, both physically and within the organization's business structure
- Column 5 lists those measurements and other indications of performance one would expect to see in relation to the COP or Support Process area
- Column 6 contains a listing of the clauses, which apply as a requirement to this COP or Support Process. An option would be to link this information to the actual requirement wording or check sheet/evaluation tool
- Column 7 contains a listing of the clauses, which apply as references to this COP or Support Process
- Column 8 is the space provided for the auditor to take notes while auditing the processes; these notes can then be converted into appropriate findings, observations, etc. as time and opportunity presents itself during the audit
- Column 9 provides space for the auditor to begin the process of classifying the contents of column 8 for use in audit reporting

**The vision for the worksheet is to assist an auditor's planning of an audit**, either in the classroom or on an actual audit, or both, **by breaking the audit into practical, concrete audit paths** (that is, processes that are linked together, but have definable and individual characteristics attributable to processes, and are processes that actually exist). **Once completed this audit "map" could provide information for planning and conducting an audit**. Once completed an auditor (internal or third party) could be assigned a complete COP, or a number of linked processes within a COP, or could be assigned however one could logically make the assignment leading to full coverage of the quality system, or at least, a relatively good sampling of the quality system.

**Other uses of the worksheet could be 1) the organization's completion of it; that is, use the worksheet as an exercise for defining their processes and/or 2) as a required piece of information the organization provides to the Certification Body prior to certification or surveillance audits**. Either use of the worksheet would provide value to the organization and would take much of the guesswork out of the audit.

## Approach Audit Worksheet to assist in Audit Scheduling and Evaluation Tool Creation/Completion

**Column Identification Number**

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|
| *Six Process Characteristics:*<br>• Has an owner<br>• Is defined<br>• Is documented<br>• Linkages are established<br>• Is monitored<br>• Has records maintained | | | *Four Support Process Questions (related to risk)*<br>• With What? (Material, Equipment)<br>• With Who? (Skills, Training)<br>• With What Key Criteria? (Measurement, Assessment)<br>• How? (Methods, Techniques) | | | | Descriptions of Audit Observations, Evidence, Potential and Actual Findings | Classification:<br>• Needs Further Research (NR)<br>• Opportunities for Improvement (OI)<br>• Non-Conformance (NC) |
| **Customer Oriented Process (COP)** | **Support Processes for COP** | **Management Processes** | **Organization Location (*Physical and Organizational*)** | **Expected or Required Key Indicators, Measurement** | **Applicable Requirements** | **Applicable References** | | |
| *(row 1 is to be used for the COP identified in this box)*<br><br>Financing | | Mgmt Review<br>Data Control<br>Records<br>Customer satisfaction | Administrative Offices | ROI Credit Rating Loan Approval | All loan regs 4.1, 4.2.1, 4.2.3, 4.2.4, 5.2, 5.6.1, 6.2.2, 7.2.1, 7.2.2, 7.2.3, 7.5.1, 7.5.2, 7.5.3, 8.2.2, 8.2.3, 8.4, 8.5.1, 8.5.2, 8.5.3 | Federal and State Loan Regulations | | |
| Input: customer wants financial services | Completion of Loan Application | (same as for COP plus)<br>Internal Audit<br>Corrective & Preventive Action | Administrative Offices Sales Area | Completion Accuracy Help Required | (same as COP plus) 5.6.2, 6.4, 7.4.3, 7.6 | (same as COP) | | |
| Output: customer has an offer for financial services | Approval/ Disapproval of Loan Application | (same as for COP) | Administrative Offices | Ratio Defaults<br>Customer Satisfaction Indicators | (same as COP plus) 5.5.1, 8.2.1 | (same as COP) | | |

# APPENDIX K - CERTIFICATION/SURVEILLANCE AUDIT PLAN INSTRUCTIONS

**Scope:**

The purpose of this document is to provide a suggested template to capture the key information for an effective automotive process based audit plan.

