AUTOMOTIVE QUALITY MANAGEMENT SYSTEM STANDARD

IATF 16949

汽车质量管理体系标准

Quality management system requirements for automotive production and relevant service parts organizations

汽车生产件及相关服务件组织的质量管理体系要求

International Automotive Task Force

国际汽车推动小组

1st Edition第一版

1 October2016年10月1日

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Table of Contents 目录

Table Of Contents	**目录**	**3**
Foreword -Automotive Qms Standard	**前言----汽车质量管理体系标准**	9
History	**历史**	9
Goal	**目标**	10
Remarks For Certification	**有关认证的说明**	10
Introduction	**引言**	11
0.1 General	**0.1 总则**	11
0.2 Quality Management Principles	**0.2 质量管理原则**	12
0.3 Process Approach	**0.3 过程方法**	13
0.3.1 General	**0.3.1 总则**	13
0.3.2 Plan-Do-Check-Act Cycle	**0.3.2 计划 - 执行 - 检查 - 处理循环**	15
0.3.3 Risk-Based Thinking	**0.3.3 基于风险的思维**	16
0.4Relationship With Other Management System Standards	**0.4 与其他管理体系标准的关系**	16
Quality Management Systems —Requirements	**质量管理体系----要求**	18
1 Scope 1.1 Scope -Automotive Supplemental To Iso 9001:2015	**1.范围** 1.1 范围----汽车行业对ISO9001:2015补充	18
2 Normative References 2.1 Normative And Informative References	**2. 引用标准** 2.1 规范性引用标准和参考性引用标准	19
3 Terms And Definitions 3.1 Terms And Definitions For The Automotive Industry	**3. 术语和定义** 3.1 汽车行业的术语和定义	20
4 Context Of The Organization	**4. 组织的背景环境**	**26**
4.1 Understanding The Organization And Its Context	**4.1 理解组织及其背景环境**	26
4.2 Understanding The Needs And Expectations Of Interested Parties	**4.2 理解相关方的需求和期望**	26
4.3 Determining The Scope Of The Quality Management System 4.3.1 Determining The Scope Of The Quality Management System -Supplemental 4.3.2 Customer-Specific Requirements	**4.3 确定质量管理体系范围** 4.3.1 确定质量管理体系范围----补充 4.3.2 顾客特定要求	27
4.4 Quality Management System And Its Processes **4.4.1** 4.4.1.1 Conformance Of Products And Processes 4.4.1.2 Product Safety	**4.4 质量管理体系及其过程** **4.4.1** 4.4.1.1 产品和过程的符合性 4.4.1.2 产品安全	28
4.4.2	**4.4.2**	30

Table of Contents 目录

5 LEADERSHIP	**5. 领导作用**	**31**
5.1 LEADERSHIP AND COMMITMENT	**5.1 领导作用与承诺**	31
5.1.1 GENERAL 5.1.1.1 Corporate responsibility 5.1.1.2 Process effectiveness and efficiency 5.1.1.3 Process owners	**5.1.1 总则** 5.1.1.1 公司责任 5.1.1.2 过程有效性和效率 5.1.1.3 过程拥有者	31
5.1.2 CUSTOMER FOCUS	**5.1.2 以顾客为关注焦点**	32
5.2 POLICY	**5.2 方针**	32
5.2.1 ESTABLISHING THE QUALITY POLICY	**5.2.1 建立质量方针**	32
5.2.2 COMMUNICATING THE QUALITY POLICY	**5.2.2 沟通质量方针**	33
5.3 ORGANIZATIONAL ROLES, RESPONSIBILITIES AND AUTHORITIES 5.3.1 Organizational roles, responsibilities, and authorities -supplemental 5.3.2 Responsibility and authority for product requirements and corrective actions	**5.3 组织的作用、职责和权限** 5.3.1组织的作用、职责和权限-补充 5.3.2 产品要求和纠正措施的职责和权限	33 34 34
6 PLANNING	**6. 策划**	**35**
6.1 ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES	**6.1 应对风险和机遇的措施**	**35**
6.1.1 AND 6.1.2 6.1.2.1 Risk analysis 6.1.2.2 Preventive action 6.1.2.3 Contingency plans	**6.1.1和6.1.2** 6.1.2.1 风险分析 6.1.2.2 预防措施 6.1.2.3 应急计划	35 36 36 36
6.2 QUALITY OBJECTIVES AND PLANNING TO ACHIEVE THEM	**6.2 质量目标及其实施策划**	37
6.2.1 AND 6.2.2 6.2.2.1 Quality objectives and planning to achieve them -supplemental	**6.2.1 和 6.2.2** 6.2.2.1质量目标及其实施策划-补充	37
6.3 PLANNING OF CHANGES	**6.3 更改的策划**	38
7 SUPPORT	**7. 支持**	39
7.1 RESOURCES	**7.1 资源**	39
7.1.1 GENERAL	**7.1.1 总则**	39
7.1.2 PEOPLE	**7.1.2 人员**	39
7.1.3 INFRASTRUCTURE 7.1.3.1 Plant, facility, and equipment planning	**7.1.3 基础设施** 7.1.3.1 工厂、设施及设备策划-补充	39 40
7.1.4 ENVIRONMENT FOR THE OPERATION OF PROCESSES 7.1.4.1 Environment for the operation of processes -supplemental	**7.1.4 过程操作的环境** 7.1.4.1**过程操作的环境**	40 41
7.1.5 MONITORING AND MEASURING RESOURCES **7.1.5.1 GENERAL** 7.1.5.1.1 Measurement systems analysis	**7.1.5 监视和测量资源** **7.1.5.1总则** 7.1.5.1.1 测量系统分析	41

7.1.5.2 MEASUREMENT TRACEABILITY 7.1.5.2.1 Calibration/verification records	**7.1.5.2 测量可追溯性** 7.1.5.2.1 校准/验证记录	42

Table of Contents 目录

7.1.5.3 Laboratory Requirements 7.1.5.3.1 Internal Laboratory 7.1.5.3.2 External Laboratory	**7.1.5.3 实验室要求** 7.1.5.3.1 内部实验室 7.1.5.3.2 外部实验室	43 43 44
7.1.6 Organizational Knowledge	**7.1.6 组织知识**	44
7.2 Competence 7.2.1 Competence -Supplemental 7.2.2 Competence -On-The-Job Training 7.2.3 Internal Auditor Competency 7.2.4 Second-Party Auditor Competency	**7.2 能力** 7.2.1 能力-补充 7.2.2 能力-在职培训 7.2.3 内部审核员能力 7.2.4 第二方审核员能力	45 45 46 46 47
7.3 Awareness 7.3.1 Awareness -Supplemental 7.3.2 Employee Motivation And Empowerment	**7.3 意识** 7.3.1 意识-补充 7.3.2 员工激励和授权	47 48 48
7.4 Communication	**7.4 沟通**	48
7.5 Documented Information	**7.5 形成文件的信息**	48
7.5.1 General 7.5.1.1 Quality Management System Documentation	**7.5.1 总则** 7.5.1.1 质量管理体系文件	48 49
7.5.2 Creating And Updating	**7.5.2 编制和更新**	50
7.5.3 Control Of Documented Information	**7.5.3 形成文件的信息的控制**	50
7.5.3.1 And 7.5.3.2 7.5.3.2.1 Record Retention 7.5.3.2.2 Engineering Specifications	**7.5.3.1 和 7.5.3.2** 7.5.3.2.1 记录保留 7.5.3.2.2 工程规范	50 51 51
8 OPERATION	**8. 运行**	52
8.1 Operational Planning And Control 8.1.1 Operational Planning And Control -Supplemental 8.1.2 Confidentiality	**8.1 运行策划和控制** 8.1.1运行策划和控制-补充 8.1.2 保密	52 52 53
8.2 Requirements For Products And Services	**8.2 产品和服务要求**	53
8.2.1 Customer Communication 8.2.1.1 Customer Communication -Supplemental	**8.2.1 顾客沟通** 8.2.1.1 顾客沟通-补充	53 53
8.2.2 Determining The Requirements For Products And Services 8.2.2.1 Determining The Requirements For Products And Services -Supplemental	**8.2.2 产品和服务要求的确定** 8.2.2.1产品和服务要求的确定—补充	54 54
8.2.3 Review Of The Requirements For Products And Services	**8.2.3 产品和服务要求的评审**	54
8.2.3.1 8.2.3.1.1 Review Of The Requirements For Products And Services -Supplemental 8.2.3.1.2 Customer-Designated Special Characteristics 8.2.3.1.3 Organization Manufacturing Feasibility	**8.2.3.1** 8.2.3.1.1**产品和服务要求的评审**-补充 8.2.3.1.2 顾客指定的特殊特性 8.2.3.1.3 组织制造可行性	54 55 55 55
8.2.3.2	**8.2.3.2**	56

