AIAG

Automotive Industry Action Group

CQI-16

ISO/TS 16949:2009 指南手册

CQI-16

ISO/TS 16949:2009 指南手册

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Published by:
Automotive Industry Action Group
26200 Lahser Road, Suite 200
Southfield, Michigan 48033
Phone: (248) 358-3570 • Fax: (248) 358-3253

ISBN#: 978 1 60534 159 0

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出版发行：
美国汽车工业行动集团
26200 Lahser Road, Suite 200
Southfield, Michigan 48033
电话：(248) 358-3570 • 传真：(248) 358-3253

ISBN#: 978 1 60534 159 0

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OVERVIEW

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

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

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

1 PROCESS APPROACH

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

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

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

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

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

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

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

1.1 Quality Management System Requirements

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

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

概论

本实施指南是为了帮助组织从当前的质量管理体系（QMS）过渡到 ISO/TS 16949:2009，它只作为一个指南文件而存在。请注意 ISO/TS 16949:2009 使用了 ISO 9001:2008 作为它的基本规范。在使用本指南前，你可以登录 AIAG 的网站：www.aiag.org，查询怎样购买 ISO 标准。

值得注意的是，ISO/TS 16949:2009 使用了“过程方法”的术语，在本指南文件中也将对它进一步阐述。根据组织当前的质量管理体系的设立情况，该 QMS 可能已经遵循了“过程方法”。

ISO/TS 16949:2009 注重的是顾客的满意，据此来设计、实施、维护组织的质量管理体系是非常重要的。它包括更加重视顾客的特殊要求以及组织达成要求的能力。写你所做和做你所写已经不够，而是要验证组织在满足顾客和内部要求时的过程有效性。

1 过程方法

ISO/TS 16949:2009 的 0.2“过程方法”指出：

……为使组织有效运行，必须确定和管理众多相互关联的活动。通过使用资源和管理，将输入转化为输出的一项或一组活动，可以视为一个过程。通常，一个过程的输出直接形成下一个过程的输入。

为了产生期望的结果，由过程组成的系统在组织内的应用，连同这些过程的识别和相互作用，以及对这些过程的管理，可称之为“过程方法”。

过程方法的一个优点是对过程系统中单个过程之间的联系以及过程的组合和相互作用进行持续的控制。在质量管理体系中应用过程方法时，强调以下方面的重要性：

a) 理解和满足要求；
b) 需要从增值的角度考虑；
c) 获得过程绩效和有效性的结果；
d) 在客观测量的基础上，持续改进过程。

它通常是通过组织的质量管理体系的过程描绘（比如：流程图），并且至少要对照技术规范的所有要求来评审已经实施的步骤来实现的。

1.1 质量管理体系要求

ISO/TS 16949:2009 在条款 4.1 中指出组织应：

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

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

2 EXPLANATION OF PROCESS APPROACH / AUDIT

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

2.1 Benefits of Using the Process Approach

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

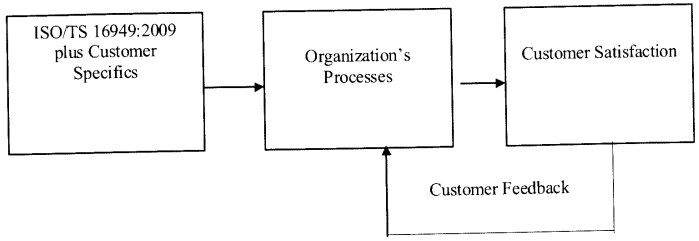


Figure 1. Alignment to Customer Metrics

- 确定质量管理体系所需的过程及其在整个组织中的应用；
- 确定这些过程的顺序和相互作用；
- 确定所需的准则和方法，以确保这些过程的运行和控制有效；
- 确保可以获得必要的资源和信息，以支持这些过程的运行和监视；
- 监视、测量（适用时）和分析这些过程；
- 实施必要的措施，以实现所策划的结果和对这些过程的持续改进。

它通常是使用“过程方法”，通过过程描绘或者形成文件的方针、程序和作业指导书来文件化的。

2 对过程方法/审核的说明

本章节显示了建议的怎样识别、定义、形成文件并审核过程来准备 ISO/TS 16949:2009 认证的最佳实践。

2.1 使用过程方法的益处

- 提高对过程接口和相互关系的理解
- 组织活动与顾客衡量指标的直接对应（见图 1）
- 通过顾客衡量指标的反馈，对组织的过程有效性提供了顾客的感受
- 过程方法是已被全球汽车业所理解的一种“通用语言”
- 通过非增值活动的减少/消除，改进组织的效率
- 对于每个组织而言，可通过它们自己的过程来制定合适的审核
- 第三方机构和内部审核着重于对顾客满意最为重要的活动和目标
- 当顾客目标达到时，过程审核提供了一种持续改进的基础

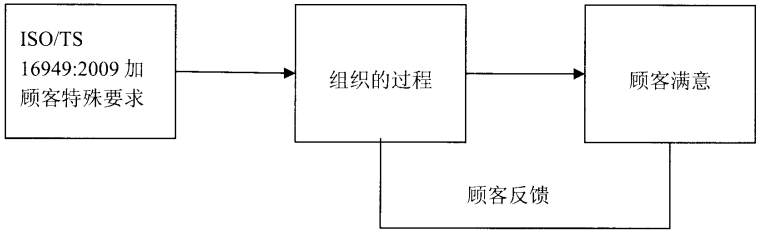


图 1. 与顾客衡量指标的直接对应

2.2 What Is A Process?

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

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

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

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

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

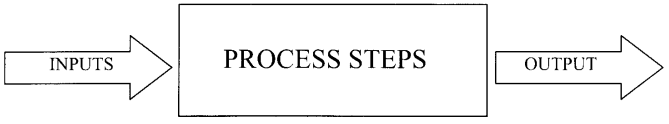


Figure 2. Classical Process Model

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

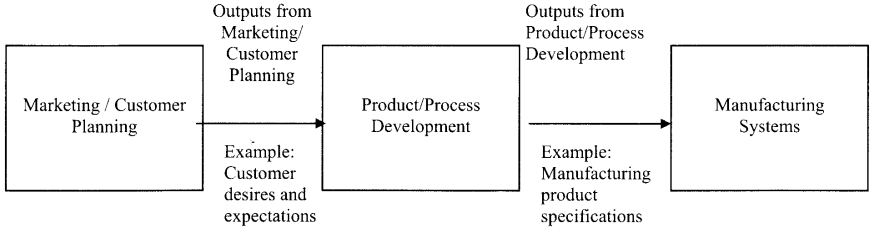


Figure 3. Interactions between Processes

2.3 The Building Blocks of a Process

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

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

2.2 什么是过程？

定义：ISO 9001:2008“质量管理体系——基础和术语”提供了以下定义：

过程 = 将输入转化为输出的一系列相互关系或相互作用的活动

注 1：一个过程的输入通常是其他过程的输出。

注 2：出于增值的目的，组织内的许多过程通常是在受控状态下被策划和执行的。

下面的图 2 描述了输入和输出的基本方法。

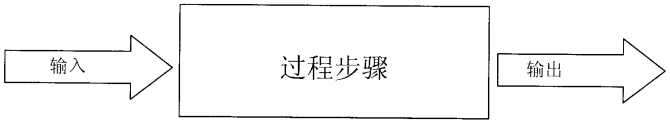


图 2. 典型的过程模式

下方图 3 描述的是一个典型的过程模式的范例：

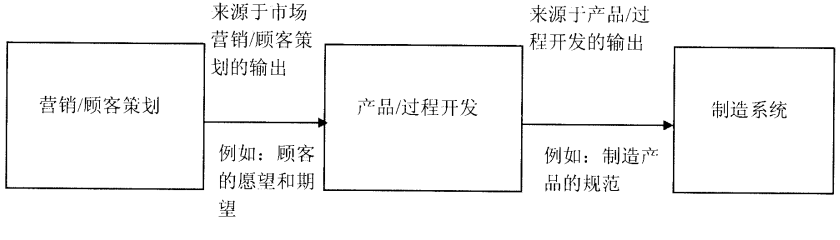


图 3. 过程间的相互作用

2.3 建立过程的框图

过程可以描述为包括以下方面的系列活动和职责：

- 管理职责（过程负责人）
- 资源管理（人员、技能、设备、设施、物料）
- 产品实现（生产的步骤——实现——产品）
- 测量、分析和改进（了解何所需，何所有）

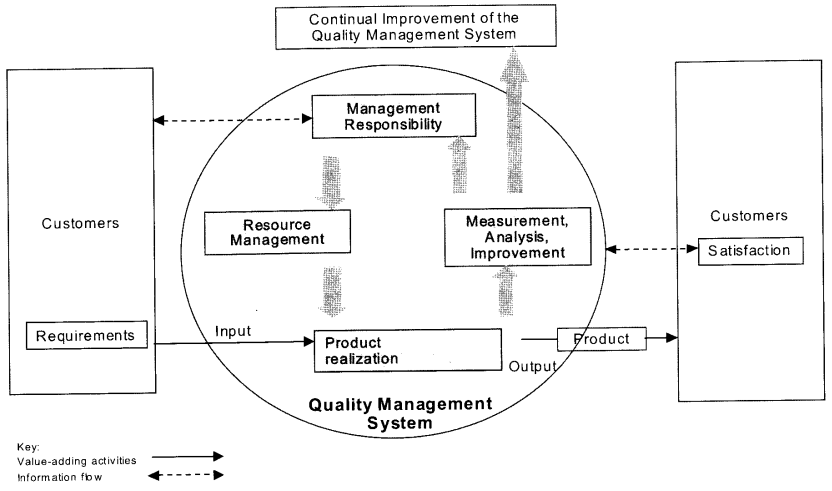


Figure 4. ISO/TS 16949:2009 Model of a Process-Based Quality Management System

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

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

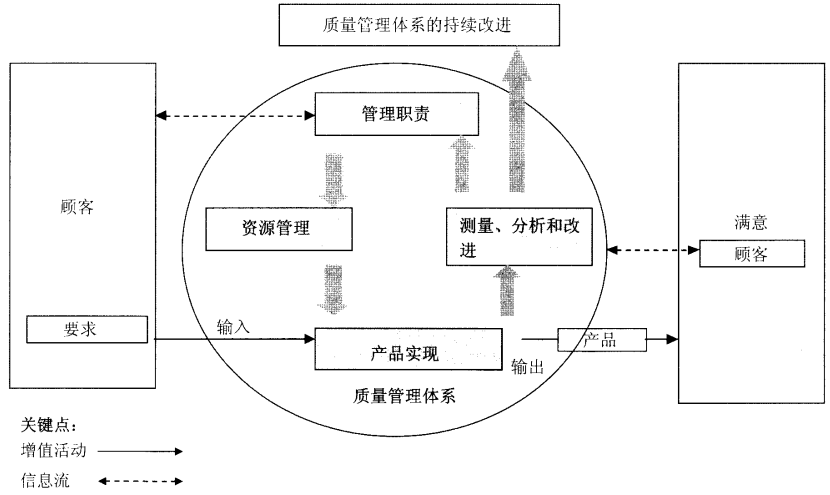


图 4. 一个以过程为基础的质量管理体系的 ISO/TS 16949:2009 模型

图 4 显示了一个以过程为基础的质量管理体系的结构。尽管该结构没有在 ISO/TS 16949:2009 中明确要求，图上四个强调的区域都和汽车工业相关，并且对过程描述是有用的。这四个强调区域对应的是 ISO/TS 16949:2009 第 5 章到第 8 章的条款。第 4 章（质量管理体系）给出了适用于整个质量管理体系的文件化和结构的要求。

第 5 到第 8 章的应用可用于任何过程（适用于所有类型的过程，不仅限于制造）：

第 5 章：管理职责——代表了管理监督的措施，以确保所有过程步骤都致力于达成顾客的要求。

第 6 章：资源管理——为过程提供适当且足够的资源（技能、人员、设备、设施）以达到顾客满意。

第 7 章：产品实现——包括必要的策划、理解顾客要求、设计、采购、生产、质量控制和物流的步骤，以生产预期的产品。

第 8 章：测量、分析和改进——包括对过程和对顾客要求的最终产品的符合性的确认，以及通过纠正和预防措施的持续改进。

参见附录 A – 热处理过程范例。该范例显示了上述四章内容在一个汽车过程中的用途。

2.4 The Process Approach

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

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

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

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

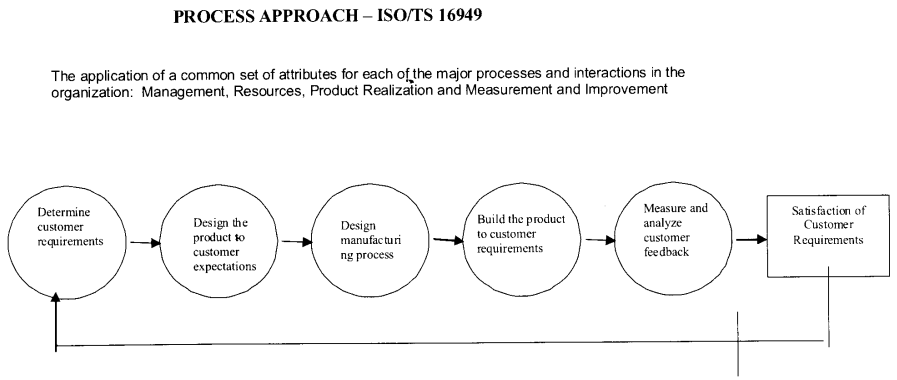


Figure 6. Process Approach – ISO/TS 16949:2009 Process Attributes

2.4 过程方法

过程方法是设计、实施、维护质量管理体系的方法。它明确了 ISO/TS 16949:2009 内的每个要求的过程输入和输出。方法可以包括图形演示法（参见附录 D，过程描绘范例图 1）、书面化的指导书（比如政策、程序）、流程图、可视化媒介或电子媒体方法。

顾客要求构成了质量管理体系中不可缺少的部分。关于该信息可参见每一个特定的顾客（比如：顾客网站）。
下方图 6 显示的过程方法显示了围绕着顾客满意和组织过程的组织的质量管理体系的结构。通过明确输入和输出以及顺序和相互作用，可以按照顾客的要求来测量质量管理体系以验证其有效性（横向整合）。

图 6 显示了过程审核中需要评审的每个过程的特性。水平箭头代表了组织中适用于每个过程的区域。

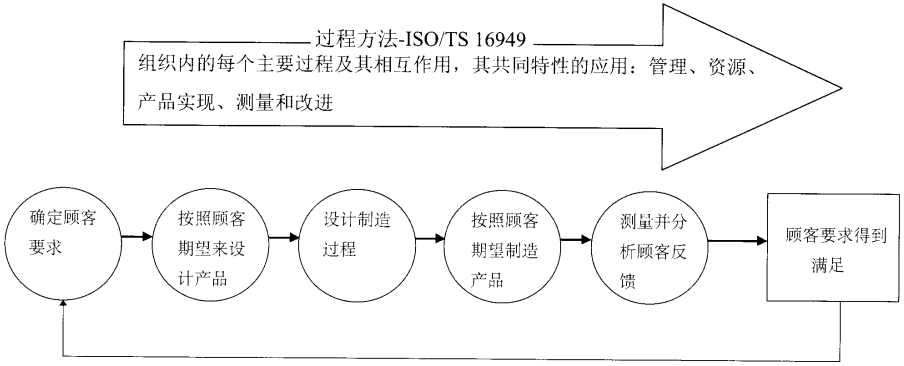


图 6. 过程方法——ISO/TS 16949:2009 的过程特性

3 SETTING UP THE QUALITY MANAGEMENT SYSTEM

3.1 Step 1 – Process Identification

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

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

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

3.2 Step 2 – Process Mapping

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

See Appendix D - Process Mapping Examples for additional information.

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

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

3 建立质量管理体系

3.1 步骤 1 – 过程识别

ISO/TS 16949:2009 的第 4.1a 条款指出："组织应确定质量管理体系所需的过程及其在整个组织中的应用"。组织须要显示是怎样满足 ISO/TS 16949:2009 的所有要求的。

在评审本文件时，组织须要识别在质量管理体系的哪个环节满足了 ISO/TS 16949:2009 的要求。然后审核员通过组织的过程来关注组织的有效性。

顾客要求是质量管理体系中不可缺少的一部分。参见每一个特定顾客的相关信息（比如：顾客网站）。

3.2 步骤 2 – 过程描绘

ISO/TS 16949:2009 的第 4.1b 条款指出："组织应确定这些过程的顺序和相互作用"。组织须要显示它从过程输入——过程步骤——过程输出，怎样以逻辑的顺序相互作用来满足 ISO/TS 16949:2009 的所有要求。这步骤地另一个术语称之为："过程描绘"。

参见附录 D——过程路径图范例，以获得更多信息。

一旦组织的过程已按照要求被绘制出来，组织就可以准备计划其内部基于过程的审核。

如图 7 所示，过程审核方法是通过其自然的工作流程来遵循组织的质量管理体系的。

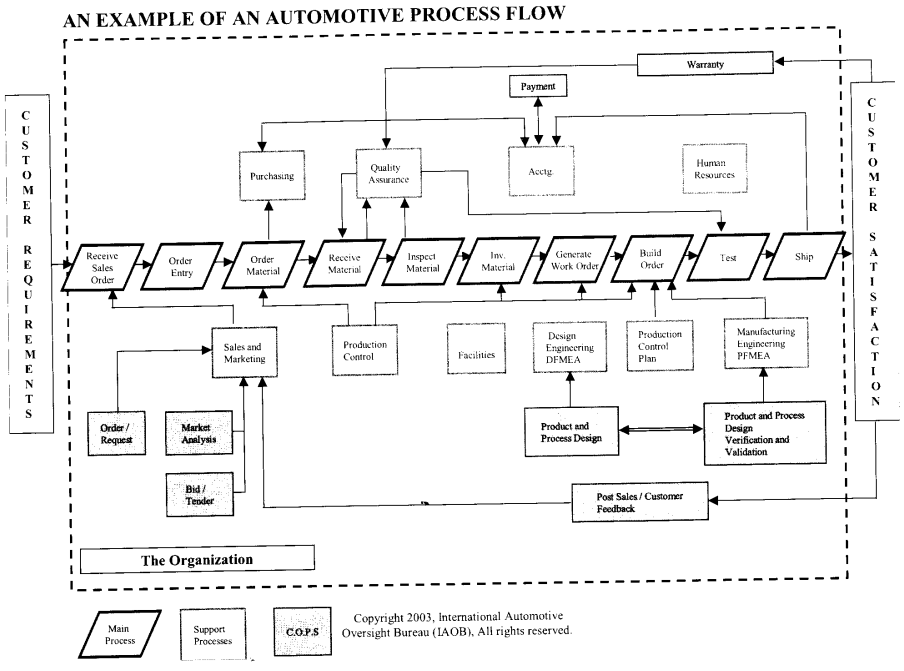


Figure 7. An Example of an Automotive Process Flow

3.3 Step 3 – Effectiveness

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

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

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

汽车过程流程范例

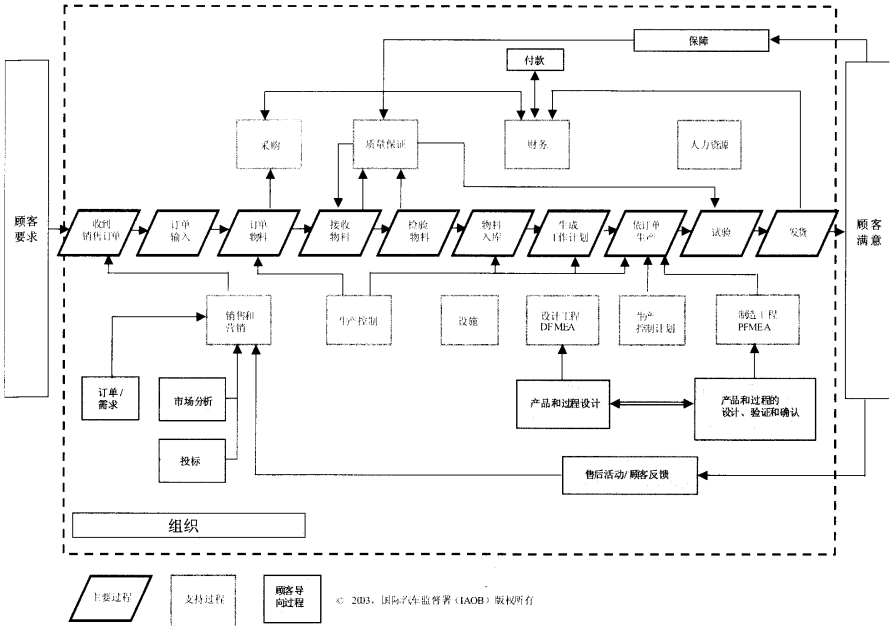


图 7. 汽车过程流程范例

3.3 步骤 3 – 有效性

ISO/TS 16949:2009 的第 4.1c 条款指出："组织应确定所需的准则和方法，以确保这些过程的运行和控制有效"。

ISO 9000:2000 将"有效性"定义为："所策划的活动被实现，且达成策划结果的程度"。

在绘制过程时，根据输入来评审过程的输出。把过程输出和组织的目标作比较。分析正在使用的，或者确定将要使用的衡量指标。这些衡量指标用于跟踪进程，指出纠正或者推动质量管理体系的改进。衡量指标并不总是量化的。也可以应用来源于管理评审的措施项目的结果。→ 例如什么？难以快速全文费解

3.4 Step 4 - Auditing

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

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

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

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

The basic steps in a process approach audit can include:

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

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

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

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

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

3.4 步骤 4 – 审核

ISO/TS 16949:2009 要求三种类型的审核：

- 8.2.2.1 质量管理体系审核
- 8.2.2.2 制造过程审核
- 8.2.2.3 产品审核

所有这些审核都必须使用过程方法来执行。

ISO/TS 16949:2009 条款 8.2.2.5 内部审核员资格："组织应具备有资格审核本技术规范要求的内部审核员（参见 6.2.2.2）"。特殊准则请参考顾客的特殊要求。

过程方法审核中的基本步骤可包括：

- 评审顾客清单及其顾客特殊要求
- 识别过程负责人，他们的职责和权限
- 执行审核前，评审过程测量，尤其是对顾客来说很重要的衡量指标。将业务目的和目标与顾客的目的和目标作比较。
- 理解组织内基本的业务过程并遵循这些过程
- 评审连接（过程间的传递）及其相互作用（比如：从员工到员工、班次到班次、某职能到另一职能、某工厂到另一工厂、某过程到另一过程）

如果产品/过程满足规范且没有负面趋势：

- 询问过程的基本构建框图以及输入/输出，以确定该过程的知识
- 询问组织怎样测量过程的有效性，以及他们如何解读测量结果
- 询问他们如何建立持续改进的步骤
- 询问他们是否使用基准数据来实现持续改进

如果产品/过程无法满足规范或者 有负面趋势：

- 是否有最高管理者介入
- 询问由谁负责（过程负责人）
- 着重于产品实现（涉及的步骤）。哪个步骤没有被遵循或者没有被有效的执行？
- 组织是否知道负面趋势缘何而来（测量是从哪里开始显现问题的？）
- 组织怎样遏制问题（保护顾客）
- 组织怎样调查以发现不符合规范的零件或过程的根本原因
- 在纠正措施上获得了什么进展
- 评审了相似的过程，防止问题再发生
- 如果过程还涉及制造：

- 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:

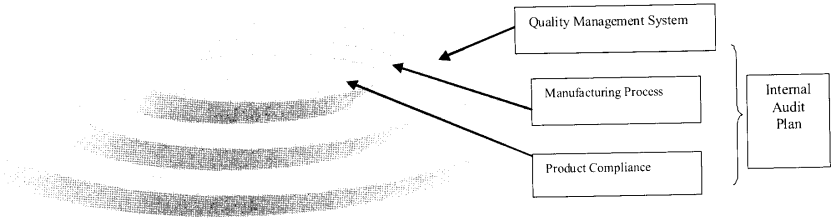


Figure 8. The Three Audits Types build upon each other

- 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 16949:2009 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 16949:2009 may be performed as separate or combined events as shown in Figure 9.

- FMEA 和控制计划是否被评审及更新
- 是否评审和/或增加产品审核

这三种类型的审核是相互关联的，如图 8 所示：

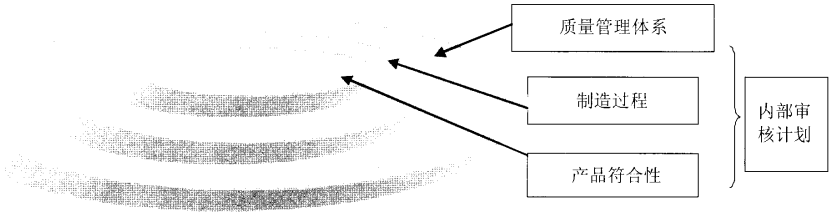


图 8. 三种审核类型是相互依赖的

- 质量管理体系审核使用过程方法来监视组织，通过其自然的流程，从过程到过程来验证对 ISO/TS 16949:2009 和顾客要求的符合性。
- 制造过程审核着重整个质量管理体系内的制造过程。
- 产品审核着重于驱使达成产品要求验证有关的产品特性。

这三种 ISO/TS 16949:2009 要求的审核既可以独立执行，也可以合并执行，如下方图 9 所示。

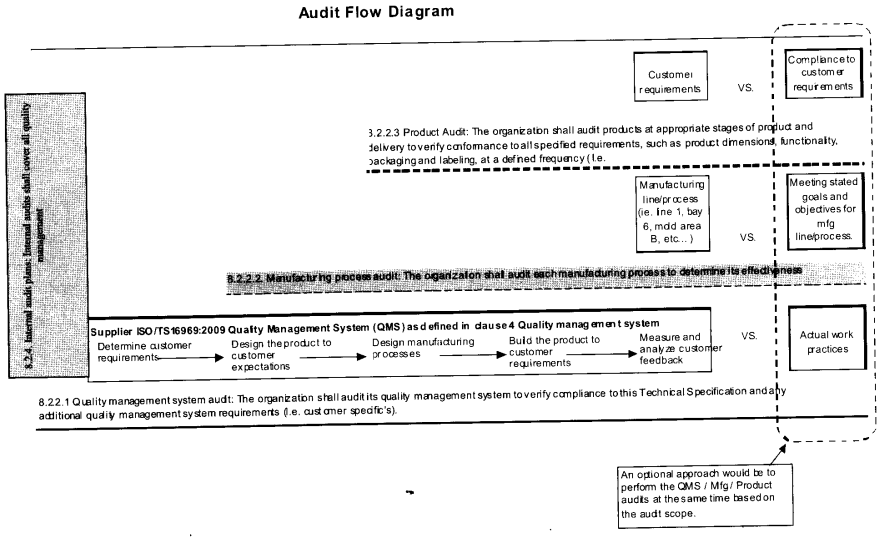


Figure 9. Audit Flow Diagram

3.4.1 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 16949:2009.

