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System Standard

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production and relevant service parts organizations



**International
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体系标准

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国际
汽车
推动小组

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Foreword – Automotive QMS Standard

This Automotive Quality Management System Standard, herein referred to as “Automotive QMS Standard” or “IATF 16949,” along with applicable automotive customer-specific requirements, ISO 9001:2015 requirements, and ISO 9000:2015 defines the fundamental quality management system requirements for automotive production and relevant service parts organizations. As such, this Automotive QMS Standard cannot be considered a stand-alone QMS Standard but has to be comprehended as a supplement to and used in conjunction with ISO 9001:2015. ISO 9001:2015 is published as a separate ISO Standard.

IATF 16949:2016 (1st edition) represents an innovative document, given the strong orientation to the customer, with inclusion of a number of consolidated previous customer specific requirements.

Annex B is provided for guidance to implement the IATF 16949 requirements unless otherwise specified by customer specific requirements.

History

ISO/TS 16949 (1st edition) was originally created in 1999 by the International Automotive Task Force (IATF) with the aim of harmonizing the different assessment and certification systems worldwide in the supply chain for the automotive sector. Other revisions were created (2nd edition in 2002, and 3rd edition in 2009) as necessary for either automotive sector enhancements or ISO 9001 revisions. ISO/TS 16949 (along with supporting technical publications developed by original equipment manufacturers [herein referred to as OEMs] and the national automotive trade associations) introduced a common set of techniques and methods for common product and process development for automotive manufacturing worldwide.

In preparation for migrating from ISO/TS 16949:2009 (3rd edition) to this Automotive QMS Standard, IATF 16949, feedback was solicited from certification bodies, auditors, suppliers, and OEMs to create IATF 16949:2016 (1st edition), which cancels and replaces ISO/TS 16949:2009 (3rd edition).

The IATF maintains strong cooperation with ISO by continuing liaison committee status ensuring continued alignment with ISO 9001.

Goal

The goal of this Automotive QMS standard is the development of a quality management system that provides for continual improvement, emphasizing defect prevention and the reduction of variation and waste in the supply chain.

前言——汽车质量管理体系标准

本汽车质量管理体系标准（本文中简称为“汽车 QMS 标准”或“IATF 16949”），连同适用的汽车顾客特定要求，ISO 9001:2015 要求以及 ISO 9000:2015 一起定义了对汽车生产件及相关服务件组织的基本质量管理体系要求。正因为如此，汽车 QMS 标准不能被视为一部独立的质量管理体系标准，而是必须当作 ISO 9001:2015 的补充进行理解，并与 ISO 9001:2015 结合使用。ISO 9001:2015 是一部单独出版的 ISO 标准。

IATF 16949:2016（第一版）是一份创新文件，着重考虑了顾客导向性，综合了许多以前的顾客特定要求。

附录 B 供实施 IATF 16949 要求时参考使用，除非顾客特定要求另有规定。

历史

ISO/TS 16949（第一版）最初由国际汽车推动小组（International Automotive Task Force, IATF）创建于 1999 年，旨在协调全球汽车行业供应链中的不同评估与认证体系。其后，因汽车行业增强或 ISO 9001 修订的需要，创建了其它版本（2002 年的第二版和 2009 年的第三版）。ISO/TS 16949（连同原始设备制造商[本文中简称为 OEM]和各国家汽车行业协会开发的支持性技术出版物）引入了一套适用于全球汽车制造业的共同产品和过程开发的常见技术和方法。

在准备从 ISO/TS 16949:2009（第三版）迁移至本汽车 QMS 标准——IATF 16949 过程中，征求了认证机构、审核员、供应商和 OEM 的反馈意见；IATF 16949:2016（第一版）的创建注销并取代 ISO/TS 16949:2009（第三版）。

IATF 通过延续联络委员会的身份，与国际标准化组织（International Standardization Organization, ISO）保持着强有力的合作，确保持续与 ISO 9001 保持一致。

目标

本汽车 QMS 标准的目标是在供应链中开发提供持续改进、强调缺陷预防，以及减少变差和浪费的质量管理体系。

Remarks for certification

Requirements for certification to this Automotive QMS Standard are defined in the Rules for achieving and maintaining IATF recognition.

Details can be obtained from the local Oversight Offices of the IATF cited below:

Associazione Nazionale Filiera Industrie Automobilistiche (ANFIA)
Web site: www.anfia.it
e-mail: anfia@anfia.it

International Automotive Oversight Bureau (IAOB)
Web site: www.iaob.org
e-mail: iatf16949feedback@iaob.org

IATF France
Web site: www.iatf-france.com
e-mail: iatf@iatf-france.com

Society of Motor Manufacturers and Traders Ltd. (SMMT Ltd.)
Web site: www.smmtoversight.co.uk
e-mail: iatf16949@smmt.co.uk

Verband der Automobilindustrie – Qualitäts Management Center (VDA QMC)
Web site: www.vda-qmc.de
e-mail: info@vda-qmc.de

All public information about the IATF can be found at the IATF website: www.iatfglobaloversight.org

有关认证的说明

获得并保持 IATF 认可的规则中规定了根据本汽车 QMS 标准进行认证的要求。

详细情况可从国际汽车推动小组的当地监督办公室处获得：

意大利汽车工业协会 (ANFIA)

网址: www.anfia.it

e-mail: anfia@anfia.it

美国国际汽车监督署 (IAOB)

网址: www.iaob.org

e-mail: iatf16949feedback@iaob.org

IATF France

网址: www.iatf-france.com

e-mail: iatf@iatf-france.com

英国汽车制造与贸易商协会 (SMMT Ltd.)

网址: www.smmtoversight.co.uk

e-mail: iatf16949@smmt.co.uk

德国汽车工业协会 - 质量管理中心 (VDA QMC)

网址: www.vda-qmc.de

e-mail: info@vda-qmc.de

登录 www.iatfglobaloversight.org 可找到所有关于 IATF 的公开信息。

Introduction

0.1 General

See ISO 9001:2015 requirements.

0.2 Quality management principles

See ISO 9001:2015 requirements.

0.3 Process approach

0.3.1 General

See ISO 9001:2015 requirements.

0.3.2 Plan-Do-Check-Act cycle

See ISO 9001:2015 requirements.

0.3.3 Risk-based thinking

See ISO 9001:2015 requirements.

0.4 Relationship with other management system standards

See ISO 9001:2015 requirements.

Quality management systems – Requirements

1 Scope

See ISO 9001:2015 requirements.

1.1 Scope – automotive supplemental to ISO 9001:2015

This Automotive QMS Standard defines the quality management system requirements for the design and development, production and, when relevant, assembly, installation, and services of automotive-related products, including products with embedded software.

This Automotive QMS Standard is applicable to sites of the organization where manufacturing of customer-specified production parts, service parts, and/or accessory parts occur.

This Automotive QMS Standard should be applied throughout the automotive supply chain.

引言

0.1 总则

见 ISO 9001:2015 的要求。

0.2 质量管理原则

见 ISO 9001:2015 的要求。

0.3 过程方法

0.3.1 总则

见 ISO 9001:2015 的要求。

0.3.2 计划-执行-检查-处理循环

见 ISO 9001:2015 的要求。

0.3.3 基于风险的思维

见 ISO 9001:2015 的要求。

0.4 与其他管理体系标准的关系

见 ISO 9001:2015 的要求。

质量管理体系——要求

1 范围

见 ISO 9001:2015 的要求。

1.1 范围——汽车行业对 ISO 9001:2015 的补充

本汽车 QMS 标准规定了汽车相关产品（包括装有嵌入式软件的产品）的设计和开发、生产，以及（相关时）装配、安装和服务的质量管理体系要求。

本汽车 QMS 标准适用于制造顾客指定生产件、服务件和/或配件的组织的现场。

应当在整个汽车供应链中实施本汽车 QMS 标准。

2 Normative references

See ISO 9001:2015 requirements.

2.1 Normative and informative references

Annex A (Control Plan) is a normative part of this Automotive QMS standard.

Annex B (Bibliography – automotive supplemental) is informative, which provides additional information intended to assist the understanding or use of this Automotive QMS standard.

3 Terms and definitions

See ISO 9001:2015 requirements.

3.1 Terms and definitions for the automotive industry

accessory part

customer-specified additional component(s) that are either mechanically or electronically connected to the vehicle or powertrain before (or after) delivery to the final customer (e.g., custom floor mats, truck bed liners, wheel covers, sound system enhancements, sunroofs, spoilers, super-chargers, etc.)

advanced product quality planning (APQP)

product quality planning process that supports development of a product or service that will satisfy customer requirements; APQP serves as a guide in the development process and also a standard way to share results between organizations and their customers; APQP covers design robustness, design testing and specification compliance, production process design, quality inspection standards, process capability, production capacity, product packaging, product testing and operator training plan, among other items

aftermarket part

replacement part(s) not procured or released by an OEM for service part applications, which may or may not be produced to original equipment specifications

authorization

documented permission for a person(s) specifying rights and responsibilities related to giving or denying permissions or sanctions within an organization

2 引用标准

见 ISO 9001:2015 的要求。

2.1 规范性引用标准和参考性引用标准

附录 A（控制计划）为本汽车 QMS 标准的规范性部分。

附录 B（参考书目——汽车行业补充）为参考性部分，提供了有助于理解或使用本汽车 QMS 标准的附加信息。

3 术语和定义

见 ISO 9001:2015 的要求。

3.1 汽车行业的术语和定义

配件

在交付给最终顾客之前（或之后），与车辆或动力总成以机械或电子方式相连的顾客指定的附加部件（如：定制地垫、车厢衬、轮罩、音响系统加强件、天窗、尾翼、增压器等等）。

产品质量先期策划（APQP）

对开发某一满足顾客要求的产品或服务提供支持的产品质量策划过程；APQP 对开发过程具有指导意义，并且是组织与其顾客之间共享结果的标准方式；APQP 涵盖的项目包括设计稳健性，设计试验和规范符合性，生产过程设计，质量检验标准，过程能力，生产能力，产品包装，产品试验和操作员培训计划。

售后市场零件

并非由 OEM 为服务件应用而采购或放行的替换零件，可能按照或未按照原始设备规范进行生产。

授权

对某（些）人的成文许可，规定了其在组织内部授予或拒绝权限或制裁有关的权利和责任。

challenge (master) part

part(s) of known specification, calibrated and traceable to standards, with expected results (pass or fail) that are used to validate the functionality of an error-proofing device or check fixtures (e.g., go / no-go gauging)

control plan

documented description of the systems and processes required for controlling the manufacturing of product (see Annex A)

customer requirements

all requirements specified by the customer (e.g., technical, commercial, product and manufacturing process-related requirements, general terms and conditions, customer-specific requirements, etc.)

customer-specific requirements (CSRs)

interpretations of or supplemental requirements linked to a specific clause(s) of this Automotive QMS Standard

design for assembly (DFA)

process by which products are designed with ease of assembly considerations. (e.g., if a product contains fewer parts it will take less time to assemble, thereby reducing assembly costs)

design for manufacturing (DFM)

integration of product design and process planning to design a product that is easily and economically manufactured

design for manufacturing and assembly (DFMA)

combination of two methodologies: Design for Manufacture (DFM), which is the process of optimizing the design to be easier to produce, have higher throughput, and improved quality; and Design for Assembly (DFA), which is the optimization of the design to reduce risk of error, lowering costs, and making it easier to assemble

挑战（原版）件

具有已知规范、经校准并且可追溯到标准的零件，其预期结果（通过或不通过）用于确认防错装置或检具（如通止规）的功能性。

控制计划

对控制产品制造所要求的系统及过程的成文描述（见附录 A）。

顾客要求

顾客规定的一切要求（如：技术、商业、产品及制造过程相关要求；一般条款与条件；顾客特定要求等等）。

顾客特定要求（CSR）

对本汽车 QMS 标准特定条款的解释或与该条款有关的补充要求。

装配的设计（DFA）

出于便于装配的考虑设计产品的过程。（例如，若产品含有较少零件，产品的装配时间则较短，从而减少装配成本。）

制造的设计（DFM）

产品设计和过程策划的整合，用于设计出可简单经济地制造的产品。

制造和装配的设计（DFMA）

两种方法的结合：制造的设计（DFM）- 为更易生产，更高产量及改进的质量的优化设计的过程，装配的设计（DFA）为减少出错风险、降低成本并更易装配的设计优化。

design for six sigma (DFSS)

systematic methodology, tools, and techniques with the aim of being a robust design of products or processes that meets customer expectations and can be produced at a six sigma quality level

design-responsible organization

organization with authority to establish a new, or change an existing, product specification

NOTE This responsibility includes testing and verification of design performance within the customer's specified application.

error proofing

product and manufacturing process design and development to prevent manufacture of nonconforming products

escalation process

process used to highlight or flag certain issues within an organization so that the appropriate personnel can respond to these situations and monitor the resolutions

fault tree analysis (FTA)

deductive failure analysis methodology in which an undesired state of a system is analysed; fault tree analysis maps the relationship between faults, subsystems, and redundant design elements by creating a logic diagram of the overall system

laboratory

facility for inspection, test, or calibration that may include but is not limited to the following: chemical, metallurgical, dimensional, physical, electrical, or reliability testing

laboratory scope

controlled document containing

- specific tests, evaluations, and calibrations that a laboratory is qualified to perform;
- a list of the equipment that the laboratory uses to perform the above; and
- a list of methods and standards to which the laboratory performs the above

六西格玛设计 (DFSS)

系统化的方法、工具和技术，旨在稳健设计满足顾客期望并且能够在六西格玛质量水平生产的产品或过程的。

具有设计职责的组织

有权制定一个新的或更改现有的产品规范的组织。

注：该职责包括在顾客指定的应用范围内，试验并验证设计性能。

防错

为防止制造不合格产品而进行的产品和制造过程的设计及开发。

升级过程

用于在组织内部强调或触发特定问题的过程，以便适当人员可对这些情况作出响应并监控其解决。

故障树分析法 (FTA)

分析系统非理想状态的演绎故障分析法；通过创建整个系统的逻辑框图，故障树分析法显示出各故障、子系统及冗余设计要素之间的关系。

试验室

用于检验、试验或校准的设施，可能包括但不限于，化学、冶金、尺寸、物理、电性能或可靠性试验。

试验室范围

包含下列内容的受控文件：

- 试验室有资格进行的特定试验、评价或校准；
- 用来进行上述活动的设备的清单；以及
- 用来进行上述活动的方法和标准的清单。

manufacturing

process of making or fabricating

- production materials;
- production parts or service parts;
- assemblies; or
- heat treating, welding, painting, plating, or other finishing services

manufacturing feasibility

an analysis and evaluation of a proposed project to determine if it is technically feasible to manufacture the product to meet customer requirements. This includes but is not limited to the following (as applicable): within the estimated costs, and if the necessary resources, facilities, tooling, capacity, software, and personnel with required skills, including support functions, are or are planned to be available

manufacturing services

companies that test, manufacture, distribute, and provide repair services for components and assemblies

multi-disciplinary approach

method to capture input from all interested parties who may influence how a process is administered by a team whose members include personnel from the organization and may include customer and supplier representatives; team members may be internal or external to the organization; either existing teams or ad hoc teams may be used as circumstances warrant; input to the team may include both organization and customer inputs

no trouble found (NTF)

designation applied to a part replaced during a service event that, when analysed by the vehicle or parts manufacturer, meets all the requirements of a "good part" (also referred to as "No Fault Found" or "Trouble Not Found")

outsourced process

portion of an organization's function (or processes) that is performed by an external organization

制造

制作或加工的过程

- 生产原材料；
- 生产件或服务件；
- 装配；或
- 热处理、焊接、涂漆、电镀或其他表面处理服务。

制造可行性

对拟建项目的分析和评价，以确定该项目是否在技术上是可行的，能够制造出符合顾客要求的产品。这包括但不限于以下方面（如适用）：在预计成本范围内；是否必要的资源、设施、工装、产能、软件及具有所需技能的人员，包括支持功能，是或者计划是可用的。

制造服务

试验、制造、分销部件和组件并为其提供维修服务的公司。

多方论证方法

从可能会影响一个团队如何管理过程的所有相关方获取输入信息的方法，团队成员包括来自组织的人员，也可能包括顾客代表和供应商代表；团队成员可能来自组织内部或外部；若情况许可，可采用现有团队或特设团队；对团队的输入可能同时包含组织输入和顾客输入。

未发现故障（NTF）

表示针对服务期间被替换的零件，经车辆或零件制造商分析，满足“良品件”的全部要求（亦称为“未发现错误或“故障未发现”）。

外包过程

由外部组织履行的一部分组织功能（或过程）。

periodic overhaul

maintenance methodology to prevent a major unplanned breakdown where, based on fault or interruption history, a piece of equipment, or subsystem of the equipment, is proactively taken out of service and disassembled, repaired, parts replaced, reassembled, and then returned to service

predictive maintenance

an approach and set of techniques to evaluate the condition of in-service equipment by performing periodic or continuous monitoring of equipment conditions, in order to predict when maintenance should be performed

premium freight

extra costs or charges incurred in addition to contracted delivery

NOTE This can be caused by method, quantity, unscheduled or late deliveries, etc.

preventive maintenance

planned activities at regular intervals (time-based, periodic inspection, and overhaul) to eliminate causes of equipment failure and unscheduled interruptions to production, as an output of the manufacturing process design

product

applies to any intended output resulting from the product realization process

product safety

standards relating to the design and manufacturing of products to ensure they do not represent harm or hazards to customers

production shutdown

condition where manufacturing processes are idle; time span may be a few hours to a few months

reaction plan

action or series of steps prescribed in a control plan in the event abnormal or nonconforming events are detected

周期性检修

用于防止发生重大意外故障的维护方法，此方法根据故障或中断历史，主动停止使用某一设备或设备子系统，然后对其进行拆卸、修理、更换零件、重新装配并恢复使用。

预测性维护

通过对设备状况实施周期性或持续监视来评价在役设备状况的一种方法或一套技术，以便预测应当进行维护的具体时间。

超额运费

合同交付之外发生的超出成本或费用。

注：它可能是由于方法、数量、未按计划或延迟交付等原因引起的。

预防性维护

为了消除设备失效和非计划性生产中断的原因而策划的定期活动（基于时间的周期性检验和检修），它是制造过程设计的一项输出。

产品

适用于产品实现过程产生的任何预期输出。

产品安全

与产品设计和制造有关的标准，确保产品不会对顾客造成伤害或危害。

生产停工

制造过程空闲的情况；时间跨度可从几个小时到几个月不等。

反应计划

检测到异常或不合格事件时，控制计划中规定的行动或一系列步骤。

remote location

location that supports manufacturing sites and at which non-production processes occur

service part

replacement part(s) manufactured to OEM specifications that are procured or released by the OEM for service part applications, including remanufactured parts

site

location at which value-added manufacturing processes occur

special characteristic

classification of a product characteristic or manufacturing process parameter that can affect safety or compliance with regulations, fit, function, performance, requirements, or subsequent processing of product

special status

notification of a customer-identified classification assigned to an organization where one or more customer requirements are not being satisfied due to a significant quality or delivery issue

support function

non-production activity (conducted on site or at a remote location) that supports one (or more) manufacturing sites of the same organization

total productive maintenance

a system of maintaining and improving the integrity of production and quality systems through machines, equipment, processes, and employees that add value to the organization

trade-off curves

tool to understand and communicate the relationship of various design characteristics of a product to each other; a product's performance on one characteristic is mapped on the Y-axis and another on the x-axis, then a curve is plotted to illustrate product performance relative to the two characteristics

外部场所

支持现场并且为非生产过程发生的场所。

服务件

按照 OEM 规范制造的，由 OEM 为服务件应用而采购或放行的替换件，包括再制造件。

现场

发生增值制造过程的场所。

特殊特性

可能影响安全性或产品法规符合性、可装配性、功能、性能、要求或产品的后续处理的产品特性或制造过程参数。

特殊状态

一种顾客识别分类的通知，分配给由于重大质量或交付问题，未能满足一项或多项顾客要求的组织。

支持功能

对同一组织的一个（或多个）制造现场提供支持的（在现场或外部场所进行的）非生产活动。

全面生产维护

一个通过为组织增值的机器、设备、过程和员工，维护并改善生产及质量体系完整性的系统。

权衡曲线

用于理解产品各设计特性的关系并使其相互沟通的一种工具；产品一个特性的性能映射于 Y 轴，另一特性的性能映射于 x 轴，然后可绘制出一条曲线，显示产品相对于这两个特性的性能。

trade-off process

methodology of developing and using trade-off curves for products and their performance characteristics that establish the customer, technical, and economic relationship between design alternatives

权衡过程

绘制并使用产品及其性能特性的权衡曲线的一种方法，这些特性确立了设计替代方案之间的顾客、技术及经济关系。

4 Context of the organization

4.1 Understanding the organization and its context

See ISO 9001:2015 requirements.