Table of Contents 目录

8.2.4 Changes To Requirements For Products And Services	**8.2.4 产品和服务要求的更改**	56
8.3 Design And Development Of Products And Services	**8.3 产品和服务的设计和开发**	56
8.3.1 General 8.3.1.1Design And Development Of Products And Services -Supplemental	**8.3.1 总则** 8.3.1.1**产品和服务的设计和开发**-补充	56
8.3.2 Design And Development Planning	**8.3.2产品和服务策划**	57
8.3.2.1 Design And Development Planning -Supplemental	8.3.2.1 产品和服务策服-补充	57
8.3.2.2 Product Design Skills	8.3.2.2产品设计技能	58
8.3.2.3 Development Of Products With Embedded Software	8.3.2.3带有嵌入式软件的产品的开发	58
8.3.3 Design And Development Inputs	**8.3.3 设计和开发输入**	58
8.3.3.1 Product Design Input	8.3.3.1 产品设计输入	59
8.3.3.2 Manufacturing Process Design Input	8.3.3.2 制造过程输入	60
8.3.3.3 Special Characteristics	8.3.3.3 特殊特性	60
8.3.4 Design And Development Controls	**8.3.4 设计和开发控制**	61
8.3.4.1 Monitoring	8.3.4.1 监视	61
8.3.4.2 Design And Development Validation	8.3.4.2 设计和开发确认	62
8.3.4.3 Prototype Programme	8.3.4.3原型样件方案	62
8.3.4.4 Product Approval Process	8.3.4.4 产品批准过程	62
8.3.5 Design And Development Outputs	**8.3.5 设计和开发输出**	63
8.3.5.1 Design And Development Outputs -Supplemental	8.3.5.1设计和开发输出-补充	63
8.3.5.2 Manufacturing Process Design Output	8.3.5.2 制造过程设计输出	64
8.3.6 Design And Development Changes	**8.3.6 设计和开发更改**	64
8.3.6.1 Design And Development Changes -Supplemental	8.3.6.1设计和开发更改-补充	65
8.4 Control Of Externally Provided Processes, Products And Services	**8.4外部提供的过程、产品和服务的控制**	65
8.4.1 General	**8.4.1 总则**	65
8.4.1.1 General -Supplemental	8.4.1.1总则-补充	66
8.4.1.2 Supplier Selection Process	8.4.1.2供应商选择过程	66
8.4.1.3 Customer-Directed Sources (Also Known As "Directed–Buy")	8.4.1.3顾客指定的货源	67
8.4.2 Type And Extent Of Control	**8.4.2 控制的类型和程度**	67
8.4.2.1 Type And Extent Of Control -Supplemental	8.4.2.1 控制的类型和程度-补充	68
8.4.2.2 Statutory And Regulatory Requirements	8.4.2.2 法律法规要求	68
8.4.2.3 Supplier Quality Management System Development	8.4.2.3 供应商质量管理体系开发	68
8.4.2.3.1 Automotive Product-Related Software Or Automotive Products With Embedded Software	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	69
8.4.2.4 Supplier Monitoring	8.4.2.4 供应商监视	69
8.4.2.4.1 Second-Party Audits	8.4.2.4.1 第二方审核	70
8.4.2.5 Supplier Development	8.4.2.5 供应商开发	70
8.4.3 Information For External Providers	**8.4.3 外部供方的信息**	71
8.4.3.1 Information For External Providers -Supplemental	8.4.3.1 外部供方的信息-补充	71
8.5 Production And Service Provision	**8.5 生产和服务提供**	72

8.5.1 Control Of Production And Service Provision	**8.5.1 生产和服务提供的控制**	72

Table of Contents 目录

8.5.1.1 Control Plan	8.5.1.1 控制计划	73
8.5.1.2 Standardized Work -Operator Instructions And Visual Standards	8.5.1.2 标准化作业-操作指导书和目视管理	74
8.5.1.3 Verification Of Job Set-Ups	8.5.1.3 作业准备的验证	74
8.5.1.4 Verification After Shutdown	8.5.1.4 停工后的验证	74
8.5.1.5 Total Productive Maintenance	8.5.1.5 全面生产维护	75
8.5.1.6 Management Of Production Tooling And Manufacturing, Test, Inspection Tooling And Equipment	8.5.1.6 生产工装及制造、试验、检验工装和设备的管理	75
8.5.1.7 Production Scheduling	8.5.1.7生产排程	76
8.5.2 Identification And Traceability	**8.5.2 标识和可追溯性**	76
8.5.2.1 Identification And Traceability -Supplemental	8.5.2.1 标识和可追溯性-补充	77
8.5.3 Property Belonging To Customers Or External Providers	**8.5.3 属于顾客或外部供方的财产**	78
8.5.4 Preservation	**8.5.4 防护**	78
8.5.4.1 Preservation -Supplemental	8.5.4.1 防护-补充	79
8.5.5 Post-Delivery Activities	**8.5.5 交付后活动**	79
8.5.5.1 Feedback Of Information From Service	8.5.5.1 服务信息的反馈	80
8.5.5.2 Service Agreement With Customer	8.5.5.2 与顾客的服务协议	80
8.5.6 Control Of Changes	**8.5.6 更改的控制**	80
8.5.6.1 Control Of Changes -Supplemental	8.5.6.1 更改的控制-补充	81
8.5.6.1.1 Temporary Change Of Process Controls	8.5.6.1.1 过程控制的临时更改	81
8.6 Release Of Products And Services	**8.6 产品和服务的放行**	82
8.6.1 Release Of Products And Services -Supplemental	**8.6.1 产品和服务的放行-补充**	83
8.6.2 Layout Inspection And Functional Testing	**8.6.2 全尺寸检验和功能实验**	83
8.6.3 Appearance Items	**8.6.3 外观项目**	83
8.6.4 Verification And Acceptance Of Conformity Of Externally Provided Products And Services	**8.6.4 外部提供的产品和服务符合性验证和接受**	84
8.6.5 Statutory And Regulatory Conformity	**8.6.5 法律法规的符合性**	84
8.6.6 Acceptance Criteria	**8.6.6 接收准则**	84
8.7 Control Of Nonconforming Outputs	**8.7 不符合输出的控制**	84
8.7.1	**8.7.1**	84
8.7.1.1 Customer Authorization For Concession	8.7.1.1 顾客的让步授权	85
8.7.1.2 Control Of Nonconforming Product -Customer-Specified Process	8.7.1.2 不合格品的控制-顾客规定的过程	85
8.7.1.3 Control Of Suspect Product	8.7.1.3 可疑产品的控制	85
8.7.1.4 Control Of Reworked Product	8.7.1.4 返工产品的控制	86
8.7.1.5 Control Of Repaired Product	8.7.1.5 返修产品的控制	86
8.7.1.6 Customer Notification	8.7.1.6 顾客通知	87
8.7.1.7 Nonconforming Product Disposition	8.7.1.7不合格品的处置	87
8.7.2	**8.7.2**	87