- 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 16949:2009).
- 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 16949:2009.

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 B - The Quality Management System Audit for examples of a QMS process audit.

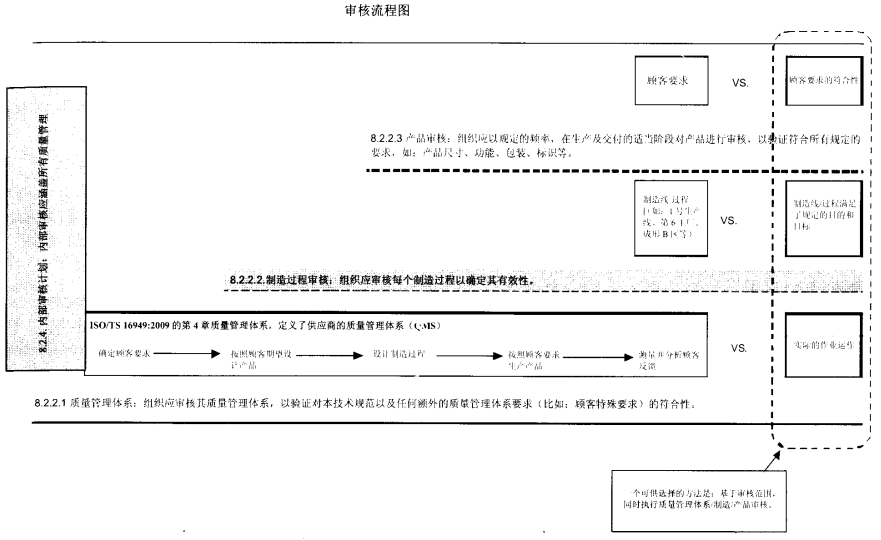


图 9. 审核流程图

3.4.1 质量管理体系 (QMS) 审核

条款 8.2.2.1 要求质量管理体系(即：条款 4.1a-f) 符合 ISO/TS 16949:2009。

- 实施 QMS 的第一步是保证 QMS 符合所有要求，包括顾客的特殊要求（范例：使用 ISO/TS 16949:2009 的传统的文件评审)。
- 第二步是保证 QMS 被遵行 (即：用过程方法来审核)。范例之一就是根据条款 8.2.2.4，在审核计划中按照规定的频率来审核组织的程序、作业指导书、过程路经等。完整的过程清单可以用作审核检查表以确保组织已经涵盖了整个 QMS，从而涵盖了 ISO/TS 16949:2009 的所有要求。

根据条款 4.1c，在质量管理体系的审核中验证每个过程的有效性是十分重要的。审核应当包括着重于顾客满意的衡量指标，包括但不限于，成本、质量、交付、顾客中断等。

制造过程审核和/或产品符合性审核也可以和该审核结合起来一同执行。

QMS 过程审核范例，见附录 B— 质量管理体系审核。

3.4.2 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.

3.4.2 制造过程审核

如 8.2.2.2 所述："组织应审核每个制造过程以确定其有效性。"

"每个制造过程"这段叙述的应用，是由组织来定义，通常是以控制计划的形式来表示。组织还定义其制造过程审核的范围。制造过程审核须要着重验证已策划的制造过程绩效已被达成，比如：过程是否达成过程设计输出所定义的绩效？

所有不同类型的过程都必须被审核。例如：如果一个相同的过程重复出现在三个制造线上，只要测量指标显示三条制造线上没有差异，则可以只审核其中的一个过程。

制造过程审核强调质量管理体系内部的制造的重要性。制造过程审核是组织的制造过程的一个审核过程（比如：装配、加工、热处理、喷漆、铸造等的审核）。

通常情况下，制造过程审核使用控制计划的有效性作为它的初始焦点。下面是须要考虑到的几个关键指标：

- 已策划的活动是什么？
- 实际的运作是否遵循策划的活动来进行？
- 顾客衡量指标是否显示控制计划是有效的？

制造过程可以包括下列活动之间或内部的接口/连接：

- 顾客评分和顾客抱怨
- 内部的不符合
- 过程流程图、PFMEA、控制计划、作业指导书
- 内部沟通
- 员工能力
- 报价的生产能力
- 预防/预测性维护

注：制造过程审核可以利用产品审核的实际测量结果来确认制造过程的有效性。

下方的图 10 显示的一个典型的制造过程审核流程图范例。

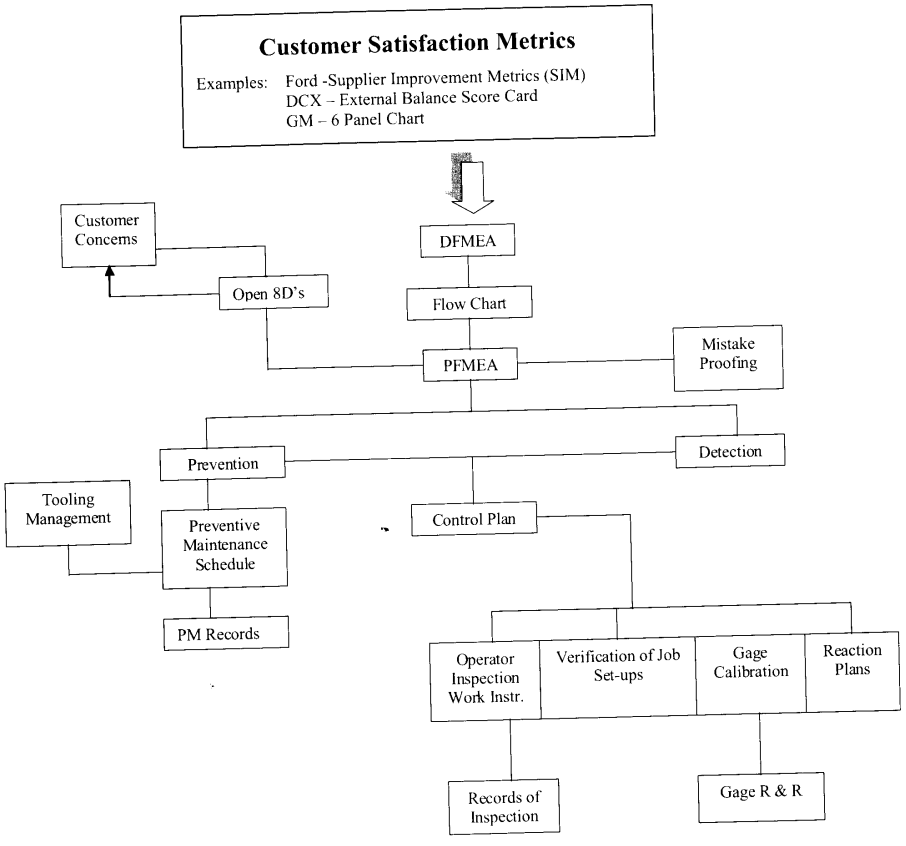


Figure 10. Typical Manufacturing Process Audit Flow Diagram

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

3.4.3 Product Audit

As stated in 8.2.2.3 of ISO/TS 16949:2009, "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."

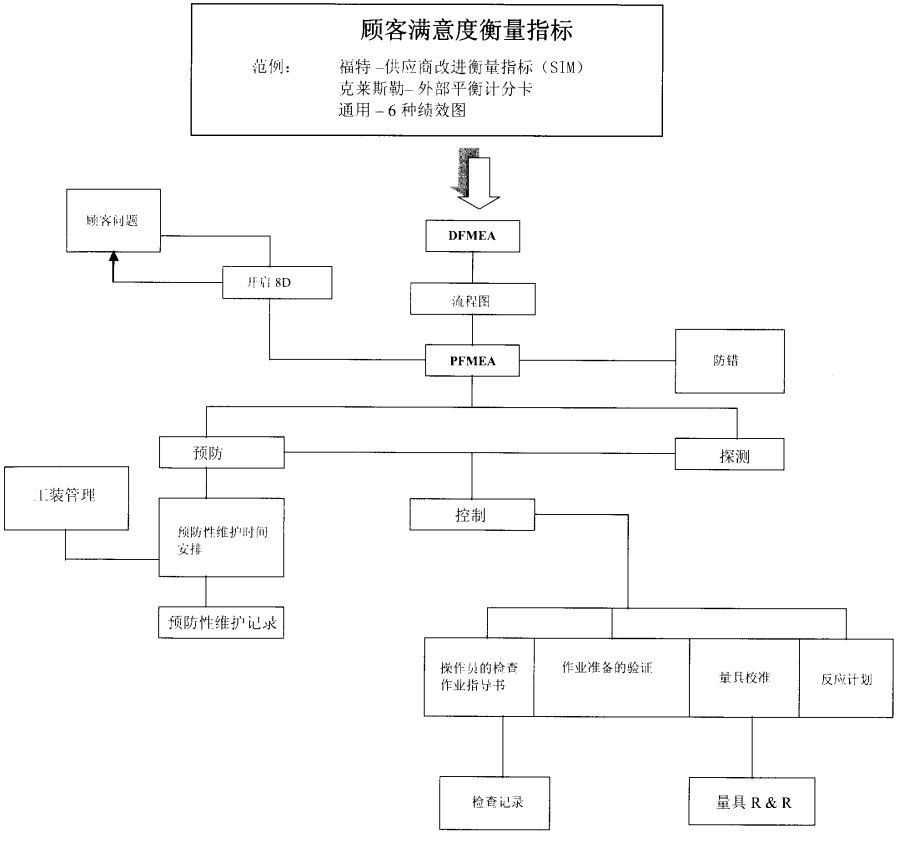


图 10. 典型的制造过程审核流程图

更多关于制造过程审核的信息，*请参见附录 C – 制造过程审核流程图*

3.4.3 产品审核

如 ISO/TS 16949:2009 的 8.2.2.3 所述："组织应以规定的频率，在生产及交付的适当阶段对产品进行审核，以验证符合所有规定的要求，例如：产品尺寸、功能、包装盒标签等。"

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.

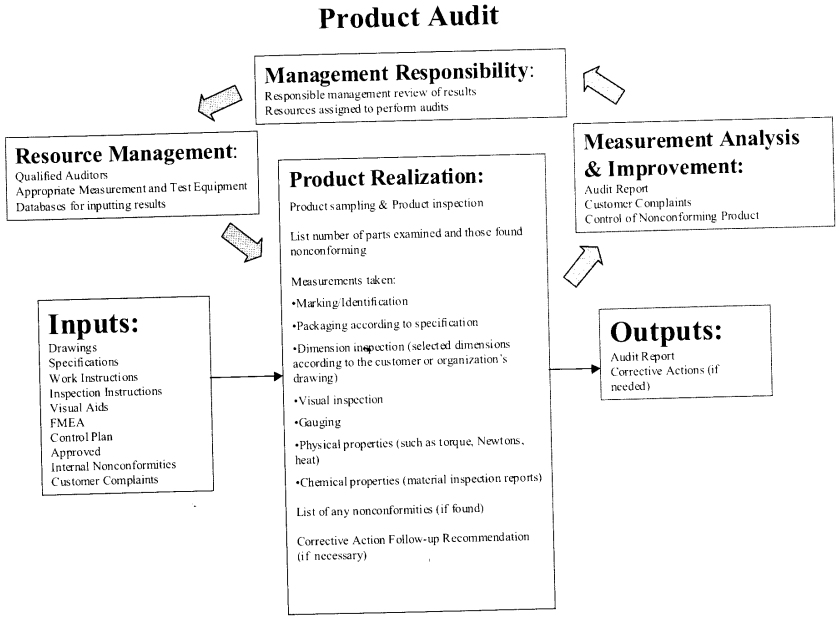


Figure 11. Product Audit

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.

3.4.4 Internal Audit Plans

As stated in 8.2.2.4 of ISO/TS 16949:2009, "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."

如图 11 所示，这种类型的审核验证了顾客的输入（比如零件图纸）能够引导出正确的输出（按照图纸正确的尺寸、功能零件、正确的包装和标签）。产品审核员测量产品，并将其与顾客的要求作比较。产品审核监督的是产品从制造过程的一个步骤到另一个步骤的进程。产品审核的实际零件测量可以用于识别未能满足规范的制造过程步骤。

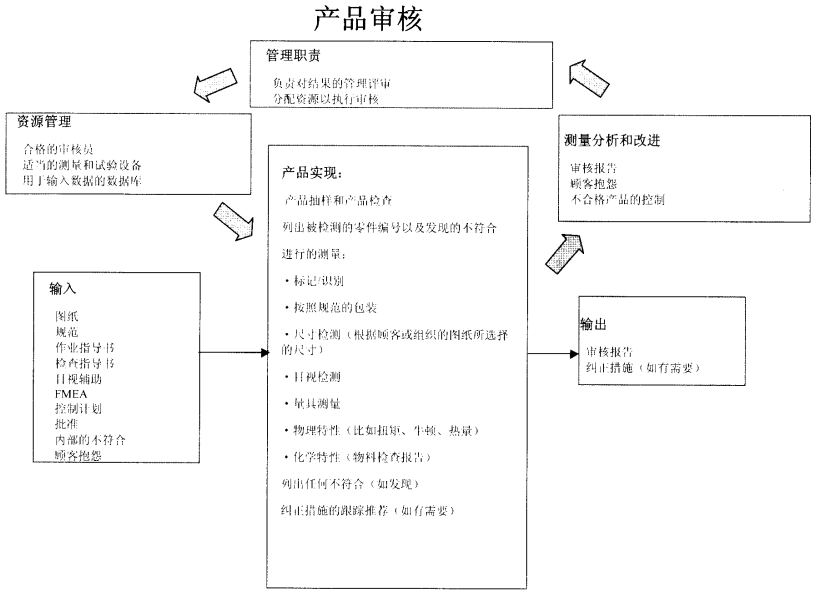


图 11. 产品审核

使用过程审核方法，产品审核的输出（结果、测量、衡量指标）可以成为制造过程审核的输入。在制造过程审核时，审核员能够观察产品审核结果是怎样用于纠正或改进制造过程的有效性的。

3.4.4 内部审核计划

如 ISO/TS 16949:2009 的 8.2.2.4 所示："内部审核应涵盖所有与质量管理有关的过程、活动及生产班次，且应按年度计划进行安排。当发生内部/外部的不符合，或顾客抱怨时，审核频率应适当的增加。"

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 16949:2009 (e.g., Quality System Audit Plan, Manufacturing Process Audit Plan, and 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.

See page 80 for 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.

年度计划定义了一年内进行的审核范围、频率和审核类型。计划必须包括 ISO/TS 16949:2009 要求的所有审核类型(比如：质量体系审核计划、制造过程审核计划、产品审核计划)，并涵盖所有与质量管理相关的过程、活动和班次。这三个审核类型能够以一种顺序或整合的过程来进行。审核员只需在他们的记录中反应所有信息即可。在确定审核频率时，受审核的过程和区域的状态和重要性，以及以往审核的结果都要考虑到。当发生顾客抱怨时，当出现外部不符合或内部不符合时，要适当增加与问题有关的区域的审核频率，以保证适当的关注着那些活动。

请参见第 80 页的准备评估工作单，可能会用到该工作单或与相似的文件。

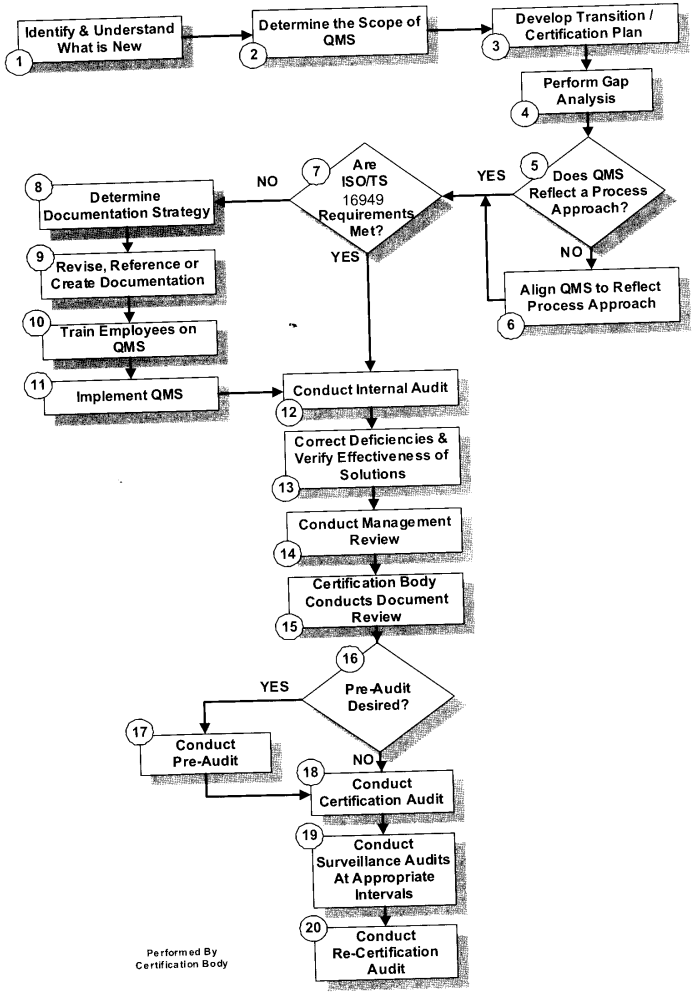
将过程方法投入使用

遵循组织从某一职能到另一职能，从某一过程到另一过程的固有正常流程，并将这实际过程与顾客的要求和衡量指标相比较，组织可以快速地识别要改进的区域，以及可作为基准的区域。同样的这种“环游过程”的方法也可以有效运用在问题解决的技巧上。审核过程的输出是审核报告。该审核报告是管理评审过程的一项重要输入。

4 STRATEGY FOR IMPLEMENTING ISO/TS 16949:2009

Objective: The objective of this section is to outline a strategy organizations may use to implement an ISO/TS 16949:2009 Quality Management System (QMS). In addition, key decisions that organizations may face whether transitioning a current QMS to ISO/TS 16949:2009 or going for initial certification are highlighted along with some action options.

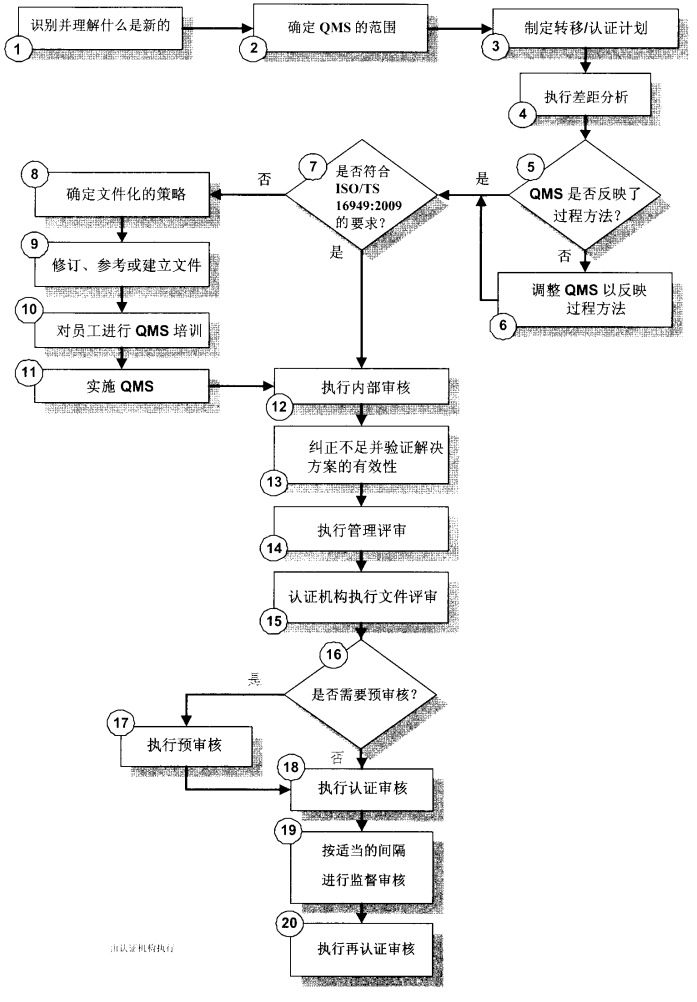
Strategy:



4 ISO/TS 16949:2009 实施策略

目标: 本部分的目标是为了概述组织可能用来实施 ISO/TS 16949:2009 质量管理体系（QMS）的策略。此外，组织可能会面临的关键决策是：是否将当前的 QMS 转移成 ISO/TS 16949:2009，或者寻求首次认证。这些决策会在一些可供选择的措施中被强调出来。

策略:



1. **Identify and understand What is New**: The first step is to identify and understand what is new and different in ISO/TS 16949:2009 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.

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 9001:2008 and the automotive processes to ISO/TS 16949:2009.

3. **Develop a Transition or Certification Plan**: Once the scope of the organization's ISO/TS 16949:2009 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 16949:2009 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.

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 16949:2009. Any requirements not covered by an organization's processes will be considered to be a gap and require correction.

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 16949:2009 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 16949:2009 are met**: Review the results of the gap analysis performed in step 4 and determine if all of the requirements of ISO/TS 16949:2009 have

1. **识别并理解什么是新的：** 第一步是要识别并理解 ISO/TS 16949:2009 新的内容是什么，与组织当前的质量管理体系有何不同。建议组织的关键人员从一个广受好评的培训机构接受关于要求的培训，从而保证能够在清楚理解要求以及这些要求如何应用于组织的情况下展开过程。

2. **确定质量管理体系的范围：**组织须要确定质量管理体系的范围及其认证范围。下面是可能要考虑到的方面：

   - 组织是寻求涵盖了几个不同现场的集团认证，还是在每一个适用的现场实施独立的认证？
   - 组织的产品线是只对汽车行业供货，还是也会有非汽车行业的生产线？

   在后一种情况下，非汽车行业的产品过程可能需要 ISO 9001:2008 认证，而汽车行业的过程需要 ISO/TS 16949:2009 的认证。

3. **制定转移或认证计划：**一旦确定了组织的 ISO/TS 16949:2009 质量管理体系范围，就可以开始制定计划以指导组织顺利通过转移/或认证的过程。转移计划应当包括关键的里程碑、任务顺序、制定的时间要求和资源要求。此外，组织的最高管理者必须保证在开发和实施 ISO/TS 16949:2009 QMS 的过程中，维持了现有的 QMS 的完整性。建议组织及其认证机构共同评审认证时程，这需要考虑到任何在组织上、运营上以及资源上的限制；考虑到认证机构的可配合性以及任何顾客特定的时间要求。

4. 执行差距分析：应当执行差距分析以确定组织当前的 QMS 对 ISO/TS 16949:2009 要求的符合性。任何没有被组织过程涵盖的要求都会被视为一项差距，需要进行纠正。

5. 确定 QMS 是否反映了过程方法：如果 QMS 反映了过程方法，则进入步骤 7。反之，进入步骤 6（参见本手册的过程方法解释）。

6. 调整质量管理体系（QMS）以反映过程方法：如果组织的 QMS 未能反映过程方法，组织需要调整 QMS 以识别关键过程以及它们之间的顺序和相互关系，如步骤 5 所述。尽管 QMS 一开始可能不会反映过程方法，但是过程描绘将会识别 QMS 的相互作用、输入和输出，还能够显示现有的 QMS 不会要求全部重建以包括过程方法。

   提示 1: 在按照过程方法重新调整 QMS 时，建议不要用 ISO/TS 16949:2009 的条款编号来识别过程或程序，因为使用那些条款编号可能会加固要素方法的习惯。

   提示 2: 过程可以用多种格式来文件化，比如程序、作业指导书、表格等等。（更多信息请参见本手册的“过程方法解释”以及“附录 J-过程描绘范例”）。使用流程图和其它的图示法通常也可以有效的就需要的信息进行沟通。

7. **确定是否满足了 ISO/TS 16949:2009 的所有要求：**评审在步骤 4 中进行的差距分析的结果，并确定组织的 QMS 是否处理并满足了 ISO/TS 16949:2009 的所有要求。如果在完成差

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 16949:2009.

- 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.

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 16949:2009 and customer-specific requirements. The following are areas where the organization may require training:

- 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 16949:2009 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 16949:2009 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 16949:2009.