4.2 Understanding the needs and expectations of interested parties

See ISO 9001:2015 requirements.

4.3 Determining the scope of the quality management system

See ISO 9001:2015 requirements.

4.3.1 Determining the scope of the quality management system – supplemental

Supporting functions, whether on-site or remote (such as design centres, corporate headquarters, and distribution centres), shall be included in the scope of the Quality Management System (QMS).

The only permitted exclusion for this Automotive QMS Standard relates to the product design and development requirements within ISO 9001, Section 8.3. The exclusion shall be justified and maintained as documented information (see ISO 9001, Section 7.5).

Permitted exclusions do not include manufacturing process design.

4.3.2 Customer-specific requirements

Customer-specific requirements shall be evaluated and included in the scope of the organization's quality management system.

4.4 Quality management system and its processes

4.4.1

See ISO 9001:2015 requirements.

4.4.1.1 Conformance of products and processes

The organization shall ensure conformance of all products and processes, including service parts and those that are outsourced, to all applicable customer, statutory, and regulatory requirements (see Section 8.4.2.2).

4.4.1.2 Product safety

The organization shall have documented processes for the management of product-safety related products and manufacturing processes, which shall include but not be limited to the following, where applicable:

4 组织的环境

4.1 理解组织及其环境

见 ISO 9001:2015 的要求。

4.2 理解相关方的需求和期望

见 ISO 9001:2015 的要求。

4.3 确定质量管理体系的范围

见 ISO 9001:2015 的要求。

4.3.1 确定质量管理体系的范围——补充

支持功能，无论其在现场或外部场所（例如：设计中心、公司总部和配送中心），应包含在质量管理体系（QMS）的范围中。

本汽车 QMS 标准唯一允许的删减是 ISO 9001 第 8.3 条中的产品设计和开发要求。删减应以形成文件的信息（见 ISO 9001 第 7.5 条）的形式进行证明和保持。

允许的删减不包括制造过程设计。

4.3.2 顾客特定要求

应对顾客特定要求进行评价，并将其包含在组织的质量管理体系范围内。

4.4 质量管理体系及其过程

4.4.1

见 ISO 9001:2015 的要求。

4.4.1.1 产品和过程的符合性

组织应确保所有产品和过程，包括服务件及外包的产品和过程，符合一切适用的顾客和法律法规要求（见第 8.4.2.2 条）。

4.4.1.2 产品安全

组织应有形成文件的过程，用于与产品安全有关的产品和制造过程管理；形成文件的过程应包括但不限于（在适用情况下）：

- a) identification by the organization of statutory and regulatory product-safety requirements;
- b) customer notification of requirements in item a);
- c) special approvals for design FMEA;
- d) identification of product safety-related characteristics;
- e) identification and controls of safety-related characteristics of product and at the point of manufacture;
- f) special approval of control plans and process FMEAs;
- g) reaction plans (see Section 9.1.1.1);
- h) defined responsibilities, definition of escalation process and flow of information, including top management, and customer notification;
- i) training identified by the organization or customer for personnel involved in product-safety related products and associated manufacturing processes;
- j) changes of product or process shall be approved prior to implementation, including evaluation of potential effects on product safety from process and product changes (see ISO 9001, Section 8.3.6);
- k) transfer of requirements with regard to product safety throughout the supply chain, including customer-designated sources (see Section 8.4.3.1);
- l) product traceability by manufactured lot (at a minimum) throughout the supply chain (see Section 8.5.2.1);
- m) lessons learned for new product introduction.

NOTE: Special approval is an additional approval by the function (typically the customer) that is responsible to approve such documents with safety-related content.

4.4.2

See ISO 9001:2015 requirements.

5 Leadership

5.1 Leadership and commitment

5.1.1 General

See ISO 9001:2015 requirements.

5.1.1.1 Corporate responsibility

The organization shall define and implement corporate responsibility policies, including at a minimum an anti-bribery policy, an employee code of conduct, and an ethics escalation policy ("whistle-blowing policy").

- a) 组织对产品安全法律法规要求的识别;
- b) 向顾客通知 a) 项中的要求;
- c) 设计 FMEA 的特殊批准;
- d) 产品安全相关特性的识别;
- e) 产品及制造时安全相关特性的识别和控制;
- f) 控制计划和过程 FMEA 的特殊批准;
- g) 反应计划 (见第 9.1.1.1 条);
- h) 包括最高管理者在内的,明确的职责,升级过程和信息流的定义,以及顾客通知;
- i) 组织或顾客为与产品安全有关的产品和相关制造过程中涉及的人员确定的培训;
- j) 产品或过程的更改在实施之前应获得批准,包括对过程和产品更改带给产品安全的潜在影响进行评价 (见 ISO 9001 第 8.3.6 条);
- k) 整个供应链中关于产品安全的要求转移,包括顾客指定的货源 (见第 8.4.3.1 条);
- l) 整个供应链中按制造批次 (至少) 的产品可追溯性 (见第 8.5.2.1 条);
- m) 为新产品导入的经验教训。

注:特殊批准是指负责批准含有安全相关内容文件的职能机构 (通常为顾客) 作出的额外批准。

4.4.2

见 ISO 9001:2015 的要求。

5 领导作用

5.1 领导作用与承诺

5.1.1 总则

见 ISO 9001:2015 的要求。

5.1.1.1 公司责任

组织应明确并实施公司责任方针,至少包括反贿赂方针、员工行为准则以及道德准则升级政策 (“举报政策”)。

5.1.1.2 Process effectiveness and efficiency

Top management shall review the product realization processes and support processes to evaluate and improve their effectiveness and efficiency. The results of the process review activities shall be included as input to the management review (see Section 9.3.2.1.).

5.1.1.3 Process owners

Top management shall identify process owners who are responsible for managing the organization's processes and related outputs. Process owners shall understand their roles and be competent to perform those roles (see ISO 9001, Section 7.2).

5.1.2 Customer focus

See ISO 9001:2015 requirements.

5.2 Policy

5.2.1 Establishing the quality policy

See ISO 9001:2015 requirements.

5.2.2 Communicating the quality policy

See ISO 9001:2015 requirements.

5.3 Organizational roles, responsibilities and authorities

See ISO 9001:2015 requirements.

5.3.1 Organizational roles, responsibilities, and authorities – supplemental

Top management shall assign personnel with the responsibility and authority to ensure that customer requirements are met. These assignments shall be documented. This includes but is not limited to: the selection of special characteristics, setting quality objectives and related training, corrective and preventive actions, product design and development, capacity analysis, logistics information, customer scorecards, and customer portals.

5.3.2 Responsibility and authority for product requirements and corrective actions

Top management shall ensure that:

- a) personnel responsible for conformity to product requirements have the authority to stop shipment and stop production to correct quality problems;

NOTE Due to the process design in some industries, it might not always be possible to stop production immediately. In this case, the affected batch must be contained and shipment to the customer prevented.

5.1.1.2 过程有效性和效率

最高管理者应评审产品实现过程和支持过程，以评价并改进过程有效性和效率。过程评审活动的结果应作为管理评审的输入（见第 9.3.2.1 条）。

5.1.1.3 过程所有者

最高管理者应确定过程所有者，由其负责组织的各过程和相关输出的管理。过程所有者应了解他们的角色，并且具备胜任其角色的能力（见 ISO 9001 第 7.2 条）。

5.1.2 以顾客为关注焦点

见 ISO 9001:2015 的要求。

5.2 方针

5.2.1 建立质量方针

见 ISO 9001:2015 的要求。

5.2.2 沟通质量方针

见 ISO 9001:2015 的要求。

5.3 组织的作用、职责和权限

见 ISO 9001:2015 的要求。

5.3.1 组织的作用、职责和权限——补充

最高管理者应向人员指派职责和权限，以确保顾客要求得到满足。这些指派应形成文件。这包括但不限于：特殊特性的选择，质量目标和相关培训的设置，纠正和预防措施，产品设计和开发，产能分析，物流信息，顾客计分卡以及顾客门户。

5.3.2 产品要求和纠正措施的职责和权限

最高管理者应确保：

- a) 负责产品要求符合性的人员有权停止发运或生产以纠正质量问题；
注：由于一些行业中的过程设计，并非总是能立即停止生产。在这种情况下，必须对受影响批次进行控制，以防将其发运给顾客。

- b) personnel with authority and responsibility for corrective action are promptly informed of products or processes that do not conform to requirements to ensure that nonconforming product is not shipped to the customer and that all potential nonconforming product is identified and contained;
- c) production operations across all shifts are staffed with personnel in charge of, or delegated responsibility for, ensuring conformity to product requirements.

6 Planning

6.1 Actions to address risks and opportunities

6.1.1 and 6.1.2

See ISO 9001:2015 requirements.

6.1.2.1 Risk analysis

The organization shall include in its risk analysis, at a minimum, lessons learned from product recalls, product audits, field returns and repairs, complaints, scrap, and rework.

The organization shall retain documented information as evidence of the results of risk analysis.

6.1.2.2 Preventive action

The organization shall determine and implement action(s) to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the severity of the potential issues.

The organization shall establish a process to lessen the impact of negative effects of risk including the following:

- a) determining potential nonconformities and their causes;
- b) evaluating the need for action to prevent occurrence of nonconformities;
- c) determining and implementing action needed;
- d) documented information of action taken;
- e) reviewing the effectiveness of the preventive action taken;
- f) utilizing lessons learned to prevent recurrence in similar processes (see ISO 9001, Section 7.1.6).

6.1.2.3 Contingency plans

The organization shall:

- a) identify and evaluate internal and external risks to all manufacturing processes and infrastructure equipment essential to maintain production output and to ensure that customer requirements are met;

- b) 拥有纠正措施权限和职责的人员能够及时获知与要求不符的产品或过程，以确保避免将不合格品发运给顾客，并确保所有潜在不合格品得到识别与控制；
- c) 所有班次的生产作业都安排有负责确保产品要求符合性的负责人员或代理职责人员。

6 策划

6.1 风险和机遇的应对措施

6.1.1 和 6.1.2

见 ISO 9001:2015 的要求。

6.1.2.1 风险分析

组织应在风险分析中至少包含从产品召回、产品审核、使用现场的退货和修理、投诉、报废及返工中吸取的经验教训。

组织应保留形成文件的信息，作为风险分析结果的证据。

6.1.2.2 预防措施

组织应确定并实施措施，以消除潜在不合格的原因，防止不合格发生。预防措施应与潜在问题的严重程度相适应。

组织应建立一个用于减轻风险负面影响的过程，过程包括以下方面：

- a) 确定潜在不合格及其原因；
- b) 评价防止不合格发生的措施的需求；
- c) 确定并实施所需的措施；
- d) 所采取措施的成文信息；
- e) 评审所采取的预防措施的有效性；
- f) 利用取得的经验教训预防类似过程中的再次发生（见 ISO 9001 第 7.1.6 条）。

6.1.2.3 应急计划

组织应：

- a) 对保持生产输出并确保顾客要求得以满足而言必不可少的所有制造过程和基础设施设备，识别并评价相关的内部和外部风险；

- b) define contingency plans according to risk and impact to the customer;
- c) prepare contingency plans for continuity of supply in the event of any of the following: key equipment failures (also see Section 8.5.6.1.1); interruption from externally provided products, processes, and services; recurring natural disasters; fire; utility interruptions; labour shortages; or infrastructure disruptions;
- d) include, as a supplement to the contingency plans, a notification process to the customer and other interested parties for the extent and duration of any situation impacting customer operations;
- e) periodically test the contingency plans for effectiveness (e.g., simulations, as appropriate);
- f) conduct contingency plan reviews (at a minimum annually) using a multidisciplinary team including top management, and update as required;
- g) document the contingency plans and retain documented information describing any revision(s), including the person(s) who authorized the change(s).

The contingency plans shall include provisions to validate that the manufactured product continues to meet customer specifications after the re-start of production following an emergency in which production was stopped and if the regular shutdown processes were not followed.

6.2 Quality objectives and planning to achieve them

6.2.1 and 6.2.2

See ISO 9001:2015 requirements.

6.2.2.1 Quality objectives and planning to achieve them – supplemental

Top management shall ensure that quality objectives to meet customer requirements are defined, established, and maintained for relevant functions, processes, and levels throughout the organization.

The results of the organization's review regarding interested parties and their relevant requirements shall be considered when the organization establishes its annual (at a minimum) quality objectives and related performance targets (internal and external).

6.3 Planning of changes

See ISO 9001:2015 requirements.

- b) 根据风险和对顾客的影响制定应急计划；
- c) 准备应急计划，以在下列任一情况下保证供应的持续性：关键设备故障（另见第 8.5.6.1.1 条）；外部提供的产品、过程或服务中断；常见自然灾害；火灾；公共事业中断；劳动力短缺；或者基础设施破坏；
- d) 作为对应急计划的补充，包含一个通知顾客和其他相关方的过程，告知影响顾客作业的任何情况的程度和持续时间；
- e) 定期测试应急计划的有效性（如：模拟，视情况而定）；
- f) 利用包括最高管理者在内的跨部门小组对应急计划进行评审（至少每年一次），并在需要时进行更新；
- g) 对应急计划形成文件，并保留描述修订以及更改授权人员的形成文件的信息。

应急计划应包含相关规定，用以在发生生产停止的紧急情况后重新开始生产之后，以及在常规停机过程未得到遵循的情况下，确认制造的产品持续符合顾客规范。

6.2 质量目标及其实施的策划

6.2.1 和 6.2.2

见 ISO 9001:2015 的要求。

6.2.2.1 质量目标及其实施的策划——补充

最高管理者应确保为整个组织内的相关职能、过程和级别，明确、建立并保持符合顾客要求的质量目标。

组织在建立其年度（至少每年一次）质量目标和相关性能指标（内部和外部）时，应考虑组织对相关方及其有关要求的评审结果。

6.3 更改的策划

见 ISO 9001:2015 的要求。

7 Support

7.1 Resources

7.1.1 General

See ISO 9001:2015 requirements.

7.1.2 People

See ISO 9001:2015 requirements.

7.1.3 Infrastructure

See ISO 9001:2015 requirements.

7.1.3.1 Plant, facility, and equipment planning

The organization shall use a multidisciplinary approach including risk identification and risk mitigation methods for developing and improving plant, facility, and equipment plans. In designing plant layouts, the organization shall:

- a) optimize material flow, material handling, and value-added use of floor space including control of nonconforming product, and
- b) facilitate synchronous material flow, as applicable.

Methods shall be developed and implemented to evaluate manufacturing feasibility for new product or new operations. Manufacturing feasibility assessments shall include capacity planning. These methods shall also be applicable for evaluating proposed changes to existing operations.

The organization shall maintain process effectiveness, including periodic re-evaluation relative to risk, to incorporate any changes made during process approval, control plan maintenance (see Section 8.5.1.1), and verification of job set-ups (see Section 8.5.1.3).

Assessments of manufacturing feasibility and evaluation of capacity planning shall be inputs to management reviews (see ISO 9001, Section 9.3).

NOTE 1 These requirements should include the application of lean manufacturing principles.

NOTE 2 These requirements should apply to on-site supplier activities, as applicable.

7.1.4 Environment for the operation of processes

See ISO 9001:2015 requirements.

NOTE Where third-party certification to ISO 45001 (or equivalent) is recognized, it may be used to demonstrate the organization's conformity to the personnel safety aspects of this requirement.