Table of Contents 目录

9 Performance Evaluation	**9 绩效评价**	88
9.1 Monitoring, Measurement, Analysis And Evaluation	**9.1 监视、测量、分析和评价**	88
9.1.1 General	**9.1.1总则**	88
9.1.1.1 Monitoring And Measurement Of Manufacturing Processes	9.1.1.1制造过程的监视和测量	88
9.1.1.2 Identification Of Statistical Tools	9.1.1.2 统计工具的确定	89
9.1.1.3 Application Of Statistical Concepts	9.1.1.3 统计概念的应用	89
9.1.2 Customer Satisfaction	**9.1.2顾客满意**	90
9.1.2.1 Customer Satisfaction -Supplemental	9.1.2.1 顾客满意-补充	90
9.1.3 Analysis And Evaluation	**9.1.3 分析和评价**	91
9.1.3.1 Prioritization	9.1.3.1 优先级	91
9.2 Internal Audit	**9.2 内部审核**	92
9.2.1 And 9.2.2	**9.2.1 And 9.2.2**	92
9.2.2.1 Internal Audit Programme	9.2.2.1 内部审核方案	92
9.2.2.2 Quality Management System Audit	9.2.2.2 质量管理休系审核	93
9.2.2.3 Manufacturing Process Audit	9.2.2.3 制造过程审核	93
9.2.2.4 Product Audit	9.2.2.4 产品审核	93
9.3 Management Review	**9.3 管理评审**	93
9.3.1 General	**9.3.1 总则**	94
9.3.1.1 Management Review -Supplemental	9.3.1.1 管理评审-补充	94
9.3.2 Management Review Inputs	**9.3.2 管理评审输入**	94
9.3.2.1 Management Review Inputs -Supplemental	9.3.2.1 管理评审输入-补充	95
9.3.3 Management Review Outputs	**9.3.3 管理评审输出**	95
9.3.3.1 Management Review Outputs -Supplemental	9.3.3.1 管理评审输出-补充	95
10 Improvement	**10 改进**	96
10.1 General	**10.1 总则**	96
10.2 Nonconformity And Corrective Action	**10.2 不符合和纠正措施**	96
10.2.1 And 10.2.2	**10.2.1 And 10.2.2**	96
10.2.3 Problem Solving	**10.2.3 问题解决**	97
10.2,4 Error-Proofing	**10.2,4 防错**	97
10.2.5 Warranty Management Systems	**10.2.5 保修管理体系**	97
10.2.6 Customer Complaints And Field Failure Test Analysis	**10.2.6 顾客投诉和使用现场失效试验分析**	98
10.3 Continual Improvement	**10.3 持续改进**	99
10.3.1 Continual Improvement -Supplemental	**10.3.1持续改进-补充**	99
Annex A: Control Plan	**Annex A: 控制计划**	100
A.1 Phases Of The Control Plan	**A.1 控制计划的阶段**	100
A.2 Elements Of The Control Plan	**A.2 控制计划的要素**	101
Annex B: Bibliography Supplemental Automotive	**Annex B: 参考书目-汽车行业补充**	102

Foreword -- Automotive QMS Standard
前言--汽车质量管理体系标准

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.
本汽车质量管理体系标准(本文中简称为“汽车QMS标准”或“IATF16949”)，连同适用的汽车顾客特定要求,ISO9001:2015要求以及ISO9000:2015一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ISO9001:2015的补充进行理解，并与ISO9001:2015结合使用。ISO9001:2015是一部单独出版的ISO标准。

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.
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。

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

History历史

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.
ISO/TS 16949(第一版)最初由国际汽车推动小组(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年的第二版以及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。

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 1ATF 16949:2016 (1st edition), which cancels and replaces ISO/TS 16949:2009 (3rd edition).
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；IATF16949:2016(第一版)的创建注销并取代ISO/TS 16949:2009(第三版)。

The IATF maintains strong cooperation with ISO by continuing liaison committee status ensuring continued alignment with ISO 9001.
IATF通过延续联络委员会的身份 ,与国际标准化组织(ISO)保持着强有力的合作 ,确保持续与ISO9001保持一致。

Goal目标

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.
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
有关认证的说明

Requirements for certification to this Automotive QMS Standard are defined in the Rules for achieving and maintaining IATF recognition.
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。
Details can be obtained from the local Oversight Offices of the IATF cited below:
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；

Associazione Nazionale Filiera Industrie Automobilistiche (ANFIA) 意大利汽车工业协会(ANFIA)
网址Web site: www.anfia.it
邮箱 E-mail: anfia@anfia.it

International Automotive Oversight Bureau (IAOB) 美国国际汽车工业协会(IAOB)
网址Web site: www.iaob.org
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IATF France IATF 法国
网址Web site: www.iatf-france.com
邮箱 E-mail: iatf@iatf-france.com

Society of Motor Manufacturers and Traders Ltd. (SMMT Ltd.) 英国汽车制造与贸易商协会(SMMT Ltd.)
网址Web site: www.smmtoversight.co.uk
邮箱 E-mail: iatf16949@smmt.co.uk

Verband der Automobilindustrie — Qualitats Management Center (VDA QMC)
德国汽车工业协会-质量管理中心(VDA-QMC)
网址Web site: www.vda-qmc.de
邮箱 E-mail: info@vda-qmc.de

All public information about the IATF can be found at the IATF website: www.iatfglobaloversight.org
登录www.iatfglobaloversight.org可找到所有关于IATF的公开信息

Introduction引言

0.1 General总则

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

1.1 General总则

The adoption of a quality management system is a strategic decision for an organization that can help to improve its overall performance and provide a sound basis for sustainable development initiatives.

采用质量管理体系是组织的一项战略决策，能够帮助其提高整体绩效，为推动可持续发展奠定良好基础。

The potential benefits to an organization of implementing a quality management system based on this International Standard are:

组织根据本标准实施质量管理体系的潜在益处是：

a) theabilitytoconsistentlyprovideproductsandservicesthatmeetcustomerandapplicable statutory and regulatory requirements;
   稳定提供满足顾客要求以及适用的法律法规要求的产品和服务的能力；
b) facilitating opportunities to enhance customer satisfaction;
   促成增强顾客满意的机会；
c) addressing risks and opportunities associated with its context and objectives;
   应对与组织环境和目标相关的风险和机遇；
d) the ability to demonstrate conformity to specified quality management system requirements.
   证实符合规定的质量管理体系要求的能力。

This International Standard can be used by internal and external parties.

本标准可用于内部和外部各方。

It is not the intent of this International Standard to imply the need for:

实施本标准并非要：

— uniformity in the structure of different quality management systems;
   统一不同质量管理体系的架构；
— alignment of documentation to the clause structure of this International Standard;
   形成与本标准条款结构相一致的文件；
— the use of the specific terminology of this International Standard within the organization.
   在组织内使用本标准的特定术语。

ThequalitymanagementsystemrequirementsspecifiedinthisInternationalStandardare complementary to requirements for products and services.

本标准规定的质量管理体系要求是对产品和服务要求的补充。

This International Standard employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking.

本标准采用过程方法，该方法结合了“策划—实施—检查—处置”（PDCA）循环与基于风险的思维。

The process approach enables an organization to plan its processes and their interactions.

过程方法使组织能够策划过程及其相互作用。

The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined and acted on.

PDCA 循环使组织能够确保其过程得到充分的资源和管理，确定改进机会并采取行动。

Risk-based thinking enables an organization to determine the factors that could cause its processes and its quality

management system to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise (see Clause A.4).

基于风险的思维使组织能够确定可能导致其过程和质量管理体系偏离策划结果的各种因素，采取预防控制，最大限度地降低不利影响，并最大限度地利用出现的机遇（见附录A.4）。

Consistently meeting requirements and addressing future needs and expectations poses a challenge for organizations in an increasingly dynamic and complex environment. To achieve this objective, the organization might find it necessary to adopt various forms of improvement in addition to correction and continual improvement, such as breakthrough change, innovation and re-organization.

在日益复杂的动态环境中持续满足要求，并针对未来需求和期望采取适当行动，这无疑是组织面临的一项挑战。为了实现这一目标，组织可能会发现，除了纠正和持续改进，还有必要采取各种形式的改进，如破变性变革、创新和重组。

In this International Standard, the following verbal forms are used:

在本标准中使用如下助动词：

— "shall" indicates a requirement;

"应"表示要求；

— "should" indicates a recommendation;

"宜"表示建议；

— "may" indicates a permission;

"可"表示允许；

— "can" indicates a possibility or a capability.

"能"表示可能或能够。

— Information marked as "NOTE" is for guidance in understanding or clarifying the associated requirement.

"注"的内容是理解和说明有关要求的指南。

0.2 Quality management principles质量管理原则

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

1.2 Quality management principles质量管理原则

This International Standard is based on the quality management principles described in ISO 9000. The descriptions include a statement of each principle, a rationale of why the principle is important for the organization, some examples of benefits associated with the principle and examples of typical actions to improve the organization's performance when applying the principle.

本标准是在 GB/T 19000 所阐述的质量管理原则基础上制定的。每项原则的介绍均包含概述、该原则对组织的重要性的依据，应用该原则的主要益处示例以及应用该原则提高组织绩效的典型措施示例。

The quality management principles are:

质量管理原则包括：

— customer focus;

以顾客为关注焦点；

— leadership;

领导作用；

— engagement of people;

全员参与；

— Process approach;
过程方法；
— improvement;
改进；
— evidence-based decision making;
循证决策；
— relationship management.
关系管理。

0.3 Process approach过程方法

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

0.3 Process approach过程方法

0.3.1General总则

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements. Specific requirements considered essential to the adoption of a process approach are included in 4.4.
本标准倡导在建立、实施质量管理体系以及提高其有效性时采用过程方法，通过满足顾客要求增强顾客满意。采用过程方法所需考虑的具体要求见4.4.

Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results. This approach enables the organization to control the interrelationships and interdependencies among the processes of the system, so that the overall performance of the organization can be enhanced.
将相互关联的过程作为一个体系加以理解和管理，有助于组织有效和高效地实现其预期结果。这种方法使组织能够对其体系的过程之间相互关联和相互依赖的关系进行有效控制，以提高组织整体绩效。

The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the PDCA cycle (see 0.3.2) with an overall focus on risk-based thinking (see 0.3.3) aimed at taking advantage of opportunities and preventing undesirable results.
过程方法包括按照组织的质量方针和战略方向，对各过程及其相互作用进行系统的规定和管理，从而实现预期结果。可通过采用PDCA循环（见 0.3.2）以及始终基于风险的思维（见0.3.3）对过程和整个体系进行管理，旨在有效利用机遇并防止发生不良结果。

The application of the process approach in a quality management system enables:
在质量管理体系中应用过程方法能够：

a) Understanding and consistency in meeting requirements;
理解并持续满足要求.
b) The consideration of processes in terms of added value;
从增值的角度考虑过程.

c) The achievement of effective process performance;

获得有效的过程绩效.

d) Improvement of processes based on evaluation of data and information.

在评价数据和信息的基础上改进过程.

Figure 1 gives a schematic representation of any process and shows the interaction of its elements. The monitoring and measuring check points, which are necessary for control, are specific to each process and will vary depending on the related risks.

单一过程各要素及其相互作用如图 1 所示。每一过程均有特定的监视和和测量检查点，以用于控制，这些检查点根据相关的风险有所不同。

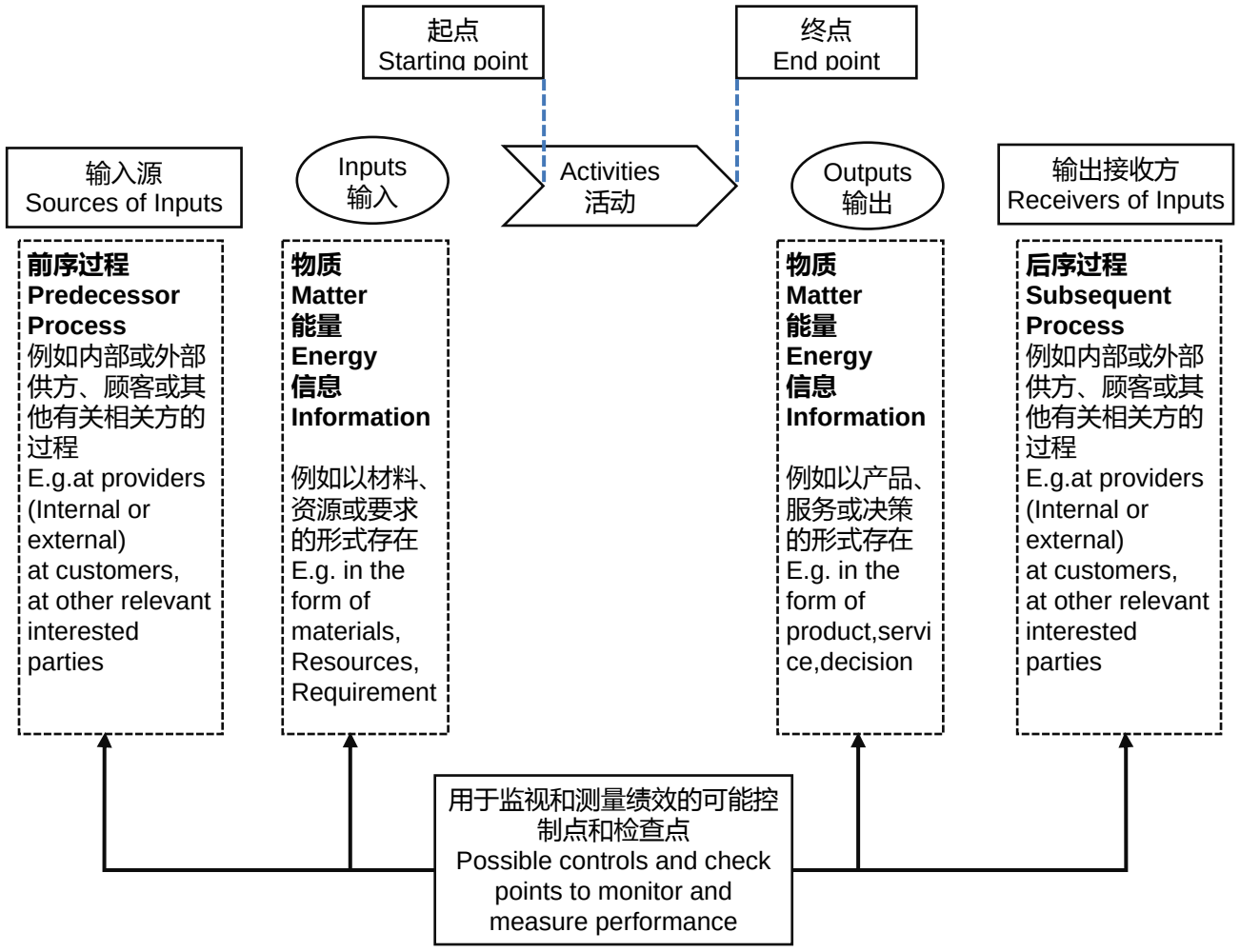


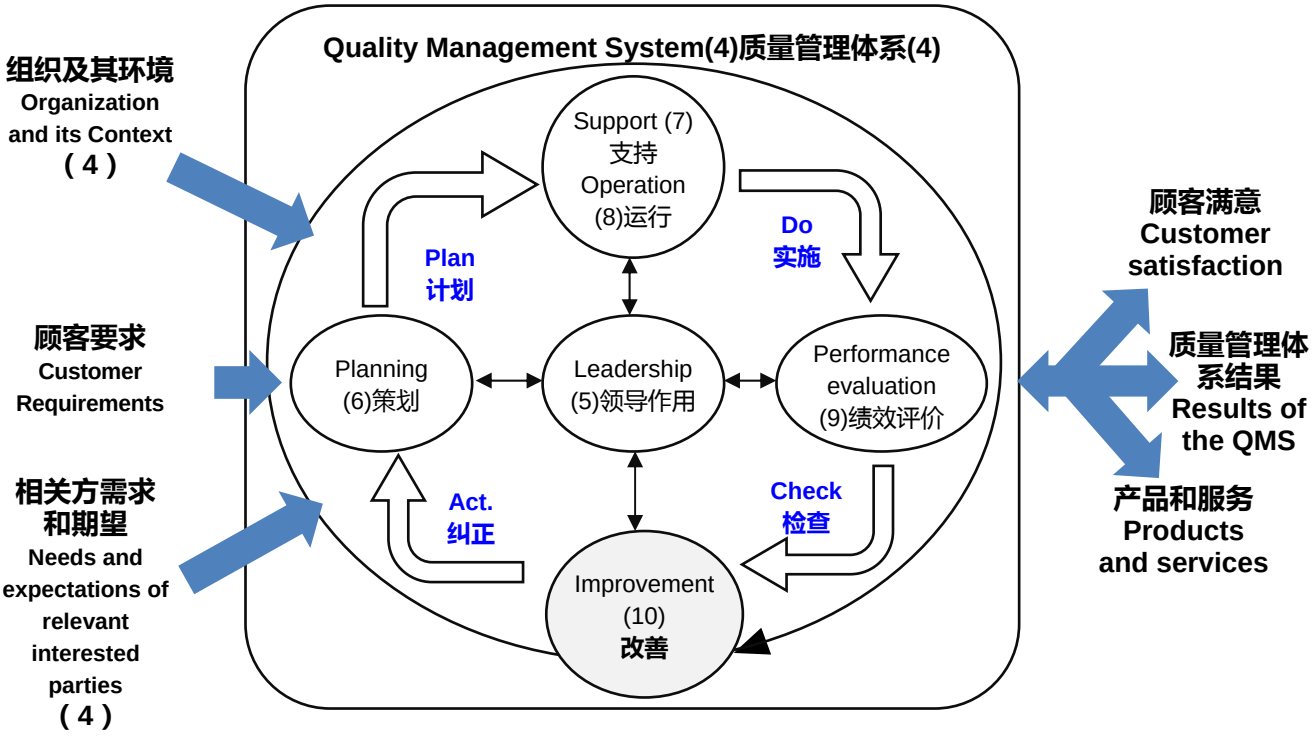
Figure 1 — Schematic representation of the elements of a single process

图 1：单一过程要素示意图

0.3.2 Plan-Do-Check-Act cycle PDCA循环

The PDCA cycle can be applied to all processes and to the quality management system as a whole. Figure 2 illustrates how Clauses 4 to 10 can be grouped in relation to the PDCA cycle.