距分析后，组织确定当前的系统能够反映过程方法（步骤 5），那么组织可以为认证过程（步骤 12）开始审核过程的准备工作。反之，则进入步骤 8。

8. **确定文件化的策略**：许多组织将会发现需要对质量管理体系文件进行的一些调整来满足 ISO/TS 16949:2009 的要求。

- 矩阵方法
- 修订当前的文件
- 新建或更新现有的系统

注: 这些策略并未按照优先顺序来列举，组织应当仔细考虑到每个策略的利害。

9. **修订、参照或建立 QMS 文件**：一旦确定了组织的文件化策略，就必须对文件进行更新。开发或调整任何 QMS 文件都应当由跨职能小组完成，小组成员来自各个主要的利益相关者。一旦完成，一定要和文件的使用者一起确认内容是否精确、清楚且相关。

10. **对员工进行新 QMS 的培训**：组织需要对其员工进行培训以保证员工理解了新的系统，以及应用于工作上的 ISO/TS 16949:2009 和顾客的特殊要求。下面是组织可能需要进行培训的方面：

- 最高管理者必须接受固有职责且不能将职责委任他人。当最高管理者可以将职责委任他人的情况下，管理者必须确保委任的任务已被完成。下面是几种常见情况：

ISO/TS 16949:2009 的描述	最高管理者的角色
最高管理者应确保	最高管理者可以委任这些项目。 必须由最高管理者来跟踪，以确保有效的实施了要求。
最高管理者应评审	最高管理者必须执行评审。
最高管理者应提供	提供所述项目是最高管理者的职责。
最高管理者应定义	定义所述项目是最高管理者的职责。
最高管理者应指派/任命	指派/任命相应的员工是最高管理者的职责。

- 如果最高管理者对于所有的要求没有掌握一般性的知识，或是对于 ISO/TS 16949:2009 的条款 5 没有深刻认识的话，符合 ISO/TS 16949:2009 的要求并有效实施 QMS 是不可能的。

- Management awareness (focusing on the benefits that can be added to business as a result of the new customer-focused approach to ISO/TS 16949:2009).
- 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 16949:2009 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 16949:2009 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-

- 管理者的意识（着重于可以增加到商务上的利益，它是对 ISO/TS 16949:2009 以新的顾客焦点方法实施的结果）。
- 内部审核员培训（着重于过程审核以及当前技术规范和新的技术规范之间的变更）。保证审核员都受过培训/有资格来审核顾客特殊要求和过程衡量指标。
- 激发员工意识的项目（顾客员工全面参与并理解 ISO/TS 16949:2009 的要求、过程方法、质量目标、监督、测量和改进活动）。
- 对所有员工进行适用于他们的职责领域的过程、程序和质量目标的培训，以及他们的活动是怎样帮助组织达成目标的。

11. 实施 QMS：当每个人都进行了新的 QMS 及其职责的培训之后，就可以开始实施新系统了。组织可以考虑使用一个渐进的方法或一个全面实施的方法。

- **渐进方法：** 在某一阶段中，组织实施选择的 QMS 过程和程序；当它们完成且运作之后，在另一阶段实施更多的过程和程序。持续该方法直至完成所有的 QMS 过程和程序。当然，实际的过程实施顺序将随每个组织而不同。实施的顺序应当考虑顾客满意的重要事项或注册范围。

优点

- 可以逐渐的引进变更，对持续运营的干扰较少。

缺点

- QMS 中新的过程方法无法和老系统的要素部分完全兼容。
- **全面实施方法：**组织一次性的完成所有的 QMS 过程、程序和转移。这些新的过程和程序被实施，并废除任何旧系统的文件，在适用的情况下，同时从工作场所移除。

优点

- 避免了兼容性问题：所有的过程、交互、输入和输出都被定义。

缺点

- 可能会干扰持续的运营，需要急转弯来同时全面理解新系统。

12. **进行内部审核：**审核整个 QMS 以评估系统、过程实施的有效性，以及对 ISO/TS 16949:2009 和顾客特殊要求的符合性。

13. **纠正缺陷并验证解决方案的有效性：** 组织必须纠正所有在内部审核中识别到的缺陷。实施组织的纠正措施以保证根本原因得到了识别并且已经生成了有效的解决方案。在所有受影响的过程中实施了纠正措施后，组织必须跟踪以验证解决方案有效地解决了不符合。但

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 16949:2009, 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 16949:2009 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.

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 16949:2009 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.

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

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.iatfglobaloversight.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 16949:2009 Rules for Achieving IATF Recognition.

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

当缺陷并没有导致不符合，但可以预知其潜在的不符合时，应当改进过程以影响预防措施。

14. **进行管理评审**：一旦完成了审核且缺陷得到纠正和验证，组织分析所有要求的输入和输出并进行管理评审。最高管理者评估所有要求的信息并确定其QMS是否满足期望。期望包括ISO/TS 16949:2009的要求、组织和顾客的特殊要求。如果期望未能满足，最高管理者提供指导和必要的资源以进行适当的纠正和改进。为达到此目的，可能需要数次的管理评审。例如：质量体系衡量指标可能会在每个月都要视需要进行总结性评审。（必要的数据和输入请参见ISO/TS 16949:2009的5.6管理评审。）

步骤15到20是由认证机构执行

15. **文件评审:**当最高管理者认为组织符合了要求并且正在有效运行时，就可以让认证机构评审QMS文件了。

16. **确定组织是否需要进行预审核：**

组织可以在它们的认证审核之前，选择进行预审核。预审核是评估组织对ISO/TS 16949:2009要求和任何适用的顾客特殊要求的符合性。

预审核绝对是可选择的，然而，很多组织喜欢从一个第三方确认它们的QMS是否已经做好认证的准备。请记住，即使预审核是由认证机构完成的，这也不会减少认证审核所需要的人日数。

17. **进行预审核**(可选)：进行预审核以确定组织是否准备就绪。

18. **进行认证审核**：当组织已完成认证准备时，由一个IATF认可的认证机构来执行审核。询问当前IATF认可的认证机构，可以访问国际汽车监督署（IAOB），网址：www.iatfglobaloversight.org.

IAAR (汽车业认证机构独立协会) 的审核策划样版可以用来帮助策划基于过程的审核。参见附录K— IAAR审核策划范例。

19. **按适当的间隔进行监督审核**：参照ISO/TS 16949:2009汽车认证方案— IATF认可规则。

组织应向认证机构提供下列文件以供评审及审核策划：

- 质量管理体系变更（通常只更新的信息/章节，且只在认证机构需要时提供）。
- 顾客抱怨、回应、当前状态
- 最近12个月的内部审核和管理评审策划及其结果
- 至少最近12个月的运行绩效趋势
- 朝着持续改进目标的进展

- 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 16949:2009 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.

- 上一次监督审核后，纠正措施的有效性及其验证

认证机构分析组织的文件以策划其审核。

注: 运行绩效趋势应当包括内部的组织绩效测量和顾客结果这两者。

20. **进行再认证审核**：ISO/TS 16949:2009 认证期限为 3 年。除非认证机构另有指定，再认证审核要求一次性完整的提交文件和资料。

APPENDIX A – 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.

附录 A – 热处理过程范例

本附录的目的是对现有的制造线的热处理过程重新安排的开发案例中，提供该过程的四个特性的范例：

- 管理职责
- 资源管理
- 产品实现
- 测量、分析和改进

过程：设计一个热处理的顺序。

产品：制造线的新设计。

顾客要求：制造线以规定的能力来生产所有零件，并符合图纸的规范。

顾客：制造设施。

管理职责

定义：指管理监督的措施，保证所有过程步骤都有助于顾客要求的达成。

ABC 公司的管理者意识到尽管他们在制造现场有必备的设备，但仍旧需要调整制造顺序，把热处理过程移动到涂装过程之后，以满足顾客 XYZ 的要求。目前，热处理过程是在电镀过程之前。

顾客 XYZ 批准了供应商组织 ABC 的制造过程的重组。

顾客提出时间要求：变更要在 10 天内实现以满足工厂要求，并且不能对成本有负面影响。

ABC 公司的管理者派遣员工设计过程变更，并且满足以下要求：

- 法律和法规的要求
- 符合组织的质量政策
- 当变更被实施后，保证满足所有的质量目标（单个过程、顾客、整个供应商组织）
- 对过程的成功或失败进行管理评审，并吸取经验教训用于将来类似变更

资源管理

定义：为过程提供适当且充分的资源（技能、人力、设备、基础设施）以达成顾客满意。

管理者召集并授权一个小组以开发对制造过程的调整。小组成员是基于他们对设备、过程流程、设计技术的知识以及对于顾客要求的熟悉程度，从各部门中挑选出来的。小组为此设计项目选择适当的工具（比如：CAD 和计算机设备）。该项目不需要外部资源。

In meeting customer requirements, the team must also consider contingencies and the work environment (as outlined by section 6 of ISO/TS 16949:2009). 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.

在满足顾客要求时，小组还必须考虑应急计划和工作环境（如 ISO/TS 16949:2009 第 6 章所述）。第一天的时候，小组的一个关键成员被调去另一个项目，小组从另一个项目组调来一人接替原来的组员。

注：知识可以通过培训或经验来获得。

产品实现

定义：包括生产预期产品所需的策划、理解顾客要求、设计、采购、生产质量控制和物流等步骤。

为了满足顾客要求，必须清楚地定义期望的输出。

在本范例中，产品是一个满足或超出了顾客要求的已被调整的制造过程流程。

小组定义了一项计划以确保在管理层规定的时间内满足顾客的质量要求。

由于欲重新设计的生产线还生产另外两种产品，所以相关过程的相互作用已被评审。小组引入也使用该生产线的其它产品的代表人，以确保其它产品在生产线最后变更时没有受到影响。

在策划过程设计的变更时，小组至少要考虑：顾客和组织定义的特殊特性、控制计划和 FMEA 的更新内容，以及其它适当的文件，尤其应当评审以往相似的设计项目以吸取经验教训。

一旦设计工作开始后，要按照设计计划在适当的阶段评审设计进展。

生产线原型的设计方法是基于技术规范的过程优化工具和技术规范程序。

为了减少当前对利用此生产线的三种零件的生产的影响，开发了一个试产线来代表制造过程原型。三种零件都在此生产线原型上生产，并且完成了全部零件的确认和工程规范试验。

一旦这三种零件在此生产线原型上满足了所有预期的输入范围，包括物料、操作者、工具磨损、环境、需求波动等，调整生产线的设计就必须包括以下各项以满足对能力的要求：

- 预防性维护
- 工装管理
- 生产计划
- 应急计划
- 防护、搬运和可追踪性
- 线内监视

测量、分析和改进：

定义：确认过程以及最终成品对顾客要求的符合性，通过纠正及预防措施来进行持续改进。

测量涵盖了过程的所有阶段。另外，还必须使用适当的测量和数据分析技术。

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 16949:2009 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.

在本制造线变更的范例中，测量能够应用于下列几个阶段：

- 当收到对该变更过程的规范时：
  - 控制计划或者过程测量的其它指标
  - 显示零件或样品符合要求的最终检验
- 新的生产线开发的确认检查点
- 制造线设计过程对所有公司和顾客要求的符合性，包括持续改进的经验教训
- 在量产和生产后的绩效验证之前，对样件进行签定确认的检查

对于一个测量，并不是 ISO/TS 16949:2009 要求手册第 8 章 (测量、分析和改进)中的所有要求都要被满足，但必须相应地满足。下面的范例应当有助于解释每个要求的适用性。

通常情况下，在进行测量时，下列要求要应用于所有情况：

- 必须使用适当的统计工具
- 必须知道顾客的衡量指标以确定顾客的满意度
- 要使用的测量技术的类型（比如：审核、产品测量、管理评审）
- 人员或测量设备所要求的技能或能力
- 顾客视情况进行评审、弃权/接受过程
- 当绩效未能满足顾客期望时，管理纠正措施的方式
- 保证持续改进的经验教训或纠正措施

上述一般的应用要求之外：

对于这个在制造过程中的变更设计的过程范例，测量可能不如在实际的制造线上当产品是一个零部件时那样直接。在这种情况下，产品就是指制造线及其能力。测量的是进行生产线变更的过程。制造线生产的零部件可以显示此制造线的能力，但它不是本范例过程的产品。

以下显示在测量和持续改进的初始阶段，对已列出的测量阶段的测量要求的应用。

当收到规范时：

- 新的制造线必须满足所有的产品规范要求
  - 在建立和测试制造线时，小组必须知道他们有能力测量新制造线上要求的特性，以确保长期的绩效能力。当一个产品不同于工厂的另一线上生产的产品时就显得尤为重要。
  - 此处的测量类型通常是实际的产品测量。但是在测量制造线开发绩效的时候，该测量可能是计数性质的——制造线能或不能按顾客要求来测量。

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.

新制造线开发的确认检查点。

- 它是一个典型的管理工具，和 APQP 很相似，拥有要求的完成期限和目标日期以及交付物。
  - 当管理者按照计划来评审进展，以及迄今为止批准或拒绝的进展，该测量可以是基于时间或特性。
  - 这些衡量指标通常在管理评审中得到评审，作为监督制造线开发过程的有效性的一部分。
  - 完成日期通常是在内部制定以满足顾客对交付日期的要求。顾客可能没有规定或关注这些中间的检查点，尽管顾客（制造组织）可能要求进展报告以评估达成完成期限的可能性。

制造线设计过程对所有集团和顾客要求的符合性，包括为持续改进而吸取的经验教训。

- 在开发新制造线时，组织可能有一些需要被遵守的特殊的内部过程。
  - 这些过程可以包括商务策划、项目的文件化和批准、记录保持、健康和安全、人员培训、环境、设备校准、机械设置等。
  - 这些过程的符合性通常可通过对新制造线开发过程的内部审核来进行评审。正如在本实施工具的过程审核章节中所说明的，通过选择此特定过程作为例子，此变更的制造线的开发过程可以接受审核。
  - 内部审核结果通常被作为管理评审的一部分来进行评审，对任何发现的问题进行分析以确定对其它相似制造线开发过程的适用性。如果对那些还未出现问题的过程实施纠正措施，那么等于已经采取了预防措施——从而引入了持续改进，并吸取在变更的制造线的设计过程中得到的经验教训。

在批量生产和生产后的绩效验证之前，对样件进行签定确认的检查。

- 这证实了新制造线满足了顾客要求。
  - 该测量的类型可以包括测量的制造过程和产品类型。
  - 管理者需要查看制造的批准证据，对证实和长期的产品运行，所有制造线绩效和零件规范都按要求被满足。
    - 必须遵守批准程序，包括应用适当的问题解决/预防再发生的工具来纠正任何已发现的问题（用过程审核来评审）。
    - 必须满足产品的符合性（测量能力、统计方法、平面布置、降低潜在的过程变差、防误、产品试验等）。
    - 制造要求的其它测量或证实。

APPENDIX B – 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 16949:2009. 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 16949:2009, 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

附录 B – 质量管理体系审核

本附录对如何以过程方法来进行质量管理体系审核提出了一些范例和指南。

准备质量管理体系审核：

- 验证组织的质量管理体系是否符合 ISO/TS 16949:2009。在实施阶段，在文件评审的初始阶段确定其符合性。审核员评审从上次审核后质量管理体系产生的变更（参见 ISO/TS 16949:2009，5.4.2）。
- 在“环游过程”之前，先评审和该过程相关的衡量指标和目标——但是，并不是所有的过程都有直接的衡量指标。你可能需要识别反映该过程的“健康状况”的衡量指标。例如，一个加工过程可以用生产线终端 PPM（每百万件零件中的不合格零件数）来测量，该 PPM 和机械零件的特性有关。
- 重要的是通过收集的数据来识别可能导致衡量指标绩效不佳的过程区域。如果审核是针对加工，规范内有三种产品线，但是有一条生产线不符合规范，那么就应审核不合规的那条生产线。审核可以被视为改进产品的机遇。这是过程审核的基础，是一个增值活动。
- 当衡量指标显示组织达成了目标，则可以转换到预防措施的审核。着重于组织对于评审并减少变差来源的这一过程，因为该过程会关系到组织的持续改进过程。
- 为了测量质量管理体系的有效性，就要验证组织的衡量指标是否符合顾客的期望。在维修前后，在每条生产线的每个班次，从产品中抽取数据，以囊括典型的过程变差来源。
- 获得顾客对每个过程的要求（内部和外部）清单。

进行过程审核

过程审核方法是通过组织固有的流程来审核组织的系统。根据数据来选择没有按照顾客要求来执行的那些过程。评审过程的不同部分，可能会发现顾客满意度不佳的来源。当所有产品都符合了顾客的要求后，使用测量和目标来致力于持续改进。

审核员应当从过程负责人（比如：负责该过程的最高管理者）那里得到一个关于即将被审核的过程的概况，从而建立关于过程的输入、支持过程、测量等信息，保证审核的有效。

一个过程方法的基本步骤为：

- 对过程的输入是什么 – 过程的顾客是谁？
- 管理职责 - 过程是怎样被指派的，并且在谁的授权下执行工作？
- 资源管理 - 资源要求怎样满足？
- 产品实现 – （各职能之间）接口是什么？怎样保证职责从一个职能到下一个职能在产品实现过程中能够被执行，以满足顾客要求？制造产品需要哪些步骤，并且这

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:

些步骤是按照规范完成的吗？如果产品不符合顾客要求该怎么办？

- 测量、分析和改进 – 过程怎样被测量、分析并改进？朝着目标的进展如何？
- 过程的输出是什么？

任何过程都需要遵循这些基本步骤以确定过程是否有效。

在审核时评审衡量指标

接下来是评审衡量指标：

- 衡量指标（目的和目标）是否被达到？针对审核策划时确定的具体的衡量指标进行询问。
- 是否有顾客规定需要改进的部分？询问在策划时发现的问题。
- 审核时，着重于需要改进的部分。
- 为了达到目标，组织做了什么？
- 如果组织没有达成他们的目的和目标，则采取了哪些纠正措施？
- 如果组织达成了目的和目标，他们采取什么措施来进行改进（持续改进）？

正确的关注点将指导组织对顾客最重要的地方进行改进。

其次，检查组织所涵盖的过程，以了解这些过程的指派、执行和有效性。有效性是通过对验证顾客和内部要求的符合情况来判断。组织的能力指标至少应包括顾客的期望。遵守组织内的过程流程。

- 过程中所涉及的每个职能领域，需要了解其过程步骤的输入（包括各式各样的主题）和输出。过程中各职能的职责是否被理解并实施？
- 员工如何得知该何时完成他/她的任务？
- 员工是否知道接下来过程怎样将把他/她的职责带向下一个步骤或过程？
- 换言之，接口和连接是否被理解？

过程方法超越了传统的"围墙"或"现场"审核。这种审核的过程需要依循整体的组织过程，以确保所有职能相互连接在一起。不仅是着重每个职能份内的执行，而更着重这些职能之间是否相互连接以产生预期的结果。

在要素方法下，每个职能都可能运作良好，但彼此并不会朝着一个组织的共同目标而工作。职能领域通常总认为他们的工作是有贡献的，直到他们发现他们原先认为有价值的却对过程的下一步骤造成了混乱、不一致或矛盾。下面是组织可能会发生例子：

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.

一个领域的制造质量部门监控着数据库内的不符合，包括废料。该部门的衡量指标针对的是减少废料。使用一种硬质的材料将会增加20%的报废率。通过数据分析，该部门开始使用软质材料，更易于加工，能够减少报废，因而推动部门的改进。

同时，由于零件太过柔软，不再符合耐久性的要求，使得使用该产品的顾客和制造部门遭遇到80%的报废率。

从上述例子可以看出，在没有全面理解顾客要求的情况下就进行局部优化，可能导致更低的效率和更大的损失。

注：审核结果会提交给管理评审。

APPENDIX C – 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 16949:2009 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 16949:2009 "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)

附录 C –制造过程审核

本附录提出了如何进行制造过程审核的范例或建议。

确定组织内的制造过程（例如生产线、工厂内相似的过程）。

- 对制造过程的输入是什么?有效的审核制造过程的一个方法就是验证其是否符合组织的过程和适用的顾客规定要求。
- 在制造过程内，制造步骤是否按固有的流程，按部就班的有效实施？
- 过程的输出是什么？顾客是谁？他们的要求有哪些？
- 确定现场怎样保证产品实现的制造部分是有效的。过程有哪些测量？

有用的工具：过程规范，如 ISO/TS 16949:2009 的 7.3.3.2 制造过程设计输出中所定义的，可以用于确定审核范围。比较 PFD（过程流程图）、PFMEA、控制计划和作业指导书。确保这些文件都已得到更新，能够处理所有的内部和外部的问题——询问最近的顾客问题以及这些问题在什么地方通过对过程的更新而加以阐明。

- 在控制计划中抽样选择一些步骤。在选择适当的步骤时，应当将内部和外部的问题以及质量问题视为输入。在制造现场遵循这些步骤以观察控制计划中的这些问题是否与实际的实施相符合。
- 在此抽样步骤中，在开始、中间和末端选择步骤是有帮助的。
- 如果包括了检查的相关步骤也会有所帮助。
- 在评审控制计划和相应的作业指导书的实施时，确认检验和试验状态是否被清楚的定义，以致在每个作业者的工作传递中（每次的生产班次之间，以及同一班次的每个工序之间）的质量都能被保证。每个作业者是否知道何时开始和停止他们的过程？作业者是否知道怎样清楚的和下一个工序沟通情况？

制造过程审核中的另一个有用的工具就是 PFMEA。查看从 PFMEA 到控制计划的连接、接口。

ISO/TS 16949:2009 的 6.2.2.4 "员工激励与授权" 指出："组织应有过程来测量员工对其活动的相关性和重要性，以及如何为质量目标的实现作出贡献的认知程度。"

- 询问各阶层的员工，他们的任务是怎样对产品质量产生贡献，不仅是直接的作业者，比如："过程负责人、经理、主管、支持人员。"
- 如果他们做错了，会对顾客造成什么影响？（参考 PFMEA，潜在失效的原因）

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?

评审制造过程时的其它关键步骤包括顾客抱怨和内部不符合与流程图、PFMEA、控制计划、作业指导书和培训之间的接口/连接。

- 不符合报告中所识别到的失效是否被评审并被考虑在 PFMEA 中？
- 控制计划是否识别这些失效并提供防误或遏制措施？
- 是否对 PFMEA 和控制计划进行变更？这些变更及相关变更和作业指导书之间的联系是怎样的？
- 顾客的申诉问题是否已告知了员工？
- 和培训之间的联系是怎样的？

在制造过程中评审零件的认证要求以保证持续的有效性。

- 重要特性的能力要求是否持续被满足？
- 制造工厂是否仍能满足图纸公差？
- 节拍生产/能力要求是否仍能被满足？

APPENDIX D – 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 16949:2009.

Mapping the system versus mapping a process: When considering using process mapping as a tool to meet the requirements of ISO/TS 16949:2009 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 determine 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 16949:2009 requirements stated above.