7 支持

7.1 资源

7.1.1 总则

见 ISO 9001:2015 的要求。

7.1.2 人员

见 ISO 9001:2015 的要求。

7.1.3 基础设施

见 ISO 9001:2015 的要求。

7.1.3.1 工厂、设施及设备策划

组织应使用多方论证的方法，包括风险识别和风险缓解方法，来开发并改进工厂、设施和设备的计划。在设计工厂布局时，组织应：

- a) 优化材料的流动和搬运，以及对空间场地的增值利用，包括对不合格品的控制，并且
- b) 在适用时，便于材料的同步流动。

应开发并实施对新产品或新操作的制造可行性进行评价的方法。制造可行性评估应包括产能策划。这些方法还应适用于评价对现有操作的提议更改。

组织应保持过程有效性，包括定期风险复评，以纳入在过程批准、控制计划维护（见第 8.5.1.1 条）及作业准备的验证（见第 8.5.1.3 条）期间作出的任何更改。

制造可行性评估和产能策划的评价应为管理评审的输入（见 ISO 9001 第 9.3 条）。

注 1：这些要求应当包括对精益制造原则的应用。

注 2：这些要求应当应用于现场供应商活动，如适用。

7.1.4 过程操作的环境

见 ISO 9001:2015 的要求。

注：在 ISO 45001（或等效标准）第三方认证被认可的情况下，该认证可以证明组织符合本要求的人员安全方面。

7.1.4.1 Environment for the operation of processes – supplemental

The organization shall maintain its premises in a state of order, cleanliness, and repair that is consistent with the product and manufacturing process needs.

7.1.5 Monitoring and measuring resources

7.1.5.1 General

See ISO 9001:2015 requirements.

7.1.5.1.1 Measurement system analysis

Statistical studies shall be conducted to analyse the variation present in the results of each type of inspection, measurement, and test equipment system identified in the control plan. The analytical methods and acceptance criteria used shall conform to those in reference manuals on measurement systems analysis. Other analytical methods and acceptance criteria may be used if approved by the customer.

Records of customer acceptance of alternative methods shall be retained along with results from alternative measurement systems analysis (see Section 9.1.1.1).

NOTE Prioritization of MSA studies should focus on critical or special product or process characteristics.

7.1.5.2 Measurement traceability

See ISO 9001:2015 requirements.

NOTE A number or another identifier traceable to the device calibration record meets the intent of the requirements in ISO 9001:2015.

7.1.5.2.1 Calibration/verification records

The organization shall have a documented process for managing calibration/verification records. Records of the calibration/verification activity for all gauges and measuring and test equipment (including employee-owned equipment relevant for measuring, customer-owned equipment, or on-site supplier-owned equipment) needed to provide evidence of conformity to internal requirements, legislative and regulatory requirements, and customer-defined requirements shall be retained.

The organization shall ensure that calibration/verification activities and records shall include the following details:

- a) revisions following engineering changes that impact measurement systems;
- b) any out-of-specification readings as received for calibration/verification;

7.1.4.1 过程操作的环境——补充

组织应保持生产现场处于与产品和制造过程需求相协调的有序、清洁和整理的状态。

7.1.5 监视和测量资源

7.1.5.1 总则

见 ISO 9001:2015 的要求。

7.1.5.1.1 测量系统分析

应进行统计研究来分析在控制计划所识别的每种检验、测量和试验设备系统的结果中呈现的变异，。所采用的分析方法及接收准则，应与测量系统分析的参考手册相一致。如果得到顾客的批准，其它分析方法和接收准则也可以应用。

替代方法的顾客接受记录应与替代测量系统分析的结果一起保留（见第 9.1.1.1 条）。

注：测量系统分析研究的优先级应当着重于关键或特殊产品或过程特性。

7.1.5.2 测量可追溯性

见 ISO 9001:2015 的要求。

注：一个可追溯到装置校准记录的编号或其它标识符，满足 ISO 9001:2015 要求的意图。

7.1.5.2.1 校准/验证记录

组织应有一个形成文件的过程，用于管理校准/验证记录。用以提供符合内部要求、法律法规要求及顾客规定要求证明的所有量具、测量和试验设备（包括员工拥有的测量设备、顾客拥有的设备或现场供应商拥有的设备），其校准/验证活动的记录应予以保持。

组织应确保校准/验证活动和记录应包括以下细节：

- a) 根据影响测量系统的工程更改进行的修订；
- b) 校准/验证时获得的任何偏离规范的读数；

- c) an assessment of the risk of the intended use of the product caused by the out-of-specification condition;
- d) when a piece of inspection measurement and test equipment is found to be out of calibration or defective during its planned verification or calibration or during its use, documented information on the validity of previous measurement results obtained with this piece of inspection measurement and test equipment shall be retained, including the associated standard's last calibration date and the next due date on the calibration report;
- e) notification to the customer if suspect product or material has been shipped;
- f) statements of conformity to specification after calibration/verification;
- g) verification that the software version used for product and process control is as specified;
- h) records of the calibration and maintenance activities for all gauging (including employee-owned equipment, customer-owned equipment, or on-site supplier-owned equipment);
- i) production-related software verification used for product and process control (including software installed on employee-owned equipment, customer-owned equipment, or on-site supplier-owned equipment).

7.1.5.3 Laboratory requirements

7.1.5.3.1 Internal laboratory

An organization's internal laboratory facility shall have a defined scope that includes its capability to perform the required inspection, test, or calibration services. This laboratory scope shall be included in the quality management system documentation. The laboratory shall specify and implement, as a minimum, requirements for:

- a) adequacy of the laboratory technical procedures;
- b) competency of the laboratory personnel;
- c) testing of the product;
- d) capability to perform these services correctly, traceable to the relevant process standard (such as ASTM, EN, etc.); when no national or international standard(s) is available, the organization shall define and implement a methodology to verify measurement system capability;
- e) customer requirements, if any;
- f) review of the related records.

NOTE Third-party accreditation to ISO/IEC 17025 (or equivalent) may be used to demonstrate the organization's in-house laboratory conformity to this requirement.

7.1.5.3.2 External laboratory

External/commercial/independent laboratory facilities used for inspection, test, or calibration services by the organization shall have a defined laboratory scope that includes the capability to perform the required inspection, test, or calibration, and either:

- the laboratory shall be accredited to ISO/IEC 17025 or national equivalent and include the relevant inspection, test, or calibration service in the scope of the accreditation (certificate); the certificate of calibration or test report shall include the mark of a national accreditation body; or

- c) 对偏离规范情况导致的产品预期使用风险的评估;
- d) 当在计划验证或校准期间, 或在其使用期间, 检验、测量和试验设备被查出偏离校准或存在缺陷, 应保留有关此检验、测量和试验设备先前测量结果有效性的形成文件的信息, 包括校准报告上显示的相关标准的最后一次校准日期和下一次校准到期日;
- e) 如果可疑产品或材料已被发运, 对顾客的通知;
- f) 校准/验证后, 有关符合规范的声明;
- g) 对用于产品和过程控制的软件版本符合规定的验证;
- h) 所有量具 (包括员工拥有的设备、顾客拥有的设备或现场供应商拥有的设备) 校准和维护活动的记录;
- i) 对用于产品和过程控制的生产相关软件的验证 (包括安装于员工拥有的设备、顾客拥有的设备或现场供应商拥有的设备的软件)。

7.1.5.3 实验室要求

7.1.5.3.1 内部实验室

组织的内部实验室设施应有一个确定的范围, 包括其从事所要求的检验、试验或校准服务的能力。该实验室范围应包括在质量管理体系文件中。实验室至少应为以下事项明确规定并实施要求:

- a) 实验室技术程序的充分性;
- b) 实验室人员的资格;
- c) 产品试验;
- d) 正确执行这些服务的能力, 可追溯到相关过程标准 (例如: ASTM、EN 等); 如果没有可用的国家或国际标准, 组织应明确并实施一个验证测量系统能力的方法;
- e) 顾客要求, 如有;
- f) 对有关记录的评审。

注: 通过 ISO/IEC 17025 (或等效标准) 第三方认可可以证明组织内部实验室符合这个要求。

7.1.5.3.2 外部实验室

为组织提供检验、试验或校准服务的外部/商业/独立实验室应有一个确定的范围, 包括其从事所要求的检验、试验或校准的能力, 并且:

- 实验室应通过 ISO/IEC 17025 或等效的国家标准的认可, 认可 (证书) 范围应包括相关检验、试验或校准服务; 校准证书或试验报告应包含国家认可机构的标志; 或

- there shall be evidence that the external laboratory is acceptable to the customer.

NOTE Such evidence may be demonstrated by customer assessment, for example, or by customer-approved second-party assessment that the laboratory meets the intent of ISO/IEC 17025 or national equivalent. The second-party assessment may be performed by the organization assessing the laboratory using a customer-approved method of assessment.

Calibration services may be performed by the equipment manufacturer when a qualified laboratory is not available for a given piece of equipment. In such cases, the organization shall ensure that the requirements listed in Section 7.1.5.3.1 have been met.

Use of calibration services, other than by qualified (or customer accepted) laboratories, may be subject to government regulatory confirmation, if required.

7.1.6 Organizational knowledge

See ISO 9001:2015 requirements.

7.2 Competence

See ISO 9001:2015 requirements.

7.2.1 Competence – supplemental

The organization shall establish and maintain a documented process(es) for identifying training needs including awareness (see Section 7.3.1) and achieving competence of all personnel performing activities affecting conformity to product and process requirements. Personnel performing specific assigned tasks shall be qualified, as required, with particular attention to the satisfaction of customer requirements.

7.2.2 Competence – on-the-job training

The organization shall provide on-the-job training (which shall include customer requirements training) for personnel in any new or modified responsibilities affecting conformity to quality requirements, internal requirements, regulatory or legislative requirements; this shall include contract or agency personnel. The level of detail required for on-the-job training shall be commensurate with the level of education the personnel possess and the complexity of the task(s) they are required to perform for their daily work. Persons whose work can affect quality shall be informed about the consequences of nonconformity to customer requirements.

7.2.3 Internal auditor competency

The organization shall have a documented process(es) to verify that internal auditors are competent, taking into account any customer-specific requirements. For additional guidance on auditor competencies, refer to ISO 19011. The organization shall maintain a list of qualified internal auditors.

Quality management system auditors, manufacturing process auditors, and product auditors shall all be able to demonstrate the following minimum competencies:

- a) understanding of the automotive process approach for auditing, including risk-based thinking;
- b) understanding of applicable customer-specific requirements;

一 应有证据证明该外部实验室可以被顾客接受。

注：这些证据可以通过顾客评估来证实，或由顾客批准的第三方机构评估，来证明该实验室满足了 ISO/IEC 17025 或等效国家标准的意图。第三方机构评估可由评估实验室的组织，采用顾客批准的评估方法进行。

当某一设备没有具备资格的实验室时，校准服务可以由设备制造商进行。在这种情况下，组织应确保第 7.1.5.3.1 条中的要求得到满足。

校准服务的采用，除了由具备资格的（或顾客接受的）实验室提供的以外，需要时，可能需要获得政府监管机构的确认。

7.1.6 组织知识

见 ISO 9001:2015 的要求。

7.2 能力

见 ISO 9001:2015 的要求。

7.2.1 能力——补充

组织应建立并保持形成文件的过程，识别包括意识（见第 7.3.1 条）在内的培训需求，并使所有从事影响产品要求和过程要求符合性的活动的人员具备能力。从事特定指派任务的人员应按要求进行资格认可，尤其关注对顾客要求的满足。

7.2.2 能力——在职培训

对于承担影响质量要求、内部要求、法规或法律要求符合性的新的或调整职责的人员，组织应对其进行在职培训（其中还应包括顾客要求培训），包括合同工或代理工。在职培训的详细程度应与人员的教育程度及其要在日常工作中执行的任务的复杂程度相称。从事影响质量的工作的人员应被告知不符合顾客要求的后果。

7.2.3 内部审核员能力

组织应有形成文件的过程，用于验证内部审核员的能力，要考虑到顾客特定要求。关于审核员能力的更多参考，参见 ISO 19011。组织应保持一份合格内部审核员名单。

质量管理体系审核员、制造过程审核员和产品审核员应全部能够证实最少具备以下能力：

- a) 了解汽车审核过程方法，包括基于风险的思维；
- b) 了解适用的顾客特定要求；

- c) understanding of applicable ISO 9001 and IATF 16949 requirements related to the scope of the audit;
- d) understanding of applicable core tool requirements related to the scope of the audit;
- e) understanding how to plan, conduct, report, and close out audit findings.

Additionally, manufacturing process auditors shall demonstrate technical understanding of the relevant manufacturing process(es) to be audited, including process risk analysis (such as PFMEA) and control plan. Product auditors shall demonstrate competence in understanding product requirements and use of relevant measuring and test equipment to verify product conformity.

Where training is provided to achieve competency, documented information shall be retained to demonstrate the trainer's competency with the above requirements.

Maintenance of and improvement in internal auditor competence shall be demonstrated through:

- f) executing a minimum number of audits per year, as defined by the organization; and
- g) maintaining knowledge of relevant requirements based on internal changes (e.g., process technology, product technology) and external changes (e.g., ISO 9001, IATF 16949, core tools, and customer specific requirements).

7.2.4 Second-party auditor competency

The organization shall demonstrate the competence of the auditors undertaking the second-party audits. Second-party auditors shall meet customer specific requirements for auditor qualification and demonstrate the minimum following core competencies, including understanding of:

- a) the automotive process approach to auditing, including risk based thinking;
- b) applicable customer and organization specific requirements;
- c) applicable ISO 9001 and IATF 16949 requirements related to the scope of the audit;
- d) applicable manufacturing process(es) to be audited, including PFMEA and control plan;
- e) applicable core tool requirements related to the scope of the audit;
- f) how to plan, conduct, prepare audit reports, and close out audit findings.

- c) 了解 ISO 9001 和 IATF 16949 中适用的与审核范围有关的要求;
- d) 了解与审核范围有关的适用的核心工具要求;
- e) 了解如何计划审核、实施审核、报告审核以及关闭审核发现。

另外, 制造过程审核员还应证实对于待审核的相关制造过程, 其具有技术知识, 包括过程风险分析 (例如 PFMEA) 和控制计划。产品审核员还应证实其了解产品要求, 并能够使用相关测量和试验设备验证产品符合性。

在通过培训来取得人员能力的情况下, 应保留形成文件的信息, 证实培训师的能力符合上述要求。

内部审核员能力的维持与改进应通过以下方法进行证实:

- f) 每年执行组织规定的最小数量的审核, 并且
- g) 保持基于内部更改 (如: 过程技术、产品技术) 和外部更改 (如: ISO 9001、IATF 16949、核心工具及顾客特定要求) 对相关要求的认知。

7.2.4 第二方审核员能力

组织应证实从事第二方审核的审核员的能力。第二方审核员应符合顾客对审核员资质的特定要求, 并证实最少具备以下核心能力, 包括了解:

- a) 汽车审核过程方法, 包括基于风险的思维;
- b) 适用的顾客特定和组织特定要求;
- c) ISO 9001 和 IATF 16949 中适用的与审核范围有关的要求;
- d) 适用的待审核制造过程, 包括 PFMEA 和控制计划;
- e) 与审核范围有关的适用的核心工具要求;
- f) 如何计划审核、实施审核、编制审核报告并关闭审核发现。

7.3 Awareness

See ISO 9001:2015 requirements.

7.3.1 Awareness – supplemental

The organization shall maintain documented information that demonstrates that all employees are aware of their impact on product quality and the importance of their activities in achieving, maintaining, and improving quality, including customer requirements and the risks involved for the customer with non-conforming product.

7.3.2 Employee motivation and empowerment

The organization shall maintain a documented process(es) to motivate employees to achieve quality objectives, to make continual improvements, and to create an environment that promotes innovation. The process shall include the promotion of quality and technological awareness throughout the whole organization.

7.4 Communication

See ISO 9001:2015 requirements.

7.5 Documented information

7.5.1 General

See ISO 9001:2015 requirements.

7.5.1.1 Quality management system documentation

The organization's quality management system shall be documented and include a quality manual, which can be a series of documents (electronic or hard copy).

The format and structure of the quality manual is at the discretion of the organization and will depend on the organization's size, culture, and complexity. If a series of documents is used, then a list shall be retained of the documents that comprise the quality manual for the organization.

The quality manual shall include, at a minimum, the following:

- a) the scope of the quality management system, including details of and justification for any exclusions;
- b) documented processes established for the quality management system, or reference to them;
- c) the organization's processes and their sequence and interactions (inputs and outputs), including type and extent of control of any outsourced processes;
- d) a document (i.e., matrix) indicating where within the organization's quality management system their customer-specific requirements are addressed.

7.3 意识

见 ISO 9001:2015 的要求。

7.3.1 意识——补充

组织应保持形成文件的信息，证实所有员工都认识到其对产品质量的影响，以及他们所从事的活动在实现、保持并改进质量中的重要性，还包括顾客要求及不合格品带给顾客的风险。

7.3.2 员工激励和授权

组织应保持形成文件的过程，激励员工实现质量目标，进行持续改进，并建立一个提倡创新的环境。该过程应包括促进整个组织对质量和技术的认知程度。

7.4 沟通

见 ISO 9001:2015 的要求。

7.5 形成文件的信息

7.5.1 总则

见 ISO 9001:2015 的要求。

7.5.1.1 质量管理体系文件

组织的质量管理体系应形成文件，并包括一份质量手册，可由一系列（电子或硬拷贝形式的）文件构成。

质量手册的格式和结构由组织自行决定，将取决于组织的规模、文化和复杂性。如果采用一系列文件，则应保留一份构成组织质量手册的文件的清单。

质量手册应至少包括以下内容：

- a) 质量管理体系的范围，包括任何删减的细节和正当的理由；
- b) 为质量管理体系建立的形成文件的过程或对其引用；
- c) 组织的过程及其顺序和相互作用（输入和输出），包括任何外包过程控制的类型和程度；
- d) 一个显示组织质量管理体系内哪些地方满足了顾客特定要求的文件（即：矩阵）。

NOTE A matrix of how the requirements of this Automotive QMS standard are addressed by the organization's processes may be used to assist with linkages of the organization's processes and this Automotive QMS.

7.5.2 Creating and updating

See ISO 9001:2015 requirements.

7.5.3 Control of documented information

7.5.3.1 and 7.5.3.2

See ISO 9001:2015 requirements.

7.5.3.2.1 Record retention

The organization shall define, document, and implement a record retention policy. The control of records shall satisfy statutory, regulatory, organizational, and customer requirements.