PDCA 循环能够应用于所有过程以及整个质量管理体系。图 2 表明了本标准第 4 章至第 10 章是如何构成 PDCA 循环的。



NOTENumbers in brackets refer to the clauses in this International Standard.

注：括号中的数字表示本标准中相应的章节

Figure 2 — Representation of the structure of this International Standard in the PDCA cycle

图 2：本标准的结构在 PDCA 循环中的展示

The PDCA cycle can be briefly described as follows:

PDCA 循环可以简要描述如下

- Plan: establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organization's policies, and identify and address risks and opportunities;

  策划（Plan）：根据顾客的要求和组织的方针，建立体系的目标及其过程、确定实现结果所需的资源,并识别和应对风险和机遇

- Do: implement what was planned;

  实施（Do）：执行所做的策划

- Check: monitor and (where applicable) measure processes and the resulting products and services against policies, objectives, requirements and planned activities, and report the results;

  检查（Check）:根据方针、目标、要求和所策划的活动，对过程以及形成产品和服务进行监视和测量（适用时），并报告结果

- Act: take actions to improve performance, as necessary.

  处置（Act）：必要时，采取措施提高绩效。

0.3.3 Risk-based thinking基于风险的思维

Risk-based thinking (see Clause A.4) is essential for achieving an effective quality management system. The concept of risk-based thinking has been implicit in previous editions of this International Standard including, for example, carrying out preventive action to eliminate potential nonconformities, analyzing any nonconformity that do occur, and taking action to prevent recurrence that is appropriate for the effects of the nonconformity.

基于风险的思维（见附录 A.4）是实现质量管理体系有效性的基础。本标准以前的版本已经隐含基于风险思维的概念，例如：采取预防措施消除潜在的不合格，对发生的不合格进行分析，并采取与不合格的影响相适当措施，防止其再次发生。

To conform to the requirements of this International Standard, an organization needs to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the quality management system, achieving improved results and preventing negative effects.

为了满足本标准的要求,组织需策划和实施应对风险和机遇的措施。应对风险和机遇，为提高质量管理体系有效性、获得改进结果以及防止不利影响奠定基础。

Opportunities can arise as a result of a situation favorable to achieving an intended result, for example, a set of circumstances that allow the organization to attract customers, develop new products and services, reduce waste or improve productivity. Actions to address opportunities can also include consideration of associated risks. Risk is the effect of uncertainty and any such uncertainty can have positive or negative effects. A positive deviation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities.

某些有利于实现预期结果的情况可能导致机遇的出现，例如：有利于组织吸引顾客、开发新产品和服务、减少浪费或提高生产率的一系列情形。利用机遇所采取的实施也可能包括考虑相关风险。风险是不确定性的影响，不确定性可能有正面的影响，也可能有负面的影响。风险的正面影响可能提供机遇，但并非所有的正面影响均可提供机遇。

0.4 Relationship with other management system standards
与其他管理体系标准的关系

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

1.4 Relationship with other management system standards
与其他管理体系标准的关系

This International Standard applies the framework developed by ISO to improve alignment among its International Standards for management systems (see Clause A.1).

本标准采用ISO 制定的管理体系标准框架，以提高与其他管理体系标准的协调一致性（见附录A.1）。

This International Standard enables an organization to use the process approach, coupled with the PDCA cycle and risk-based thinking, to align or integrate its quality management system with the requirements of other management system standards.

本标准使组织能够使用过程方法，并结合 PDCA 循环和基于风险的思维，将其质量管理体系与其他管理体系标准要求进行协调或整合。

This International Standard relates to ISO 9000 and ISO 9004 as follows:
本标准与ISO 9000 和ISO 9004 存在如下关系：

- ISO 9000 Quality management systems — Fundamentals and vocabulary provides essential background for the proper understanding and implementation of this International Standard;
  ISO 9000《质量管理体系基础和术语》为正确理解和实施本标准提供必要基础；
- ISO 9004 Managing for the sustained success of an organization — A quality management approach provides guidance for organizations that choose to progress beyond the requirements of this International Standard.
  ISO 9004 《追求组织的持续成功质量管理方法》为选择超出本标准要求的组织提供指南。

Annex B provides details of other International Standards on quality management and quality management systems that have been developed by ISO/TC 176.
附录B给出了SAC/TC 151 制定的其他质量管理和质量管理体系标准（等同采用ISO/TC 176 质量管理和质量保证技术委员会制定的国际标准）的详细信息。

This International Standard does not include requirements specific to other management systems, such as those for environmental management, occupational health and safety management, or financial management.
本标准不包括针对环境管理、职业健康和安全管理或财务管理等其他管理体系的特定要求。

Sector-specific quality management system standards based on the requirements of this International Standard have been developed for a number of sectors. Some of these standards specify additional quality management system requirements, while others are limited to providing guidance to the application of this International Standard within the particular sector.
在本标准的基础上，已经制定了若干行业特定要求的质量管理体系标准。其中的某些标准规定了质量管理体系的附加要求，而另一些标准则仅限于提供在特定行业应用本标准的指南。

A matrix showing the correlation between the clauses of this edition of this International Standard and the previous edition (ISO 9001:2008) can be found on the ISO/TC 176/SC 2 open access web site at: www.iso.org/tc176/sc02/public.
本标准的章节内容与之前版本（GB/T 19001-2008/ISO 9001:2008）章节内容之间的对应关系见ISO/TC176/SC2（国际标准化组织/质量管理和质量保证技术委员会/质量体系分委员会）的公开网站：www.iso.org/tc176/sc02/public。

Quality management systems — Requirements
质量管理体系-要求

1.Scope范围

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

1. Scope范围

This International Standard specifies requirements for a quality management system when an organization:
本标准为下列组织规定了质量管理体系要求:

a) Needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
需要证实其具有稳定提供满足顾客要求及适用法律法规要求的产品和服务的能力；

b) Aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.
通过体系的有效应用，包括体系改进的过程，以及保证符合顾客要求和适用的法律法规要求，旨在增强顾客满意。

All the requirements of this International Standard are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides.
本标准规定的所有要求是通用的，旨在适用于各种类型、不同规模和提供不同产品和服务的组织。

NOTE 1: In this International Standard, the terms “product” or “service” only apply to products and services intended for, or required by, a customer.
注 1：在本标准中，术语“产品”或“服务”仅适用于预期提供给顾客或顾客所要求的产品和服务；

NOTE 2: Statutory and regulatory requirements can be expressed as legal requirements.
注 2：法律法规要求可称作为法定要求。

1.1 Scope – automotive supplemental to ISO 9001:2015
范围- 汽车行业对ISO9001:2015的补充

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.
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。

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.
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。

This Automotive QMS Standard should be applied throughout the automotive supply chain.
应当在整个汽车供应链中实施本汽车QMS标准。

2 Normative references引用标准

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

2.Normative references引用标准

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

下列文件对于本文件的应用是必不可少的。凡是注日期的引用文件，仅注日期的版本适用于本文件。凡是不注日期的引用文件，其最新版本（包括所有的修改单）适用于本文件。

ISO 9000:2015, Quality management systems — Fundamentals and vocabulary

ISO 9000-2015 质量管理体系基础和术语

2.1 Normative and informative references规范性引用标准和参考性引用标准

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

附录A（控制计划）为本汽车QMS标准的规范性部分。

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

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

3 Terms and definitions术语和定义

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

3.Terms and definitions术语和定义

For the purposes of this document, the terms and definitions given in ISO 9000:2015 apply.
ISO 9000:2015标准界定的术语和定义适用于本文件。

3.1Terms and definitions for the automotive industry汽车行业的术语和定义

3.1.1 Accessory part配件

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.)
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）。

3.1.2 Advanced product quality planning (APQP)产品质量先期策划(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；
对开发满足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。

3.1.3 Aftermarket part售后市场零件

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
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。

3.1.4 Authorization授权

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

3.1.5 Challenge (master) part挑战(原版)件

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)
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。

3.1.6 Control plan控制计划

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

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）。

3.1.7 Customer requirements顾客要求

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

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）。

3.1.8 Customer-specific requirements (CSRs)顾客特殊要求(CSRs)

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

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。

3.1.9 Design for assembly (DFA)可装配的设计

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)

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。）

3.1.10 Design for manufacturing (DFM)可制造的设计

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

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。

3.1.11Design for manufacturing and assembly (DFMA)可制造和可装配的设计

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.