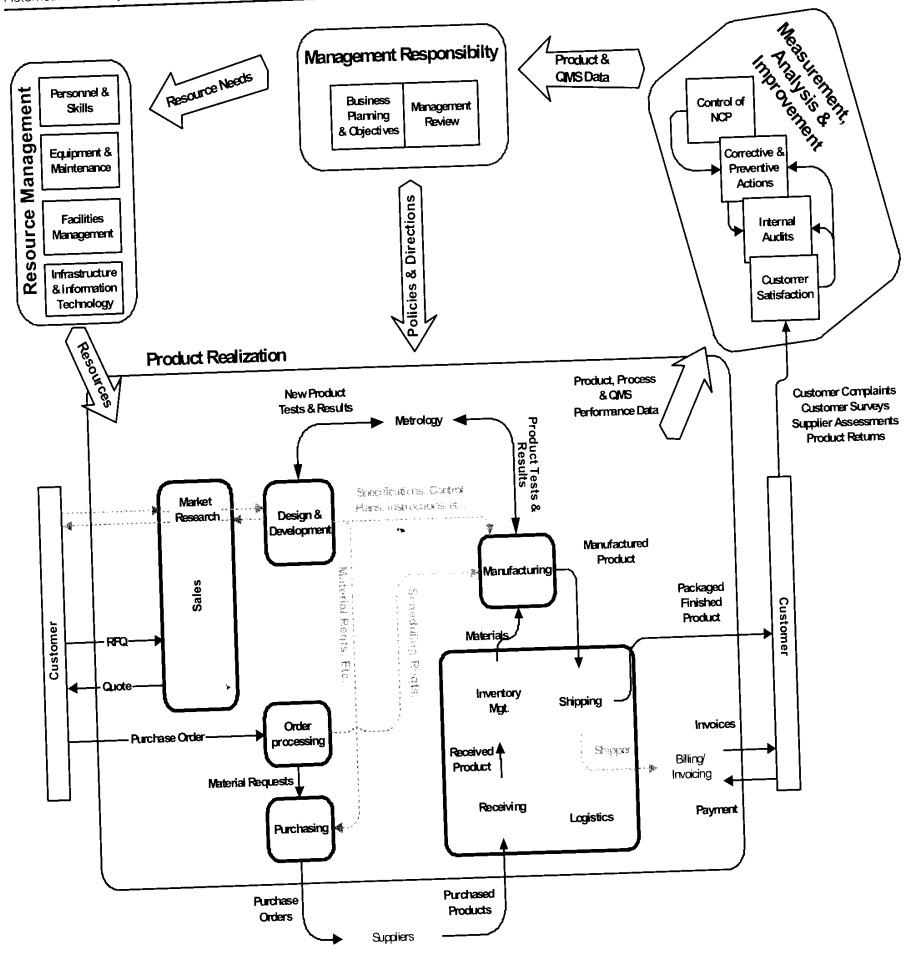
附录 D – 过程描绘范例

目的：本部分的目的是为组织提供一些范例，显示怎样使用过程描绘以帮助组织理解其质量管理体系及过程，以便满足 ISO/TS 16949:2009 的要求。

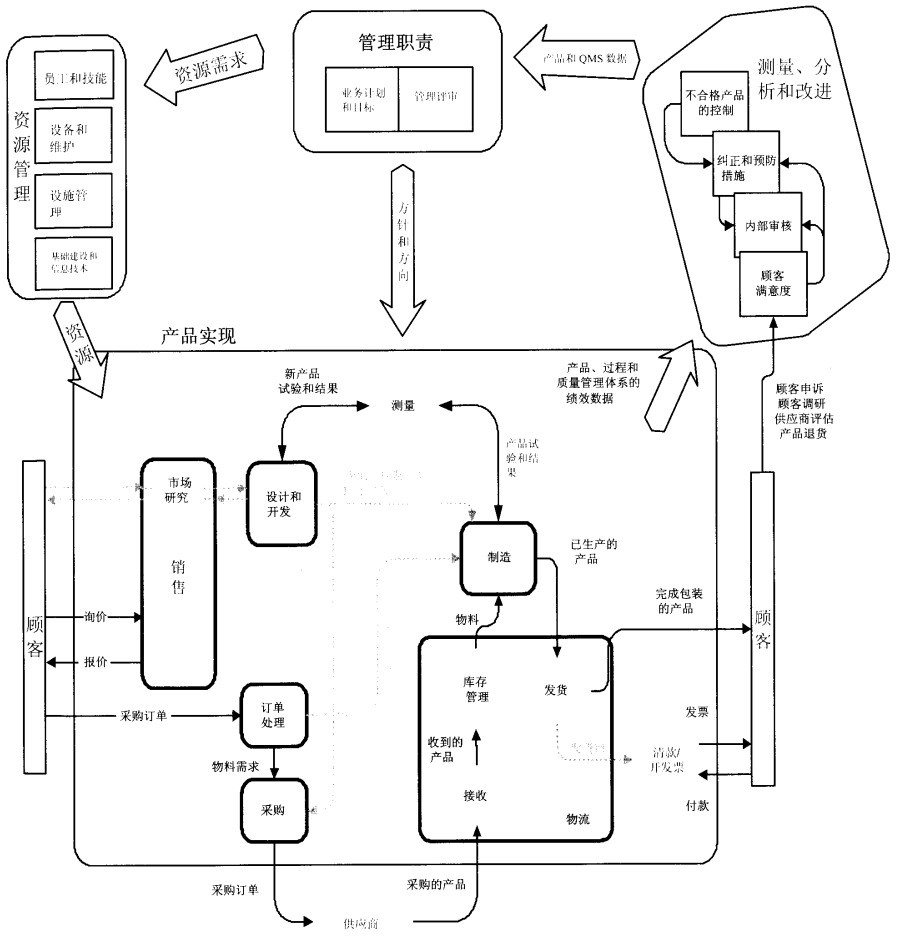
系统描绘与过程描绘：当考虑使用过程描绘作为工具来满足 ISO/TS 16949:2009 的要求时，组织应当明白过程描绘应当在两个不同的等级上进行评审。一个等级是描绘质量管理体系的关键过程，另一个等级是使用过程来描绘关键过程本身，以及必要的时候描绘关键过程的子过程。

描绘 QMS: 要求条款 4.1.a) 指出：组织应确定质量管理体系所需的过程及其在整个组织中的应用。要求条款 4.1.b) 指出：组织应确定这些过程的顺序和相互作用。要求条款 4.2.2.c) 指出：组织应包括对质量手册内的质量管理体系过程之间的相互作用的表述。描绘 QMS 的过程显示了每个过程的顺序和关键输入（顾客要求）和输出（下一个过程的输如），这对组织满足要求是一个极好的方法。另外，它还会帮助组织理解它们的过程和其它过程是如何一起运作（相互作用），以生产满足顾客要求的产品。

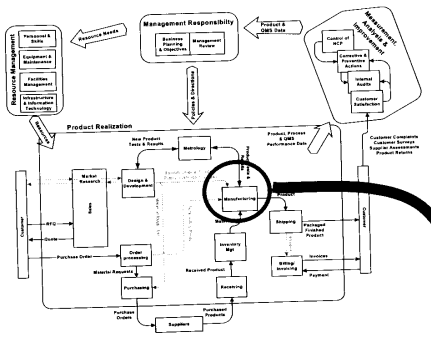
注：完成过程定义时应当考虑：管理职责、资源管理、过程实现的步骤、衡量指标和测量。每个组织的 QMS 都是特有的，所以不会有"一个正确的范例"让组织参照着进行自己的过程路径描绘。从宏观角度看，QMS 可以被视为一个框架，确定如何最好的去满足上述的 ISO/TS 16949:2009 要求。



Note: Bolded and shaded processes represent key product realization processes



注: 加粗的字体和阴影部分的过程代表了关键的产品实现过程。



Manufacturing Process

Management Responsibility

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

Monitoring and 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
- Specificatons
- Control Plans
- Acceptance Criteria
- Customer Requirements
- Product Test Results

Foundry → **Machining** → **Assembly** → **Painting**

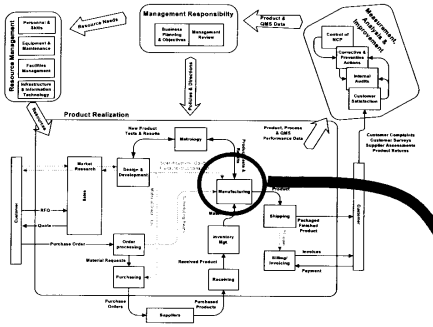
Manufacturing Process

Process Realization Steps

(Or Sub-Processes)

Process Output

Manufactured Product



制造过程

管理职责

- 过程负责人：制造部门经理
- 提供
  - 准则和方针
  - 目的和目标
  - 资源
- 监控
  - QMS 绩效
  - 目的和目标的进展
  - 产品的符合性
  - 质量指标的成本
  - 顾客满意度指标

监控和测量

- 过程绩效 / 能力
- 产品的符合性 (PPMs)
- 过程中/最终检验和试验

过程输入

资源输入

- 有能力的员工
- 物料
- 设备/工装
- 资金

其它输入

- 时间排程
- 要求
- 规范
- 控制计划
- 接收准则
- 顾客要求
- 产品试验结果

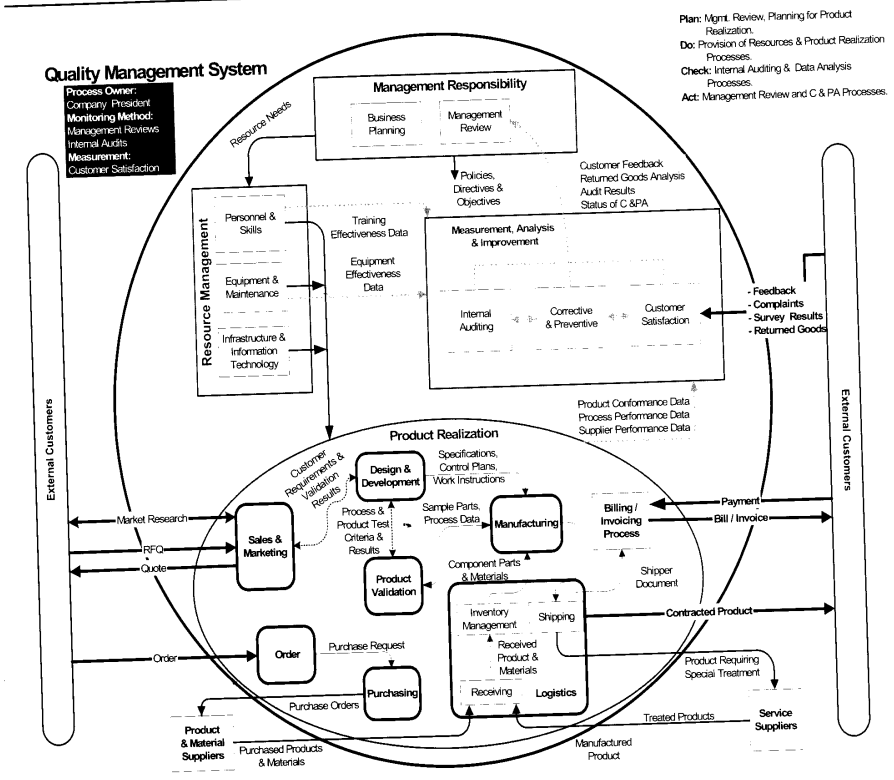
铸造 → **加工** → **装配** → **涂装**

制造过程

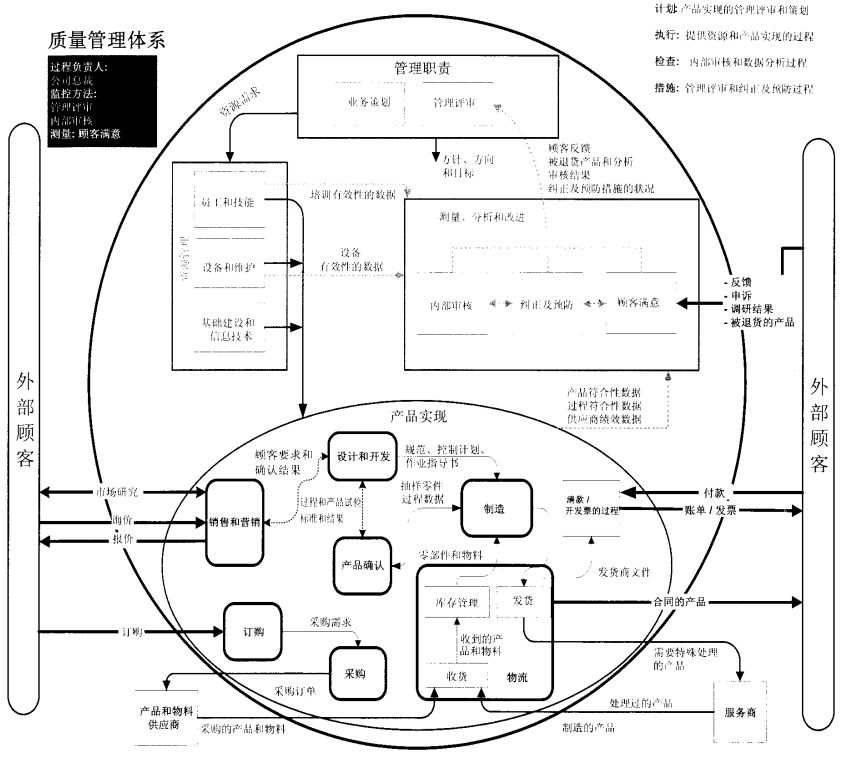
过程实现的步骤
(或子过程)

过程输出

制造的产品

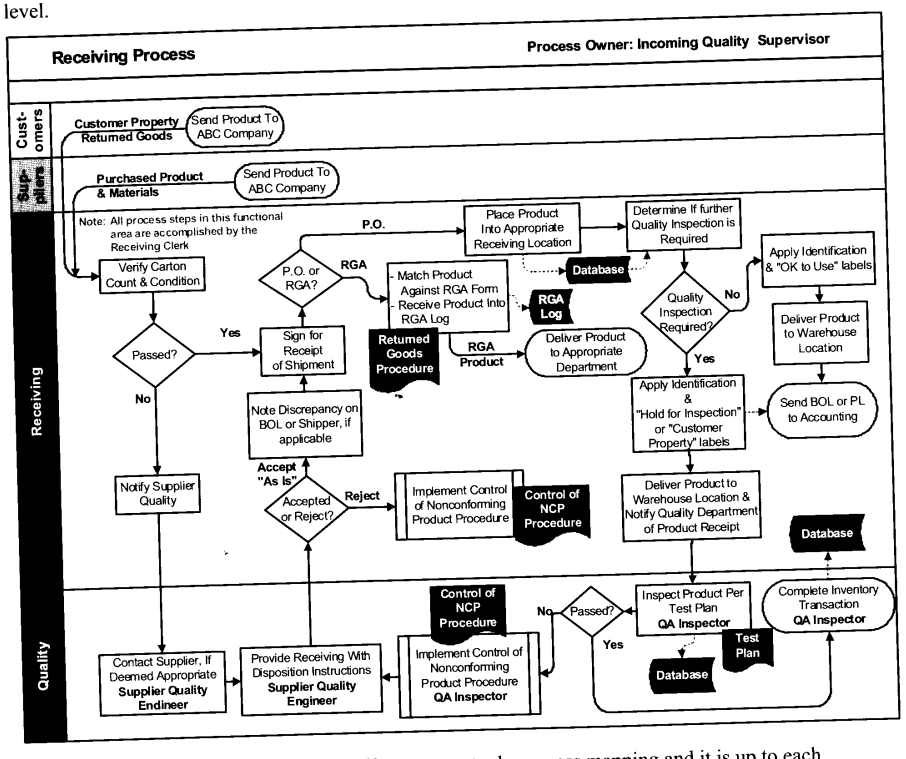


Note: Bold and shaded processes represent key product realization processes.



注:粗体字和阴影部分的过程代表了关键的产品实现过程。

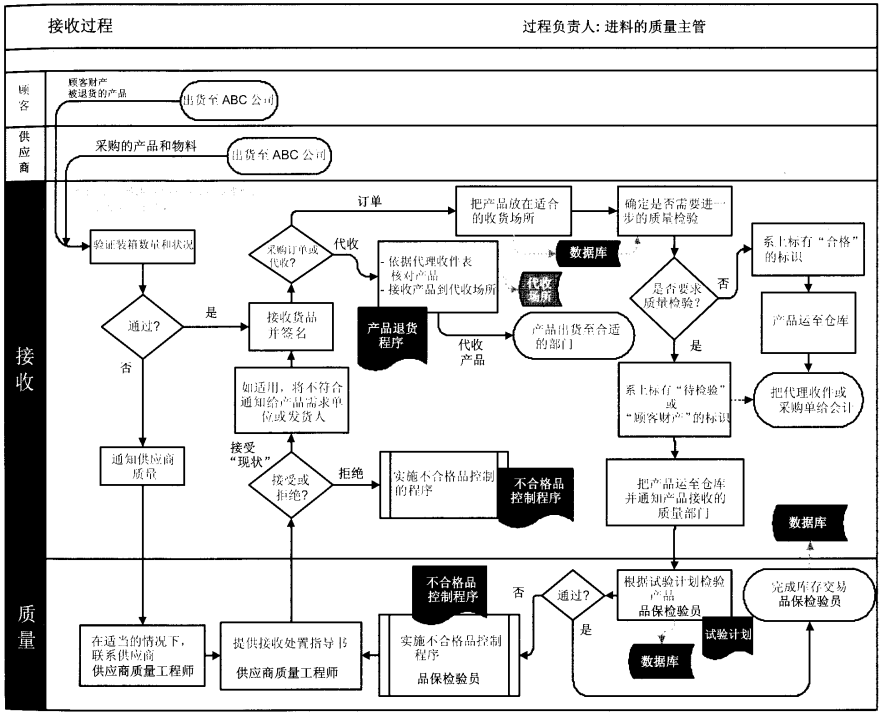
Mapping individual processes: Mapping processes can help organizations understand the activities within a process as well as its linkages (inputs and outputs) with other processes. Looking at the process steps graphically often helps organizations identify redundant steps and other inefficiencies that 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.

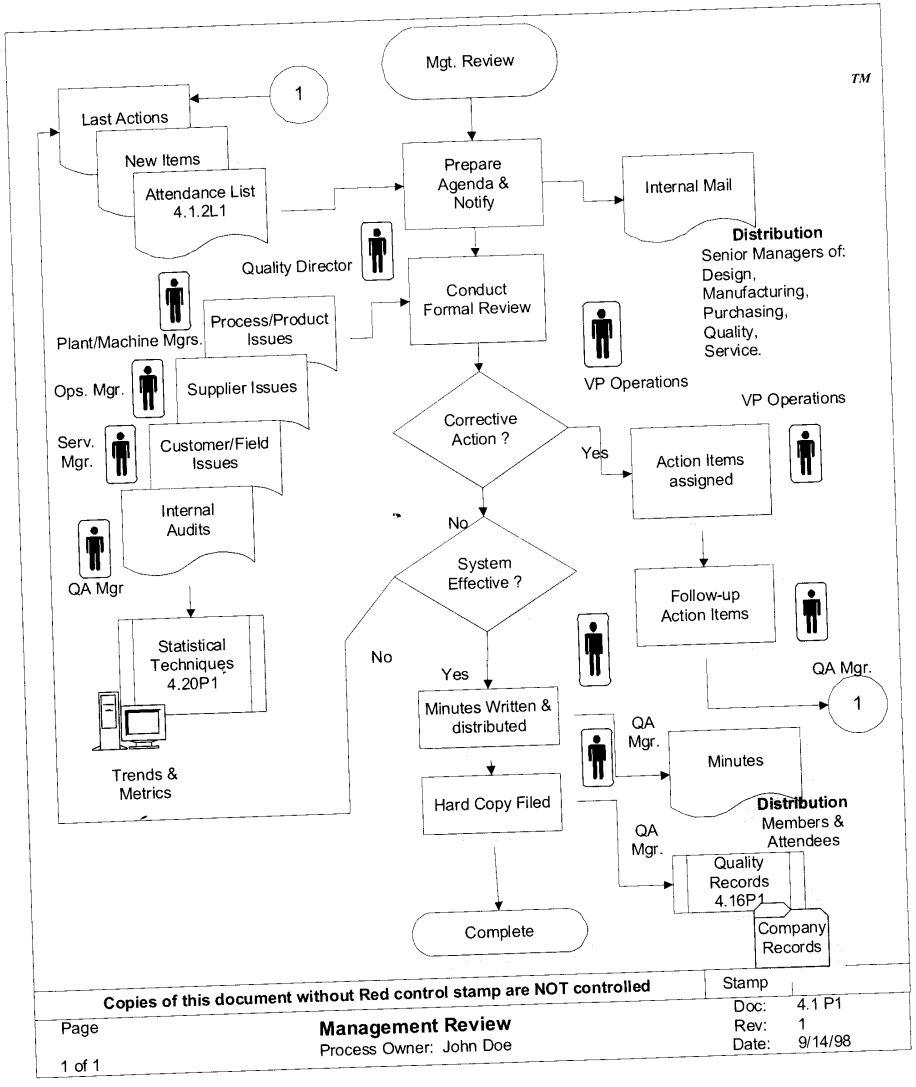
Processes can be defined by a series of procedures, which together meet all the requirements of having all attributes of a process.

描绘个别的过程：描绘过程可以帮助组织理解过程内的活动以及和其它过程的联系（输入和输出）。用图示法来查看过程步骤通常能帮助组织识别冗余的步骤，以及其它低下的效率，它可以成为过程改进和成本降低的机遇。下面是一个过程的描绘范例。



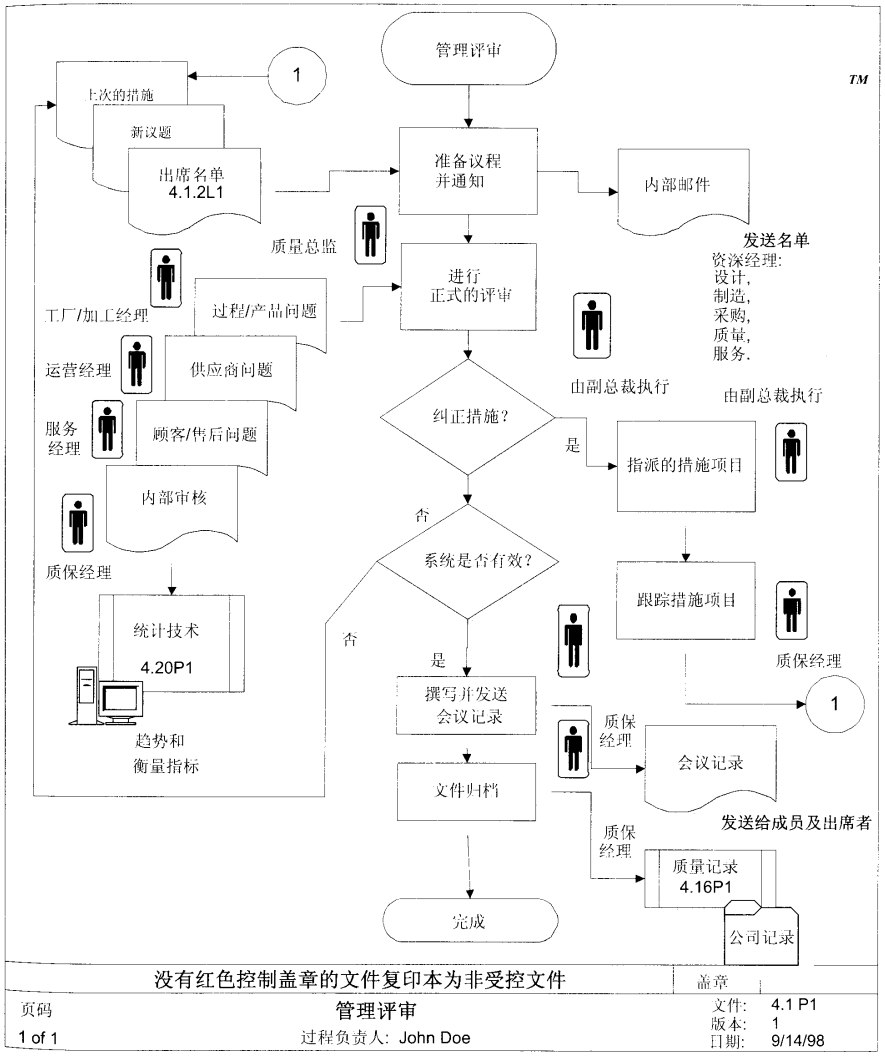
关键的考虑事项：过程描绘有多种方法，由组织自行决定适合其组织和质量管理体系的方法。如果使用了图形流程图，建议使用标准的符号。建议组织定义一套标准的符号，用于组织所有的过程路径描绘。它能够确保每个人都明白建立在整个组织的过程路径描绘。过程本身固有的特性能够帮助确定哪个过程描绘方法是最好的。

过程可以通过一系列的程序来定义，这些聚集的程序满足了拥有一个过程的所有特性的要求。

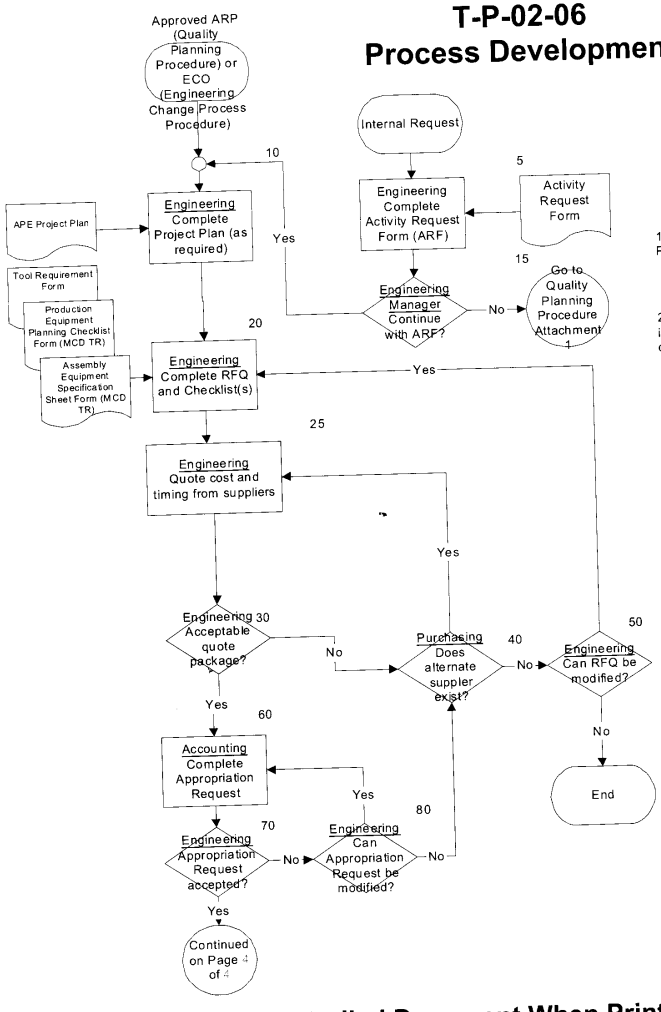


CQI-16
ISO/TS 16949:2009 Guidance Manual
Version 1 Issued 9/09

AIAG
Automotive Industry Action Group



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

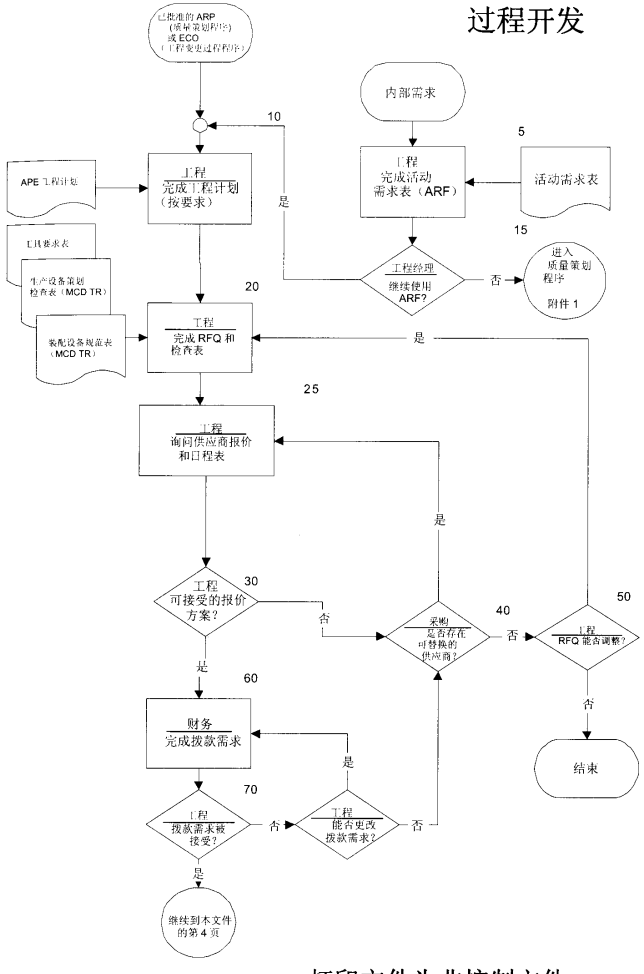
Note

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

Uncontrolled Document When Printed

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

T-P-02-06
过程开发



10 按要求，工程部门建立工程计划并更新。

20 报价需求表包括工程计划以及下列文件所列出的要求：

工具要求表
生产设备策划检验表
装配设备规范表

注：

70 和 80 不适用于备件或金额少于 $1,500.00 的采购项目。

打印文件为非控制文件

共同要素负责人	非共同要素负责人	修订版本:10	修订日期	参考文件
N/A		批准途径: T-02	2003 年 2 月 7 日	

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 42 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 44 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 42 and 44 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 45 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 48-51 introduce explain and apply the "turtle" tool. The turtle tool is a simple, yet powerful, tool used to analyze processes. Page 48 introduces the elements of the tool. Page 47 applies the tool to the Car Dealer example from Page 45. Page 51 reasserts the tool in a template form, along with a simple set of directions.