Production part approvals, tooling records (including maintenance and ownership), product and process design records, purchase orders (if applicable), or contracts and amendments shall be retained for the length of time that the product is active for production and service requirements, plus one calendar year, unless otherwise specified by the customer or regulatory agency.

NOTE Production part approval documented information may include approved product, applicable test equipment records, or approved test data.

See ISO 9001:2015

7.5.3.2.2 Engineering specifications

The organization shall have a documented process describing the review, distribution, and implementation of all customer engineering standards/specifications and related revisions based on customer schedules, as required.

When an engineering standard/specification change results in a product design change, refer to the requirements in ISO 9001, Section 8.3.6. When an engineering standard/specification change results in a product realization process change, refer to the requirements in Section 8.5.6.1. The organization shall retain a record of the date on which each change is implemented in production. Implementation shall include updated documents.

Review should be completed within 10 working days of receipt of notification of engineering standards/specifications changes.

NOTE A change in these standards/specifications may require an updated record of customer production part approval when these specifications are referenced on the design record or if they affect documents of the production part approval process, such as control plan, risk analysis (such as FMEAs), etc.

注：可采用一个显示组织过程如何满足本汽车 QMS 标准要求的矩阵来辅助在组织过程与本汽车 QMS 标准之间建立联系。

7.5.2 编制和更新

见 ISO 9001:2015 的要求。

7.5.3 形成文件的信息的控制

7.5.3.1 和 7.5.3.2

见 ISO 9001:2015 的要求。

7.5.3.2.1 记录保存

组织应有一个确定的、形成文件的并且被执行的记录保存政策。对记录的控制应满足法律法规、组织及顾客要求。

应保存生产件批准文件、工装记录（包括维护和所有权）、产品和过程设计记录、采购订单（如适用）或者合同和修正，保存时间为产品在现行生产和服务中要求的有效期，再加一个日历年，除非顾客或监管机构另有特殊要求。

注：生产件批准形成文件的信息可包括已批准产品、适用的试验设备记录或已批准试验数据。

7.5.3.2.2 工程规范

组织应有形成文件的过程，描述基于顾客要求的进度进行的所有顾客工程标准/规范及相关修订的评审、分发和实施。

当工程标准/规范更改导致产品设计更改时，请参见 ISO 9001 第 8.3.6 条的要求。当工程标准/规范更改导致产品实现过程更改时，请参见 ISO 9001 第 8.5.6.1 条的要求。组织应保留每项更改在生产中实施日期的记录。实施应包括更新过的文件。

应当在收到工程标准/规范更改通知后 10 个工作日内完成评审。

注：当设计记录引用了这些规范，或这些规范影响了生产件批准过程的文件，例如：控制计划、风险分析（如 FMEA）等时，这些标准/规范的更改需要对顾客的生产件批准记录进行更新。

8 Operation

8.1 Operational planning and control

See ISO 9001:2015 requirements.

8.1.1 Operational planning and control — supplemental

When planning for product realization, the following topics shall be included:

- a) customer product requirements and technical specifications;
- b) logistics requirements;
- c) manufacturing feasibility;
- d) project planning (refer to ISO 9001, Section 8.3.2);
- e) acceptance criteria.

The resources identified in ISO 9001, Section 8.1 c), refer to the required verification, validation, monitoring, measurement, inspection, and test activities specific to the product and the criteria for product acceptance.

8.1.2 Confidentiality

The organization shall ensure the confidentiality of customer-contracted products and projects under development, including related product information.

8.2 Requirements for products and services

8.2.1 Customer communication

See ISO 9001:2015 requirements.

8.2.1.1 Customer communication — supplemental

Written or verbal communication shall be in the language agreed with the customer. The organization shall have the ability to communicate necessary information, including data in a customer-specified computer language and format (e.g., computer-aided design data, electronic data interchange).

8.2.2 Determining the requirements for products and services

See ISO 9001:2015 requirements.

8 运行

8.1 运行策划和控制

见 ISO 9001:2015 的要求。

8.1.1 运行策划和控制——补充

在对产品实现进行策划时，应包含以下主题：

- a) 顾客产品要求和技术规范；
- b) 物流要求；
- c) 制造可行性；
- d) 项目策划（参见 ISO 9001 第 8.3.2 条）；
- e) 接收准则。

ISO 9001 第 8.1 条 c) 项中的资源是指所要求的产品特定的验证、确认、监视、测量、检验和试验活动以及产品接收准则。

8.1.2 保密

组织应确保正在开发中的顾客签约产品和项目及有关产品信息的保密。

8.2 产品和服务要求

8.2.1 顾客沟通

见 ISO 9001:2015 的要求。

8.2.1.1 顾客沟通——补充

应按顾客同意的语言进行书面或口头沟通。组织应有能力按顾客规定的语言和形式来沟通必要的信息，包括按顾客规定的计算机语言和格式的数据（例如：计算机辅助设计数据、电子数据交换等）。

8.2.2 产品和服务要求的确定

见 ISO 9001:2015 的要求。

8.2.2.1 *Determining the requirements for products and services - supplemental*

These requirements shall include recycling, environmental impact, and characteristics identified as a result of the organization's knowledge of the product and manufacturing processes.

Compliance to ISO 9001, Section 8.2.2 item a) 1), shall include but not be limited to the following: all applicable government, safety, and environmental regulations related to acquisition, storage, handling, recycling, elimination, or disposal of material.

8.2.3 Review of the requirements for products and services

8.2.3.1

See ISO 9001:2015 requirements.

8.2.3.1.1 *Review of the requirements for products and services — supplemental*

The organization shall retain documented evidence of a customer-authorized waiver for the requirements stated in ISO 9001, Section 8.2.3.1, for a formal review.

8.2.3.1.2 *Customer-designated special characteristics*

The organization shall conform to customer requirements for designation, approval documentation, and control of special characteristics.

8.2.3.1.3 *Organization manufacturing feasibility*

The organization shall utilize a multidisciplinary approach to conduct an analysis to determine if it is feasible that the organization's manufacturing processes are capable of consistently producing product that meets all of the engineering and capacity requirements specified by the customer. The organization shall conduct this feasibility analysis for any manufacturing or product technology new to the organization and for any changed manufacturing process or product design.

Additionally, the organization should validate through production runs, benchmarking studies, or other appropriate methods, their ability to make product to specifications at the required rate.

8.2.3.2

See ISO 9001:2015 requirements.

8.2.4 Changes to requirements for products and services

See ISO 9001:2015 requirements.

8.2.2.1 产品和服务要求的确定——补充

这些要求应包括回收再利用、对环境的影响，以及根据组织对产品和制造过程的认知所识别的特性。

遵守 ISO 9001 第 8.2.2 条 a) 1) 项的要求应包括但不限于：

所有适用的与材料的获得、存储、搬运、回收、销毁或废弃有关的政府、安全 and 环境法规。

8.2.3 产品和服务要求的评审

8.2.3.1

见 ISO 9001:2015 的要求。

8.2.3.1.1 产品和服务要求的评审——补充

组织应保留形成文件的证据，证明对 ISO 9001 第 8.2.3.1 条中正式评审要求的弃权有顾客授权。

8.2.3.1.2 顾客指定的特殊特性

组织应符合顾客对特殊特性的指定、批准文件和控制的要求。

8.2.3.1.3 组织制造可行性

组织应采用多方论证方法来进行分析，以确定组织的制造过程是否是可行的，能够始终生产出符合顾客规定的全部工程和产能要求的产品。组织应为任何对其而言新的制造或产品技术，以及任何更改过的制造过程或产品设计进行本可行性分析。

此外，组织应当通过生产运行、标杆管理研究或其它适当的方法，确认其能够以所要求的速率生产出符合规范的产品。

8.2.3.2

见 ISO 9001:2015 的要求。

8.2.4 产品和服务要求的更改

见 ISO 9001:2015 的要求。

8.3 Design and development of products and services

8.3.1 General

See ISO 9001:2015 requirements.

8.3.1.1 Design and development of products and services – supplemental

The requirements of ISO 9001, Section 8.3.1, shall apply to product and manufacturing process design and development and shall focus on error prevention rather than detection.

The organization shall document the design and development process.

8.3.2 Design and development planning

See ISO 9001:2015 requirements.

8.3.2.1 Design and development planning - supplemental

The organization shall ensure that design and development planning includes all affected stakeholders within the organization and, as appropriate, its supply chain. Examples of areas for using such a multidisciplinary approach include but are not limited to the following:

- a) project management (for example, APQP or VDA-RGA);
- b) product and manufacturing process design activities (for example, DFM and DFA), such as consideration of the use of alternative designs and manufacturing processes;
- c) development and review of product design risk analysis (FMEAs), including actions to reduce potential risks;
- d) development and review of manufacturing process risk analysis (for example, FMEAs, process flows, control plans, and standard work instructions).

NOTE A multidisciplinary approach typically includes the organization's design, manufacturing, engineering, quality, production, purchasing, supplier, maintenance, and other appropriate functions.

8.3.2.2 Product design skills

The organization shall ensure that personnel with product design responsibility are competent to achieve design requirements and are skilled in applicable product design tools and techniques. Applicable tools and techniques shall be identified by the organization.

NOTE An example of product design skills is the application of digitized mathematically based data.

8.3.2.3 Development of products with embedded software

The organization shall use a process for quality assurance for their products with internally developed embedded software. A software development assessment methodology shall be utilized to assess the organization's software development process. Using prioritization based on risk and potential impact to the customer, the organization shall retain documented information of a software development capability self-assessment.

8.3 产品和服务的设计和开发

8.3.1 总则

见 ISO 9001:2015 的要求。

8.3.1.1 产品和服务的设计和开发——补充

ISO 9001 第 8.3.1 条的要求应适用于产品和制造过程的设计和开发，并且应着重于错误预防，而不是探测。

组织应对设计和开发过程形成文件。

8.3.2 设计和开发策划

见 ISO 9001:2015 的要求。

8.3.2.1 设计和开发策划——补充

组织应确保设计和开发策划涵盖组织内部所有受影响的利益相关者及其（适当的）供应链。使用多方论证方法的方面包括但不限于：

- a) 项目管理（例如：APQP 或 VDA-RGA）；
- b) 产品和制造过程设计活动（如：DFM 和 DFA），例如：考虑使用替代的设计和制造过程；
- c) 产品设计风险分析（FMEA）的开发和评审，包括降低潜在风险的措施；
- d) 制造过程风险分析（如：FMEA、过程流程、控制计划和标准的工作指导书）的开发和评审。

注：多方论证方法通常包括组织的设计、制造、工程、质量、生产、采购、供应、维护和其它适当职能。

8.3.2.2 产品设计技能

组织应确保负有产品设计职责的人员有能力达成设计要求，并具备适用的产品设计工具和技术技能。适合的工具和技术应得到组织的识别。

注：基于数学的数字化数据的应用便是一种产品设计技能。

8.3.2.3 带有嵌入式软件的产品开发

组织应有一个质量保证过程，用于其带有内部开发的嵌入式软件的产品。应采用软件开发评估方法来评估组织的软件开发过程。组织应按照风险和对顾客潜在影响的优先级，为软件开发能力自评估保留形成文件的信息。

The organization shall include software development within the scope of their internal audit programme (see Section 9.2.2.1).

8.3.3 Design and development inputs

See ISO 9001:2015 requirements.

8.3.3.1 Product design input

The organization shall identify, document, and review product design input requirements as a result of contract review. Product design input requirements include but are not limited to the following:

- a) product specifications including but not limited to special characteristics (see Section 8.3.3.3);
- b) boundary and interface requirements;
- c) identification, traceability, and packaging;
- d) consideration of design alternatives;
- e) assessment of risks with the input requirements and the organization's ability to mitigate/manage the risks, including from the feasibility analysis;
- f) targets for conformity to product requirements including preservation, reliability, durability, serviceability, health, safety, environmental, development timing, and cost;
- g) applicable statutory and regulatory requirements of the customer-identified country of destination, if provided;
- h) embedded software requirements.

The organization shall have a process to deploy information gained from previous design projects, competitive product analysis (benchmarking), supplier feedback, internal input, field data, and other relevant sources for current and future projects of a similar nature.

NOTE One approach for considering design alternatives is the use of trade-off curves.

8.3.3.2 Manufacturing process design input

The organization shall identify, document, and review manufacturing process design input requirements including but not limited to the following:

- a) product design output data including special characteristics;
- b) targets for productivity, process capability, timing, and cost;
- c) manufacturing technology alternatives;
- d) customer requirements, if any;
- e) experience from previous developments;
- f) new materials;
- g) product handling and ergonomic requirements; and
- h) design for manufacturing and design for assembly.

The manufacturing process design shall include the use of error-proofing methods to a degree appropriate to the magnitude of the problem(s) and commensurate with the risks encountered.

组织应将软件开发纳入其内部审核方案的范围（见第 9.2.2.1 条）。

8.3.3 设计和开发输入

见 ISO 9001:2015 的要求。

8.3.3.1 产品设计输入

组织应对作为合同评审结果的产品设计输入要求进行识别、形成文件并进行评审。产品设计输入要求包括但不限于：

- a) 产品规范，包括但不限于特殊特性（见第 8.3.3.3 条）；
- b) 边界和对接要求；
- c) 标识、可追溯性和包装；
- d) 对设计的替代选择的考虑；
- e) 对输入要求风险的评估，以及对组织缓解/管理风险（包括来自可行性分析的风险）的能力的评估；
- f) 产品要求符合性的目标，包括防护、可靠性、耐久性、可服务性、健康、安全、环境、开发时程安排和成本等方面；
- g) 顾客确定的目的国（如有提供）的适用法律法规要求；
- h) 嵌入式软件要求。

组织应有一个过程，将从以前的设计项目、竞争产品分析（标杆）、供应商反馈、内部输入、使用现场数据和其它相关资源中获取的信息，推广应用于当前和未来相似性质的项目。

注：使用权衡曲线是考虑设计的替代选择的一种方法。

8.3.3.2 制造过程设计输入

组织应对制造过程设计输入要求进行识别、形成文件并进行评审，包括但不限于：

- a) 产品设计输出的数据，包括特殊特性；
- b) 生产力、过程能力、时程安排及成本的目标；
- c) 制造技术替代选择；
- d) 顾客要求，如有；
- e) 以往的开发经验；
- f) 新材料；
- g) 产品搬运和人体工学要求；以及
- h) 制造设计和装配设计。

制造过程设计应包括，针对问题适当的重要性程度，和所遭遇到风险相称的程度来使用防错方法。

8.3.3.3 Special characteristics

The organization shall use a multidisciplinary approach to establish, document, and implement its process(es) to identify special characteristics, including those determined by the customer and the risk analysis performed by the organization, and shall include the following:

- a) documentation of all special characteristics in the drawings (as required), risk analysis (such as FMEA), control plans, and standard work/operator instructions; special characteristics are identified with specific markings and are cascaded through each of these documents;
- b) development of control and monitoring strategies for special characteristics of products and production processes;
- c) customer-specified approvals, when required;
- d) compliance with customer-specified definitions and symbols or the organization's equivalent symbols or notations, as defined in a symbol conversion table. The symbol conversion table shall be submitted to the customer, if required.

8.3.4 Design and development controls

See ISO 9001:2015 requirements.

8.3.4.1 Monitoring

Measurements at specified stages during the design and development of products and processes shall be defined, analysed, and reported with summary results as an input to management review (see Section 9.3.2.1).

When required by the customer, measurements of the product and process development activity shall be reported to the customer at stages specified, or agreed to, by the customer.

NOTE When appropriate, these measurements may include quality risks, costs, lead times, critical paths, and other measurements.

8.3.4.2 Design and development validation

Design and development validation shall be performed in accordance with customer requirements, including any applicable industry and governmental agency-issued regulatory standards. The timing of design and development validation shall be planned in alignment with customer-specified timing, as applicable.

Where contractually agreed with the customer, this shall include evaluation of the interaction of the organization's product, including embedded software, within the system of the final customer's product.

8.3.4.3 Prototype programme

When required by the customer, the organization shall have a prototype programme and control plan. The organization shall use, whenever possible, the same suppliers, tooling, and manufacturing processes as will be used in production.

All performance-testing activities shall be monitored for timely completion and conformity to requirements.

8.3.3.3 特殊特性

组织应采用多方论证方法来建立、形成文件并实施用于识别特殊特性的过程，包括顾客确定的以及组织风险分析所确定的特殊特性，应包括：

- a) 将所有特殊特性记录进图纸（按要求）、风险分析（例如 FMEA）、控制计划和标准的工作/操作说明书；特殊特性用特定的标记进行标识，并且贯穿这些文件中的每一个；
- b) 为产品和生产过程的特殊特性开发控制和监视策略；
- c) 顾客规定的批准，如有要求；
- d) 遵守顾客规定的定义和符号或组织的等效符号或标记，如符号转换表所示。如有要求，应向顾客提交符号转换表。

8.3.4 设计和开发控制

见 ISO 9001:2015 的要求。

8.3.4.1 监视

产品和过程的设计和开发期间特定阶段的测量应被确定、分析，以汇总结果的形式来报告，作为对管理评审的输入（见第 9.3.2.1 条）。

在顾客有所要求时，应在顾客规定或同意的阶段向顾客报告对产品和过程开发活动的测量。

注：在适当的情况下，这些测量可包括质量风险、成本、前置期、关键路径和其它测量。

8.3.4.2 设计和开发确认

应根据顾客要求，包括适用的行业和政府机构发布的监管标准，对设计和开发进行确认。设计和开发确认的时程安排应与顾客规定的适用时程相符。

在与顾客有合同约定的情况下，设计和开发确认应包括评价组织的产品，包括嵌入式软件在最终顾客产品系统内的相互作用。

8.3.4.3 原型样件方案

当顾客要求时，组织应制定原型样件方案和控制计划。组织应尽可能地使用与正式生产相同的供应商、工装和制造过程。

应监视所有的性能试验活动的及时完成和要求符合性。

When services are outsourced, the organization shall include the type and extent of control in the scope of its quality management system to ensure that outsourced services conform to requirements (see ISO 9001, Section 8.4).

8.3.4.4 Product approval process

The organization shall establish, implement, and maintain a product and manufacturing approval process conforming to requirements defined by the customer(s).