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为新减少出错风险、降低成本并更易装配的设计优化。

3.1.12 Design for six sigma (DFSS)六西格玛设计

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

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。

3.1.13 Design-responsible organization具有设计职责的组织

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

有权制定一个新的或更改现有的产品规范的组织。

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

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。

3.1.14 Error proofing防错

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

为防止制造不合格产品而进行的产品和制造过程的设计和开发。

3.1.15 Escalation process升级过程

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

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。

3.1.16 Fault tree analysis (FTA)故障树分析法

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

分析系统非理想状态的演绎故障分析法；通过创建这个系统的逻辑框图，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。

3.1.17 Laboratory试验室

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

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。

3.1.18 Laboratory scope试验室范围

Controlled document containing

包含下列内容的受控文件

— Specific tests, evaluations, and calibrations that a laboratory is qualified to perform;
试验室有资格进行的特定试验、评价或校准；

— A list of the equipment that the laboratory uses to perform the above; and
用来进行上述活动的设备的清单；以及

— A list of methods and standards to which the laboratory performs the above
用来进行上述活动的方法和标准的清单。

3.1.19 Manufacturing制造

Process of making or fabricating**制作或加工的过程**

— Production materials;
生产原材料

— Production parts or service parts;
生产件或服务件

— Assemblies; or
装配；或

— Heat treating, welding, painting, plating, or other finishing services
热处理、焊接、涂漆、电镀或其他表面处理服务。

3.1.20 Manufacturing feasibility制造可行性

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；

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。

3.1.21 Manufacturing services制造服务

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

试验、制造、分销部件和组件并为其提供维修服务的公司

3.1.22 Multi-disciplinary approach多方论证方法

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.

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。

3.1.23 No trouble found (NTF)未发现故障

Designation applied to a part replaced during a service event that, when analyzed 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")

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”）。

3.1.24 Outsourced process外包过程

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

由外部组织履行的一部分组织功能（或过程）。

3.1.25 Periodic overhaul周期性检修

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；

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。

3.1.26 Predictive maintenance预测性维护

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

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。

3.1.27 Premium freight超额运费

Extra costs or charges incurred in addition to contracted delivery

合同交付之外发生的超出成本或费用。

Note this can be caused by method, quantity, unscheduled or late deliveries, etc.

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。

3.1.28 Preventive maintenance预防性维护

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；

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。

3.1.29 Product产品

Applies to any intended output resulting from the product realization process；

适用于产品实现过程产生的任何预期输出

3.1.30 Product safety产品安全

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

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

3.1.31 Production shutdown生产停工

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

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。

3.1.32 Reaction plan反应计划

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

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

3.1.33 Remote location外部场所

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

支持现场并且为非生产过程发生的场所

3.1.34 Service part服务件

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

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。

3.1.35 Site现场

Location at which value-added manufacturing processes occur

发生增值制造过程的场所

3.1.36 Special characteristic特殊特性

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

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。

3.1.37 Special status特殊状态

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

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。

3.1.38 Support function支持功能

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

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

3.1.39 Total productive maintenance全面生产维护

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；

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

3.1.40 Trade-off curves权衡曲线

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；

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；产品的一个特性的功能映射于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。

3.1.41 Trade-off process权衡过程

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

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组织的环境

4.1 Understanding the organization and its context理解组织及其环境

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

4. Context of the organization组织的环境

4.1 Understanding the organization and its context理解组织及其环境

The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.
组织应确定与其宗旨和战略方向相关并影响其实现质量管理体系预期结果的能力的各种外部和内部因素。

The organization shall monitor and review information about these external and internal issues.
组织应对这些内部和外部因素的相关信息进行监视和评审。

NOTE 1: Issues can include positive and negative factors or conditions for consideration.
注 1：这些因素可以包括需要考虑的正面和负面要素或条件。
NOTE 2: Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.
注 2：考虑来自于国际、国内、地区和当地的各种法律法规、技术、竞争、市场、文化、社会和经济因素，有助于理解外部环境。
NOTE 3: Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.
注 3：考虑组织的价值观、文化、知识和绩效等相关因素，有助于理解内部环境。

4.2 Understanding the needs and expectations of interested parties 理解相关的需求和期望

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

4.2 Understanding the needs and expectations of interested parties 理解相关的需求和期望

Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:
由于相关方对组织稳定提供符合顾客要求及适用法律法规要求的产品和服务的能力具有影响或潜在影响，因此，组织应确定：

a) the interested parties that are relevant to the quality management system;
与质量管理体系有关的相关方；
b) The requirements of these interested parties that are relevant to the quality management system.
与质量管理体系有关的相关方的要求。

The organization shall monitor and review information about these interested parties and their relevant requirements.
组织应监视和评审这些相关方的信息及其相关要求.

4.3 Determining the scope of the quality management system
确定质量管理体系的范围

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

4.3 Determining the scope of the quality management system
确定质量管理体系的范围

The organization shall determine the boundaries and applicability of the quality management system to establish its scope.

组织应明确质量管理体系的边界和适用性，以确定其范围。

When determining this scope, the organization shall consider:

在确定范围时，组织应考虑：

a) The external and internal issues referred to in 4.1;
   4.1 中提及的各种外部和内部因素
b) The requirements of relevant interested parties referred to in 4.2;
   4.2 中提及的相关方的要求
c) The products and services of the organization.
   组织的产品和服务。

The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.

如果本标准的全部要求适用于组织确定的质量管理体系范围，组织应实施本标准的全部要求。

The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.

组织的质量管理体系范围应作为形成文件的信息，可获得并得到保持。该范围应描述所覆盖的产品和服务类型，如果组织确定本标准的某些要求不适用于其质量管理体系范围，应说明理由。

Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

只有所确定的不适用的要求不影响组织确保其产品和服务合格的能力或责任，对增强顾客满意也不会产生影响，方可声称符合本标准的要求。

4.3.1 Determining the scope of the quality management system — supplemental

确定质量管理体系的范围 - 补充

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).

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。

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).

本汽车QMS标准唯一允许的删减是ISO9001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ISO9001第7.5条）的形式进行证明和保持。

Permitted exclusions do not include manufacturing process design.

允许的删减不包括制造过程设计。

4.3.2 Customer-specific requirements顾客特殊要求

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

应以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 Quality management system and its processes质量管理体系及其过程

4.4.1

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

4.4 Quality management system and its processes质量管理体系及其过程

4.4.1 The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

组织应按照本标准的要求，建立、实施、保持和持续改进质量管理体系，包括所需过程及其相互作用。

The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall:

组织应确定质量管理体系所需的过程及其在整个组织中的应用，且应：

a) Determine the inputs required and the outputs expected from these processes;
   确定这些过程所需的输入和期望的输出；
b) Determine the sequence and interaction of these processes;
   确定这些过程的顺序和相互作用；
c) Determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;
   确定和应用所需的准则和方法（包括监视、测量和相关绩效指标），以确保这些过程的有效运行和控制；

d) Determine the resources needed for these processes and ensure their availability;
确定这些过程所需的资源并确保可获得；
e) Assign the responsibilities and authorities for these processes;
分配这些过程的职责和权限
f) Address the risks and opportunities as determined in accordance with the requirements of 6.1;
按照 6.1 的要求应对风险和机遇；
g) Evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;
评价这些过程，实施所需的变更，以确保实现这些过程的预期结果；
h) Improve the processes and the quality management system.
改进过程和质量管理体系。

4.4.1.1 Conformance of products and processes产品和过程的符合性

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).
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 Product safety产品安全

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:
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;
组织对产品安全法律法规要求的识别；
b) Customer notification of requirements in item a);
向顾客通知a)项中的要求；
c) Special approvals for design FMEA;
设计FEMA的特殊批准；
d) Identification of product safety-related characteristics;
产品安全相关特性的识别；
e) Identification and controls of safety-related characteristics of product and at the point of manufacture;
产品及制造时安全相关特性的识别和控制
f) Special approval of control plans and process FMEAs;
控制计划和过程FMEA的特殊批准
g) Reaction plans (see Section 9.1.1.1);
反应计划（见第9.1.1.1条）
h) Defined responsibilities, definition of escalation process and flow of information, including top management, and customer notification;
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) Training identified by the organization or customer for personnel involved in product-safety related products and associated manufacturing processes;
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) 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);
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ISO9001第8.3.6条）；

k) Transfer of requirements with regard to product safety throughout the supply chain, including customer-designated sources (see Section 8.4.3.1);
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) Product traceability by manufactured lot (at a minimum) throughout the supply chain (see Section 8.5.2.1);
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) Lessons learned for new product introduction.
为新产品导入的经验教训。

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

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

4.4.2 To the extent necessary, the organization shall:

在必要的范围和程度上，组织应：

a) Maintain documented information to support the operation of its processes;
保持形成文件信息以支持过程运行

b) Retain documented information to have confidence that the processes are being carried out as planned.
保留形成文件信息以确信其过程按策划进行。