5) Page 49 is an illustration of a process approach audit, planning tool called the Process Approach Audit Worksheet.

6) Page 49 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

过程方法分析

包括以下方面的信息：

- "乌龟图"过程分析工具
- 过程的基本定义
- 审核策划矩阵

说明

该分析针对了理解和 应用过程方法来进行管理的三个重要层面，它们包括：

- 需要理解过程的基本要素
- 需要工具以协助分析过程
- 需要工具以协助将组织的过程总结成一种形态，以支持审核和其它评审的策划和执行。

下面是接下来几页的信息顺序以及将其包括在内的原因：

1) 42 页对过程进行了简单的说明/定义，它引导出怎样理解一般过程以及质量体系过程模型的 简要说明，以及把组织着重于顾客的过程汇聚成一个单一的概念。这是理解过程的第一步。

2) 44 页简要的列举了 10 个一般的（建议的）顾客导向过程 (COP) *(COP 是直接连接到，和/或着重外部顾客的过程)*。图示用一个模型显示了如何概念化的看待这 10 个 COP。42 页和 44 页 用图形向读者提供了如何个别的/一起的审视这些所描述的概念。这样做的目的是为了帮助读者在脑海中形成一个对这些概念的基准图形。

3) 45 页对一个一般的组织应用了过程方法。由于该组织是一个服务组织，并不是直接涉及汽车行业，所以不能完全使用 COP。选择这个例子是为了帮助读者理解"章鱼图"模型是怎样应用于任何组织。 需要注意的是，这种方法并非一定要用于汽车行业的组织。*[组织需要确定哪种模型对它们最有效，而且需要记住，在汽车供应链中，着重顾客导向是首要考虑的事项——它不是规则，而是需要考虑的事项。]*

4) 48-51 页介绍、说明并应用了"乌龟图"。它是一个简单却功能显著的过程分析工具。48 页介绍了该工具的要素。47 页把这个工具用于第 45 页的汽车经销商这一范例中。51 页用模板的形式和一系列简单的指示，再次对该工具进行了说明。

5) 49 页显示了一个过程方法审核的例子——名为"过程方法审核工作表"的策划工具。

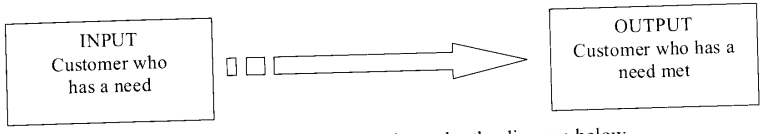
6) 49 页是一个过程方法审核工作表，此表是引用了汽车经销商的范例而完成的（为了达到最大的可能，不以实际组织 作为讨论基础来填写每一栏）。它让实施者和审核员明白怎样支持这类型的分析。这个过程方法审核工作表的范例是根据"财

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.*

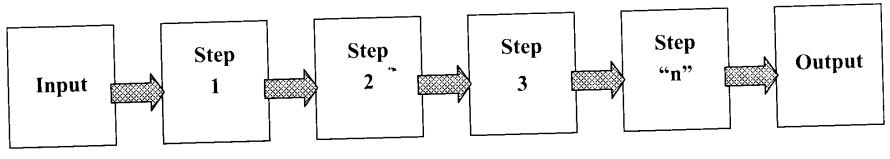
Process Defined

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

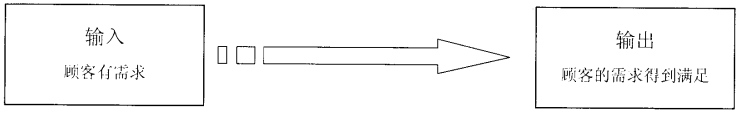


务”COP 而完成的。其它的 COP（1-5）会要求另外的矩阵表格。*注:这是一个 ISO 9001 的范例，虽然汽车经销商没有进行 TS 认证的资格，但是 TS 工作表会以相同的方式完成。*

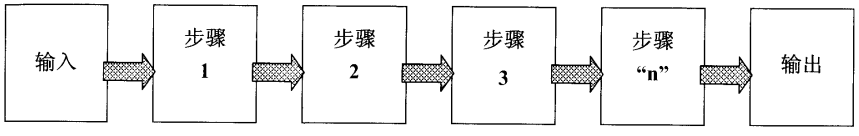
定义的过程

一个过程是指向过程的顾客（内部或外部）提供产品或服务的一串增值活动。

如下图所示，一个过程具有由两个端点规定的起点和终点。

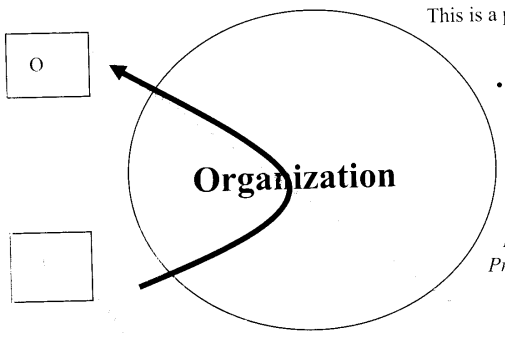


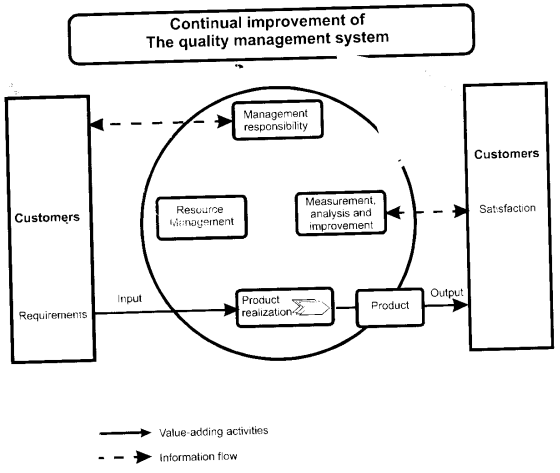
如下图所示，在这两个端点之间的一连串的活动。



Customer Oriented Process Defined

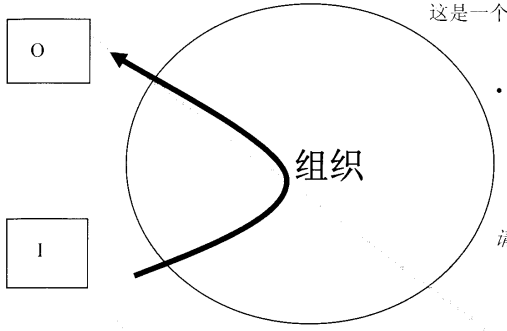
Internal/external interface between an organization and a customer

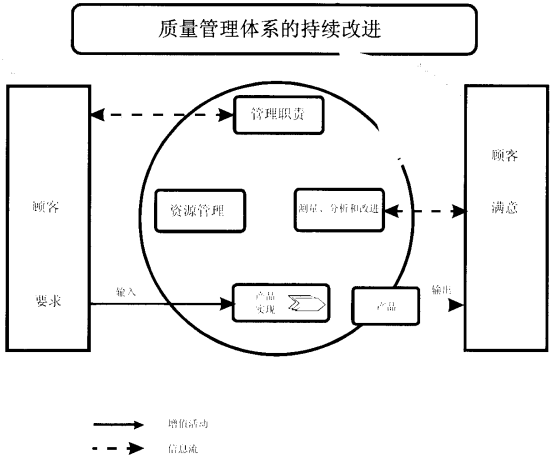




顾客导向过程的定义

组织和顾客之间内部/外部的接口





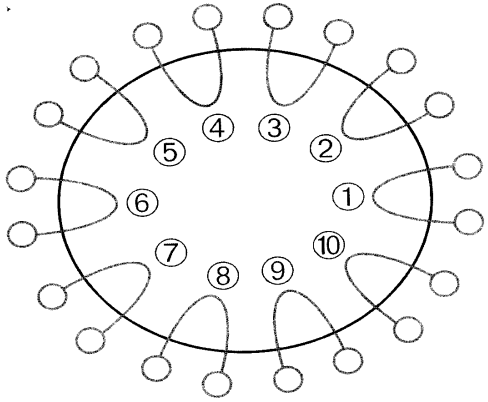
List of Customer Oriented Processes for the Automotive Industry

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"



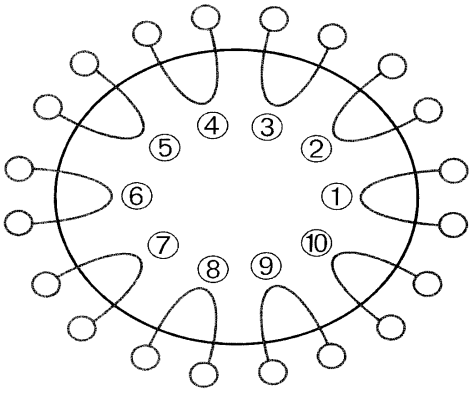
汽车行业的顾客导向过程清单

建议的 COP:

在汽车行业的组织中，虽然并不仅仅只会观察到以下 **10** 个 **COP**，但它们却有足够的普遍性，可以作为开始进行识别过程的一个良好的基准，然后再根据组织及其运营的要求加上其它过程。它们适用于机电、化学和机械类产品的组织和/或供应商。注：COP 4 – 7 对大多数 OEM 影响最大。

1.	市场分析/顾客要求
2.	询价/投标
3.	订单/需求
4.	产品和过程设计
5.	产品和过程验证/确认
6.	产品生产
7.	交付
8.	付款
9.	保修/服务
10.	售后服务/顾客反馈

顾客导向过程形成了一个组织化的“章鱼图”模型。



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 9001:2008. The documents provided support an ISO 9001:2008 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.

"章鱼图"用图解的形式说明了从顾客到组织的直接**输入**，以及由此产生的从组织到顾客的直接输出。以上描述的顾客导向过程（COP）的数量（10）并不意在指出 COP 建议的或全部的数量。该数字是用于说明顾客/组织的相互作用的多种性质；也不是意图要组织在使用该模型来描述其系统时，要求和这个模型看起来一致。它能够帮助组织将模型可视化，该模型可用于描绘组织的质量管理体系内的"顺序和相互作用"。

注： 为了避免惯例，本范例采用了汽车业相关的组织。经销商没有资格做 TS 认证，但是可以做 ISO 9001:2008 认证。本范例提供的文件支持 ISO 9001:2008 注册。

COP 分析

范例：汽车经销商和服务中心

下面范例可以帮助汽车过程方法的实施者获得如何应用过程方法这样一种认知。

史密斯先生并不满意自己汽车的性能，他打算抽时间去汽车经销商和服务中心为自己的汽车诊断一下。这对他来说是一个新领域，所以他对于服务中心所提供的服务并不熟悉。史密斯先生希望他的汽车能够得到诊断并完成维修，但是如果诊断和维修在价格上不划算的话，他打算重新购买一辆新车或二手车。

抵达汽车经销商处时，他看见了指示汽车经销商和服务中心入口的标志。史密斯先生进入了服务中心，询问服务中心的经理关于汽车诊断的事宜，并被告知服务中心可以立即为他进行诊断。

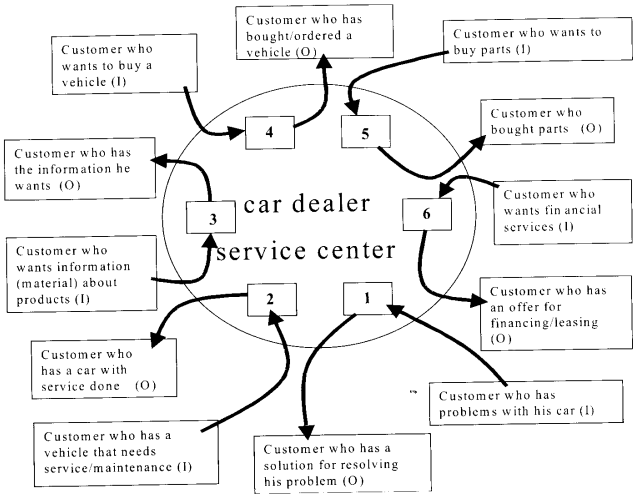
诊断之后，服务中心的经理向史密斯先生说明情况。由于问题比较严重，史密斯先生决定还是买一辆新车或者二手车。

史密斯先生被介绍给一位汽车销售员琼斯先生，了解了史密斯先生在购车方面的要求。在讨论过汽车大小、汽车颜色及价格之后，琼斯先生给他看了几辆车。

史密斯先生觉得最好的办法就是把自己的车维修一下，再买一辆二手车。他自己的那辆车可以给正在就读大学的女儿，而那辆新挑选的二手车则正好符合他目前的需求。

商定以后，史密斯先生决定为车辆的维修和所购二手车付款。于是，他又被介绍给业务经理菲鲁格先生。菲鲁格先生向他说明了支付和借贷方式。在史密斯先生选定支付方式后，万事具备。他开着自己新买的二手车离开了，过一段时间之后他可以来领取自己修好的那辆车。史密斯先生非常高兴。

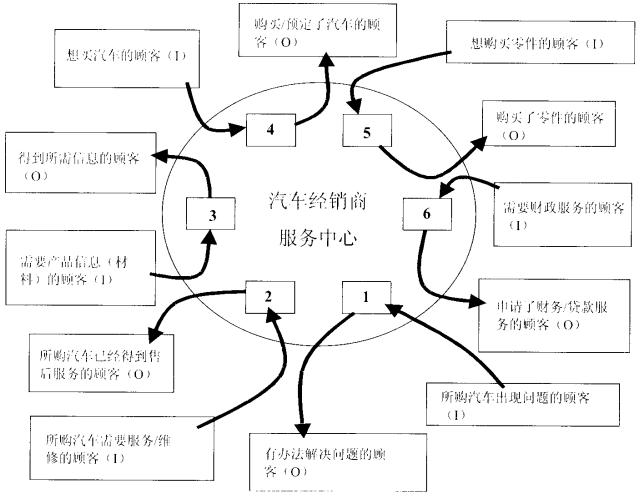
Process Approach Octopus for example Car Dealer and Service Center



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

过程方法章鱼图的范例：汽车经销商和服务中心

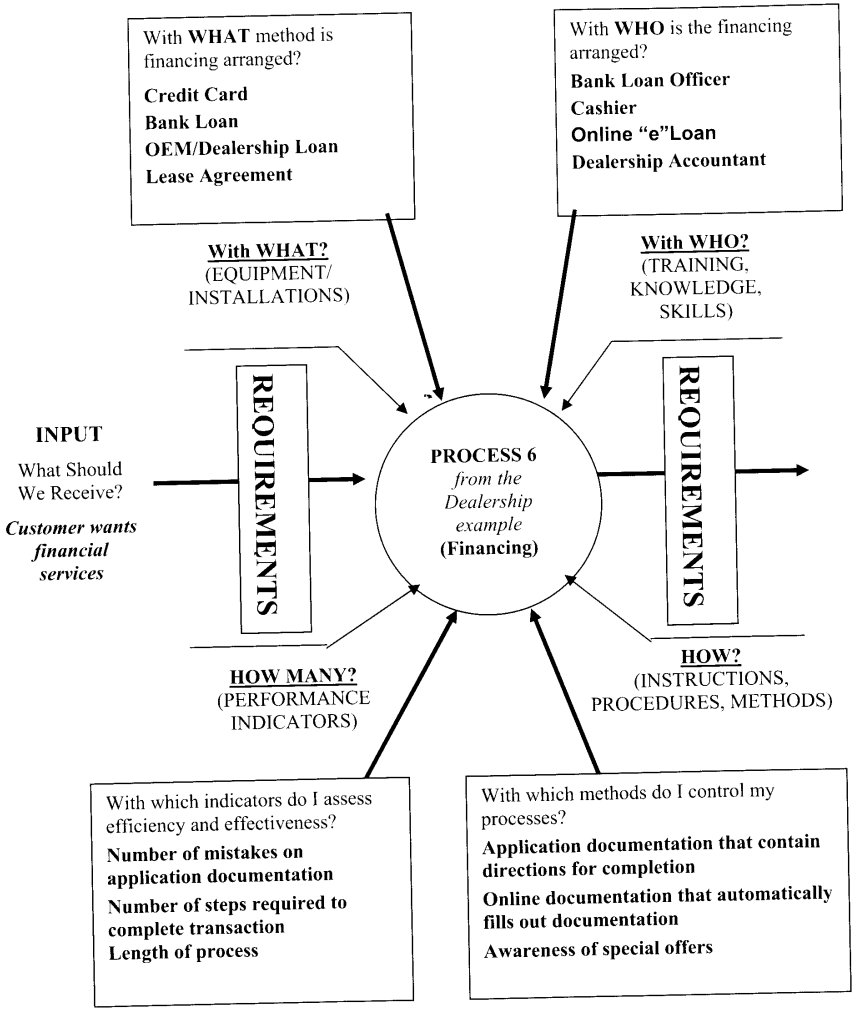


COP 范例清单:汽车经销商和服务中心

1. 客户服务
2. 汽车服务
3. 销售支援
4. 汽车销售
5. 零件销售
6. 财务

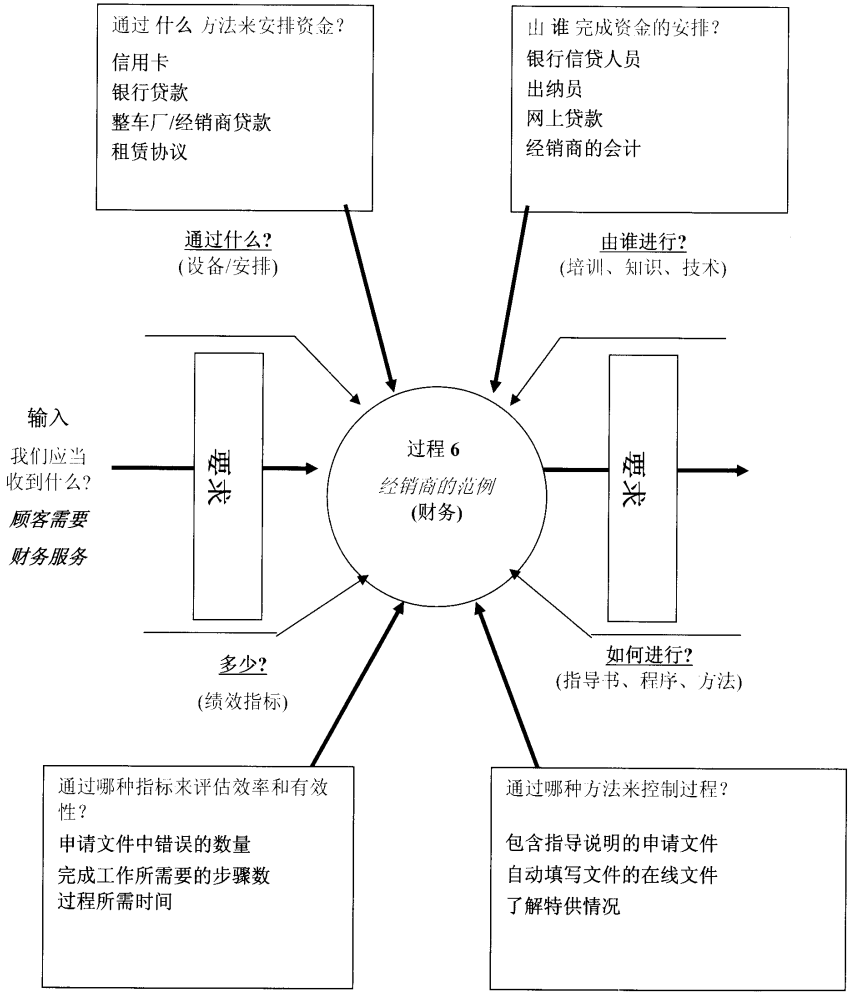
Four Questions About a Process

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.



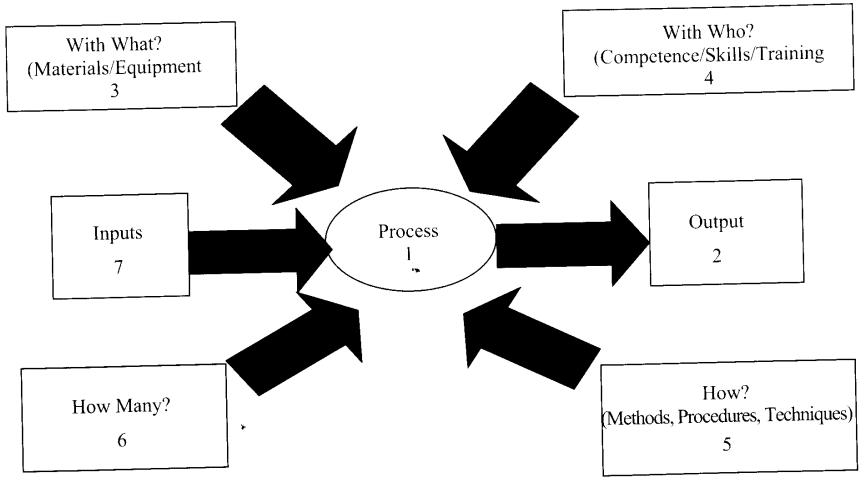
关于过程的四个问题

下面描述的是应用于一个汽车经销商范例的 COP 之 ----- 过程 6 财务的四个问题。 有关输入和输出的两个问题也被概括在本图中。



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

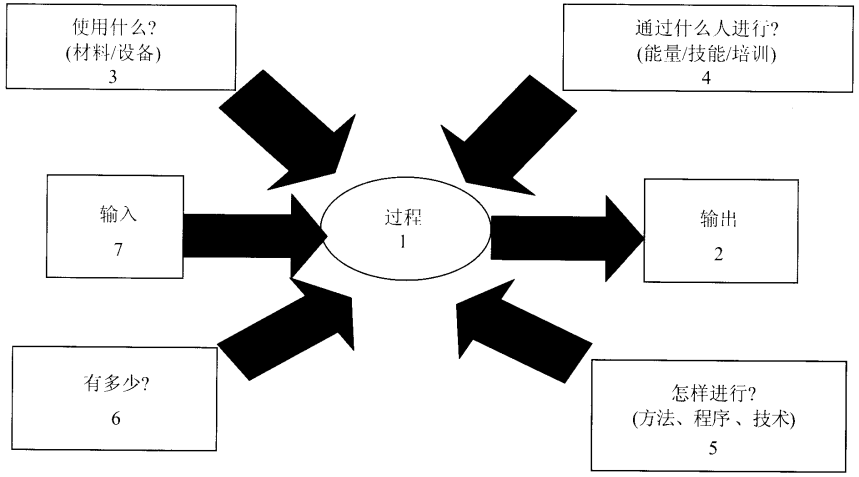
Below is a simplified version of the tool, which indicates the order that many practitioners have found most helpful when using the tool (particularly when using the tool for auditing). The boxes invite note-taking by the user, particularly, if used as an audit tool on-site. The matrix at the bottom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

过程方法“乌龟图”：
对于审核和实施非常有用的分析工具

下面是该工具的简单描述，指出了很多从业者在使用该工具时（尤其是用此工具审核时），发现的最有用的顺序。使用者，特别是用于现场审核工具时，可以在方框内填写记录。页面底部的矩阵简要的说明了每个方框的意图。



编号	详细说明
1	填写 COP 或者支持过程的名称。
2	填写实际输出的详细情况，这可以是一个产品或文件，而且应当是实际的有效性测量。
3	填写过程中所使用的机械、材料（包括试验设备）、计算机系统、软件的详细情况。
4	填写资源要求，尤其要注意要求的技能和能力准则、安全设备等。
5	填写过程相关的控制、支持过程、程序、方法等。
6	填写过程有效性的测量，即：矩阵和目标。
7	填写详细的实际输入，它可以是一个文件、材料、工装、日程等等。

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.

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: • Has an owner • Is defined • Is documented • Linkages are established • Is monitored • Has records maintained			*Four Support Process Questions (related to risk)* • With What? (Material, Equipment) • With Who? (Skills, Training) • With What Key Criteria? (Measurement, Assessment) • How? (Methods, Techniques)				Descriptions of Audit Observations, Evidence, Potential and Actual Findings	Classification: •Needs Further Research (NR) •Opportunities for Improvement (OI) • 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)								

过程方法审核工作表

下面是对过程方法审核工作表的说明，包括了一系列的说明指导。另外，还须注意工作表上方的两个方框内列举了过程特性和过程分析的四个问题的说明。

有助于审核时间的安排和确认工具的建立/完成的过程方法审核工作表

行列识别编号

1	2	3	4	5	6	7	8	9
六个过程特性： • 有负责人 • 已被定义 • 已被记录 • 已建立联系 • 受到监控 • 记录得到维持			四个支持过程的问题（有关风险）： • 使用什么？(材料、设备) • 由谁进行？(技能、培训) • 使用什么关键标准？(测量、评估) • 怎样进行？(方法、技术)				描述在审核中的观察、证明，以及潜在和实际的发现	分类： •需要进一步的研究 (NR) •改进机遇(OI) •不符合项 (NC)
顾客导向过程 (COP)	COP 的支持过程	管理过程	组织的地点 *(实际的和组织上的)*	期望的或要求的关键指标、测量	适用的要求	适用的参考		
(第 1 列是用于本方框中明确的 COP)								

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; Management, System, and 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 decision, 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 the 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:

- The organization's completion of it; that is, use the worksheet as an exercise for defining their processes, and/or
- 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.