The organization shall approve externally provided products and services per ISO 9001, Section 8.4.3, prior to submission of their part approval to the customer.

The organization shall obtain documented product approval prior to shipment, if required by the customer. Records of such approval shall be retained.

NOTE Product approval should be subsequent to the verification of the manufacturing process.

8.3.5 Design and development outputs

See ISO 9001:2015 requirements.

8.3.5.1 Design and development outputs – supplemental

The product design output shall be expressed in terms that can be verified and validated against product design input requirements. The product design output shall include but is not limited to the following, as applicable:

- a) design risk analysis (FMEA);
- b) reliability study results;
- c) product special characteristics;
- d) results of product design error-proofing, such as DFSS, DFMA, and FTA;
- e) product definition including 3D models, technical data packages, product manufacturing information, and geometric dimensioning & tolerancing (GD&T);
- f) 2D drawings, product manufacturing information, and geometric dimensioning & tolerancing (GD&T);
- g) product design review results;
- h) service diagnostic guidelines and repair and serviceability instructions;
- i) service part requirements;
- j) packaging and labeling requirements for shipping.

NOTE Interim design outputs should include any engineering problems being resolved through a trade-off process.

8.3.5.2 Manufacturing process design output

The organization shall document the manufacturing process design output in a manner that enables verification against the manufacturing process design inputs. The organization shall verify the outputs against manufacturing process design input requirements. The manufacturing process design output shall include but is not limited to the following:

当服务被外包时，组织应将控制的类型和程度纳入其质量管理体系的范围，以确保外包服务符合要求（见 ISO 9001 第 8.4 条）。

8.3.4.4 产品批准过程

组织应建立、实施并保持一个符合顾客规定要求的产品和制造批准过程。

在向顾客提交其零件批准之前，组织应根据 ISO 9001 第 8.4.3 条，对外部提供的产品和服务进行审批。

如顾客有所要求，组织应在发运之前获得形成文件的产品批准。此类批准的记录应予以保存。

注：产品的批准应当是制造过程验证的后续步骤。

8.3.5 设计和开发输出

见 ISO 9001:2015 的要求。

8.3.5.1 设计和开发输出——补充

产品设计输出的陈述方式应适合于对照产品设计输入要求进行验证和确认。产品设计输出应包括但不限于（如适用）：

- a) 设计风险分析（FMEA）；
- b) 可靠性研究结果；
- c) 产品特殊特性；
- d) 产品设计防错结果，例如：DFSS、DFMA 和 FTA；
- e) 产品定义，包括三维模型、技术数据包、产品制造信息，以及几何尺寸与公差（GD&T）；
- f) 二维图纸、产品制造信息以及几何尺寸与公差（GD&T）；
- g) 产品设计评审结果；
- h) 服务诊断指南及修理和可服务性说明；
- i) 服务件要求；
- j) 运输的包装和标签要求。

注：临时设计输出应当包含通过权衡过程正在解决的工程问题。

8.3.5.2 制造过程设计输出

组织应对制造过程设计输出形成文件，采用的方式应能够对照制造过程设计输入进行验证。组织应对照制造过程设计输入要求对输出进行验证。制造过程设计输出应包括但不限于：

- a) specifications and drawings;
- b) special characteristics for product and manufacturing process;
- c) identification of process input variables that impact characteristics;
- d) tooling and equipment for production and control, including capability studies of equipment and process(es);
- e) manufacturing process flow charts/layout, including linkage of product, process, and tooling;
- f) capacity analysis;
- g) manufacturing process FMEA;
- h) maintenance plans and instructions;
- i) control plan (see Annex A);
- j) standard work and work instructions;
- k) process approval acceptance criteria;
- l) data for quality, reliability, maintainability, and measurability;
- m) results of error-proofing identification and verification, as appropriate;
- n) methods of rapid detection, feedback, and correction of product/manufacturing process nonconformities.

8.3.6 Design and development changes

See ISO 9001:2015 requirements.

8.3.6.1 Design and development changes - supplemental

The organization shall evaluate all design changes after initial product approval, including those proposed by the organization or its suppliers, for potential impact on fit, form, function, performance, and/or durability. These changes shall be validated against customer requirements and approved internally, prior to production implementation.

If required by the customer, the organization shall obtain documented approval, or a documented waiver, from the customer prior to production implementation.

For products with embedded software, the organization shall document the revision level of software and hardware as part of the change record.

NOTE: Internal design control

6.5 process

8.3.6.1 Design and development changes

- a) 规范和图纸;
- b) 产品和制造过程的特殊特性;
- c) 对影响特性的过程输入变量的识别;
- d) 用于生产和控制的工装和设备, 包括设备和过程的能力研究;
- e) 制造流程图/制造过程平面布置图, 包括产品、过程和工装的联系;
- f) 产能分析;
- g) 制造过程 FMEA;
- h) 维护计划和说明;
- i) 控制计划 (见附录 A) ;
- j) 标准作业和工作指导书;
- k) 过程批准的接收准则;
- l) 质量、可靠性、可维护性和可测量性的数据;
- m) 适用时, 防错识别和验证的结果;
- n) 产品/制造过程不符合的快速探测、反馈和纠正的方法。

8.3.6 设计和开发更改

见 ISO 9001:2015 的要求。

8.3.6.1 设计和开发更改——补充

组织应评价初始产品批准之后的所有设计更改, 包括组织或其供应商提议的更改, 评价这些更改对可装配性、形式、功能、性能和/或耐久性的影响。这些更改应对照顾客要求进行确认, 并在生产实施之前得到内部批准。

如顾客有所要求, 组织应在生产实施之前, 从顾客处获得形成文件的批准或弃权。

对于带有嵌入式软件的产品, 组织应对软硬件的版本级别形成文件, 作为更改记录的一部分。

8.4 Control of externally provided processes, products and services

8.4.1 General

See ISO 9001:2015 requirements.

8.4.1.1 General - supplemental

The organization shall include all products and services that affect customer requirements such as sub-assembly, sequencing, sorting, rework, and calibration services in the scope of their definition of externally provided products, processes, and services.

8.4.1.2 Supplier selection process

The organization shall have a documented supplier selection process. The selection process shall include:

- a) an assessment of the selected supplier's risk to product conformity and uninterrupted supply of the organization's product to their customers;
- b) relevant quality and delivery performance;
- c) an evaluation of the supplier's quality management system;
- d) multidisciplinary decision making; and
- e) an assessment of software development capabilities, if applicable.

Other supplier selection criteria that should be considered include the following:

- volume of automotive business (absolute and as a percentage of total business);
- financial stability;
- purchased product, material, or service complexity;
- required technology (product or process);
- adequacy of available resources (e.g., people, infrastructure);
- design and development capabilities (including project management);
- manufacturing capability;
- change management process;
- business continuity planning (e.g., disaster preparedness, contingency planning);
- logistics process;
- customer service.

8.4.1.3 Customer-directed sources (also known as "Directed-Buy")

When specified by the customer, the organization shall purchase products, materials, or services from customer-directed sources.

All requirements of Section 8.4 (except the requirements in IATF 16949, Section 8.4.1.2) are applicable to the organization's control of customer-directed sources unless specific agreements are otherwise defined by the contract between the organization and the customer.

8.4 外部提供的过程、产品和服务的控制

8.4.1 总则

见 ISO 9001:2015 的要求。

8.4.1.1 总则——补充

组织应将影响顾客要求的所有产品和服务，例如子总成、排序、挑选、返工和校准服务，纳入其对外部提供的产品、过程和服务的定义范围。

8.4.1.2 供应商选择过程

组织应有一个形成文件的供应商选择过程。选择过程应包括：

- a) 对所选供应商产品符合性以及组织向其顾客不间断产品供应的风险评估；
- b) 相关质量和交付绩效；
- c) 对供应商质量管理体系的评价；
- d) 多方论证决策；以及
- e) 对软件开发能力的评估，如适用。

应当考虑的其它供应商选择准则包括：

- 汽车业务量（绝对值，以及占总业务量的百分比）；
- 财务稳定性；
- 采购的产品、材料或服务的复杂性；
- 所需技术（产品或过程）；
- 可用资源（如：人员、基础设施）的充分性；
- 设计和开发能力（包括项目管理）；
- 制造能力；
- 更改管理过程；
- 业务连续性规划（如：防灾准备、应急计划）；
- 物流过程；
- 顾客服务。

8.4.1.3 顾客指定的货源（亦称“指向性购买”）

当顾客指定时，组织应从顾客指定的货源处采购产品、材料或服务。

第 8.4 条的所有要求（除了 IATF 16949 第 8.4.1.2 条中的要求）适用于组织对顾客指定货源的控制，除非组织与顾客之间的合同另有特殊约定。

8.4.2 Type and extent of control

See ISO 9001:2015 requirements.

See ISO 9001:2015

8.4.2.1 Type and extent of control – supplemental

The organization shall have a documented process to identify outsourced processes and to select the types and extent of controls used to verify conformity of externally provided products, processes, and services to internal (organizational) and external customer requirements.

The process shall include the criteria and actions to escalate or reduce the types and extent of controls and development activities based on supplier performance and assessment of product, material, or service risks.

8.4.2.2 Statutory and regulatory requirements

The organization shall document their process to ensure that purchased products, processes, and services conform to the current applicable statutory and regulatory requirements in the country of receipt, the country of shipment, and the customer-identified country of destination, if provided.

If the customer defines special controls for certain products with statutory and regulatory requirements, the organization shall ensure they are implemented and maintained as defined, including at suppliers.

8.4.2.3 Supplier quality management system development

The organization shall require their suppliers of automotive products and services to develop, implement, and improve a quality management system certified to ISO 9001, unless otherwise authorized by the customer [e.g., item a) below], with the ultimate objective of becoming certified to this Automotive QMS Standard. Unless otherwise specified by the customer, the following sequence should be applied to achieve this requirement:

- a) compliance to ISO 9001 through second-party audits;
- b) certification to ISO 9001 through third-party audits; unless otherwise specified by the customer, suppliers to the organization shall demonstrate conformity to ISO 9001 by maintaining a third-party certification issued by a certification body bearing the accreditation mark of a recognized IAF MLA (International Accreditation Forum Multilateral Recognition Arrangement) member and where the accreditation body's main scope includes management system certification to ISO/IEC 17021;
- c) certification to ISO 9001 with compliance to other customer-defined QMS requirements (such as Minimum Automotive Quality Management System Requirements for Sub-Tier Suppliers [MAQMSR] or equivalent) through second-party audits;
- d) certification to ISO 9001 with compliance to IATF 16949 through second-party audits;
- e) certification to IATF 16949 through third-party audits (valid third-party certification of the supplier to IATF 16949 by an IATF-recognized certification body).

8.4.2.3.1 Automotive product-related software or automotive products with embedded software

The organization shall require their suppliers of automotive product-related software, or automotive products with embedded software, to implement and maintain a process for software quality assurance for their products.

8.4.2 控制的类型和程度

见 ISO 9001:2015 的要求。

8.4.2.1 控制的类型和程度——补充

组织应有一个形成文件的过程，以识别外包过程并选择控制的类型和程度，用于验证外部提供的产品、过程和服务对内部（组织的）要求和外部顾客要求的符合性。

该过程应包括根据供应商绩效和产品、材料或服务风险评估，增加或减少控制类型和程度以及开发活动的准则和措施。

8.4.2.2 法律法规要求

组织应有形成文件的过程，确保所采购的产品、过程和服务符合收货国、发运国和顾客确定的目的国（如有提供）的现行适用法律法规要求。

如果顾客为特定产品符合法律法规要求确定了特殊控制，组织应确保按照规定实施并保持这些控制，包括在供应商处。

8.4.2.3 供应商质量管理体系开发

组织应要求其汽车产品和服务供应商开发、实施并改进一个通过 ISO 9001 认证的质量管理体系，除非顾客另行授权[如：下文的 a) 项]，最终目标是通过本汽车 QMS 标准的认证。除非顾客另有规定，应当根据以下顺序来达成本要求：

- a) 经由第二方审核符合 ISO 9001；
- b) 经由第三方审核通过 ISO 9001 认证；除非顾客另有规定，组织的供应商应通过保持认证机构出具的第三方认证证明来证实对 ISO 9001 的符合性，证明上应有被承认的 IAF MLA（国际认可论坛多边相互承认协议）成员的认可标志，其中，认可机构的主要范围包括 ISO/IEC 17021 管理体系认证；
- c) 经由第二方审核通过 ISO 9001 认证，同时符合其它顾客确定的质量管理体系要求（例如：次级供应商最低汽车质量管理体系要求[MAQMSR]或等效要求）；
- d) 通过 ISO 9001 认证，同时经由第二方审核符合 IATF 16949；
- e) 经由第三方审核通过 IATF 16949 认证（IATF 认可的认证机构进行的有效供应商 IATF 16949 第三方认证）。

8.4.2.3.1 汽车产品相关软件或带有嵌入式软件的汽车产品

组织应要求其汽车产品相关软件或带有嵌入式软件的汽车产品的供应商为各自产品实施并保持一个软件质量保证过程。

A software development assessment methodology shall be utilized to assess the supplier's software development process. Using prioritization based on risk and potential impact to the customer, the organization shall require the supplier to retain documented information of a software development capability self-assessment.

8.4.2.4 Supplier monitoring

The organization shall have a documented process and criteria to evaluate supplier performance in order to ensure conformity of externally provided products, processes, and services to internal and external customer requirements.

At a minimum, the following supplier performance indicators shall be monitored:

- a) delivered product conformity to requirements;
- b) customer disruptions at the receiving plant, including yard holds and stop ships;
- c) delivery schedule performance;
- d) number of occurrences of premium freight.

If provided by the customer, the organization shall also include the following, as appropriate, in their supplier performance monitoring:

- e) special status customer notifications related to quality or delivery issues;
- f) dealer returns, warranty, field actions, and recalls.

8.4.2.4.1 Second-party audits

The organization shall include a second-party audit process in their supplier management approach. Second-party audits may be used for the following:

- a) supplier risk assessment;
- b) supplier monitoring;
- c) supplier QMS development;
- d) product audits;
- e) process audits.

Based on a risk analysis, including product safety/regulatory requirements, performance of the supplier, and QMS certification level, at a minimum, the organization shall document the criteria for determining the need, type, frequency, and scope of second-party audits.

The organization shall retain records of the second-party audit reports.

If the scope of the second-party audit is to assess the supplier's quality management system, then the approach shall be consistent with the automotive process approach.

NOTE Guidance may be found in the IATF Auditor Guide and ISO 19011.

8.4.2.5 Supplier development

The organization shall determine the priority, type, extent, and timing of required supplier development actions for its active suppliers. Determination inputs shall include but are not limited to the following:

应采用软件开发评估方法来评估供应商的软件开发过程。组织应按照风险和对顾客潜在影响的优先级，要求供应商为软件开发能力自评估保存形成文件的信息。

8.4.2.4 供应商监视

组织应为供应商绩效评价制定形成文件的过程和准则，以便确保外部提供的产品、过程和服务符合内部要求和外部顾客要求。

至少应监视以下供应商绩效指标：

- a) 已交付产品对要求的符合性；
- b) 在收货工厂对顾客造成的干扰，包括整车候检和停止出货；
- c) 交付排程的绩效；
- d) 超额运费发生次数。

如顾客有所规定，组织还应视情况在供应商绩效监视中包括：

- e) 与质量或交付有关的特殊状态顾客通知；
- f) 经销商退货、保修、使用现场措施和召回。

8.4.2.4.1 第二方审核

组织的供应商管理方法中应包括一个第二方审核过程。第二方审核可以用于：

- a) 供应商风险评估；
- b) 供应商监视；
- c) 供应商质量管理体系开发；
- d) 产品审核；
- e) 过程审核。

基于风险分析，包括产品安全/法规要求、供应商绩效和质量管理体系认证水平，组织应至少对第二方审核的需求、类型、频率和范围的确定准则形成文件。

组织应保留第二方审核报告的记录。

如果第二方审核的范围是评估供应商的质量管理体系，则方法应与汽车过程方法相符。

注：可从 IATF 审核员指南和 ISO 19011 获得指导。

8.4.2.5 供应商开发

组织应为其活跃供应商确定所需供应商开发行动的优先级、类型、程度和时程安排。用于确定的输入应包括但不限于：

- a) performance issues identified through supplier monitoring (see Section 8.4.2.4);
- b) second-party audit findings (see Section 8.4.2.4.1);
- c) third-party quality management system certification status;
- d) risk analysis.

The organization shall implement actions necessary to resolve open (unsatisfactory) performance issues and pursue opportunities for continual improvement.

8.4.3 Information for external providers

See ISO 9001:2015 requirements.

8.4.3.1 Information for external providers - supplemental

The organization shall pass down all applicable statutory and regulatory requirements and special product and process characteristics to their suppliers and require the suppliers to cascade all applicable requirements down the supply chain to the point of manufacture.

8.5 Production and service provision

8.5.1 Control of production and service provision

See ISO 9001:2015 requirements.

NOTE Suitable infrastructure includes appropriate manufacturing equipment required to ensure product compliance. Monitoring and measuring resources include appropriate monitoring and measuring equipment required to ensure effective control of manufacturing processes.

8.5.1.1 Control plan

The organization shall develop control plans (in accordance with Annex A) at the system, subsystem, component, and/or material level for the relevant manufacturing site and all product supplied, including those for processes producing bulk materials as well as parts. Family control plans are acceptable for bulk material and similar parts using a common manufacturing process.

The organization shall have a control plan for pre-launch and production that shows linkage and incorporates information from the design risk analysis (if provided by the customer), process flow diagram, and manufacturing process risk analysis outputs (such as FMEA).