At a minimum audit plans must include the information on the template noted by an *.

**Company Information:**

- The certificate will contain the information exactly as entered in this section.
- Number of employees should include all employees at the site including temporary or seasonal.
- Shifts should be clearly identified (time may be necessary if not noted elsewhere.)
- PPE – Personal Protective Equipment
- Attire for example business casual/business
- Language(s) used by the organization
- Contact Information may include phone, fax, email, etc.

**Support Site Information:**

- The certificate will contain the information exactly as entered in this section.
- The audit report will contain the information exactly as entered in this section.
- Processes must be defined to show interface between the organizations sites and the support functions.
- Contact information as necessary.

**Audit Information:**

- OEM and/or Customer Supplier Codes must be supplied where applicable. These codes can be obtained from the organizations accounting group or sales group.
- Major Customers/Customer Specifics. This may not be an all-inclusive list. This list should include customers that represent (in most cases) the majority of the organizations business. The ^ denotes those customers with customer specific requirements.
- Scope Statement must be the same statement as found on the organizations certificate.

**Audit Times:**

- This information is optional. This information will be reflected on the detailed audit plan supplied to the organization.

**Special Items/Issues to be audited:**

- This area should contain any issues that will be focused on based on the readiness review information or information supplied by the OEM. This may include negative trends, customer complaints, new products, significant changes in employee counts, etc.

**Top Management Availability:**

- This must be the top management personnel at the site.

**Customer Satisfaction Input:**

- This information should be received no less than 30 – 45 days prior to the on-site audit.
- 12 months of data is required at the time of the readiness review for initial certification. This should include all information as defined in the IATF Rules applicable to ISO/TS 16949:2002 at a minimum.
- With the exception of the customer metrics it is acceptable for the organization to send a summary of the results (example: management review, corrective actions, preventive actions, internal audit information) for surveillance.

**Update to Customer Satisfaction Input:**

- This time should be used to focus the audit plan on the processes/products that are new, have negative trends, customer dissatisfaction, warranty issues, etc.

The intent of the process approach is to provide value to the organization and their customers thru value added auditing. The audit must focus on elimination of problems and improvement over time.

# QMS Certification/Surveillance

## Process Approach Audit Plan

**Company Information**

Customer ABC Company
Address 1000 Pennsylvania Ave.
Address Somewhere, USA
Employee Levels 100
Standard ISO/TS 16949:2002
PPE glasses Attire bus. casual

Management Representative
Jeb Bush
Phone 555-867-5309
Fax 555-867-5308
Shifts 7 – 3, 3 – 11, 11 - 7
(All shifts for QS-9000 & ISO/TS 16949 will be audited)

**Support Site(s) Information**

Address 1500 Pennsylvania Ave.
Somewhere, USA
Processes: R & D Design
Phone: 555-867-5400
Fax: 555-867-5401

Address
Processes:
Phone:
Fax:

**Audit Information**

Audit Dates January 9, 10, 2003
Assessor(s) Frank Bean
Lead: Joe Dunn

Monday's Required 4
# of Guides 2
Supplier Codes:
GM X1401 Ford
DaimlerChrysler

Scope Statement: Design and Manufacture of injection-molded components for the automotive industry.

**Audit Times**

| | Day 1 | Day 2 |
|---|---|---|
| Auditor Arrival/Opening Meeting: | 7:30 a.m. | 6:00 a.m. |
| Closing Meeting: | | 3:00 p.m. |
| Auditor Departure: | 5:00 p.m. | 3:30 p.m. |

Debriefs will be scheduled as needed
Tentative Time for working lunch: Noon

**Special Items/Issues to be audited (based on pre-audit information – performance issues, new products/projects, concerns/complaints, ownership/management changes):**
**Part number: XXXXXXXX GM Level 1 containment**