关于工作表内容的解释：

- 1-7 列需要在审核计划（由组织指派的审核员或工作人员进行）之前完成。
- 第 1 列列出了 COP （第 1 列应当用于详细记录审核 COP 所需要的信息）。
- 第 2 列列出了直接的支持过程（这些发生在三个等级上：独立或结合在一起的管理、系统、运营）。
- 第 3 列列出了管理过程，即评估 COP 和支持过程绩效的过程，以及生成组织的重大决定、目标、变更等的管理过程 。
- 第 4 列列出了期望能在实体或组织的业务结构内找到的整个或部分的过程的位置。
- 第 5 列列出了期望能看到的与 COP 或支持过程领域相关的测量以及绩效的其它指标。
- 第 6 列包括一系列对 COP 或支持过程的要求条款。可以选择把这些信息和实际的要求文字或检查表/评估工具联系到一起。
- 第 7 列包含一系列用 COP 或支持过程的参考条款。
- 第 8 列 是让审核员在审核过程中作笔记用的。这些笔记可以转化为适当的发现、观察等. 在审核过程中随着时间和机遇呈现。
- 第 9 列是用于记录审核员在审核报告中对第 8 列内容的分类结果。

本工作表是为了帮助审核员在教室学习或实际审核中策划审核，将审核细分为可实施的、具体的审核路径（也就是说，过程是彼此连接的，但过程自身具有可定义且独立的特性，这些过程是实际存在的）。完成后，这个审核“路径图”能够提供策划并实施审核的信息。完成后，可以指派给审核员（内部或第三方）一个完整的 COP，或者是 COP 内的相互连接的数个过程，或者指派在逻辑上可以涵盖整个质量管理体系的审核；至少，是质量体系中一个相对良好的抽样审核。

工作表的其它用途：

- 组织完成工作表，也就是将工作表作为定义其过程的手段，和/或
- 作为要求的信息，组织在认证或监督审核之前将其提交给认证机构。

无论怎样使用工作表，都将向组织提供其价值，并在审核过程中减少许多猜测的工作。

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: • Has an owner • Is defined • Is documented • Linkages are established • Is monitored • Has records maintained			*Four Support Process Questions (related to risk)* • With What? (Material, Equipment) • With Who? (Skills, Training) • With What Key Criteria? (Measurement, Assessment) • How? (Methods, Techniques)				Descriptions of Audit Observations, Evidence, Potential and Actual Findings	Classification: •Needs Further Research (NR) •Opportunities for Improvement (OI) • 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) Financing		Mgmt Review Data Control Records 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) Internal Audit 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 Customer Satisfaction Indicators	(same as COP plus) 5.5.1, 8.2.1	(same as COP)		

有助于审核时间的安排和确认工具的建立/完成的过程方法审核工作表

行列识别编号

1	2	3	4	5	6	7	8	9
六个过程特性: • 有负责人 • 已被定义 • 已被记录 • 已建立联系 • 受到监控 • 记录得到维持			*四个支持过程的问题（有关风险）:* • 使用什么?(材料、设备) • 由谁进行?(技能、培训) • 使用什么关键标准?(测量、评估) • 怎样进行?(方法、技术)				描述在审核中的观察、证明，以及潜在和实际的发现	分类: •需要进一步的研究(NR) •改进机遇(OI) •不符合项(NC)
顾客导向过程 (COP)	COP 的支持过程	管理过程	组织的地点 *(实际的和组织上的)*	期望的或要求的关键指标、测量	适用的要求	适用的参考		
(第 1 列是用于本方框中明确的 COP) 财务		管理评审 数据控制 记录 顾客满意度	行政办公室	ROI 信用等级 贷款批准率	所有的贷款要求 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	国家和地方的贷款法规		
输入: 顾客需要财务服务	完成贷款申请	(同 COP 外加) 内部审核 的纠正和预防措施	行政办公室的销售区域	所需帮助的完成准确性	(同 COP 外加) 5.6.2, 6.4, 7.4.3, 7.6	(和 COP 相同)		
输出: 顾客申请财务服务	批准/ 未批准贷款申请	(和 COP 相同)	行政办公室	履行率 顾客满意指数	(同 COP 外加) 5.5.1, 8.2.1	(和 COP 相同)		

APPENDIX E - 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.

附录 E – 认证/监督审核计划指导书

范围：

本文件的目的是为了提供一项建议性的模版，以捕获基于审核计划的有效的汽车过程的关键信息。

审核计划至少必须包括模版中用“*”标出的信息。

公司信息：

- 此处输入的信息将会包含进证书。
- 员工人数应当包括现场的所有员工，含临时工和季节性员工。
- 应当清楚的识别班次 (班次时间如果没有在其它地方说明，则需要在此处说明)。
- PPE – 个人防护设备
- 着装，比如：商务休闲/商务正装
- 组织所用的语言
- 联络信息可以包括电话、传真、电邮等

支持现场的信息：

- 此处输入的信息将会包含进证书。
- 此处输入的信息将会包含进审核报告。
- 必须定义过程以显示组织的现场和支持职能之间的接口。
- 必要时，填写联络信息。

审核信息：

- 必须在适当情况下提供 OEM 和/或顾客的供应商代码。这些代码可以从组织的财务部或销售部门取得。
- 主要的顾客/顾客特殊要求。 这可能不是一个全面的清单。该清单应当包括代表大部分情况下与组织业务有大量往来的顾客。 “ ^”代表的是那些有特殊要求的顾客。
- 范围声明必须和组织证书上的声明一致。

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 16949:2009 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.

审核时间：

- 这部分的信息可以自行选择是否填写。信息会反映在提交给组织的详细的审核计划中。

需要审核的特殊项目/问题：

- 这部分应当包含完成准备的评审信息或 OEM 提供的信息这两方面所关注的任何问题。它可以包括负面的趋势、顾客申诉、新产品、重大的人事变动等。

最高管理者的出席：

- 必须是在现场的最高管理人员。

顾客满意度的输入：

- 该信息应当在现场审核的 30-45 天之前收到。
- 在初次认证的准备评审时，要求为期 12 个月的数据。它至少应当包括适用于 ISO/TS 16949:2009 的 IATF 准则中所定义的所有信息。
- 除了顾客的衡量指标之外，由组织提供一份结果汇总以供监督（比如：管理评审、纠正措施、预防措施、内部的审核信息）。

对顾客满意度的输入的更新：

- 这时应当把审核计划着重于新的、有负面趋势的、顾客不满意的、有保修问题等等的过程/产品。

过程方法的目的是为了通过增值审核，向组织及其顾客提供价值。审核必须着重于消除问题并进行长期的改进。

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 16949:2009
PPE glasses Attire bus. casual

Management Representative
Paige Turner
Phone 555-867-5309
Fax 555-867-5308
Shifts 7 – 3, 3 – 11, 11 - 7
(All shifts for ISO/TS 16949 will be audited)

Support Site(s) Information
Address 1500 Pennsylvania Ave.
Somewhere, USA

Address

Processes: R & D Design
Phone: 555-867-5400
Fax: 555-867-5401
Processes:
Phone:
Fax:

Audit Information
Audit Dates January 9, 10, 2009
Assessor(s) Frank Bean
Lead: Joe Dunn

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

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.

QMS 认证/监督

过程方法审核计划

公司信息
顾客 ABC 公司
地址 1000 Pennsylvania Ave.
地址 USA 某处
员工数 100
标准 ISO/TS 16949:2009
PPE 眼镜 着装 商务休闲

管理代表
Paige Turner
电话 555-867-5309
传真 555-867-5308
班次 7 – 3, 3 – 11, 11 - 7
(ISO/TS 16949 的所有班次都会被审核。)

支持现场的信息
地址 1500 Pennsylvania Ave.
USA 某处

地址

过程: 研发设计
电话: 555-867-5400
传真: 555-867-5401
过程:
电话:
传真:

审核信息
审核日前 2009 年 1 月 9，10 日
审核员 Frank Bean
组长 Joe Dunn

要求的人日数 4
向导数 2
供应商代码
通用 X1401 福特
克莱斯勒

范围声明：汽车行业的注塑型零部件的设计和制造。

审核时间

	第 1 天	第 2 天
审核员抵达/开始会议:	7:30 a.m.	6:00 a.m.
结束会议:		3:00 p.m.
审核员离开:	5:00 p.m.	3:30 p.m.

视情况安排工作汇报
工作午餐暂定时间：午间

需要审核的特殊项目/问题(根据预审核的信息 – 绩效问题、新产品/项目、关注点/申诉、所有权/管理变更):
零件编号：XXXXXXXX 通用第一等级遏制

注：管理者代表以及现场的执行管理必须出席本评审。

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.	Update to Customer Satisfaction Input: -Delivered Part or Service Quality -Stop Shipment Notification -Continuous Improvement -Management Review (including Internal Audit & Corrective Actions)		-On Time Delivery -Field Returns, Complaints, disruptions
The remainder of the schedule may be changed based on trends in any of the areas noted above			
9:00 a.m.	Design Planning Project Management	9:00 a.m. 9:30 a.m. 10:30 a.m. 11:00 a.m.	Material Procurement Sales Order Entry Product & Process Changes Resources & Qualifications
12:00 p.m.	Assessor Debrief/Lunch		
1:00 p.m.	Process Planning Project Management	1:00 p.m.	Tool Management Maintenance Planning Facility Design
3:00 p.m.	Manufacturing Validation of Process & Product	3:00 p.m.	Lab. Testing Quality Eval. 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 Validation of Process & Product	6:00 a.m. 7:00 a.m.	Manufacturing Validation of Process & Product Manufacturing Receiving & Receiving Inspection
8:00 a.m.	Manufacturing Non-Conforming Process	8:00 a.m.	Resource Competence Training
10:00 a.m.	Shipping Production Control 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 Maintenance
2:30 p.m.	Auditor Debrief & Caucus		
3:00 p.m.	Closing Meeting		

认证/监督评估计划

审核员工作表/计划

第 1 天

时间	审核员 A	时间	审核员 B
7:30 a.m.	开始会议		
8:00 a.m.	更新顾客满意的输入： -已交付零件或服务质量 -停止发货的通知 -持续改进 -管理评审的结果（包括内部审核、预防及纠正措施）		-及时交货 -售后退货、申诉、干扰
剩余的计划安排可以根据上述任何一项内容的趋势状况而更改。			
9:00 a.m.	设计策划 工程管理	9:00 a.m. 9:30 a.m. 10:30 a.m. 11:00 a.m.	物料采购 销售订单输入 产品和过程变更 资源和资格鉴定
12:00 p.m.	审核员工作汇报/午餐		
1:00 p.m.	过程策划 工程管理	1:00 p.m.	工具管理 维护保养策划 设施设计
3:00 p.m.	制造 过程和产品的确认	3:00 p.m.	实验室试验 质量评估 时间安排
4:30 p.m.	审核员和客户的工作汇报	4:30 p.m.	审核员和客户的工作汇报

第 2 天

时间	审核员	时间	审核员 B
6:00 a.m.	制造 过程和产品的确认	6:00 a.m. 7:00 a.m.	制造 过程和产品的确认 制造 接收和接收检验
8:00 a.m.	制造 不符合的过程	8:00 a.m.	资源能力 培训
10:00 a.m.	发货 生产控制 沟通	10:00 a.m.	顾客特殊要求的审核
12:00 p.m.	审核员工作汇报/午餐		
1:00 p.m.	测量系统的确认	1:00 p.m.	制造 维护
2:30 p.m.	审核员工作汇报和会议		
3:00 p.m.	结束会议		

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 ISO/TS 16949 will be audited)

***Support Site(s) Information (if any)**
Address _____
_____
Address_____
_____

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

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

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

*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):**

QMS 认证/监督 过程方法审核计划 (“*” 号表示的是必须填写的信息)

公司信息
认证现场:
*顾客 _____
*地址_____
*地址_____
员工总人数 _____
*标准_____
PPE _____着装_____
使用语言_____

*管理者代表
_____
联络信息:
_____
*生产班次_____
(ISO/TS 16949 的所有班次都会被审核。)

*支持现场的信息 (如果有)
地址 _____
_____
地址_____
_____

过程:_____
电话:_____
传真:_____
过程:_____
电话:_____
传真:_____

审核信息
*审核日期_____
*审核员_____
*组长_____

* 需要的审核人日数
向导数 _____
*供应商代码_____
通用 _____福特_____
克莱斯勒_____

*范围声明:

* 主要的顾客和顾客特殊要求（如适用）:

注: 用 ^ 来表示有特殊要求的顾客 – 参见完成准备的评审信息

审核时间

	第 1 天	第 2 天
审核员抵达/开始会议:		
结束会议:		
审核员离开:		

视情况安排工作汇报
工作午餐的暂定时间: 午间

*需要审核的特殊项目/问题(根据预审核的信息 – 绩效问题、新产品/项目、关注点/申诉、所有权/管理变更):

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: -Delivered Part or Service Quality -On Time Delivery -Stop Shipment Notification -Field Returns, Complaints, disruptions, -Continual Improvement -Warranty Issues -Management Review Results (including Internal Audit, Preventive &Corrective Actions) -Prior audit issues (if applicable) -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		

认证/监督评估计划

审核员工作表/计划

第 1 天

(将会指派组织所识别的过程)

时间	审核员 A	时间	审核员 B
	开始会议		
	更新顾客满意的输入： -已交付零件或服务质量 -及时交货 -停止发货的通知 -售后退货、申诉、干扰 -持续改进 -保障问题 -管理评审的结果（包括内部审核、预防及纠正措施） -先前的审核问题（如适用） -适当情况下，其他顾客的衡量指标		
剩余的计划安排可以根据上述任何一项内容的趋势状况而更改。			
	审核员的工作汇报和会议		
	结束会议		

APPENDIX F – GUIDANCE MATRIX

Introduction

The following Guidance Matrix is limited to providing assistance in the application of ISO/TS 16949:2009. This matrix is for reference only and is not intended as a requirement for certification.

ISO/TS 16949:2009 is an automotive requirements document. This guidance matrix provides automotive industry guidance for the requirements specified in ISO/TS 16949:2009.

AIAG GUIDANCE STRUCTURE

Left column:..... ISO/TS 16949:2009 clause number & title.

Right column:..... Practices, examples, applications, explanations. If there is no additional information provided for a particular clause, then "No Guidance." will be indicated.

Reference within this document to the original ISO 9001:2008 text is italicized, normal font.

Reference to automotive-industry specific text is in normal, bolded text.

附录 F – 指南矩阵

引言

下面的指南仅限于向实施 **ISO/TS 16949:2009** 提供帮助。本文件仅供参考，目的不是认证的要求。

ISO/TS 16949:2009 是一份汽车行业要求的文件。本指南文件针对 **ISO/TS16949:2009** 中规定的要求，提供了对汽车行业的指南。

AIAG 指南结构

左侧的一列: **ISO/TS 16949:2009** 条款编号和标题。

右侧的一列: 实践、范例、应用、解释。如果没有针对某个条款的额外信息，将标明“没有指南”。

本文件中引用到原版 ISO 9001:2008 的文字是斜体字、细体字。

引用到汽车行业专用的文字是正体、粗体字。

ISO/TS 16949:2009 Clause number and title	**Practices, examples, applications, explanations**
1 Scope – 1.1 General	**Remote locations that support "sites" cannot achieve stand-alone certification to ISO/TS 16949:2009. The automotive application of the process-oriented audit approach includes the review, identification, and management of linked activities. The process audit approach examines the ongoing control over the linkage between the individual processes within the system as well as their combination and interaction in meeting the requirements of the Technical Specification. In particular, evidence should be obtained of the links between the processes identified for the audited site and the processes identified in the supporting entities such as design centers, headquarters, and distribution centers that the output from one process directly forms the input to the next.**
1.2 Application	**Exclusions to the requirements of ISO/TS 16949:2009 edition are limited as follows:** **1) those requirements contained in clause 7.3 where the organization is not responsible for product design and development,** **2) vehicle assembly organizations are limited to those exclusions defined in the Automotive Certification Scheme for ISO/TS 16949:2009, Rules for achieving IATF recognition, 3rd edition.** **The quality management system must address all requirements of ISO/TS 16949:2009, except those specified above. Non-applicability may occur under the condition where the process exists, but is not currently applicable, e.g. No customer-owned tooling exists at the audited site, or no written servicing agreement between customer and organization.**
2 Normative reference	**No further guidance on this automotive requirements clause.**
3 Terms and definitions	**No further guidance on this automotive requirements clause.**
4 Quality Management System	**No further guidance on this automotive requirements clause.**
4.1 General requirements	*No further guidance on this ISO 9001:2008 clause.*

ISO/TS 16949:2009 条款编号和标题	实践、范例、应用、解释
1 范围 - 1.1 总则	支持"现场"的外部场所不能获得**ISO/TS 16949:2009**的单独认证。汽车行业应用过程导向的审核方法包括评审 、识别和管理相联的活动。过程审核方法在体系内检查单个过程间的连接以及他们的结合和相互作用满足技术规范的要求的现行控制。特别应当获得受审核的现场识别的过程与支持性实体（例如，设计中心、总部、配送中心等输出直接形成输入的实体）识别的过程之间的联接的证据。
1.2 应用	对 **ISO/TS 16949:2009** 要求的豁免仅限于以下： **1)** 对于没有产品设计和开发职责的组织，包含在条款 **7.3** 中的要求； **2)** 车辆装配组织仅限于由 **IATF** 在 **ISO/TS 16949:2009** 汽车认证方案，**IATF** 认可规则，第三版中所规定的豁免。 除以上说明外，质量管理体系必须落实 **ISO/TS 16949:2009** 的所有要求。非适用性可能会出现于过程存在，但目前没有应用的情况，例如：在被审核现场不存在顾客所有的工装，或顾客和组织间不存在书面服务协议。
2 引用标准	对此汽车业的要求条文，没有进一步的指南。
3 术语和定义	对此汽车业的要求条文，没有进一步的指南。
4 质量管理体系	对此汽车业的要求条文，没有进一步的指南。
4.1 总要求	*对此ISO 9001:2008条文，没有进一步的指南。*

ISO/TS 16949:2009 Clause number and title	**Practices, examples, applications, explanations**
4.1.1 General Requirements - Supplemental	**When the organization outsources, it is not permitted to delegate the technical responsibility. Particular attention should be given to the Product and Process Design and development. (Section 7.3). As an example, conformance with the customer part approval process, including all in-house or outsourced activities, is the responsibility of the organization.**
4.2 Documentation requirements	**Examples of automotive industry related documents referred to in 4.2 are:** • **business plans,** • **calibration procedures,** • **control plan,** • **customer-specific requirements,** • **engineering drawings,** • **engineering standards,** • **industry standards where applicable,** • **inspection instructions,** • **job descriptions (where used to define minimum) requirements, for education, qualification, training, etc,** • **job set-up sheets,** • **material specifications,** • **mathematical (CAD) data,** • **operating procedures,** • **process maps, process flow charts or descriptions,** • **quality assurance procedures,** • **quality Manual,** • **quality plan,** • **quality policy,** • **test procedures,** • **work instruction.** **A record is a special type of document that provides evidence that states results achieved or provides evidence of activities performed. For example:** • **calibration results,** • **contract review results,** • **customer-specified records,** • **design review results,** • **internal audit reports,** • **management review minutes,** • **records of engineering changes – product and process,** • **test/inspection results.**

ISO/TS 16949:2009 条款编号和标题	实践、范例、应用、解释
4.1.1 总要求-补充	当组织外包时，不允许委托技术职责。应当对产品和过程的设计和开发（**7.3**）给予特别的注意。例如：符合顾客零件批准过程，包括内部和外包活动，是组织的职责。
4. 2 文件要求	**4.2** 中涉及的与汽车行业有关的文件举例包括： • 业务计划， • 校准程序， • 控制计划， • 顾客特殊要求， • 工程图样， • 工程标准， • 适用的行业标准， • 检验指导书， • 教育、资格、培训等的工作描述要求（用以定义最低要求） • 作业准备表， • 材料规范， • 数学（**CAD**）数据， • 操作程序， • 过程图、过程流程图或描述， • 质量保证程序， • 质量手册， • 质量计划， • 质量方针， • 试验程序， • 作业指导书。 记录是为证明规定的结果已经达到或活动已经进行提供证据的特殊类型的文件。例如： • 校准结果， • 合同评审结果， • 顾客指定的记录， • 设计评审结果， • 内部审核报告， • 管理评审会议纪要， • 产品和过程的工程更改记录， • 试验/检验结果。

ISO/TS 16949:2009 Clause number and title	Practices, examples, applications, explanations
4.2.1 General	*No further guidance on this ISO 9001:2008 clause.*
4.2.2 Quality manual	*No further guidance on this ISO 9001:2008 clause.*
4.2.3 Control of documents	*No further guidance on this ISO 9001:2008 clause.*
4.2.3.1 Engineering specifications	**No further guidance on this automotive requirements clause**
4.2.4 Control of Records	*No further guidance on this ISO 9001:2008 clause.*
4.2.4.1 Records retention	**No further guidance on this automotive requirements clause.**
5 Management Responsibility	**No further guidance on this automotive requirements clause.**
5.1 Management commitment	*No further guidance on this ISO 9001:2008 clause.*
5.1.1 Process efficiency	**Top management in a corporate certification scenario would not necessarily be the same as for site certification, but in any event should be clearly defined.** **Top management review may include:** • **continual improvement as an objective for processes of the organization analysis and optimization of the interaction of processes,** • **identification of the organization's product realization processes, as these are directly related to the success of the organization,** • **identification of those support processes that affect the efficiency of the realization processes,** • **verification during the process changes, that the resources and communication needed to maintain the functions of the quality management system are provided,** • **verification that processes operate as an effective and efficient network,** • **cost trends and benchmarking of key processes.**
5.2 Customer focus	*No further guidance on this ISO 9001:2008 clause.*

ISO/TS 16949:2009 条款编号和标题	实践、范例、应用、解释
4.2.1 总则	*对此 ISO 9001:2008 条文，没有进一步的指南。*
4.2.2 质量手册	*对此 ISO 9001:2008 条文，没有进一步的指南。*
4.2.3 文件控制	*对此 ISO 9001:2008 条文，没有进一步的指南。*
4.2.3.1 工程规范	对此汽车业的要求条文，没有进一步的指南。
4.2.4 记录控制	*对此 ISO 9001:2008 条文，没有进一步的指南。*
4.2.4.1 记录保存	对此汽车业的要求条文，没有进一步的指南。
5 管理职责	对此汽车业的要求条文，没有进一步的指南。
5.1 管理承诺	*对此 ISO 9001:2008 条文，没有进一步的指南。*
5.1.1 过程效率	在集团认证情景中的最高管理者不必与现场认证相同，但在任何情况下都必须清楚地加以定义。 最高管理者评审可以包括： • 持续改进作为组织分析和最优化过程间相互作用的过程的目标， • 直接关系到组织的成功的产品实现过程的识别， • 影响实现过程效率的支持过程的识别， • 过程更改中的验证，保持质量管理体系提供的功能所需的资源和沟通， • 验证过程以有效的和有效率的网络形式运作， • 关键过程的成本趋势和标杆分析。
5.2 以顾客为关注的焦点	*对此 ISO 9001:2008 条文，没有进一步的指南。*

ISO/TS 16949:2009 Clause number and title	Practices, examples, applications, explanations
5.3 Quality policy	*No further guidance on this ISO 9001:2008 clause.*
5.4 Planning	*No further guidance on this ISO 9001:2008 clause.*
5.4.1.1 Quality objectives - Supplemental	**Business plan: plan approved by executive management that contains goals, objectives and measurements for the organization, including those for quality.** **The audit should verify that the organization has a process for creating, disseminating, and monitoring quality objectives in the business plan. This limits audit of the business plan to quality objectives.** **The objectives should be:** • **customer focused,** • **derived from the business plan,** • **stipulated and deployed,** • **measureable,** • **measured,** • **used to facilitate an effective and efficient review by management,** • **utilized for corrective action and continual improvement.**
5.4.2 Quality management system planning	*No further guidance on this ISO 9001:2008 clause.*
5.5.1 Responsibility and authority	*No further guidance on this ISO 9001:2008 clause.*
5.5.1.1 Responsibility for quality	**Emphasis should be placed on situations in which things went wrong, which should be audited to determine who made decisions, and what action was taken, and timing involved. Particular attention should be given to the review of the control plan. Accountability across all shifts, for the actions taken as a result should be reviewed.**
5.5.2 Management representative	*No further guidance on this ISO 9001:2008 clause.*