The organization shall, if required by the customer, provide measurement and conformity data collected during execution of either the pre-launch or production control plans. The organization shall include in the control plan:

- a) controls used for the manufacturing process control, including verification of job set-ups;
- b) first-off/last-off part validation, as applicable;
- c) methods for monitoring of control exercised over special characteristics (see Annex A) defined by both the customer and the organization;
- d) the customer-required information, if any;

- a) 通过供应商监视（见第 8.4.2.4 条）识别的绩效问题；
- b) 第二方审核发现（见第 8.4.2.4.1 条）；
- c) 第三方质量管理体系认证状态；
- d) 风险分析。

组织应采取必要措施，以解决未决的（不符合要求的）绩效问题并寻求持续改进的机会。

8.4.3 外部供方的信息

见 ISO 9001:2015 的要求。

8.4.3.1 外部供方的信息——补充

组织应向其供应商传达所有适用的法律法规要求以及产品和过程特殊特性，并要求供应商沿着供应链直至制造，贯彻所有适用的要求。

8.5 生产和服务提供

8.5.1 生产和服务提供的控制

见 ISO 9001:2015 的要求。

注：适当的基础设施包括保证产品符合性所需的适当制造设备。监视和测量资源包括确保制造过程有效控制所需的适当监视和测量设备。

8.5.1.1 控制计划

组织应针对相关制造现场和所有提供的产品，在系统、子系统、部件和/或材料各层次上（根据附录 A）制定控制计划，包括那些生产散装材料和零件的过程。采用共同制造过程的散装材料和相似零件可接受使用控制计划族。

组织应制定投产前控制计划和量产控制计划，显示设计风险分析（如果顾客提供了）、过程流程图和制造过程风险分析输出（例如 FMEA）的联系，并在计划中包含从这些方面获得的信息。

如果顾客要求，组织应提供在投产前或量产控制计划执行期间收集的测量和符合性数据。组织应在控制计划中包含以下内容：

- a) 用于制造过程的控制手段，包括作业准备的验证；
- b) 首件/末件确认，如适用；
- c) 用于顾客和组织确定的特殊特性（见附录 A）控制的监视方法；
- d) 顾客要求的信息，如有；

- e) specified reaction plan (see Annex A); when nonconforming product is detected, the process becomes statistically unstable or not statistically capable.

The organization shall review control plans, and update as required, for any of the following:

- f) the organization determines it has shipped nonconforming product to the customer;
- g) when any change occurs affecting product, manufacturing process, measurement, logistics, supply sources, production volume changes, or risk analysis (FMEA) (see Annex A);
- h) after a customer complaint and implementation of the associated corrective action, when applicable;
- i) at a set frequency based on a risk analysis.

If required by the customer, the organization shall obtain customer approval after review or revision of the control plan.

8.5.1.2 Standardised work – operator instructions and visual standards

The organization shall ensure that standardised work documents are:

- a) communicated to and understood by the employees who are responsible for performing the work;
- b) legible;
- c) presented in the language(s) understood by the personnel responsible to follow them;
- d) accessible for use at the designated work area(s).

The standardised work documents shall also include rules for operator safety.

8.5.1.3 Verification of job set-ups

The organization shall:

- a) verify job set-ups when performed, such as an initial run of a job, material changeover, or job change that requires a new set-up;
- b) maintain documented information for set-up personnel;
- c) use statistical methods of verification, where applicable;
- d) perform first-off/last-off part validation, as applicable; where appropriate, first-off parts should be retained for comparison with the last-off parts; where appropriate, last-off-parts should be retained for comparison with first-off parts in subsequent runs;
- e) retain records of process and product approval following set-up and first-off/last-off part validations.

8.5.1.4 Verification after shutdown

The organization shall define and implement the necessary actions to ensure product compliance with requirements after a planned or unplanned production shutdown period.

- e) 规定的反应计划（见附录 A）；当检测到不合格品，过程会变得不稳定或统计能力不足时。

组织应针对如下任一情况对控制计划进行评审，并在需要时更新：

- f) 当组织确定其已经向顾客发运了不合格品；
- g) 当发生任何影响产品、制造过程、测量、物流、供应货源、生产量或风险分析（FMEA）的变更（见附录 A）；
- h) 在收到顾客投诉并实施了相关纠正措施之后，当适用时；
- i) 以基于风险分析的设定频率。

如果顾客要求，组织应在控制计划评审和修订后获得顾客批准。

8.5.1.2 标准化作业——操作指导书和目视标准

组织应确保标准化作业文件：

- a) 被传达给负责相关工作的员工，并被员工理解；
- b) 是清晰易读的；
- c) 用有责任遵守这些文件的人员能够理解的语言表述；
- d) 在指定的工作区域易于得到。

标准化作业文件还应包含操作员安全规则。

8.5.1.3 作业准备的验证

组织应：

- a) 当执行作业准备时进行作业准备验证，例如：需要新作业准备的一项工作的首次运行、材料的更换或工作的变更；
- b) 保持有关准备人员的形成文件的信息；
- c) 适用时采用统计的验证方法；
- d) 进行首件/末件确认，如适用；适当时，应当保留首件用于与末件比较；适当时，应当保留末件用于与后续运行中的首件比较；
- e) 保留作业准备和首件/末件确认之后过程和产品批准的记录。

8.5.1.4 停工后的验证

组织应确定并采取必要的措施，确保在计划或非计划生产停工期之后，产品对要求的符合性。

8.5.1.5 Total productive maintenance

The organization shall develop, implement, and maintain a documented total productive maintenance system.

At a minimum, the system shall include the following:

- a) identification of process equipment necessary to produce conforming product at the required volume;
- b) availability of replacement parts for the equipment identified in item a);
- c) provision of resource for machine, equipment, and facility maintenance;
- d) packaging and preservation of equipment, tooling, and gauging;
- e) applicable customer-specific requirements;
- f) documented maintenance objectives, for example: OEE (Overall Equipment Effectiveness), MTBF (Mean Time Between Failure), and MTTR (Mean Time To Repair), and Preventive Maintenance compliance metrics. Performance to the maintenance objectives shall form an input into management review (see ISO 9001, Section 9.3);
- g) regular review of maintenance plan and objectives and a documented action plan to address corrective actions where objectives are not achieved;
- h) use of preventive maintenance methods;
- i) use of predictive maintenance methods, as applicable;
- j) periodic overhaul.

8.5.1.6 Management of production tooling and manufacturing, test, inspection tooling and equipment

The organization shall provide resources for tool and gauge design, fabrication, and verification activities for production and service materials and for bulk materials, as applicable.

The organization shall establish and implement a system for production tooling management, whether owned by the organization or the customer, including:

- a) maintenance and repair facilities and personnel;
- b) storage and recovery;
- c) set-up;
- d) tool-change programmes for perishable tools;
- e) tool design modification documentation, including engineering change level of the product;
- f) tool modification and revision to documentation;
- g) tool identification, such as serial or asset number; the status, such as production, repair or disposal; ownership; and location.

The organization shall verify that customer-owned tools, manufacturing equipment, and test/inspection equipment are permanently marked in a visible location so that the ownership and application of each item can be determined.

8.5.1.5 全面生产维护

组织应制定、实施并保持一个形成文件的全面生产维护系统。

该系统应至少包含：

- a) 对按照要求产量生产合格产品所必需的过程设备的识别；
- b) a) 项中被识别设备的替换件的可用性；
- c) 机器、设备和设施维护的资源提供；
- d) 设备、工装和量具的包装和防护；
- e) 适用的顾客特定要求；
- f) 形成文件的维护目标，例如：OEE（全局设备效率）、MTBF（平均故障间隔时间）和 MTTR（平均维修时间），以及预防性维护符合性指标。维护目标的绩效应作为管理评审的输入（见 ISO 9001 第 9.3 条）；
- g) 维护计划和目标以及形成文件的措施计划的定期评审，以在未达到目标时采取纠正措施；
- h) 对预防性维护方法的使用；
- i) 对预测性维护方法的使用，如适用；
- j) 周期性检修。

8.5.1.6 生产工装及制造、试验、检验工装和设备的管理

组织应针对生产和服务材料和散装材料（如适用），为工具、量具的设计、制造和验证活动提供资源。

组织应建立并实施一个生产工装管理体系，不管归组织或顾客所有，其中包括：

- a) 维护、维修设施与人员；
- b) 存储与修复；
- c) 工装准备；
- d) 易损工具的工具更换方案；
- e) 工具设计修改的文件，包括产品的工程变更等级；
- f) 工具的修改和文件的修订；
- g) 工具标识，例如：序列号或资产编号；状态，如生产、修理或废弃；所有权；以及位置。

组织应验证顾客拥有的工具、制造设备和试验/检验设备是在明显的位置永久标记的，以便能够确定每件工具或设备的所有权和用途。

The organization shall implement a system to monitor these activities if any work is outsourced.

8.5.1.7 Production scheduling

The organization shall ensure that production is scheduled in order to meet customer orders/demands such as Just-In-Time (JIT) and is supported by an information system that permits access to production information at key stages of the process and is order driven.

The organization shall include relevant planning information during production scheduling, e.g., customer orders, supplier on-time delivery performance, capacity, shared loading (multi-part station), lead time, inventory level, preventive maintenance, and calibration.

8.5.2 Identification and traceability

See ISO 9001:2015 requirements.

NOTE Inspection and test status is not indicated by the location of product in the production flow unless inherently obvious, such as material in an automated production transfer process. Alternatives are permitted if the status is clearly identified, documented, and achieves the designated purpose.

8.5.2.1 Identification and traceability — supplemental

The purpose of traceability is to support identification of clear start and stop points for product received by the customer or in the field that may contain quality and/or safety-related nonconformities. Therefore, the organization shall implement identification and traceability processes as described below.

The organization shall conduct an analysis of internal, customer, and regulatory traceability requirements for all automotive products, including developing and documenting traceability plans, based on the levels of risk or failure severity for employees, customers, and consumers. These plans shall define the appropriate traceability systems, processes, and methods by product, process, and manufacturing location that:

- a) enable the organization to identify nonconforming and/or suspect product;
- b) enable the organization to segregate nonconforming and/or suspect product;
- c) ensure the ability to meet the customer and/or regulatory response time requirements;
- d) ensure documented information is retained in the format (electronic, hardcopy, archive) that enables the organization to meet the response time requirements;
- e) ensure serialized identification of individual products, if specified by the customer or regulatory standards;
- f) ensure the identification and traceability requirements are extended to externally provided products with safety/regulatory characteristics.

8.5.3 Property belonging to customers or external providers

See ISO 9001:2015 requirements.

如果任何工作被外包，组织应实施监视这些活动的系统。

8.5.1.7 生产排程

组织应确保为满足顾客订单/需求来安排生产，例如准时生产（JIT），并且确保生产由一个信息系统支持，该系统允许在过程的关键阶段取得生产信息，并且是由订单驱动的。

组织应在生产排程期间包含相关策划信息，如：顾客订单、供应商准时交付绩效、产能、共享载荷（共线工位）、前置期、库存水平、预防性维护及校准。

8.5.2 标识和可追溯性

见 ISO 9001:2015 的要求。

注：检验和试验状态并不能以产品在生产流程中所处的位置来表明，除非产品本身状态明显（如在自动化生产传递过程中的物料）。如果该状态已清晰地标识、文件化且达到了指定的目的，允许采用其它方法来标识。

8.5.2.1 标识和可追溯性——补充

可追溯性的目的在于支持对顾客所收产品的开始点和停止点的清楚识别，或者用于发生质量和/或安全相关不符合的情况。因此，组织应按照下文描述实施标识和可追溯过程。

组织应对所有汽车产品的内部、顾客及法规可追溯性要求进行分析，包括根据风险等级或失效对员工、顾客的严重程度，制定可追溯性计划并形成文件。这些计划应按产品、过程和制造位置明确适当的可追溯系统、过程和方法，应：

- a) 使组织能够识别不合格品和/或可疑产品；
- b) 使组织能够隔离不合格品和/或可疑产品；
- c) 确保能够满足顾客要求和/或法规对响应时间的要求；
- d) 确保保留了形成文件的信息，保留的形式（电子、硬拷贝、档案）使组织能够满足响应时间要求；
- e) 确保各单个产品的序列化标识，如顾客或监管标准有所规定；
- f) 确保标识和可追溯性要求被扩展应用至外部提供的具有安全/监管特性的产品。

8.5.3 属于顾客或外部供方的财产

见 ISO 9001:2015 的要求。

8.5.4 Preservation

See ISO 9001:2015 requirements.

8.5.4.1 Preservation - supplemental

Preservation shall include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

Preservation shall apply to materials and components from external and/or internal providers from receipt through processing, including shipment and until delivery to/acceptance by the customer.

In order to detect deterioration, the organization shall assess at appropriate planned intervals the condition of product in stock, the place/type of storage container, and the storage environment.

The organization shall use an inventory management system to optimize inventory turns over time and ensure stock rotation, such as "first-in-first-out" (FIFO).

The organization shall ensure that obsolete product is controlled in a manner similar to that of nonconforming product.

Organizations shall comply with preservation, packaging, shipping, and labeling requirements as provided by their customers.

8.5.5 Post-delivery activities

See ISO 9001:2015 requirements.

8.5.5.1 Feedback of information from service

The organization shall ensure that a process for communication of information on service concerns to manufacturing, material handling, logistics, engineering, and design activities is established, implemented, and maintained.

NOTE 1 The intent of the addition of "service concerns" to this sub-clause is to ensure that the organization is aware of nonconforming product(s) and material(s) that may be identified at the customer location or in the field.

NOTE 2 "Service concerns" should include the results of field failure test analysis (see Section 10.2.6) where applicable.

8.5.5.2 Service agreement with customer

When there is a service agreement with the customer, the organization shall:

- a) verify that the relevant service centres comply with applicable requirements;
- b) verify the effectiveness of any special purpose tools or measurement equipment;
- c) ensure that all service personnel are trained in applicable requirements.

8.5.4 防护

见 ISO 9001:2015 的要求。

8.5.4.1 防护——补充

防护应包括标识、搬运、污染控制、包装、存储、输送或运输以及保护。

应对来自外部和/或内部供方的材料和部件，在从收货到处理的期间提供防护，包括发运并直到交付给顾客/被顾客验收。

组织应按适当计划的时间间隔来评估库存品状况、存储容器放置/类型以及存储环境，以便及时探测变质情况。

组织应使用库存管理系统以优化库存的周转期，确保库存周转，如“先进先出（FIFO）”。

组织应确保过期产品按对待不合格品的类似方法进行控制。

组织应满足其顾客规定的防护、包装、发运和标签要求。

8.5.5 交付后的活动

见 ISO 9001:2015 的要求。

8.5.5.1 服务信息的反馈

组织应确保建立、实施并保持一个在制造、材料搬运、物流、工程和设计活动之间沟通服务问题信息的过程。

注 1：将“服务问题”增加到这个子条款，是为了确保组织知晓可能在顾客地点或使用现场被识别的不合格品和材料。

注 2：“服务问题”应当在适用时包括使用现场失效试验分析（见第 10.2.6 条）的结果。

8.5.5.2 与顾客的服务协议

当与顾客达成服务协议时，组织应：

- a) 验证相关服务中心满足适用要求；
- b) 验证任何特殊用途的工具或测量设备的有效性；
- c) 确保所有服务人员得到了对适用要求的培训。

8.5.6 Control of changes

See ISO 9001:2015 requirements.

8.5.6.1 Control of changes - supplemental

The organization shall have a documented process to control and react to changes that impact product realization. The effects of any change, including those changes caused by the organization, the customer, or any supplier, shall be assessed.

The organization shall:

- a) define verification and validation activities to ensure compliance with customer requirements;
- b) validate changes before implementation;
- c) document the evidence of related risk analysis;
- d) retain records of verification and validation.

Changes, including those made at suppliers, should require a production trial run for verification of changes (such as changes to part design, manufacturing location, or manufacturing process) to validate the impact of any changes on the manufacturing process.

When required by the customer, the organization shall:

- e) notify the customer of any planned product realization changes after the most recent product approval;
- f) obtain documented approval, prior to implementation of the change;
- g) complete additional verification or identification requirements, such as production trial run and new product validation.

8.5.6.1.1 Temporary change of process controls

The organization shall identify, document, and maintain a list of the process controls, including inspection, measuring, test, and error-proofing devices, that includes the primary process control and the approved back-up or alternate methods.

The organization shall document the process that manages the use of alternate control methods. The organization shall include in this process, based on risk analysis (such as FMEA), severity, and the internal approvals to be obtained prior to production implementation of the alternate control method.

Before shipping product that was inspected or tested using the alternate method, if required, the organization shall obtain approval from the customer(s). The organization shall maintain and periodically review a list of approved alternate process control methods that are referenced in the control plan.

Standard work instructions shall be available for each alternate process control method. The organization shall review the operation of alternate process controls on a daily basis, at a minimum, to verify implementation of standard work with the goal to return to the standard process as defined by the control plan as soon as possible. Example methods include but are not limited to the following:

- a) daily quality focused audits (e.g., layered process audits, as applicable);

8.5.6 更改的控制

见 ISO 9001:2015 的要求。

8.5.6.1 更改的控制——补充

组织应有一个形成文件的过程，对影响产品实现的更改进行控制和反应。任何更改的影响，包括由组织、顾客或任何供应商所引起的更改，都应进行评估。

组织应：

- a) 明确验证和确认活动，以确保与顾客要求相一致；
- b) 在实施前对更改予以确认；
- c) 对相关风险分析的证据形成文件；
- d) 保留验证和确认的记录。

应当对更改（例如：对零件设计、制造地点或制造过程的更改），包括供应商作出的更改，进行以验证为目的的试生产，以便确认更改对制造过程带来的影响。

当顾客要求时，组织应：

- e) 向顾客通知最近一次产品批准之后任何计划产品实现的更改；
- f) 在实施更改之前获得形成文件的批准；
- g) 达成额外验证或标识要求，例如：试生产和新产品确认。

8.5.6.1.1 过程控制的临时更改

组织应识别过程控制手段，包括检验、测量、试验和防错装置，形成文件化的清单并予以保持，清单包含主要过程控制和经批准的备用或替代方法。

组织应有一个形成文件的过程，对替代控制方法的使用进行管理。组织应基于风险分析（例如 FMEA）和严重程度，在本过程中包含要在生产中实施替代控制方法之前获得的内部批准。

在发运采用替代方法检验或试验的产品之前，如有要求，组织应获得顾客批准。组织应保持一份控制计划中提及的经批准替代过程控制方法的清单并定期评审。

每个替代过程控制方法应有标准的工作指导书。组织应至少每日评审替代过程控制手段的运行，以验证标准作业的实施，旨在尽早返回到控制计划规定的标准过程。方法范例包括但不限于：

- a) 以质量为重点的每日审核（如：分层过程审核，如适用）；

- b) daily leadership meetings.