**Note:** The Management Representatives as well as Executive Management for the site must be available for this review.

# Certification/Surveillance Assessment Plan

## Auditor Worksheet/Plan

### Day 1

| Time | Auditor A | Time | Auditor B |
|---|---|---|---|
| 7:30 a.m. | **Opening Meeting** | | |
| 8:00 a.m. | **Customer Satisfaction**<br>**-Delivered Part or Service Quality -On Time Delivery**<br>**-Stop Shipment Notification -Field Returns, Complaints, disruptions**<br>**-Continuous Improvement**<br>**-Management Review (including Internal Audit & Corrective Actions)** | | |
| **The remainder of the schedule may be changed based on trends in any of the areas noted above** | | | |
| 9:00 a.m. | Design Planning<br>Project Management | 9:00 a.m. | Material Procurement |
| | | 9:30 a.m. | Sales Order Entry |
| | | 10:30 a.m. | Product & Process Changes |
| | | 11:00 a.m. | Resources & Qualifications |
| 12:00 p.m. | Assessor Debrief/Lunch | | |
| 1:00 p.m. | Process Planning<br>Project Management | 1:00 p.m. | Tool Management<br>Maintenance Planning<br>Facility Design |
| 3:00 p.m. | Manufacturing<br>Validation of Process & Product | 3:00 p.m. | Lab. Testing<br>Quality Eval.<br>Scheduling |
| 4:30 p.m. | Auditor & Client Debrief | 4:30 p.m. | Auditor & Client Debrief |

### Day 2

| Time | Auditor | Time | Auditor B |
|---|---|---|---|
| 6:00 a.m. | Manufacturing<br>Validation of Process & Product | 6:00 a.m. | Manufacturing<br>Validation of Process & Product |
| | | 7:00 a.m. | Manufacturing<br>Receiving & Receiving Inspection |
| 8:00 a.m. | Manufacturing<br>Non-Conforming Process | 8:00 a.m. | Resource Competence<br>Training |
| 10:00 a.m. | Shipping<br>Production Control<br>Communication | 10:00 a.m. | Audit of Customer Specific Requirements |
| 12:00 p.m. | Assessor Debrief/Lunch | | |
| 1:00 p.m. | Validation of Measuring Equipment | 1:00 p.m. | Manufacturing<br>Maintenance |
| 2:30 p.m. | Auditor Debrief & Caucus | | |
| 3:00 p.m. | Closing Meeting | | |

# QMS Certification/Surveillance
# Process Approach Audit Plan
# (* indicates mandatory field)

**Company Information**
**Certified Site:**

*Customer _____
*Address_____
*Address_____
Total Number of Employees_____
*Standard_____
PPE _____Attire_____
Language Used_____

*Management Representative
_____
Contact Information:
_____
*Shifts_____
(All shifts for QS-9000 & ISO/TS 16949 will be audited)

***Support Site(s) Information (if any)**

Address _____
_____
Processes:_____
Phone:_____
Fax:_____

Address_____
_____
Processes:_____
Phone:_____
Fax:_____

**Audit Information**

*Audit Dates_____
*Assessor(s)_____
*Lead:_____

* Audit Days Required _
Number of Guides _____
*Supplier Codes:_____
GM _____Ford_____
DaimlerChrysler_____

*Scope Statement:

*Major Customers & Customer Specifics (if applicable):

Note: the ^ denotes customers with specifics – see readiness review information

Audit Times

| | Day 1 | Day 2 |
|---|---|---|
| Auditor Arrival/Opening Meeting: | | |
| Closing Meeting: | | |
| Auditor Departure: | | |

Debriefs will be scheduled as needed
Tentative Time for working lunch: Noon

***Special Items/Issues to be audited (based on pre-audit information – performance issues, new products/projects, concerns/complaints, ownership/management changes):**