ISO/TS 16949:2009 条款编号和标题	实践、范例、应用、解释
5.3 质量方针	*对此 ISO 9001:2008 条文，没有进一步的指南。*
5.4 策划	*对此 ISO 9001:2008 条文，没有进一步的指南。*
5.4.1.1 质量目标 – 补充	业务计划：由执行管理者所核准的计划，内容包括了对组织及其品质的目的、目标和衡量。 审核应验证这组织拥有为建立、分解和监视在业务计划中质量目标的过程。这将对业务计划的审核限制于质量目标。 目标应当是： • 以顾客为关注焦点的， • 源自业务计划， • 被规定并被贯彻， • 可衡量的， • 测量出来的， • 管理层用于进行有效的和有效率的评审， • 被用于纠正措施和持续改进。
5.4.2 质量管理体系策划	*对此 ISO 9001:2008 条文，没有进一步的指南。*
5.5.1 职责和权限	*对此 ISO 9001:2008 条文，没有进一步的指南。*
5.5.1.1 质量职责	应当把重点放在出现运行不良上，进行审核以确定进行决策的人员、采取的措施并包括时间安排。应当特别的关注控制计划的评审。作为采取措施的结果，应当评审所有班次。
5.5.2 管理者代表	*对此 ISO 9001:2008 条文，没有进一步的指南。*

ISO/TS 16949:2009 Clause number and title	Practices, examples, applications, explanations
5.5.2.1 Customer representative	**Management should ensure that the designated individual(s) and specific responsibilities are defined. An illustration of the effectiveness in the implementation of this clause may be demonstrated through the Customer Representative's participation in milestones and decision points related to Production release, Engineering release and related activities linked to customer requirements.**
5.5.3 Internal communication	*No further guidance on this ISO 9001:2008 clause.*
5.6. Management review	*No further guidance on this ISO 9001:2008 clause.*
5.6.1.1 Quality management system performance	**In this context, quality management system performance is intended to mean measurement that the system has achieved the intended output. Examples of measurement include gap analysis, timeliness, error rates, and corrective action effectiveness. In this respect continuous improvement and corrective actions should be applied. Root cause analysis is also an excellent tool that could be applied to improve overall system performance. Evaluation of cost of poor quality includes monitoring of both internal and external costs.**
5.6.2 Review input	*No further guidance on this ISO 9001:2008 clause.*
5.6.2.1 Review input – Supplemental	**In situations where a product is manufactured or distributed in a number of markets, the organization should ensure that a process has been established to ensure that there is a defined structure and decision process for information on field failures and/or returned product. In many cases there exists information derived from units operating under different certificates. Data should be collected and analyzed in one central location, and then disseminated and acted upon at all affected locations.**
5.6.3 Review output	*No further guidance on this ISO 9001:2008 clause.*
6 Resource management	**No further guidance on this automotive requirements clause.**
6.1 Provision of resources	*No further guidance on this ISO 9001:2008 clause.*
6.2.1 General	*No further guidance on this ISO 9001:2008 clause.*
6.2.2 Competence, training, and awareness	*No further guidance on this ISO 9001:2008 clause.*

ISO/TS 16949:2009 条款编号和标题	实践、范例、应用、解释
5.5.2.1 顾客代表	管理层应当确保已经指定了人员并定义了明确的职责。对本条款实施有效性的说明，可以通过顾客代表参与生产件放行、工程放行与连接到顾客要求的相关活动的相关里程碑或决策点而加以证明。
5.5.3 内部沟通	*对此 ISO 9001:2008 条文，没有进一步的指南。*
5.6. 管理评审	*对此 ISO 9001:2008 条文，没有进一步的指南。*
5.6.1.1 质量管理体系的绩效	在这一段中，质量管理体系绩效的目的是测量组织是否达到了预期的输出。测量的范围包括差异分析、及时情况、错误率、纠正措施的有效性。这里应当用持续改进和纠正措施。根本原因分析也是有效的工具，可以用来改进整个体系的绩效。评估不良质量成本，包括内部和外部成本的监视。
5.6.2 评审输入	*对此 ISO 9001:2008 条文，没有进一步的指南。*
5.6.2.1 评审输入 – 补充	在产品制造或配送到多个市场的情况下，组织应当确保已经建立过程来保证对现场失效和/或退货产品信息有结构化和决策过程。在很多案例中，存在从认证状态不同的操作单位获得的信息。应当在中心场所收集和分析数据，然后发布至所有受影响的场所并执行。
5.6.3 评审输出	*对此 ISO 9001:2008 条文，没有进一步的指南。*
6 资源管理	对此 **ISO 9001:2008** 条文，没有进一步的指南。
6.1 资源提供	*对此 ISO 9001:2008 条文，没有进一步的指南。*
6.2.1 总则	*对此 ISO 9001:2008 条文，没有进一步的指南。*
6.2.2 能力、培训和意识	*对此 ISO 9001:2008 条文，没有进一步的指南。*

ISO/TS 16949:2009 Clause number and title	Practices, examples, applications, explanations
6.2.2.1 Product design skills	Examples of tools that may be considered are: • computer-aided design (CAD), • design for manufacturing (DFM)/design for assembly (DFA), • design of experiments (DOE), • computer-aided engineering (CAE), • failure mode and effects analysis (DFMEA/PFMEA, etc.), • finite element analysis (FEA), • geometric dimensioning and tolerancing (GD&T), • quality function deployment (QFD), • reliability engineering plans, • simulation techniques, • solid modeling, • value engineering (VE).
6.2.2.2 Training	Audit experience shows that the greatest risk is at the time of rapid organization change such as: • acquisitions, mergers, joint ventures, • assimilation of new technology, • introduction of new or major change of product, process, or facility, • rapid growth or decline. In order to demonstrate competence, a typical process used within the industry is a skills matrix. These often show several ascending levels of competence. As an example, level one is "incompetent", level two is "able to do job under supervision", level three is "can perform task", level four "able to train others" or "lead". The audit should verify for example, that internal auditing personnel are qualified and trained. (See also 8.2.2.5).
6.2.2.3 Training on the job	"Consequences to the customer" includes being aware of the impact of nonconformities on both internal, external customers and end users.

ISO/TS 16949:2009 条款编号和标题	实践、范例、应用、解释
6.2.2.1 产品设计技能	可以考虑的工具范例包括： • 计算机辅助设计 (CAD)， • 制造设计 (DFM)/装配设计 (DFA)， • 试验设计(DOE)， • 计算机辅助工程 (CAE)， • 失效模式及后果分析 (DFMEA/PFMEA 等)， • 有限元分析 (FEA)， • 几何尺寸和公差 (GD&T)， • 质量功能展开(QFD)， • 可靠性工程计划， • 仿真技术， • 固体模型， • 价值工程 (VE)。
6.2.2.2 培训	审核经验显示最大的风险发生在组织发生快速变化的时候，例如： • 收购、合并、合资， • 新技术应用， • 引入新的或重要的产品、过程或设施更改， • 快速发展或衰落。 本行业中进行证明所需能的典型过程是技能矩阵，通常可以表示几个逐渐上升的能等级。例如，第一级是"不合格"，第二级是"可以在监督下进行工作"，第三级是"可以执行任务"，第四级"有能力培训其他人"或"引导"。审核应确认，例如审核员是否合格并经过培训（见8.2.2.5）。
6.2.2.3 在职培训	"对顾客的影响"包括意识到不合格对内部、外部顾客和最终使用者的影响。

ISO/TS 16949:2009 Clause number and title	Practices, examples, applications, explanations
6.2.2.4 Employee motivation, and empowerment	**Industry practices have elements that include awareness, understanding, commitment, and implementation. This is illustrated by the PDCA cycle. The organization should utilize methods that promote involvement, communication and teamwork that are linked to customer satisfaction. A common method of measurement is employee surveys.** **Additional examples include:** • **awards,** • **improvement suggestions,** • **poster campaigns, competitions,** • **quality circles,** • **training and information meetings,** • **workshops,** • **zero defects programs.**
6.3 Infrastructure	*No further guidance on this ISO 9001:2008 clause.*
6.3.1 Plant, facility and equipment planning	**Methods should be developed for evaluating the productivity and effectiveness of existing operations considering the following factors:** • **ergonomics and human factors,** • **operator and line balance,** • **storage and buffer inventory levels,** • **use of automation,** • **value-added content,** • **work plan.**
6.3.2 Contingency plans	**The contingency plans could include:** • **availability of alternative remote production sites for multi-site situations,** • **definition of a responsible person to operate emergency procedures,** • **key equipment/machinery list,** • **maintenance operations records,** • **outputs of risk analysis result.**
6.4 Work Environment	No further guidance on this ISO 9001:2008 clause.

ISO/TS 16949:2009 条款编号和标题	实践、范例、应用、解释
6.2.2.4 员工激励和授权	工业实践的要素包括意识、了解、承诺和实施。可以通过PDCA循环阐明。组织应当使用能够促进连接到顾客满意的参与、沟通和小组合作的方法。通常的测量方法是进行员工调查。 其它例子包括： • 奖励， • 改进建议， • 张贴海报，竞赛， • 质量圈， • 培训和信息会议， • 研讨会， • 零缺陷方案。
6.3 基础设施	*对此 ISO 9001:2008 条文，没有进一步的指南。*
6.3.1 工厂、设备和设施策划	应当开发评价生产力和现存操作有效性的方法，考虑以下因素： • 人机工程学， • 操作工和生产线平衡， • 贮存和周转库存水平， • 自动化的应用， • 增值含量， • 工作计划。
6.3.2 应急计划	应急计划可包括： • 多个现场时，可以选择的外部生产现场， • 确定负责人员启动紧急程序， • 关键设备/机器清单， • 维护运作操作记录， • 风险分析结果输出。
6.4 工作环境	*对此 ISO 9001:2008 条文，没有进一步的指南。*

ISO/TS 16949:2009 Clause number and title	**Practices, examples, applications, explanations**
6.4.1 Personnel safety to achieve conformity to product quality	**Implementation examples may include:** • **defined responsibilities for safety,** • **error proofing as a preventive activity in design and process control,** • **knowledge and application of regulations,** • **learning from internal/external audits and corrective actions,** • **records of accidents,** • **risk analysis such as FMEA,** • **use of protective equipment.**
6.4.2 Cleanliness of premises	**Implementation examples may include:** • **appropriate disposal conditions,** • **appropriate space and storage conditions,** • **clean, intact transport and operating equipment,** • **clean, well lighted, organized workplaces and inspection stations,** • **clear and visible identification of equipment and systems,** • **defined responsibilities for order and cleanliness.**
7 Product realization	**No further guidance on this automotive requirements clause.**
7.1 Planning of product realization - Note	**Refer to the customer-specific references for more detailed guidance on advanced product and process quality planning.**
7.1.1 Planning of product realization – Supplemental	**No further guidance on this automotive requirements clause.**
7.1.2 Acceptance criteria	**No further guidance on this automotive requirements clause.**
7.1.3 Confidentiality	**Access to storage of confidential documents and data (electronic or hard copy) should be controlled. Particular attention should be given to confidentiality related to new projects and changes.**

ISO/TS 16949:2009 条款编号和标题	实践、范例、应用、解释
6.4.1 为达成产品要求符合性的人员安全	实施范例可能包括： • 定义安全职责， • 设计和过程控制中作为预防活动的防错， • 法规的知识和应用， • 从内/外部审核和纠正措施中学习， • 事故记录， • 风险分析，例如**FMEA**， • 应用保护性设备。
6.4.2 生产现场的清洁	实施范例可能包括： • 适当的废物弃置条件， • 适当的空间和贮存环境， • 清洁、完整的传送和操作设备， • 清洁、照明良好、有秩序的工作场所和检验场所， • 设备和系统的清楚的、明显的识别， • 定义秩序和清洁的职责。
7 产品实现	对此汽车业的要求条文，没有进一步的指南。
7.1 产品实现的策划 – 注	请参阅本指南文件中的顾客要求的参考文件或书目，以获得产品和过程质量策划的更多详细指南。
7.1.1 产品实现的策划 – 补充	对此汽车业的要求条文，没有进一步的指南。
7.1.2 接收准则	对此汽车业的要求条文，没有进一步的指南。
7.1.3 保密	应当控制对贮存机密性文件和数据（电子档案或复印文件）的使用。并应当特别注意与新项目和更改有关的机密。

ISO/TS 16949:2009 Clause number and title	**Practices, examples, applications, explanations**
7.1.4 Change control	**This requirement applies to ANY change in product realization. This applies to product and manufacturing process changes. Experience demonstrates that uncontrolled change leads to both organization as well as customer quality problems. The defined process including authority for change, the consistency of implementation and communication are important factors that should be examined.** **Examples include:** • **control plans,** • **customer requirements,** • **design record,** • **inspection instructions,** • **machine process parameters,** • **material specifications/reports,** • **measuring equipment,** • **part approval requirements,** • **technical drawings,** • **work instructions.**
7.2.1 Determination of requirements related to the product	*No further guidance on this ISO 9001:2008 clause.*
7.2.1.1 Customer-designated special characteristics	**Refer to customer-specific requirements and see ISO/TS 16949:2009 - 3.1 Terms and definitions for the automotive industry. Where no customer-specific symbols and definitions for special characteristics are defined, the following chart is provided as a suggested guideline.** § **Product characteristic or process parameter which affects a product's safety or compliance with regulatory requirements.** **Product characteristic or process parameter which affects a product's fit/function or has other reasons for control and documentation such as customer requirements.** **Non-Key-Characteristic (no symbol)** **Product characteristic or process parameter with reasonably anticipated variation and which is unlikely to significantly affect a product's safety, compliance with governmental regulations, fit/function.**

ISO/TS 16949:2009 条款编号和标题	实践、范例、应用、解释
7.1.4 更改的控制	本要求适用于产品实现中的任何更改。适用于产品和制造过程更改。经验证若不控制更改会导致组织和顾客的质量问题。规定的过程包括更改的权限，实施和沟通的一致性是应当被检查的重要因素。 范例包括： • 控制计划， • 顾客要求， • 设计记录， • 检验指导书， • 机器过程参数， • 材料规范/报告， • 测量设备， • 零件批准要求， • 技术图样， • 操作指导书。
7.2.1 与产品有关的要求的确定	*对此 ISO 9001:2008 条文，没有进一步的指南。*
7.2.1.1 顾客指定的特殊特性	参见顾客特殊要求和 **ISO/TS 16949:2009-3.1**汽车行业的术语和定义。 如果没有已经定义的特殊特性的顾客指定符号或定义，以下提供的图标可以作为建议的指南。 § 影响产品的安全性或法规要求的符合性的产品特性或过程参数。 影响产品的配合/功能或关于控制和文件化的其它原因的产品特性或过程参数。 非关键特性 (无符号) 具有合理的预期变差，不大可能严重影响产品的安全性、政府法规的符合性及配合/功能的产品特性或过程参数。

ISO/TS 16949:2009 Clause number and title	Practices, examples, applications, explanations
7.2.2 Review of requirements related to the product	*No further guidance on this ISO 9001:2008 clause.*
7.2.2.1. Review of requirements related to the product - Supplemental	**No further guidance on this automotive requirements clause.**
7.2.2.2. Organization manufacturing feasibility	**Risk analysis includes an assessment of the organization's capacity and capability to effectively and efficiently provide the customer specific deliverable. The risk analysis should include program timing, resources, development costs and investments. Risk assessment should be undertaken to assess the potential for, and the effect of, possible failures or faults in processes including the organization's direct suppliers.**
7.2.3 Customer communication	*No further guidance on this ISO 9001:2008 clause.*
7.2.3.1 Customer communication – Supplemental	**Electronic data exchange (interchange - EDI) is a computerized system for online exchange of planning information such as Computer Aided Design (CAD) data, and shipping schedules. CAD utilizes computer systems capability to automate the creation and editing of geometry, dimensions, and other drafting annotations that allow a user to define the shape and physical characteristics of an object. Indications of capability include:** • **Common language for technical specifications and important documents,** • **Effective interfaces with customer.**
7.3 Design and development	**This entire element applies to the product realization process, including both design of product and manufacturing process, and extends throughout the product program life.**
7.3.1 Design and development planning	*No further guidance on this ISO 9001:2008 clause.*

ISO/TS 16949:2009 条款编号和标题	实践、范例、应用、解释
7.2.2 与产品有关的要求的评审	*对此 ISO 9001:2008 条文，没有进一步的指南。*
7.2.2.1. 与产品有关的要求的评审- 补充	对此汽车业的要求条文，没有进一步的指南。
7.2.2.2. 组织制造可行性	风险分析包括组织有效的和有效率的提供顾客指定交付的能力和生产量。风险分析应当包括：项目时间安排、资源、开发成本和投资。应当进行风险评估，以评估过程中包括组织的直接供应商，可能的失效或错误发生的可能性及其影响。
7.2.3 顾客沟通	*对此 ISO 9001:2008 条文，没有进一步的指南。*
7.2.3.1 顾客沟通 – 补充	电子数据交换（相互交换- **EDI**）是一个在线交换策划信息的计算机处理系统（例如计算机辅助设计数据和发运时间）。**CAD**利用计算机系统能力自动建立和编辑几何尺寸和其它图样注释，这样使用者可以定义对象的外形和物理特性。能力指标包括： • 技术规范和重要文件的通用语言， • 与顾客有效的接口。
7.3 设计和开发	本要求的所有要素都适用于产品实现过程，包括产品设计和制造过程，并延伸到整个产品项目寿命。
7.3.1 设计和开发策划	*对此 ISO 9001:2008 条文，没有进一步的指南。*

ISO/TS 16949:2009 Clause number and title	Practices, examples, applications, explanations
7.3.1.1 Multidisciplinary approach	**This is an activity that brings together personnel from different business functions that collectively have the knowledge and skills to complete the task or activity. In addition, a multidisciplinary approach (Cross-functional approach) is typically viewed as an activity where a group of individuals is utilized to complete a task or activity that seeks to have all relevant knowledge and skills available to the decision making process. A multidisciplinary approach may include the organization's design, manufacturing, engineering, quality, production, and other appropriate personnel. It may also include the customer's purchasing, quality, product engineering, customer plant personnel as well as suppliers.**
7.3.2 Design and development inputs	*No further guidance on this ISO 9001:2008 clause.*
7.3.2.1 Product design input	**Regarding contract review of customer requirements, see element 7.2 and in particular paragraph 7.2.2. In addition refer to customer-specific manuals regarding advance product quality planning.**
7.3.2.2 Manufacturing process design input	**See Automotive Terms, "Manufacturing". In addition refer to customer-specific manuals regarding advance product quality planning.**
7.3.2.3 Special characteristics	**Not all products necessarily have special characteristics. The organization itself may define special characteristics. Sources for recognition of special characteristics are e.g. PFMEA, customer requirements, analysis of previous concerns and regulations. After special characteristics had been recognized they will be included in all relevant technical documents and control plans. (See also 7.2.1.1, above).**
7.3.3 Design and development outputs	*No further guidance on this ISO 9001:2008 clause.*

ISO/TS 16949:2009 条款编号和标题	实践、范例、应用、解释
7.3.1.1 多方论证方法	本方法召集来自不同业务职能的人员利用知识和技能共同完成任务或活动。另外，多方论证方法（横向职能方法）经常作为利用由个体组成的团队完成需要获得所有相关知识和技术以进行决策过程的任务或活动。多方论证方法可以包括组织的设计、制造、工程、质量、生产和其它适当的人员。还可以包括顾客的采购、质量、产品工程、顾客工厂人员和供方。
7.3.2 设计和开发输入	*对此 ISO 9001:2008 条文，没有进一步的指南。*
7.3.2.1 产品设计输入	关于顾客要求的合同评审，见要素**7.2**中的**7.2.2**。关于先期产品质量策划，参考针对顾客的手册。
7.3.2.2 制造过程设计输入	见汽车行业术语"制造"。此外还可参考关于先期产品质量策划的顾客指定手册。
7.3.2.3 特殊特性	不是所有产品都有必要有特殊特性。组织自己可以定义特殊特性。识别特殊特性的资源例如：**PFMEA**、顾客要求、过去的问题分析和法规。特殊特性被识别后将被包含在所有有关技术文件和控制计划中。（见上述**7.2.1.1**）
7.3.3 设计和开发输出	*对此 ISO 9001:2008 条文，没有进一步的指南。*

ISO/TS 16949:2009 Clause number and title	Practices, examples, applications, explanations
7.3.3.1 Product design outputs – Supplemental	**The organization's design output should be the result of a process that includes efforts to simplify, optimize, innovate and reduce waste, such as:** • **analysis of cost/performance/ business risk trade-offs,** • **appropriate use of utilization of geometric dimensioning and tolerancing,** • **design for assembly (DFA),** • **design for manufacturing (DFM),** • **design of experiments (DOE),** • **quality function deployment (QFD),** • **tolerance studies or appropriate alternatives,** • **use of design FMEAs,** • **use of feedback from testing, production and the field,** • **value engineering (VE).** **"Diagnostic guidelines" refer to systems/equipment for field servicing diagnostics utilizing engineering-based data, not necessarily required to manufacture the vehicle system but essential to provide service interfacing of that vehicle system.**
7.3.3.2 Manufacturing process design output	**The organization's manufacturing design output should be the result of a process that includes efforts to simplify, optimize, innovate and reduce waste, such as lean manufacturing tools, for example:** • **ANDON system (line control system),** • **error proofing,** • **level scheduling,** • **pull system inventory control,** • **synchronous manufacturing (single-piece flow),** • **visual controls,** • **workplace organization and layout.**
7.3.4 Design and development review	*No further guidance on this ISO 9001:2008 clause.*
7.3.4.1 Monitoring	**Monitoring of design processes is essential input for "Management review" (5.6).**
7.3.5 Design and development verification	*No further guidance on this ISO 9001:2008 clause.*

ISO/TS 16949:2009 条款编号和标题	实践、范例、应用、解释
7.3.3.1 产品设计输出 – 补充	组织的设计输出应当是努力简化、优化、创新和减少浪费的过程的结果，例如： • 成本/绩效/业务风险综合分析， • 几何尺寸和公差的适当使用， • 可装配性设计（**DFA**）， • 制造设计**(DFM)**， • 试验设计**(DOE)**， • 质量功能展开 **(QFD)**， • 公差研究或适当替代， • 设计**FMEA**的使用， • 试验、生产和使用现场的反馈的使用， • 价值工程**(VE)**。 "诊断指南"指的是使用基于工程的数据进行现场诊断服务的系统/设备，不是车辆制造系统必须要求的，但对车辆系统提供服务很重要。
7.3.3.2 制造过程设计输出	组织的制造设计输出应当是包括简化、优化、创新、减少浪费的过程的结果，例如精益生产工具： • **ANDON** 系统（生产线控制系统）， • 防错， • 均衡生产安排， • 拉动系统库存控制， • 同步制造（单件流程）， • 可视控制， • 工作场所组织和规划。
7.3.4 设计和开发评审	*对此 ISO 9001:2008 条文，没有进一步的指南。*
7.3.4.1 监测	设计过程的监测是"管理评审"的重要输入（**5.6**）。
7.3.5 设计和开发验证	*对此 ISO 9001:2008 条文，没有进一步的指南。*

ISO/TS 16949:2009 Clause number and title	Practices, examples, applications, explanations
7.3.6 Design and development validation – NOTE 2	At appropriate stages of design, design verification should be performed to ensure that the design stage output meets the design stage input requirements. The design verification measures should be recorded (see 4.2.4). In addition to conducting design reviews (see 7.3.4) design verification may include activities such as: • comparing the new design with a similar proven design, if available, • performing alternative calculations, • performing tests and simulations, • reviewing the design-stage documents before release. The reference to manufacturing processes includes verification and validation to address product quality nonconformities. This is particularly relevant at product launch and the risk can be minimized by the use of tools such as process capability studies.
7.3.6.1 Design and development validation - Supplemental	Activities should include: • comparison between customer requirements and internal development plans, • design and development validation against customer requirements, • design validation records compared with customer requirements, • corrective action plan and lessons learned from documented failures.
7.3.6.2 Prototype programme	No further guidance on this automotive requirements clause.
7.3.6.3 Product approval process	Where no customer procedure exists, the organization should comply with one of the part approval manuals. Note the requirement: "This product and manufacturing process approval procedure shall also be applied to suppliers."
7.3.7 Control of design and development changes	*No further guidance on this ISO 9001:2008 clause.*
7.4.1 Purchasing process	*No further guidance on this ISO 9001:2008 clause.*
7.4.1.1 Statutory and regulatory conformity	No further guidance on this automotive requirements clause.