Restart verification is documented for a defined period based on severity and confirmation that all features of the error-proofing device or process are effectively reinstated.

The organization shall implement traceability of all product produced while any alternate process control devices or processes are being used (e.g., verification and retention of first piece and last piece from every shift).

8.6 Release of products and services

See ISO 9001:2015 requirements.

8.6.1 Release of products and services — supplemental

The organization shall ensure that the planned arrangements to verify that the product and service requirements have been met encompass the control plan and are documented as specified in the control plan (see Annex A).

The organization shall ensure that the planned arrangements for initial release of products and services encompass product or service approval.

The organization shall ensure that product or service approval is accomplished after changes following initial release, according to ISO 9001, Section 8.5.6.

8.6.2 Layout inspection and functional testing

A layout inspection and a functional verification to applicable customer engineering material and performance standards shall be performed for each product as specified in the control plans. Results shall be available for customer review.

NOTE 1 Layout inspection is the complete measurement of all product dimensions shown on the design record(s).

NOTE 2 The frequency of layout inspection is determined by the customer.

8.6.3 Appearance items

For organizations manufacturing parts designated by the customer as “appearance items,” the organization shall provide the following:

- a) appropriate resources, including lighting, for evaluation;
- b) masters for colour, grain, gloss, metallic brilliance, texture, distinctness of image (DOI), and haptic technology, as appropriate;
- c) maintenance and control of appearance masters and evaluation equipment;
- d) verification that personnel making appearance evaluations are competent and qualified to do so.

- b) 每日领导会议。

基于严重程度，并在确认防错装置或过程的所有特征均得以有效恢复的基础上，在规定时期内对重新启动验证形成文件。

在使用替代过程控制装置或过程期间，组织应实现生产的所有产品的可追溯性（如：验证并保留每个班次首件和末件）。

8.6 产品和服务的放行

见 ISO 9001:2015 的要求。

8.6.1 产品和服务的放行——补充

组织应确保用于验证产品和服务要求得以满足的所策划的安排围绕控制计划进行，并且形成文件规定在控制计划中（见附录 A）。

组织应确保为产品和服务初始放行所策划的安排围绕产品或服务批准进行。

根据 ISO 9001 第 8.5.6 条，组织应确保在初始放行后作出更改之后，完成产品或服务批准。

8.6.2 全尺寸检验和功能性试验

应按控制计划中的规定，根据顾客的工程材料和性能标准，对每一种产品进行全尺寸检验和功能性验证。其结果应可供顾客评审。

注 1：全尺寸检验是对设计记录上显示的所有产品尺寸进行完整的测量。

注 2：全尺寸检验频率由顾客确定。

8.6.3 外观项目

若组织制造的零件被顾客指定为“外观项目”，则组织应提供：

- a) 适当的资源，包括评价用的照明；
- b) 适当的颜色、纹理、金属亮度、织物结构、映像清晰度（DOI）和触感技术的原版样件；
- c) 外观原版样件及评价设备的维护和控制；
- d) 验证执行外观评价的人员有从事该工作的能力和资格。

8.6.4 Verification and acceptance of conformity of externally provided products and services

The organization shall have a process to ensure the quality of externally provided processes, products, and services utilizing one or more of the following methods:

- a) receipt and evaluation of statistical data provided by the supplier to the organization;
- b) receiving inspection and/or testing, such as sampling based on performance;
- c) second-party or third-party assessments or audits of supplier sites when coupled with records of acceptable delivered product conformance to requirements;
- d) part evaluation by a designated laboratory;
- e) another method agreed with the customer.

8.6.5 Statutory and regulatory conformity

Prior to release of externally provided products into its production flow, the organization shall confirm and be able to provide evidence that externally provided processes, products, and services conform to the latest applicable statutory, regulatory, and other requirements in the countries where they are manufactured and in the customer-identified countries of destination, if provided.

8.6.6 Acceptance criteria

Acceptance criteria shall be defined by the organization and, where appropriate or required, approved by the customer. For attribute data sampling, the acceptance level shall be zero defects (see Section 9.1.1.1).

8.7 Control of nonconforming outputs

8.7.1

See ISO 9001:2015 requirements.

8.7.1.1 Customer authorization for concession

The organization shall obtain a customer concession or deviation permit prior to further processing whenever the product or manufacturing process is different from that which is currently approved.

The organization shall obtain customer authorization prior to further processing for "use as is" and rework dispositions of nonconforming product. If sub-components are reused in the manufacturing process, that sub-component reuse shall be clearly communicated to the customer in the concession or deviation permit.

The organization shall maintain a record of the expiration date or quantity authorized under concession. The organization shall also ensure compliance with the original or superseding specifications and requirements when the authorization expires. Material shipped under concession shall be properly identified on each shipping container (this applies equally to purchased product). The organization shall approve any requests from suppliers before submission to the customer.

8.7.1.2 Control of nonconforming product – customer-specified process

The organization shall comply with applicable customer-specified controls for nonconforming product(s).

8.6.4 外部提供的产品和服务符合性的验证和接受

组织应有一个过程来确保外部提供的过程、产品和服务的质量，可采用以下一种或多种方法：

- a) 接收并评价组织供应商提供的统计数据；
- b) 接收检验和/或试验，例如基于绩效的抽样检查；
- c) 结合可接受的已交付产品对要求的符合性的记录，由第二方或第三方机构对供应商现场进行评估或审核；
- d) 指定实验室的零件评价；
- e) 顾客同意的其它方法。

8.6.5 法律法规的符合性

在放行外部提供的产品进入生产流程之前，组织应确认并能够提供证据证明，外部提供的过程、产品和服务符合制造国以及顾客确定的目的国（如有提供）最新的适用法律、法规和其它要求。

8.6.6 接收准则

接收准则应由组织确定，当被要求时，由顾客批准。对于计数型数据的抽样，其接收水平应是零缺陷（见第9.1.1.1条）。

8.7 不符合输出的控制

8.7.1

见 ISO 9001:2015 的要求。

8.7.1.1 顾客的让步授权

无论何时，当产品或制造过程与当前批准的不同时，组织在进一步加工之前应获得顾客的让步或对偏离的许可。

组织应在进一步加工之前，获得顾客对不合格品“照现状使用”和返工处置的授权。如果在制造过程中有子部件的再使用，应在让步或偏离许可中向顾客清楚传达该子部件的再使用。

组织应保持有效期限或让步授权数量方面的记录。当授权期满时，组织还应确保原有的或接替的规范与要求的符合性。让步的物料装运时，应在每个发运集装箱上做适当的标识（此要求同样适用于采购的产品）。在提交给顾客之前，组织应批准由供应商所提出的请求。

8.7.1.2 不合格品控制——顾客规定的过程

组织应遵守顾客规定的适用的不合格品控制。

8.7.1.3 Control of suspect product

The organization shall ensure that product with unidentified or suspect status is classified and controlled as nonconforming product. The organization shall ensure that all appropriate manufacturing personnel receive training for containment of suspect and nonconforming product.

8.7.1.4 Control of reworked product

The organization shall utilize risk analysis (such as FMEA) methodology to assess risks in the rework process prior to a decision to rework the product. If required by the customer, the organization shall obtain approval from the customer prior to commencing rework of the product.

The organization shall have a documented process for rework confirmation in accordance with the control plan or other relevant documented information to verify compliance to original specifications.

Instructions for disassembly or rework, including re-inspection and traceability requirements, shall be accessible to and utilized by the appropriate personnel.

The organization shall retain documented information on the disposition of reworked product including quantity, disposition, disposition date, and applicable traceability information.

8.7.1.5 Control of repaired product

The organization shall utilize risk analysis (such as FMEA) methodology to assess risks in the repair process prior to a decision to repair the product. The organization shall obtain approval from the customer before commencing repair of the product.

The organization shall have a documented process for repair confirmation in accordance with the control plan or other relevant documented information.

Instructions for disassembly or repair, including re-inspection and traceability requirements, shall be accessible to and utilized by the appropriate personnel.

The organization shall obtain a documented customer authorization for concession for the product to be repaired.

The organization shall retain documented information on the disposition of repaired product including quantity, disposition, disposition date, and applicable traceability information.

8.7.1.6 Customer notification

The organization shall immediately notify the customer(s) in the event that nonconforming product has been shipped. Initial communication shall be followed with detailed documentation of the event.

8.7.1.7 Nonconforming product disposition

The organization shall have a documented process for disposition of nonconforming product not subject to rework or repair. For product not meeting requirements, the organization shall verify that the product to be scrapped is rendered unusable prior to disposal.

The organization shall not divert nonconforming product to service or other use without prior customer approval.

8.7.1.3 可疑产品的控制

组织应确保处于未经标识或可疑状态下的产品被归类为不合格品进行控制。组织应确保所有适当的制造人员都接受了关于可疑产品和不合格品遏制的培训。

8.7.1.4 返工产品的控制

组织应在决定对产品进行返工之前，利用风险分析（如 FMEA）方法来评估返工过程中的风险。如顾客有所要求，组织应在开始产品返工之前获得顾客批准。

组织应有一个形成文件的符合控制计划的返工确认过程，或者其它形成文件的相关信息，用于验证对原始规范的符合性。

包含了重新检验和可追溯性要求的拆卸或返工指导书，应易于被适当的人员取得和使用。

组织应保留与返工产品处置有关的形成文件的信息，包括数量、处置、处置日期及适用的可追溯性信息。

8.7.1.5 返修产品的控制

组织应在决定对产品进行返修之前，利用风险分析（如 FMEA）方法来评估返修过程中的风险。组织应在开始产品返修之前获得顾客批准。

组织应有一个形成文件的符合控制计划的返修确认过程，或者其它形成文件的相关信息。

包含了重新检验和可追溯性要求的拆卸或返修指导书，应易于被适当的人员取得和使用。

组织应获得顾客对待返修产品的形成文件的让步授权。

组织应保留与返修产品处置有关的形成文件的信息，包括数量、处置、处置日期及适用的可追溯性信息。

8.7.1.6 顾客通知

当不合格品被发运时，组织应立刻通知顾客。初始通知应随附事件的详细文件。

8.7.1.7 不合格品的处置

组织应有一个形成文件的过程，用于不进行返工或返修的不合格品的处置。对于不符合要求的产品，组织应验证待报废产品在废弃之前已被变得无用。

若无顾客提前批准，组织不得将不合格品用于服务或其它用途。

8.7.2

See ISO 9001:2015 requirements.

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

See ISO 9001:2015 requirements.

9.1.1.1 Monitoring and measurement of manufacturing processes

The organization shall perform process studies on all new manufacturing (including assembly or sequencing) processes to verify process capability and to provide additional input for process control, including those for special characteristics.

NOTE For some manufacturing processes, it may not be possible to demonstrate product compliance through process capability. For those processes, alternate methods such as batch conformance to specification may be used.

The organization shall maintain manufacturing process capability or performance results as specified by the customer's part approval process requirements. The organization shall verify that the process flow diagram, PFMEA, and control plan are implemented, including adherence to the following:

- a) measurement techniques;
- b) sampling plans;
- c) acceptance criteria;
- d) records of actual measurement values and/or test results for variable data;
- e) reaction plans and escalation process when acceptance criteria are not met.

Significant process events, such as tool change or machine repair, shall be recorded and retained as documented information.

The organization shall initiate a reaction plan indicated on the control plan and evaluated for impact on compliance to specifications for characteristics that are either not statistically capable or are unstable. These reaction plans shall include containment of product and 100 percent inspection, as appropriate. A corrective action plan shall be developed and implemented by the organization indicating specific actions, timing, and assigned responsibilities to ensure that the process becomes stable and statistically capable. The plans shall be reviewed with and approved by the customer, when required.

The organization shall maintain records of effective dates of process changes.

9.1.1.2 Identification of statistical tools

The organization shall determine the appropriate use of statistical tools. The organization shall verify that appropriate statistical tools are included as part of the advanced product quality planning (or equivalent) process and included in the design risk analysis (such as DFMEA) (where applicable), the process risk analysis (such as PFMEA), and the control plan.

8.7.2

见 ISO 9001:2015 的要求。

9 绩效评价

9.1 监视、测量、分析和评价

9.1.1 总则

见 ISO 9001:2015 的要求。

9.1.1.1 制造过程的监视和测量

组织应对所有新的制造（包括装配或排序）进行过程研究，以验证过程能力，并为过程控制提供附加的输入，包括有特殊特性的过程。

注：在一些制造过程中，可能无法通过过程能力证实产品的符合性。对于这些过程，可采用替代方法，如：批次对规范的符合性。

组织应保持由顾客零件批准过程要求所规定的制造过程能力或绩效。组织应验证已实施了过程流程图、PFMEA 和控制计划，包括遵守规定的：

- a) 测量技术；
- b) 抽样计划；
- c) 接收准则；
- d) 计量数据实际测量值和/或试验结果的记录；
- e) 当不满足接收准则时的反应计划和升级过程。

应记录重要的过程活动，如更换工具或修理机器等，并将其当作形成文件的信息予以保留。

组织应对统计能力不足或不稳定的特性启动已在控制计划中标识，并且经过规范符合性影响评价的反应计划。这些反应计划应包括适当时的产品遏制和 100% 检验。为确保过程变得稳定且有统计能力，组织应制定并实施一份显示明确进度、时程安排和指派责任的纠正措施计划。当被要求时，此计划应由顾客评审和审批。

组织应保持过程变更生效日期的记录。

9.1.1.2 统计工具的确定

组织应确定统计工具的恰当使用。组织应验证产品质量先期策划（或等效策划）过程中包含了适当的统计工具，作为策划的一部分，并且适当的统计工具还包含在设计风险分析（如 DFMEA）（适用时）、过程风险分析（如 PFMEA）和控制计划中。

9.1.1.3 Application of statistical concepts

Statistical concepts, such as variation, control (stability), process capability, and the consequences of over-adjustment, shall be understood and used by employees involved in the collection, analysis, and management of statistical data.

9.1.2 Customer satisfaction

See ISO 9001:2015 requirements.

9.1.2.1 Customer satisfaction – supplemental

Customer satisfaction with the organization shall be monitored through continual evaluation of internal and external performance indicators to ensure compliance to the product and process specifications and other customer requirements.

Performance indicators shall be based on objective evidence and include but not be limited to the following:

- a) delivered part quality performance;
- b) customer disruptions;
- c) field returns, recalls, and warranty (where applicable);
- d) delivery schedule performance (including incidents of premium freight);
- e) customer notifications related to quality or delivery issues, including special status.

The organization shall monitor the performance of manufacturing processes to demonstrate compliance with customer requirements for product quality and process efficiency. The monitoring shall include the review of customer performance data including online customer portals and customer scorecards, where provided.

9.1.3 Analysis and evaluation

See ISO 9001:2015 requirements.

9.1.3.1 Prioritization

Trends in quality and operational performance shall be compared with progress toward objectives and lead to action to support prioritization of actions for improving customer satisfaction.

9.2 Internal audit

9.2.1 AND 9.2.2

See ISO 9001:2015 requirements.

9.1.1.3 统计概念的应用

从事统计数据收集、分析和管理的员工应了解和使用统计概念，例如：变差、控制（稳定性）、过程能力和过度调整后果。

9.1.2 顾客满意

见 ISO 9001:2015 的要求。

9.1.2.1 顾客满意——补充

应通过对内部和外部绩效指标的持续评价来监视顾客对组织的满意度，以确保符合产品和过程规范及其它顾客要求。

绩效指标应基于客观证据，包括但不限于：

- a) 已交付零件的质量绩效；
- b) 对顾客造成的干扰；
- c) 使用现场退货、召回和保修（在适用情况下）；
- d) 交付时间安排的绩效（包括超额运费的情况）；
- e) 与质量或交付问题有关的顾客通知，包括特殊状态。

组织应监视制造过程的绩效以证明符合顾客对产品质量和过程效率的要求。监视应包括顾客绩效数据的评审，其中包含所提供的在线顾客门户和顾客计分卡。

9.1.3 分析和评价

见 ISO 9001:2015 的要求。

9.1.3.1 优先级

质量和运行绩效的趋势应与朝向目标的进展来进行比较，并形成措施以支持顾客满意度改进措施的优先级。

9.2 内部审核

9.2.1 和 9.2.2

见 ISO 9001:2015 的要求。

9.2.2.1 Internal audit programme

The organization shall have a documented internal audit process. The process shall include the development and implementation of an internal audit programme that covers the entire quality management system including quality management system audits, manufacturing process audits, and product audits.

The audit programme shall be prioritized based upon risk, internal and external performance trends, and criticality of the process(es).

Where the organization is responsible for software development, the organization shall include software development capability assessments in their internal audit programme.

The frequency of audits shall be reviewed and, where appropriate, adjusted based on occurrence of process changes, internal and external nonconformities, and/or customer complaints. The effectiveness of the audit programme shall be reviewed as a part of management review.

9.2.2.2 Quality management system audit

The organization shall audit all quality management system processes over each three-year calendar period, according to an annual programme, using the process approach to verify compliance with this Automotive QMS Standard. Integrated with these audits, the organization shall sample customer-specific quality management system requirements for effective implementation.

9.2.2.3 Manufacturing process audit

The organization shall audit all manufacturing processes over each three-year calendar period to determine their effectiveness and efficiency using customer-specific required approaches for process audits. Where not defined by the customer, the organization shall determine the approach to be used.

Within each individual audit plan, each manufacturing process shall be audited on all shifts where it occurs, including the appropriate sampling of the shift handover.

The manufacturing process audit shall include an audit of the effective implementation of the process risk analysis (such as PFMEA), control plan, and associated documents.

9.2.2.4 Product audit

The organization shall audit products using customer-specific required approaches at appropriate stages of production and delivery to verify conformity to specified requirements. Where not defined by the customer, the organization shall define the approach to be used.

9.3 Management review

9.3.1 General

See ISO 9001:2015 requirements.