# Certification/Surveillance Assessment Plan

## Auditor Worksheet/Plan

**Day 1**

**(Processes as identified by the organization will be assigned)**

| Time | Auditor A | Time | Auditor B |
|---|---|---|---|
| | Opening Meeting | | |
| | **Update to Customer Satisfaction Input**<br>**-Delivered Part or Service Quality** **-On Time Delivery**<br>**-Stop Shipment Notification** **-Field Returns, Complaints, disruptions,**<br>**-Continual Improvement** **-Warranty Issues**<br>**-Management Review Results (including Internal Audit, Preventive &Corrective Actions)**<br>**-Prior audit issues (if applicable)**<br>**-Other customer metrics as appropriate** | | |
| **The remainder of the schedule may be changed based on trends in any of the areas noted above** | | | |
| | | | |
| | | | |
| | **Auditor Debrief & Caucus** | | |
| | **Closing Meeting** | | |

# APPENDIX L - DOCUMENTATION STRATEGY

## Strategy One

**The Matrix Approach:** This documentation approach is an option for organizations transitioning from QS-9000 Third Edition or ISO/TS 16949:1999 to ISO/TS 16949:2002. Many previously certified organizations created their quality manual, procedures and other documentation so that their structure and numbering system reflected the structure and numbering system in the technical specification or standard. ISO/TS 16949:2002 does not require organizations to change the structure of their existing documentation system. The existing quality system and numbering system for QMS document and data control can remain the same. However, organizations may find that developing a matrix to show the linkage between a new requirement and the documentation to support it very helpful; especially in helping auditors determine how the organization is meeting ISO/TS 16949:2002 requirements and what evidence is being monitored to determine the effectiveness of the QMS and its processes.

### Benefits

- An organization, especially one that is compliant to ISO 9001:2000 requirements, can easily update their documents to include the ISO/TS 16949:2002 requirements and not have to change their document structure and numbering systems.
- Saves resources by not having to recreate the documentation.
- Potentially reduces training needed to roll out the new system in the organization because people are familiar with that structure already.

### Disadvantages

- This may promote the elemental approach to auditing, rather than the required “Process Method”.
- Introduces another layer of documentation between the local procedures/processes and the actual ISO/TS 16949:2002 requirement.
- Disguises the fundamental change in approach intended by the migration to ISO/TS 16949:2002.

**Steps to accomplish the matrix approach**

**a.** Create the matrix comparing the organizations QMS system to the ISO/TS 16949:2002 requirements.
**Note:** Ideally this should be completed to the "shall" level of each requirement. The *Process Identification Tool* may be useful to facilitate this requirement mapping. (Refer to *ISO/TS 16949:2002 Process Identification Tool* at: http://www.aiag.org/isots_tool/isots_tool.asp.)

**b.** Review the adds/changes/deletions from the gap analysis. Mapping of the current documents to ISO/TS 16949:2002 also helps in identifying gaps in the existing QMS. This approach should validate the initial gap analysis from Step 4.

**c.** Develop and include the new requirements from ISO/TS 16949:2002 that have been added into the organization's QMS.
**Hint:** It may be a good practice to highlight these new additions.

Following is an example of how the Process Identification Tool may be used to create a matrix cross-referencing the organization's existing system to the new requirements:

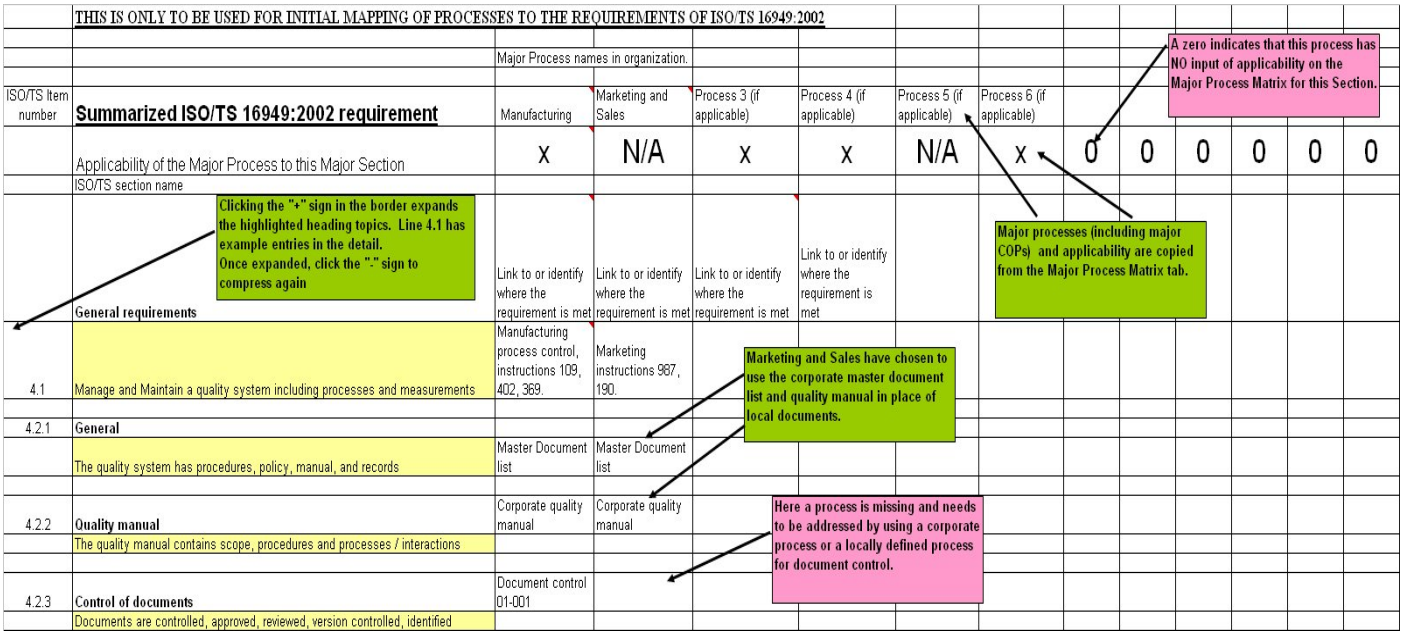



**Figure 12. Example of a matrix using the Process Identification Tool**

## Strategy Two

**Revise Current Documentation:** This is another option for organizations that are transitioning from QS-9000 Third Edition or ISO/TS 16949:1999 to ISO/TS 16949:2002. This approach may work well for organizations also interested in making their document system "lean". The new ISO/TS 16949:2002 has only seven required documented procedures giving organizations flexibility to determine what procedures/processes need to be documented.

**Benefits**

- Organizations may find this an opportunity to reevaluate their documentation looking for opportunities to reduce the amount of documents in their facility. Examine the organization's documentation to see what is still applicable, what is no longer required, and where the organization's system may benefit from some new procedures. Consider the size of the organization and the type of activities, the complexity of the organization's processes and their interactions, any customer requirements and the competence of the personnel. The end result may provide a more streamlined and effective system, less paperwork, fewer documents that require revisions and approvals, savings of time and costs and improved customer satisfaction.

**Disadvantages**

- The approach may take more time and require more resources than the matrix approach.
- Revision of existing documentation may still retain the elemental approach.

### Steps to revise documentation

**a. Identify and Map the Organization's Processes:** The process mapping method is recommended to assure that the Customer Oriented Processes (COPS) and product/document process flows are understood.

**b. Eliminate Unnecessary Documents:** Review the organization's current documents and eliminate the ones no longer needed. It may not be a good idea to just eliminate every document not specifically required. Instead look at them and see if they add value to the organization's system. The ISO/TS 16949:2002 provides minimum requirements. The organization may have many other value-added processes not specifically required by ISO/TS 16949:2002.