ISO/TS 16949:2009 条款编号和标题	实践、范例、应用、解释
7.3.6 设计和开发确认 – 注 2	在设计的适当阶段，应当进行设计验证以确保设计阶段输出满足设计阶段输入的要求。应当记录设计验证方法（见4.2.4）。 除实施设计评审外 (见 7.3.4)，设计验证可以包括下列活动： • 如果可行，将新设计与已经经过验证的类似设计进行比较， • 进行换算， • 进行试验和仿真， • 发布前评审设计阶段文件。 制造过程的检验包括验证和确认，以解决产品质量的不合格。它尤其关系到产品的投产，通过使用工具（例如过程能力研究）可以将风险最小化。
7.3.6.1 设计和开发确认 – 补充	活动应当包括： • 比较顾客要求和内部开发计划， • 按顾客要求进行设计和开发确认， • 将设计确认记录与顾客要求进行比较， • 纠正措施计划和从文件化的失效中吸取的经验教训。
7.3.6.2 原型样件计划	对此汽车业的要求条文，没有进一步的指南。
7.3.6.3 过程批准程序	当不存在顾客程序时，组织应当符合零件批准手册中的一项。 注意要求："供应商也必须遵守产品和制造过程批准程序"。
7.3.7 设计和开发更改的控制	*对此 ISO 9001:2008 条文，没有进一步的指南。*
7.4.1 采购过程	*对此 ISO 9001:2008 条文，没有进一步的指南。*
7.4.1.1 法律法规的符合性	对此汽车业的要求条文，没有进一步的指南。

ISO/TS 16949:2009 Clause number and title	Practices, examples, applications, explanations
7.4.1.2 Supplier quality management system development	**The burden is on the organization to demonstrate compliance of its suppliers to this requirement including evidence of alternative arrangements specified by the customer.** **In situations where there are multiple customers, "customer approval" of alternative arrangements is based upon those customers impacted by that supplier.** **"Supplier" in this clause (7.4.1.2) refers to sites where production and/or service parts specified by the customer are manufactured. See also the definition of "manufacturing", 3.1.6.** **Supplier quality management system development is the demonstrated performance of a process with the goal to achieve conformity with ISO/TS 16949:2009. Indicators of performance include:** • **conformity with ISO9001:2008,** • **achievement of ISO9001:2008 certification, as a minimum, unless otherwise specified by the customer,** • **compliance with ISO/TS 16949:2009, unless otherwise specified by the customer,** • **evidence of a process to achieve the above steps.**
7.4.1.3 Customer-approved sources	**No further guidance on this automotive requirements clause.**
7.4.2 Purchasing information	*No further guidance on this ISO 9001:2008 clause.*
7.4.3 Verification of purchased product	*No further guidance on this ISO 9001:2008 clause.*
7.4.3.1 Incoming product conformity to requirements	**No further guidance on this automotive requirements clause.**

ISO/TS 16949:2009 条款编号和标题	实践、范例、应用、解释
7.4.1.2 供应商质量管理体系开发	组织有责任证明供应商符合这个要求，包括顾客规定的选择性安排的证据。 当存在多个顾客时，选择性安排的"顾客批准"是基于受到供应商影响的顾客。 本条款（**7.4.1.2**）中的"供应商"是指制造顾客指定的生产和/或服务件的场所。另见"制造"的定义**3.1.6**。 供应商质量管理体系的开发证明了过程绩效实现了**ISO/TS 16949:2009**的目标。绩效指标包括： • 符合 **ISO9001:2008**， • 除非顾客指定，至少获得 **ISO 9001:2008**认证， • 除非顾客指定，符合**ISO/TS 16949:2009**， • 过程达到上述要求的证明。
7.4.1.3 顾客批准的资源	对此汽车业的要求条文，没有进一步的指南。
7.4.2 采购信息	*对此 ISO 9001:2008 条文，没有进一步的指南。*
7.4.3 采购产品的验证	*对此 ISO 9001:2008 条文，没有进一步的指南。*
7.4.3.1 进货产品对要求的符合性	对此汽车业的要求条文，没有进一步的指南。

ISO/TS 16949:2009 Clause number and title	Practices, examples, applications, explanations
7.4.3.2 Supplier monitoring	**The trend of performance through the utilization of these indicators represents a confirmation of the supplier quality system capability. This also can represent a baseline for continual improvement. These indicators should be validated. Consideration should be given to both internal and external customers. Manufacturing process performance also refers to utilization of lean manufacturing tools e.g.:** • **ANDON procedures in place,** • **direct run first time quality results,** • **lead time reduction,** • **level scheduling,** • **number of error proofing opportunities implemented,** • **planned maintenance,** • **standardized work,** • **workplace organization and visual controls deployed.**
7.5.1 Control of production and service provision	*No further guidance on this ISO 9001:2008 clause.*
7.5.1.1 Control plan	**See ISO/TS 16949:2009 Annex A – "Control Plan"**
7.5.1.2 Work instructions	**These instructions may take the form of process sheets, inspection and laboratory test instructions, shop travelers, test procedures, standard operation sheets, drawings and visual aids or other documents normally used by the organization to provide the necessary information that impacts product quality. These instructions should include or reference, as appropriate:** • **current engineering level/date,** • **customer and organization designated special characteristics if any,** • **inspection and test instructions with acceptance criteria (see 7.1.2),** • **material identification and disposition instructions,** • **operation name and number keyed to the process flow diagram,** • **part name and part number, or part family,** • **reaction plans,** • **relevant engineering and manufacturing standards,** • **required tools, gauges and other equipment,** • **revision date and approvals,** • **SPC and other process-monitoring requirements,** • **tool-change intervals and set-up instructions,** • **visual aids.**

ISO/TS 16949:2009 条款编号和标题	实践、范例、应用、解释
7.4.3.2 供应商监视	通过这些指标的使用，绩效的趋势可以确认供应商质量体系的能力，还可以代表持续改进的基准。 这些指标应当被确认。 应当考虑内部和外部的顾客。 制造过程绩效还涉及精益制造工具的使用，例如： • **ANDON** 程序就位， • 第一次直接运行的质量结果， • 前置时间的缩短， • 均衡生产安排， • 已实施的防错机会的次数， • 计划的维护， • 标准化的工作， • 工作场所的组织和开展的可视化控制。
7.5.1 生产和服务提供的控制	*对此 ISO 9001:2008 条文，没有进一步的指南。*
7.5.1.1 控制计划	见**ISO/TS 16949:2009** 附录 **A** – **"**控制计划**"**。
7.5.1.2 工作指导书	这些指导书可能采用过程单、检验和实验室试验指导书、装运清单、测试程序、标准操作单、图样和目视辅助或其它组织用于提供影响产品质量的必要信息的文件的形式。 这些指导书应当适当的包括或参考： • 当前的工程等级/日期， • 如果有，顾客和组织指定的特殊特性， • 附有接收准则的检验和试验指导书（见**7.1.2**） • 材料识别和处理指导书， • 过程流程图的关键操作名称和编号， • 零件名称和零件编号或零件族， • 反应计划， • 相关工程和制造标准， • 要求的工装、量具和其它设备， • 修订日期和批准， • **SPC** 和其它过程监视要求， • 工装更改间隔和准备指导书， • 目视辅助。

ISO/TS 16949:2009 Clause number and title	Practices, examples, applications, explanations
7.5.1.3 Verification of job set-ups	**Verification of job set-ups may include, among others:** • **comparison of data and records of the last series (quality records, corrective actions, etc.),** • **completeness of equipment and documents for production, inspection and testing,** • **determination of responsibilities for release after set-up,** • **determination of the disposition of pre-launch or set-up scrap,** • **last-off part comparison where the last piece from the last run should be compared not only to specified requirements, but also to the first piece a new run, to reference the new set up to the quality level of the last run.**
7.5.1.4 Preventive and predictive maintenance	**Predictive maintenance methods should include a review of appropriate items such as the manufacturer's recommendations, storage, tool wear, optimization of uptime, correlation of SPC data to preventive maintenance activities, important characteristics of perishable tooling, fluid analysis, monitoring of circuits and vibration analysis as appropriate. (See also terms and definitions, 3.1.7 and 3.1.8).**
7.5.1.5 Management of production tooling	**No further guidance on this automotive requirements clause.**
7.5.1.6 Production scheduling	**No further guidance on this automotive requirements clause.**
7.5.1.7 Feedback of information from service	**No further guidance on this automotive requirements clause.**
7.5.1.8 Service agreement with customer	**No further guidance on this automotive requirements clause.**
7.5.2 Validation of processes for production and service provision	*No further guidance on this ISO9001:2008 clause.*
7.5.2.1 Validation of processes for production and service provision – Supplemental	**No further guidance on this automotive requirements clause.**

ISO/TS 16949:2009 条款编号和标题	实践、范例、应用、解释
7.5.1.3 作业准备的验证	作业准备的验证可以包括： • 与上一批次数据和记录的比较（质量记录、纠正措施等）， • 生产、检验和试验设备及文件的完成， • 准备后放行职责的确定， • 试生产或准备废料处理的确定， • 末件比较，最近一次运行的最后一批不仅应当对照规定的要求，而且应当与新运行的第一批进行比较，以参考新的准备的质量水平。
7.5.1.4 预防和预测性维护	预测性维护方法应当包括对适当的事项（例如：制造商的建议、贮存、工装磨损、运行时间优化、**SPC** 数据与预防性维护活动的关系、易损工装的重要特性、流体分析、适当的回路监视和振动分析）的评审，（见术语和定义 **3.1.7** 和 **3.1.8**）。
7.5.1.5 生产工装的管理	对此汽车业的要求条文，没有进一步的指南。
7.5.1.6 生产排程	对此汽车业的要求条文，没有进一步的指南。
7.5.1.7 服务信息的反馈	对此汽车业的要求条文，没有进一步的指南。
7.5.1.8 与顾客的服务协议	对此汽车业的要求条文，没有进一步的指南。
7.5.2 生产和服务提供过程的确认	*对此 ISO 9001:2008 条文，没有进一步的指南。*
7.5.2.1 生产和服务提供过程的确认 – 补充	对此汽车业的要求条文，没有进一步的指南。

ISO/TS 16949:2009 Clause number and title	Practices, examples, applications, explanations
7.5.3 Identification and traceability - NOTE	**Examples of inspection and test status indicated by the location of the product in the production flow include parts in the material handling of a captive process such as transfer lines, integrated machining lines, etc. "Alternatives" refer to methods to achieve control of identification of inspection and test status, e.g. bar-code labels that are linked to computer records, as an alternative to a label indicating each unit has passed inspection.**
7.5.3.1 Identification and traceability – Supplemental	**No further guidance on this automotive requirements clause.**
7.5.4 Customer property	*No further guidance on this ISO9001:2008 clause.*
7.5.4.1 Customer owned production tooling	**No further guidance on this automotive requirements clause.**
7.5.5 Preservation of product	*No further guidance on this ISO9001:2008 clause.*
7.5.5.1 Storage and inventory	**Consideration should be given to the control associated with perishable materials, assessment of storage conditions, expiration dates, climatic conditions for packaging and storage.**
7.6 Control of monitoring and measuring equipment	*No further guidance on this ISO9001:2008 clause.*
7.6.1 Measurement system analysis	**No further guidance on this automotive requirements clause.**
7.6.2 Calibration/verification records	**See 7.6 NOTE in ISO/TS 16949:2009.**
7.6.3.2 External laboratory	**No further guidance on this automotive requirements clause.**
8 Measurement, analysis and improvement	**No further guidance on this automotive requirements clause.**
8.1 General	*No further guidance on this ISO 9001:2008 clause.*

ISO/TS 16949:2009 条款编号和标题	实践、范例、应用、解释
7.5.3 标识和可追溯性 – 注	生产流程中产品的场所表示的检验和试验状态的例子包括捕获过程（例如：运输生产线、综合机械生产线等）的材料搬运中的零件。 “替代性”指的是对识别达到检验和试验状态的控制的方法，例如：联结计算机记录的条码标签，标签显示每个通过检验的单位。
7.5.3.1 标识和可追溯性 – 补充	对此汽车业的要求条文，没有进一步的指南。
7.5.4 顾客财产	*对此 ISO 9001:2008 条文，没有进一步的指南。*
7.5.4.1 顾客拥有的生产工装	对此汽车业的要求条文，没有进一步的指南。
7.5.5 产品防护	*对此 ISO 9001:2008 条文，没有进一步的指南。*
7.5.5.1 存储和库存	应当注意易损材料的控制、存储环境的评估、过期日期、包装和存储的气候条件。
7.6 监视和测量设备的控制	*对此 ISO 9001:2008 条文，没有进一步的指南。*
7.6.1 测量系统分析	对此汽车业的要求条文，没有进一步的指南。
7.6.2 校准/验证记录	见**ISO/TS 16949:2009**条款 **7.6**。
7.6.3.2 外部实验室	对此汽车业的要求条文，没有进一步的指南。
8 测量、分析和改进	对此汽车业的要求条文，没有进一步的指南。
8.1 总则	*对此 ISO 9001:2008 条文，没有进一步的指南。*

ISO/TS 16949:2009 Clause number and title	Practices, examples, applications, explanations
8.1.1 Identification of statistical tools	**Applications include:** • **statistical methods used in the development of product, such as variation analysis, regression analysis, dependability analysis and prediction,** • **statistical methods for purchased product include histograms and stratification, pareto fault analysis, sampling plans, criteria for acceptance statistics,** • **statistical methods used in verification of product characteristics and process parameters frequently include process capability studies, control charts, pareto analysis, variation analysis (special cause, common cause),** • **statistical methods for field analysis include dependability assessment, pareto analysis, traceability analysis, and Shainin techniques,** • **measurement systems analysis based on statistical methods.** • **See also customer-specific manuals.**
8.1.2 Knowledge of basic statistical concepts	**The organization should be able to demonstrate suitable training and evaluation of competence related to basic statistical concepts. See also paragraph 8.1.1 above.** **"Over-adjustment" refers to making process adjustments that are not statistically appropriate i.e. tampering.**
8.2.1 Customer satisfaction	*No further guidance on this ISO 9001:2008 clause.*
8.2.1.1 Customer satisfaction – Supplemental	**The trend of performance through the utilization of these indicators represents a confirmation of the organization's quality system capability. This also can represent a baseline for continual improvement.** **These indicators should be validated.** **Consideration should be given to both internal and external customers. Incidents of premium freight impact customer satisfaction directly, as well as quality and cost.** **Manufacturing process performance also refers to utilization of lean manufacturing tools e.g.:** • **ANDON procedures in place,** • **direct run first time quality results,** • **lead time reduction,** • **level scheduling,** • **number of error proofing opportunities implemented,** • **planned maintenance,** • **standardized work,** • **workplace organization and visual controls deployed.**
8.2.2 Internal audit	*No further guidance on this ISO 9001:2008 clause.*

ISO/TS 16949:2009 条款编号和标题	实践、范例、应用、解释
8.1.1 统计工具的识别	应用包括： • 用于开发产品的统计方法，例如变差分析、回归分析、置信度分析和预测， • 用于采购产品的统计方法，例如柱状图和分层抽样、帕累托故障分析、抽样计划、统计接收标准， • 用于产品特性和过程参数的验证的统计方法通常包括过程能力研究、控制图、帕累托分析、变差分析（特殊原因、普通原因）， • 用于现场分析的统计方法包括置信度评估、帕累托分析、可追溯性分析和**Shainin**技术， • 基于统计方法的测量系统分析。 • 另见顾客特殊要求手册。
8.1.2 基本统计概念的知识	组织应当能够验证与基本统计概念相关的适当的能力培训和评价。 另见上述**8.1.1**。 "过度调整"，即"窜改"，是指进行统计上不适用的过程调整。
8.2.1 顾客满意	*对此 ISO 9001:2008 条文，没有进一步的指南。*
8.2.1.1 顾客满意 – 补充	通过这些指标的使用，绩效的趋势可以确认组织的质量管理体系能力。它还可以代表持续改进的基准。 这些指标应当被确认。 应当考虑内部和外部顾客。超额运费以及质量和成本都会直接影响顾客的满意度。 制造过程绩效还涉及精益制造工具的使用，例如： • **ANDON** 程序就位， • 第一次直接运行的质量结果， • 前置时间的缩短， • 均衡生产安排， • 已实施的防错机会的次数， • 计划的维护， • 标准化的工作， • 工作场所的组织和展开的可视化控制。
8.2.2 内部审核	*对此 ISO 9001:2008 条文，没有进一步的指南。*

ISO/TS 16949:2009 Clause number and title	Practices, examples, applications, explanations
8.2.2.1 Quality management system audit **8.2.2.2 Manufacturing process audit** **8.2.2.3 Product audit**	**There are many approaches to analyze quality management system, product quality and process performance. In the context of the internal audit clause, internal audit for the organization should be independent of those having direct responsibility for the work performed. Personnel should not audit their own work.**
8.2.2.4 Internal audit plans	**Relevant input from the area to be audited, as well as from other interested parties, should be considered in the development of internal audit plan including definition of the key customer-orientated processes. Additional planning input may include:** • **adequacy and accuracy of performance measurements,** • **analysis of quality cost data,** • **capability of processes and use of statistical techniques,** • **effective and efficient implementation of processes,** • **opportunities for continual improvement,** • **process and product performance results and expectation,** • **relationships with customers.**
8.2.2.5 Internal auditor qualification	**The organization should define the minimum qualification requirements for personnel responsible for performance of internal audits, taking into account any customer-specific requirements.**
8.2.3 Monitoring and measurement of processes	*No further guidance on this ISO 9001:2008 clause.*
8.2.3.1 Monitoring and measurement of manufacturing processes	**Monitoring and measurement of manufacturing processes refers to monitoring over time (trend) in order to:** • **verify stability and capability, and meets the requirements of the original part approval and** • **to determine levels of achieved improvement. (see 8.5.1.2).**
8.2.4 Monitoring and measurement of product	*No further guidance on this ISO 9001:2008 clause.*
8.2.4.1 Layout inspection and functional testing	**No further guidance on this automotive requirements clause.**
8.2.4.2 Appearance items	**No further guidance on this automotive requirements clause.**

ISO/TS 16949:2009 条款编号和标题	实践、范例、应用、解释
8.2.2.1 质量管理体系审核 **8.2.2.2** 制造过程审核 **8.2.2.3** 产品审核	有很多方法可以分析质量管理体系、产品质量和过程绩效。在内部审核条款的内容中，组织的内部审核应当独立于对执行工作负有直接责任的人。人员不得审核自己的工作。
8.2.2.4 内部审核计划	在开发内部审核计划，包括关键的顾客导向过程的确定时应当考虑来自被审核区域和其它相关方的有关输入。附加的策划输入可以包括： • 绩效测量的适宜性和精确性， • 对质量成本数据的分析， • 过程能力和统计技术的使用， • 过程的有效及有效率的实施， • 持续改进的机会， • 过程和产品绩效的结果和期望， • 与顾客的关系。
8.2.2.5 内部审核员资格	组织应当定义负责执行内部审核的人员的最低资格要求，并考虑所有的顾客特殊要求。
8.2.3 过程的监视和测量	*对此 ISO 9001:2008 条文，没有进一步的指南。*
8.2.3.1 制造过程的监视和测量	制造过程的监视和测量是指一段时间内（趋势）的监视，以便： • 验证稳定性和能力，满足初始零件的批准要求，以及 • 确定达到的改进的等级(见 **8.5.1.2**)。
8.2.4 产品的监视和测量	*对此 ISO 9001:2008 条文，没有进一步的指南。*
8.2.4.1 全尺寸检验和功能性试验	对此汽车业的要求条文，没有进一步的指南。
8.2.4.2 外观项目	对此汽车业的要求条文，没有进一步的指南。

ISO/TS 16949:2009 Clause number and title	Practices, examples, applications, explanations
8.3 Control of nonconforming product	*No further guidance on this ISO 9001:2008 clause.*
8.3.1 Control of nonconforming product – Supplemental	**No further guidance on this automotive requirements clause.**
8.3.2 Control of reworked product	**No further guidance on this automotive requirements clause.**
8.3.3 Customer information	**No further guidance on this automotive requirements clause.**
8.3.4 Customer waiver	**"Authorization" refers to the authorization for customer concession or deviation permit. It will normally be documented and become a quality record.**
8.4 Analysis of data	*No further guidance on this ISO 9001:2008 clause.*
8.4.1 Analysis and use of data	**Operational performance may include productivity, cost of poor quality, process efficiency and effectiveness, production output, quality performance, and equipment utilization.**
8.5.1 Continual Improvement	*No further guidance on this ISO 9001:2008 clause.*
8.5.1.1 Continual improvement of the organization	**The reference to Annex B ISO 9004:2008 is guidance. The following tools may be utilized:** • **capability studies,** • **design of experiments,** • **evaluation procedure,** • **quality control chart system,** • **risk analysis,** • **statistical process control,** • **supplier evaluation,** • **system, process and product audit,** • **test and measurement technology,** • **theory of constraints,** • **overall equipment effectiveness,** • **parts per million (ppm) to achieve zero defects,** • **value analysis,** • **benchmarking,** • **analysis of motion/ergonomics,** • **error proofing.**

ISO/TS 16949:2009 条款编号和标题	实践、范例、应用、解释
8.3 不合格产品控制	*对此 ISO 9001:2008 条文，没有进一步的指南。*
8.3.1 不合格产品控制 – 补充	对此汽车业的要求条文，没有进一步的指南。
8.3.2 返工产品的控制	对此汽车业的要求条文，没有进一步的指南。
8.3.3 顾客信息	对此汽车业的要求条文，没有进一步的指南。
8.3.4 顾客弃权	"授权"是指对顾客让步或对背离的批准。通常应当进行文件化并形成质量记录。
8.4 数据分析	*对此 ISO 9001:2008 条文，没有进一步的指南。*
8.4.1 数据的分析和使用	运行绩效可包括生产力、不良质量成本、过程效率和有效性、生产输出、质量绩效和设备利用率。
8.5.1 持续改进	*对此 ISO 9001:2008 条文，没有进一步的指南。*
8.5.1.1 组织的持续改进	**ISO 9004:2008** 附录 **B** 是参考指南。 可以使用下列工具： • 能力研究， • 试验设计， • 评价程序， • 质量控制图系统， • 风险分析， • 统计过程控制， • 供应商评价， • 体系、过程和产品审核， • 试验和测量技术， • 限度理论， • 设备总体有效性， • 每百万件**(ppm)** 以达到零缺陷， • 价值分析， • 标杆研究， • 人机分析， • 防错。

ISO/TS 16949:2009 Clause number and title	Practices, examples, applications, explanations
8.5.1.2 Manufacturing process improvement	See also paragraph 8.1.1, above In reference to NOTE 2, corrective action is not continual improvement.
8.5.2 Corrective action	*No further guidance on this ISO 9001:2008 clause.*
8.5.2.1 Problem solving	There are many examples of problem solving methods. Generically, the effective methods include the following minimum process steps: problem identification, containment, root cause identification, and verification of effectiveness of corrective action. Documentation should facilitate easy access to data for all concerned and staff. The following quality methods may be helpful: • analysis of failure mode, • capability studies, • correlation diagrams, • data collection, • fish bone diagram (Ishikawa diagram), • FMEA review, • Histograms, • Pareto analysis, • probability charts, • recording with corresponding graphic representations, • stratification (separation of data and division into categories).
8.5.2.2 Error proofing	The utilization of error-proofing methodology should be generally utilized wherever cost-effective and feasible. Within the corrective action process, error-proofing methodology may be applied to prevent recurrence or avoidance in similar products or processes.
8.5.2.3 Corrective action impact	This refers to the application of lessons learned to other products and processes and sites.

ISO/TS 16949:2009 条款编号和标题	实践、范例、应用、解释
8.5.1.2 制造过程改进	见上述8.1.1。 参考注2：纠正措施不是持续改进。
8.5.2 纠正措施	*对此 ISO 9001:2008 条文，没有进一步的指南。*
8.5.2.1 问题解决方法	有很多问题解决的范例，通常，有效的方法至少包括以下过程步骤：问题识别、遏制、根本原因识别和验证纠正措施的有效性。文件化应促进所有相关人员对数据的易于得到。 下列质量方法可能会有帮助： • 失效模式， • 能力研究， • 关联图， • 数据收集， • 鱼刺图(石川图)， • FMEA评审， • 柱状图， • 帕累托分析， • 概率图， • 相应的图解表示的记录， • 分层抽样(按不同的类别分离数据)。
8.5.2.2 防错	只要成本上可行并有效，防错方法应当被普遍使用。在纠正措施过程中，防错方法可以用于防止再次发生或避免发生在相似产品或过程中。
8.5.2.3 纠正措施影响	它指的是对其它产品、过程和现场的应用所吸取的教训。

ISO/TS 16949:2009 Clause number and title	**Practices, examples, applications, explanations**
8.5.2.4 Rejected product test/analysis	**The following quality methods or problem-solving tools may be utilized in identifying root-cause, and/or corrective action steps:** • **analysis of failure mode,** • **capability studies,** • **correlation diagrams,** • **data collection,** • **fish bone diagram (Ishikawa diagram),** • **FMEA review,** • **Histograms,** • **Pareto analysis,** • **probability charts,** • **recording with corresponding graphic representations,** • **stratification (separation of data and division into categories).**
8.5.3 Preventive action	*No further guidance on this ISO 9001:2008 clause.*

ISO/TS 16949:2009 条款编号和标题	**实践、范例、应用、解释**
8.5.2.4 退货产品的试验/分析	下列质量方法或问题解决工具可以用来识别根本原因和/或纠正措施步骤： • 失效模式分析， • 能力研究， • 关联图， • 数据收集， • 鱼刺图(石川图)， • FMEA评审， • 柱状图， • 帕累托分析， • 概率图， • 相应的图解表示的记录， • 分层抽样(按不同的类别分离数据)。
8.5.3 预防措施	*对此 ISO 9001:2008 条文，没有进一步的指南。*

Readiness Evaluation work sheet – Information to be submitted to the CB prior to onsite audit.

ISO/TS 16949:2009 READINESS EVALUATION

INFORMATION TO BE SUBMITTED BY THE ORGANIZATION	DETAILS	DOCUMENT. REFERENCE.	CB EVALUATION
Organization size			
Site to be certified			
Supporting locations			
Product Design responsibility			
Certification Scope			
Organization's processes - descriptions including sequence and interactions			
Key indicators trends (last 12 months): -customer satisfaction -employee motivation or awareness -product realization processes -suppliers performances			
Internal audit results and action plans (last 12 months)			
Management review results (last 12 months)			
Customer complaints status			
Internal auditors qualification			
Customers specific requirements to be included in the audit			
Current Certifications held			
Quality Manual			

评估准备工作单– 在现场审核之前提交给认证机构的信息。

ISO/TS 16949:2009 评估准备

由组织提交的信息	详细	文件. 参考.	认证机构评估
组织大小			
将被认证的现场			
支持场所			
产品设计职责			
认证范围			
组织的过程— 包括顺序和交互的描述			
关键指标的趋势（最近的 12 个月）： -顾客满意 -员工的激励和意识 -产品实现过程 -供应商绩效			
内部审核结果和措施计划（最近的 12 个月）			
管理评审结果(最近的 12 个月)			
顾客抱怨状态			
内部审核员资格			
将被包含在本次审核中的顾客特殊要求			
目前拥有的认证			
质量手册			

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美国汽车工业行动集团 • 上海市浦东新区福山路 500 号城建国际中心 907 室 邮编：200122
电话：（86 21）5081 8716 传真：（86 21）5081 8707
中文网站：www.aiag.org.cn