9.2.2.1 内部审核方案

组织应有一个形成文件的内部审核过程。该过程应包括制定并实施一个涵盖整个质量管理体系的内部审核方案，其中包含质量管理体系审核、制造过程审核和产品审核。

应根据风险、内部和外部绩效趋势和过程的关键程度确定审核方案的优先级。

在负责软件开发的情况下，组织应在其内部审核方案中包含软件开发能力评估。

应对审核频率进行评审，并在适当时，根据发生的过程更改、内部和外部不符合及/或顾客投诉进行调整。应对审核方案有效性进行评审，作为管理评审的一部分。

9.2.2.2 质量管理体系审核

组织应根据年度方案，每三个日历年采用过程方法审核一次全部的质量管理体系过程，以验证与本汽车 QMS 标准的符合性。结合这些审核，组织应对顾客特定的质量管理体系要求进行抽样，检查是否得到有效实施。

9.2.2.3 制造过程审核

组织应采用顾客特定要求的过程审核方法，每三个日历年审核一次全部制造过程，以确定其有效性和效率。如果顾客未指定，组织应确定要采用的审核方法。

在每个审核计划内，每个制造过程的审核应涵盖所有发生的班次，包括适当的交接班抽样。

制造过程审核应包括对过程风险分析（如 PFMEA）、控制计划和相关文件有效执行的审核。

9.2.2.4 产品审核

组织应采用顾客特定要求的方法，在生产及交付的适当阶段对产品进行审核，以验证对所规定要求的符合性。如果顾客未指定，组织应确定要采用的审核方法。

9.3 管理评审

9.3.1 总则

见 ISO 9001:2015 的要求。

9.3.1.1 Management review - supplemental

Management review shall be conducted at least annually. The frequency of management review(s) shall be increased based on risk to compliance with customer requirements resulting from internal or external changes impacting the quality management system and performance-related issues.

9.3.2 Management review inputs

See ISO 9001:2015 requirements.

9.3.2.1 Management review inputs - supplemental

Input to management review shall include:

- a) cost of poor quality (cost of internal and external nonconformance);
- b) measures of process effectiveness;
- c) measures of process efficiency;
- d) product conformance;
- e) assessments of manufacturing feasibility made for changes to existing operations and for new facilities or new product (see Section 7.1.3.1);
- f) customer satisfaction (see ISO 9001, Section 9.1.2);
- g) review of performance against maintenance objectives;
- h) warranty performance (where applicable);
- i) review of customer scorecards (where applicable);
- j) identification of potential field failures identified through risk analysis (such as FMEA);
- k) actual field failures and their impact on safety or the environment.

9.3.3 Management review outputs

See ISO 9001:2015 requirements.

9.3.3.1 Management review outputs – supplemental

Top management shall document and implement an action plan when customer performance targets are not met.

9.3.1.1 管理评审——补充

管理评审应至少每年进行一次。应基于由影响质量管理体系和绩效相关问题的内部或外部更改造成的顾客要求符合性的风险，提高管理评审的频率。

9.3.2 管理评审输入

见 ISO 9001:2015 的要求。

9.3.2.1 管理评审输入——补充

管理评审的输入应包括：

- a) 不良质量成本（内部和外部不符合成本）；
- b) 过程有效性的衡量；
- c) 过程效率的衡量；
- d) 产品符合性；
- e) 对现有操作更改和新设施或新产品进行的制造可行性评估（见第 7.1.3.1 条）；
- f) 顾客满意（见 ISO 9001 第 9.1.2 条）；
- g) 对照维护目标的绩效评审；
- h) 保修绩效（在适用情况下）；
- i) 顾客计分卡评审（在适用情况下）；
- j) 通过风险分析（如 FMEA）识别的潜在使用现场失效标识；
- k) 实际使用现场失效及其对安全或环境的影响。

9.3.3 管理评审输出

见 ISO 9001:2015 的要求。

9.3.3.1 管理评审输出——补充

当未实现顾客绩效目标时，最高管理者应形成一个文件化的措施计划并实施。

10 Improvement

10.1 General

See ISO 9001:2015 requirements.

10.2 Nonconformity and corrective action

10.2.1 and 10.2.2

See ISO 9001:2015 requirements.

10.2.3 Problem solving

The organization shall have a documented process(es) for problem solving including:

- a) defined approaches for various types and scale of problems (e.g., new product development, current manufacturing issues, field failures, audit findings);
- b) containment, interim actions, and related activities necessary for control of nonconforming outputs (see ISO 9001, Section 8.7);
- c) root cause analysis, methodology used, analysis, and results;
- d) implementation of systemic corrective actions, including consideration of the impact on similar processes and products;
- e) verification of the effectiveness of implemented corrective actions;
- f) reviewing and, where necessary, updating the appropriate documented information (e.g., PFMEA, control plan).

Where the customer has specific prescribed processes, tools, or systems for problem solving, the organization shall use those processes, tools, or systems unless otherwise approved by the customer.

10.2.4 Error-proofing

The organization shall have a documented process to determine the use of appropriate error-proofing methodologies. Details of the method used shall be documented in the process risk analysis (such as PFMEA) and test frequencies shall be documented in the control plan.

The process shall include the testing of error-proofing devices for failure or simulated failure. Records shall be maintained. Challenge parts, when used, shall be identified, controlled, verified, and calibrated where feasible. Error-proofing device failures shall have a reaction plan.

10.2.5 Warranty management systems

When the organization is required to provide warranty for their product(s), the organization shall implement a warranty management process. The organization shall include in the process a method for warranty part analysis, including NTF (no trouble found). When specified by the customer, the organization shall implement the required warranty management process.

10 改进

10.1 总则

见 ISO 9001:2015 的要求。

10.2 不符合和纠正措施

10.2.1 和 10.2.2

见 ISO 9001:2015 的要求。

10.2.3 问题解决

组织应有形成文件的问题解决过程，包括：

- a) 用于各种类型和规模的问题（如：新产品开发、当前制造问题、使用现场失效、审核发现）的明确方法；
- b) 控制不符合输出所必要的遏制、临时措施及相关活动（见 ISO 9001 第 8.7 条）；
- c) 根本原因分析、采用的方法、分析及结果；
- d) 系统性纠正措施的实施，包括考虑对相似过程和产品的影响；
- e) 对已实施纠正措施有效性的验证；
- f) 对适当形成文件的信息（如：PFMEA、控制计划）的评审，必要时进行更新。

若顾客对问题解决有特别规定的过程、工具或系统，组织应采用这些过程、工具或系统，除非顾客另行批准。

10.2.4 防错

组织应有一个形成文件的过程，用于确定适当防错方法的使用。所采用方法的详细信息应在过程风险分析中（如 PFMEA）形成文件，试验频率应记录在控制计划中。

过程应包括防错装置失效或模拟失效的试验。应保持记录。若使用挑战件，则应在可行时对挑战件进行标识、控制、验证和校准。防错装置失效应有一个反应计划。

10.2.5 保修管理体系

当组织被要求为其产品提供保修时，组织应实施一个保修管理过程。组织应在该过程中包含一个保修件分析法，包括 NTF（未发现故障）。当顾客指定时，组织应实施所要求的保修管理过程。

10.2.6 Customer complaints and field failure test analysis

The organization shall perform analysis on customer complaints and field failures, including any returned parts, and shall initiate problem solving and corrective action to prevent recurrence.

Where requested by the customer, this shall include analysis of the interaction of embedded software of the organization's product within the system of the final customer's product.

The organization shall communicate the results of testing/analysis to the customer and also within the organization.

10.3 Continual improvement

See ISO 9001:2015 requirements.

10.3.1 Continual improvement - supplemental

The organization shall have a documented process for continual improvement. The organization shall include in this process the following:

- a) identification of the methodology used, objectives, measurement, effectiveness, and documented information;
- b) a manufacturing process improvement action plan with emphasis on the reduction of process variation and waste;
- c) risk analysis (such as FMEA).

NOTE Continual improvement is implemented once manufacturing processes are statistically capable and stable or when product characteristics are predictable and meet customer requirements.

10.2.6 顾客投诉和使用现场失效试验分析

组织应对顾客投诉和使用现场失效，包括退货零件，进行分析，并且应采取问题解决和纠正措施以预防再次发生。

在顾客要求的情况下，这应包括最终顾客产品系统内，组织产品嵌入式软件相互作用的分析。

组织应向顾客并且在组织内部传达试验/分析的结果。

10.3 持续改进

见 ISO 9001:2015 的要求。

10.3.1 持续改进——补充

组织应有一个形成文件的持续改进过程。组织在本过程中包括以下内容：

- a) 对所采用方法、目标、测量、有效性和形成文件的信息的识别；
- b) 一个制造过程改进行动计划，重点放在减少过程变差和浪费。
- c) 风险分析（例如 FMEA）。

注：持续改进是当过程有统计能力且稳定，或者产品特性为可预测且满足顾客要求时实施的。

Annex A: Control Plan

A.1 Phases of the control plan

A control plan covers three distinct phases, as appropriate:

- a) **Prototype:** a description of the dimensional measurements, material, and performance tests that will occur during building of the prototype. The organization shall have a prototype control plan, if required by the customer.
- b) **Pre-launch:** a description of the dimensional measurements, material, and performance tests that occur after prototype and before full production. Pre-launch is defined as a production phase in the process of product realization that may be required after prototype build.
- c) **Production:** documentation of product/process characteristics, process controls, tests, and measurement systems that occur during mass production.

Control plans are established at a part number level; but in many cases, family control plans may cover a number of similar parts produced using a common process. Control plans are an output of the quality plan.

NOTE 1 It is recommended that the organization require its suppliers to meet the requirements of this Annex.

NOTE 2 For some bulk materials, the control plans do not list most of the production information. This information can be found in the corresponding batch formulation/recipe details.

A.2 Elements of the control plan

A control plan includes, as a minimum, the following contents:

General data

- a) control plan number
- b) issue date and revision date, if any
- c) customer information (see customer requirements)
- d) organization's name/site designation
- e) part number(s)
- f) part name/description
- g) engineering change level
- h) phase covered (prototype, pre-launch, production)
- i) key contact
- j) part/process step number
- k) process name/operation description
- l) functional group/area responsible

附录 A: 控制计划

A.1 控制计划的阶段

适当时，控制计划涵盖三个不同阶段：

- a) **原型样件 (Prototype)**：对将会出现在原型样件制造中的尺寸测量、材料和性能试验的描述。如果顾客要求，组织应有原型样件控制计划。
- b) **投产前 (Pre-launch)**：对将会出现在原型样件制造后和全面生产前的尺寸测量、材料和性能试验的描述。投产前被定义为在原型样件制造后产品实现过程中可能要求的一个生产阶段。
- c) **生产 (Production)**：出现在大规模生产中的产品/过程特性、过程控制、试验和测量系统的文件。

每个零件编号有一个控制计划；但是在很多案例中，一个控制计划族可以涵盖采用了共同过程所生产的这类相似零件。控制计划是质量计划的输出。

注 1：建议组织要求其供应商满足本附录的要求。

注 2：对于某些散装材料，大部分生产信息不在控制计划中列出。可在相应的批次配方详情中获得此类信息。

A.2 控制计划的要素

控制计划至少包括以下内容：

综合资料

- a) 控制计划编号
- b) 发布日期和修订日期，如有
- c) 顾客信息（见顾客要求）
- d) 组织名称/现场的编号
- e) 零件编号
- f) 零件名称/描述
- g) 工程更改等级
- h) 涵盖的阶段（原型样件制造、投产前、生产）
- i) 关键联络人
- j) 零件/过程步骤编号
- k) 过程名称/作业描述
- l) 负责的功能组/区域

Product control

- a) product-related special characteristics
- b) other characteristics for control (number, product or process)
- c) specification/tolerance

Process control

- a) process parameters (including process settings and tolerances)
- b) process-related special characteristics
- c) machines, jigs, fixtures, tools for manufacturing (including identifiers, as appropriate)

Methods

- a) evaluation measurement technique
- b) error-proofing
- c) sample size and frequency
- d) control method

Reaction plan

- a) reaction plan (include or reference)

A.2 Elements

A control plan

General data

- a) control plan
- b) issue control
- c) control plan
- d) control plan
- e) control plan
- f) control plan
- g) control plan
- h) control plan
- i) control plan
- j) control plan
- k) control plan
- l) control plan
- m) control plan
- n) control plan
- o) control plan
- p) control plan
- q) control plan
- r) control plan
- s) control plan
- t) control plan
- u) control plan
- v) control plan
- w) control plan
- x) control plan
- y) control plan
- z) control plan

产品控制

- a) 与产品有关的特殊特性
- b) 其它要控制的特性（编号、产品或过程）
- c) 规范/公差

过程控制

- a) 过程参数
- b) 与过程有关的特殊特性
- c) 制造用机器、卡具、夹具、工装（适当时还包括标识符）

方法

- a) 评价测量技术
- b) 防错
- c) 样本容量和抽样频次
- d) 控制方法

反应计划

- a) 反应计划（包括或引用）

ANNEX B: Bibliography – supplemental automotive

Internal audit

AIAG

- CQI-8 Layered Process Audit
- CQI-9 Special Process: Heat Treatment System Assessment
- CQI-11 Special Process: Plating System Assessment
- CQI-12 Special Process: Coating System Assessment
- CQI-15 Special Process: Welding System Assessment
- CQI-17 Special Process: Soldering System Assessment
- CQI-23 Special Process: Molding System Assessment
- CQI-27 Special Process: Casting System Assessment

ANFIA

- AQ 008 Process Audit

FIEV

- V2.0 Production Process Audit Manual

IATF

- Auditor Guide for IATF 16949

VDA

- Volume 6 part 3 Process Audit
- Volume 6 part 5 Product Audit

Nonconformity and corrective action

AIAG

- CQI-14 Automotive Warranty Management Guideline
- CQI-20 Effective Problem Solving Practitioner Guide

VDA

- Volume "Audit standard field failure analysis"
- Volume "Field failures analysis"

Measurement system analysis

AIAG

- Measurement Systems Analysis (MSA)

ANFIA

- AQ 024 MSA Measurement Systems Analysis

附录 B: 参考书目——汽车行业补充

内部审核

AIAG

- 《CQI-8 分层过程审核》
- 《CQI-9 特殊过程：热处理系统评估》
- 《CQI-11 特殊过程：电镀系统评估》
- 《CQI-12 特殊过程：涂装系统评估》
- 《CQI-15 特殊过程：焊接系统评估》
- 《CQI-17 特殊过程：锡焊系统评估》
- 《CQI-23 特殊过程：模塑系统评估》
- 《CQI-27 特殊过程：铸造系统评估》

ANFIA

- 《AQ 008 过程审核》

FIEV

- 《生产过程审核手册》V2.0

IATF

- 《IATF 16949 审核员指南》

VDA

- 第 6 卷第 3 部分“过程审核”
- 第 6 卷第 5 部分“产品审核”

不符合和纠正措施

AIAG

- 《CQI-14 汽车保修管理指南》
- 《CQI-20 有效解决问题的从业者指南》

VDA

- “审核标准使用现场失效分析”卷
- “使用现场失效分析”卷

测量系统分析

AIAG

- 测量系统分析 (MSA)

ANFIA

- 《AQ 024 测量系统分析 (MSA)》

VDA

Volume 5 "Capability of Measuring Systems"

Product approval

AIAG

Production Part Approval Process (PPAP)

VDA

Volume 2 Production process and product approval (PPA)

Volume 19 Part 1 ("Inspection of Technical Cleanliness - Particulate Contamination of Functionally Relevant Automotive Components")

Volume 19 Part 2 ("Technical cleanliness in assembly - Environment, Logistics, Personnel and Assembly Equipment")

Product design

AIAG

APQP and Control Plan

CQI-24 Design Review Based on Failure Modes (DRBFM Reference Guide)

Potential Failure Mode & Effects Analysis (FMEA)

ANFIA

AQ 009 FMEA

AQ 014 Manual of Experimental Design

AQ 025 Reliability Guide

VDA

Volume 4 Chapter Product and Process FMEA

Volume VDA-RGA "Maturity Level Assurance for New Parts"

Volume "Robust Production Process"

Volume Special Characteristics (SC)

Production control

AIAG

MMOG/LE Materials Management Operational Guidelines / Logistics Evaluation

SMMT

Implementing Standardised Work

VDA

第 5 卷 “测量系统能力”

产品批准

AIAG

生产件批准程序 (PPAP)

VDA

第 2 卷 “生产过程和产品批准 (PPA)”

第 19 卷第 1 部分 (“技术清洁度检验——汽车功能部件的颗粒污染”)

第 19 卷第 2 部分 (“装配技术清洁度——环境、物流、人员和装配设备”)

产品设计

AIAG

APQP 和控制计划

《CQI-24 基于失效模式的设计审核》(DRBFM 参考指南)

潜在失效模式及后果分析 (FMEA)

ANFIA

AQ 009 FMEA

《AQ 014 实验设计手册》

《AQ 025 可靠性指南》

VDA

第 4 卷 “产品和过程 FMEA” 章

VDA-RGA 卷 “新零件成熟度等级保证”

“稳健生产过程” 卷

“特殊特性 (SC)” 卷

生产控制

AIAG

《材料管理操作指南》/《物流评价》(MMOG/LE)

SMMT

《实施标准化作业》

Quality management system administration

ANFIA

AQ 026 Managing and improving the process

IATF

Rules for achieving and maintaining IATF recognition

Risk analysis

VDA

Volume 4 "Ring-binder" (elementary aids, risk analyses, methods, and process models)

Software Process Assessment

Capability Maturity Model Integration (CMMI)

VDA

Automotive SPICE® (Software Process Improvement and Capability Determination)

Statistical tools

AIAG

Statistical Process Control (SPC)

ANFIA

AQ 011 SPC

Supplier quality management

AIAG

CQI-19 Sub-Tier Supplier Management Process Guideline

IATF

Minimum Automotive Quality Management System Requirements for Sub-Tier Suppliers (MAQMSR)

Health and safety

ISO

ISO 45001 Occupational health and safety management systems

质量管理体系的管理

ANFIA

《AQ 026 过程的管理和改进》

IATF

《获得并保持 IATF 认可的规则》

风险分析

VDA

第 4 卷“活页夹”（基本帮助、风险分析、方法和过程模型）

软件过程评估

能力成熟度模型集成（CMMI）

VDA

汽车 SPICE®（软件过程改进和能力测定）

统计工具

AIAG

统计过程控制（SPC）

ANFIA

AQ 011 SPC

供应商质量管理

AIAG

《CQI-19 次级供应商管理过程指南》

IATF

《次级供应商最低汽车质量管理体系要求》（MAQMSR）

健康与安全

ISO

《ISO 45001 职业健康安全管理体系》