5. Leadership领导作用

5.1 Leadership and commitment 领导作用与承诺

5.1.1 General总则

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

5.1.1 General总则

Top management shalldemonstrateleadershipand commitment withrespectto the quality management system by:
最高管理者应通过以下方面，证实其对质量管理体系的领导作用和承诺：

a) Taking accountability for the effectiveness of the quality management system;
对质量管理体系的有效性负责;
b) Ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;
确保制定质量管理体系的质量方针和质量目标,并与组织环境相适应，与战略方向相一致;
c) Ensuring the integration of the quality management system requirements into the organization's business processes;
确保质量管理体系要求融入组织的业务过程;
d) Promoting the use of the process approach and risk-based thinking;
促进使用过程方法和基于风险的思维;
e) Ensuring that the resources needed for the quality management system are available;
确保质量管理体系所需的资源是可获得的;
f) Communicating the importance of effective quality management and of conforming to the quality management system requirements;
沟通有效的质量管理和符合质量管理体系要求的重要性;
g) Ensuring that the quality management system achieves its intended results;
确保质量管理体系实现预期结果;
h) Engaging, directing and supporting personstocontribute totheeffectivenessof the quality management system;
促使人员积极参与、指导和支持他们为质量管理体系的有效性作出贡献；
i) Promoting improvement;
推动改进；
j) Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.
支持其他相关管理者在其职责范围内发挥领导作用。

NOTE: Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.
注：本标准使用的"业务"一词可广义地理解为涉及组织存在目的的核心活动，无论是公营、私营、营利或非营利组织。

5.1.1.1 Corporate responsibility公司责任

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"),

公司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过程有效性和效率

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.).

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 Process owners过程拥有者

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).

最高管理者应确定过程拥有者，由其负责组织的各过程和相关输出的管理。过程拥有者应了解他们的角色，并且具备胜任其角色的能力（见ISO9001第7.2条）。

5.1.2 Customer focus以顾客为关注焦点

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

5.1.2 Customer focus以顾客为关注焦点

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

最高管理者应通过确保以下方面，证实其以顾客为关注焦点的领导作用和承诺:

a) Customer and applicable statutory and regulatory requirements are determined, understood and consistently met;
确定、理解并持续地满足顾客要求以及适用的法律法规要求;

b) The risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
确定和应对风险和机遇，这些风险和机遇可能影响产品和服务合格以及增强顾客满意能力;

c) The focus on enhancing customer satisfaction is maintained.
始终致力于增强顾客满意.

5.2 Policy方针

5.2.1 Establishing the quality policy 建立质量方针

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

5.2 Policy方针

5.2.1 Establishing the quality policy建立质量方针

Top management shall establish, implement and maintain a quality policy that:

最高管理者应制定、实施和保持质量方针,质量方针应:

a) Is appropriate to the purpose and context of the organization and supports its strategic direction;
适应组织的宗旨和环境并支持其战略方向;

b) Provides a framework for setting quality objectives;
为建立质量目标提供框架;
c) Includes a commitment to satisfy applicable requirements;
包括满足适用要求的承诺;
d) Includes a commitment to continual improvement of the quality management system.
包括持续改进质量管理体系的承诺。

5.2.2 Communicating the quality policy 沟通质量方针

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

5.2.2 Communicating the quality policy沟通质量方针

The quality policy shall:
质量方针应
a) Be available and be maintained as documented information;
可获取并保持形成文件的信息;
b) Be communicated, understood and applied within the organization;
在组织内得到沟通、理解和应用;
c) Be available to relevant interested parties, as appropriate.
适宜时，可为有关相关方所获取.

5.3 Organizational roles, responsibilities and authorities
组织的作用、职责和权限

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

5.3 Organizational roles, responsibilities and authorities
组织的作用、职责和权限

Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.
最高管理者应确保组织内相关角色的职责、权限得到分配、沟通和理解.
Top management shall assign the responsibility and authority for:
最高管理者应分配职责和权限，以:
a) Ensuringthatthequalitymanagementsystemconformstotherequirementsofthis International Standard;
确保质量管理体系符合本标准的要求;
b) Ensuring that the processes are delivering their intended outputs;
确保各过程获得其预期输出;
c) Reportingontheperformanceofthequalitymanagementsystemandonopportunitiesfor improvement (see 10.1), in particular to top management;
报告质量管理体系的绩效及其改进机会（见 10.1），特别是向最高管理者报告;
d) Ensuring the promotion of customer focus throughout the organization;
确保在整个组织推动以顾客为关注焦点;
e) Ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.
确保在策划和实施质量管理体系变更时保持其完整性.

5.3.1 Organizational roles, responsibilities, and authorities — supplemental

组织的作用、职责和权限-补充

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.

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 Responsibility and authority for product requirements and corrective actions

产品要求和纠正措施的职责和权限

Top management shall ensure that:

最高管理者应确保

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

   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；

   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

   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;

   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和控制。

c) Production operations across all shifts are staffed with personnel in charge of, or delegated responsibility for, ensuring conformity to product requirements.

   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负责人员。

6. Planning策划

6.1 Actions to address risks and opportunities 风险和机遇的应对措施

6.1.1 and 6.1.2

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

6.1.1 When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

在策划质量管理体系时，组织应考虑到 4.1 所提及的因素和 4.2 所提及的要求，并确定需要应对的风险和机遇，以便：

a) Give assurance that the quality management system can achieve its intended result(s);
确保质量管理体系能够实现其预期结果；

b) Enhance desirable effects;
增强有利影响；

c) Prevent, or reduce, undesired effects;
预防或减少不利影响；

d) Achieve improvement.
实现改进.

6.1.2 The organization shall plan:

组织应策划:

a) Actions to address these risks and opportunities;
应对这些风险和机遇的措施

b) How to:
如何：

1) Integrate and implement the actions into its quality management system processes (see 4.4);
在质量管理体系过程中整合并实施这些措施（见 4.4）

2) Evaluate the effectiveness of these actions.
评价这些措施的有效性。

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.
应对措施应与风险和机遇对产品和服务符合性的潜在影响相适应。

NOTE 1:Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

注 1：通过信息充分的决策，应对风险可选择规避风险，为寻求机遇承担风险，消除风险源，改变风险的可能性和后果，分担风险，或保留风险。

NOTE 2: Opportunitiescanleadto the adoptionofnewpractices,launchingnewproducts,openingnew markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

注 2：机遇可能导致采用新实践，推出新产品，开辟新市场，赢得新客户，建立合作伙伴关系，利用新技术和其他可行之处，以应对组织或其顾客的需求。

6.1.2.1 Risk analysis风险分析

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.

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、报废及返工中吸取经验教训。

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

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 Preventive action预防措施

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.

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。

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

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) Determining potential nonconformities and their causes;
   确定潜在不合格及其原因
b) Evaluating the need for action to prevent occurrence of nonconformities;
   评价防止不合格发生的措施的需求
c) Determining and implementing action needed;
   确定并实施所需的措施
d) Documented information of action taken;
   所采取措施的形成文件的信息
e) Reviewing the effectiveness of the preventive action taken;
   评审所采取的预防措施的有效性
f) Utilizing lessons learned to prevent recurrence in similar processes (see ISO 9001, Section 7.1.6).
   利用取得的经验教训预防类似过程中的再次发生（见ISO9001第7.1.6条）

6.1.2.3 Contingency plans应急计划

The organization shall:**组织应：**

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;
   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;
   根据风险和顾客的影响制定应急计划；
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;
   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) 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;
   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) Periodically test the contingency plans for effectiveness (e.g., simulations, as appropriate);
定期测试应急计划的有效性（如：模拟，视情况而定）。

f) Conduct contingency plan reviews (at a minimum annually) using a multidisciplinary team including top management, and update as required;
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) Document the contingency plans and retain documented information describing any revision(s), including the person(s) who authorized the change(s).
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。

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.
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前，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 Quality objectives and planning to achieve them
质量目标及其实施的策划

6.2.1 and 6.2.2

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

6.2.1 The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system.

组织应对相关职能、层次和质量管理体系所需的过程设定质量目标.

The quality objectives shall:
质量目标应：

a) Be consistent with the quality policy;
与质量方针保持一致;

b) Be measurable;
可测量；

c) Take into account applicable requirements;
考虑适用的要求;

d) Be relevant to conformity of products and services and to enhancement of customer satisfaction;
与产品和服务合格以及增强顾客满意相关

e) Be monitored;
予以监视;

f) Be communicated;
予以沟通

g) Be updated as appropriate.
适时更新。

The organization shall maintain **documented information** on the quality objectives.
组织应保持有关质量目标的形成文件的信息。

6.2.2 When planning how to achieve its quality objectives, the organization shall determine:策划如何实现质量目标时，组织应确定:

a) What will be done;
要做什么;
b) What resources will be required;
需要什么资源;
c) Who will be responsible;
由谁负责;
d) When it will be completed;
何时完成;
e) How the results will be evaluated.
如何评价结果。

6.2.2.1 Quality objectives and planning to achieve them — supplemental

质量目标及其实施的策划 - 补充

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.