**c. Create Any New Documents:** If there are procedures, work instructions or other documents needed to ensure a standardized and effective result or to meet a specified requirement that is not covered by existing documentation then they will need to be created. Try to keep the documentation as simple and concise as possible. Unless otherwise required, (e.g., customer, regulatory and environmental), documentation should only be used where its absence could have an adverse effect on customer satisfaction.

## Strategy Three

**Create New or Reinvigorate Existing Systems:** The organization identifies where within its processes it is meeting the requirements of ISO/TS 16949:2002. This can be accomplished by use of the *ISO/TS 16949:2002 Process Identification Tool.* In identifying the organization's processes, any organization structure or numbering system linked to any prior technical specification or standard should be discarded. This exercise will not only show compliance to ISO/TS 16949:2002, it will show where gaps exist. Any documents or processes or requirements "left over" after this exercise should be reconsidered for relevance to ISO/TS 16949:2002 or customer requirements. (Refer to Appendix C, *ISO/TS 16949:2002 Process Identification Tool, or* at http://www.aiag.org/isots_tool/isots_tool.asp.)

### Benefits

- Allows organizations to take a fresh, unbiased look at ISO/TS 16949:2002 requirements and to develop a streamlined QMS to support the requirements.
- By starting over the organization may gain a better understanding of its business processes, eliminate unnecessary steps, and reduce excess documentation.

### Disadvantages

- The approach requires the most time and resources.
- If organizations with a currently certified QMS employ this approach, personnel in the organization may feel they are being forced to re-create procedures from scratch that have already been fine-tuned and proven over time.
- If this change is not cascaded by top management showing justification, people may view this as a change for the sake of change or "yet another initiative".

# APPENDIX M - BIBLIOGRAPHY

**Manuals consulted:**

*ISO/TS 16949:2002 Technical Specification Quality management systems – Particular requirements for the application of ISO 9001:2000 for automotive production and relevant service part organizations*

*IATF Guidance to ISO/TS 16949:2002*

*IATF Quality System Assessment Checklist to ISO/TS 16949:2002*

*IATF Automotive Certification Scheme for ISO/TS 16949:2002- Rules for achieving IATF recognition*

*ISO 9000:2000 Quality Management systems – Fundamentals and Vocabulary*

*ISO 9001:2000 Quality Management Systems – Requirements*

*ISO 9004:2000 Quality Management systems – Guidelines for Performance Improvements*

*QS-9000 Third Edition*

**Web sites consulted:**

www.iso.org

www.iaob.org

www.aiag.org

# ABOUT AIAG

## Purpose Statement

To provide an open forum where members cooperate in developing and promoting solutions that enhance the prosperity of the automotive industry. Our focus is to continuously improve business processes and practices involving trading partners throughout the supply chain.

## Core Values

**People –** Our strength comes from passionate and personally committed volunteers and staff. We provide an environment of integrity, trust, teamwork, and mutual respect to foster open, frank communication as we achieve consensus on industry needs and solutions.

**Innovation –** With a sense of urgency, we drive and support the development and implementation of common, leading-edge solutions that provide value to the automotive industry and its customers.

**Excellence –** We provide quality and excellence in all we do and how we do it.

We do what's right for the industry!

## AIAG Organization

AIAG is made up of a board of directors, an executive director, associate directors, a full-time staff, and volunteers serving on project teams. Under the direction of the executive director, associate directors– along with the managing director, department managers, and program managers, plan, direct, and coordinate the association's activities. The executive director and loaned executives are *on loan* from member companies for varied lengths of time.

## AIAG Projects

Volunteer committees focus on business processes or supporting technologies and methodologies. They conduct research and develop, publish, and provide training on standards, conventions, standard business practices, white papers, and guidelines in the areas of automatic identification, CAD/CAM, EDI/electronic commerce, continuous quality improvement, materials and project management, returnable containers and packaging systems, and transportation/customs.

AIAG - An Association Fostering Total Supply Chain Partnering

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