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。

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).

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 Planning of changes更改的策划

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

6.3 Planning of changes更改的策划

When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4).

当组织确定需要对质量管理体系进行变更时，变更应按所策划的方式实施（见 4.4）

The organization shall consider:

织应考虑到：

a) The purpose of the changes and their potential consequences;
变更目的及其潜在后果;
b) The integrity of the quality management system;
质量管理体系的完整性;
c) The availability of resources;
资源的可获得性;
d) The allocation or reallocation of responsibilities and authorities.
责任和权限的分配或再分配。

7 Support支持

7.1 Resources资源

7.1.1 General总则

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

7.1.1 General总则

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

组织应确定并提供所需的资源，以建立、实施、保持和持续改进质量管理体系。

The organization shall consider:

组织应考虑：

a) The capabilities of, and constraints on, existing internal resources;
   现有内部资源的能力和局限；
b) What needs to be obtained from external providers.
   需要从外部供方获得的资源。

7.1.2 People人员

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

7.1.2 People人员

The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

组织应确定并提供所需要的人员，以有效实施质量管理体系，并运行和控制其过程。

7.1.3 Infrastructure基础设施

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

7.1.3 Infrastructure基础设施

The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

组织应确定、提供和维护所需的基础设施，以运行过程，并获得合格产品和服务。

NOTE Infrastructure can include:

注：基础设施可包括：

a) Buildings and associated utilities;
   建筑物和相关设施；
b) Equipment, including hard ware and software;
   设备，包括硬件和软件；
c) Transportation resources;
   运输资源；
d) Information and communication technology.
   信息和通迅技术。

7.1.3.1 Plant, facility, and equipment planning工厂、设施和设备的策划

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:

组织应使用多方认证的方法，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) Optimize material flow, material handling, and value-added use of floor space including control of nonconforming product, and

   优化材料的流动和搬运，以及对空间现场的增值利用，包括对不合格品的控制，并且

b) Facilitate synchronous material flow, as applicable.

   在适用时，便于材料的同步流动。

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.

应开发并实施对新产品或新操作的制造可行性进行评价分析。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。

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).

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。

Assessments of manufacturing feasibility and evaluation of capacity planning shall be inputs to management reviews (see , Section 9.3.2.1).

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9.3.2.1条）。

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

注1：这些要求应当包括对精益制造原则的应用。

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

注2：这些要求应当用于现场供应商活动，如适用。

7.1.4 Environment for the operation of processes过程运行的环境

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

7.1.4 Environment for the operation of processes 过程运行的环境

The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.

组织应确定、提供并维护所需的环境，以运行过程，并获得合格产品和服务。

NOTEA suitable environment can be a combination of human and physical factors, such as:

注：适当的过程运行环境可能是人文因素与物理因素的结合，例如：

a) Social(e.g. Non-discriminatory, calm, non-confrontational);

   社会因素（如无歧视、和谐稳定、无对抗）；

b) Psychological(e.g. Stress-reducing, burnout prevention, emotionally protective);

   心理因素（减压、预防过度疲劳、保证情绪稳定）；

c) Physical (e.g. Temperature, heat, humidity, light, airflow, hygiene, noise).

   物理因素（如温度、热量、湿度、照明、空气流通、卫生、噪声等）。

These factors can differ substantially depending on the products and services provided.

由于所提供的产品和服务不同，这些因素可能存在显著差异。

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.

注：在ISO45001（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过程操作的环境——补充

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

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 Monitoring and measuring resources 监视与测量资源

7.1.5.1 General总则

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

7.1.5.1 General总则

The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

当利用监视或测量来验证产品和服务符合要求时，组织应确定并提供所需的资源，以确保结果有效和可靠。

The organization shall ensure that the resources provided:

组织应确保所提供的资源：

a) Are suitable for the specifictype of monitoring and measurement activities being undertaken;
   适合所开展的监视和测量活动的特定类型
b) Are maintained to ensure their continuing fitness for their purpose.
   得到维护，以确保持续适合其用途。

The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

组织应保留适当的形成文件的信息，作为监视和测量资源适合其用途的证据。

7.1.5.1.1 Measurement systems analysis测量系统分析

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.

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。

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

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）。

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

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 Measurement traceability

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

7.1.5.2 Measurement traceability测量可追溯性

When measurement traceability is a requirement,or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

当要求测量溯源时，或组织认为测量溯源是信任测量结果有效的基础时，测量设备应：

a) Calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standard sexist, the basis used for calibration or verification shall be retained as documented information;
对照能溯源到国际或国家标准的测量标准，按照规定的时间间隔或在使用前进行校准和（或）检定，当不存在上述标准时，应保留作为校准或验证依据的形成文件的信息；

b) Identified in order to determine their status;
予以标识，以确定其状态；

c) Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.
予以保护，防止由于调整、损坏或衰减所导致的校准状态和随后的测量结果的失效。

The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.

当发现测量设备不符合预期用途时，组织应确定以往测量结果的有效性是否受到不利影响，必要时应采取适当的措施。

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

注：一个可追溯到装置校准记录的编号或其它标识符，ISO9001:2015要求的意图。

7.1.5.2.1 Calibration/verification records校准/验证记录

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.

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。

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

组织应确保校准/验证活动和记录应包括以下细节：

a) Revisions following engineering changes that impact measurement systems;
根据影响测量系统的工程更改进行的修订；

b) Any out-of-specification readings as received for calibration/verification;
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;
对偏离规范的情况导致的产品预期使用风险的评估；

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;
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) Notification to the customer if suspect product or material has been shipped;
如果可疑产品或材料已被发运，对顾客的通知；

f) Statements of conformity to specification after calibration/verification;
校准/验证后，有关符合规范的声明；

g) Verification that the software version used for product and process control is as specified;
对于产品和过程控制的软件版本符合规定的验证；

h) Records of the calibration and maintenance activities for all gauging (including employee-owned equipment, customer-owned equipment, or on-site supplier-owned equipment);
所有量具(包括员工拥有的设备、顾客期望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) 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).
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 Laboratory requirements实验室要求

7.1.5.3.1 Internal laboratory内部实验室

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:
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。实验室至少应该为以下事项明确规定并实施要求：

a) Adequacy of the laboratory technical procedures;
实验室技术程序的充分性；

b) Competency of the laboratory personnel;
实验室人员的资格；

c) Testing of the product;
产品试验；

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;
正确执行这些服务的能力，可追溯到相关过程标准（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) Customer requirements, if any;
顾客要求，如有；

f) Review of the related records.
对有关记录的评审。

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.
注：通过ISO/IEC17025（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。

7.1.5.3.2External laboratory外部实验室

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:

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：

— 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

实验室应通过ISO/IEC17025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.

应有证据证明该外部实验室可以被顾客接受。

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.

注：这些证据可以通过顾客评估来证实，或由顾客批准的第二方机构评估，来证明该实验室满足了ISO/IEC17025或等效国家标准的意图。第二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。

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.

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。

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

校准服务的采用，除了具备资格的（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 Organizational knowledge组织知识

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

7.1.6 Organizational knowledge组织知识

The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

组织应确定必要的知识，以运行过程，并获得合格产品和服务。

This knowledge shall be maintained and be made available to the extent necessary.

这些知识应予以保持，并能在所需的范围内得到。

When addressing changing needs and trends, the organization shall considerate current knowledge and determines how to acquire or access any necessary additional knowledge and required updates.

为应对不断变化的需求和发展趋势，组织应审视现有的知识，确定如何获取或接触更多必要的知识和知识更新。

NOTE 1 :Organizational knowledge is knowledge specific to the organization; it is generally gained by experience. It is information that is used and shared to achieve the organization's objectives.

注 1：组织的知识是组织特有的知识，通常从其经验中获得，是以实现组织目标所使用和共享的信息。

NOTE2Organizational knowledge can be based on:

注 2：组织的知识可以基于：

a) Internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);
内部来源（例知识产权；从经验获得的知识；从失败和成功项目吸取的经验教训；获取和分享未成文的知识和经验，过程、产品和服务的改进结果）；

b) External sources(e.g. standards; academia; conferences; gathering knowledge from customers or external providers).
外部来源（例如标准；学术交流；专业会议，从顾客或外部供方收集的知识）。

7.2 Competence能力

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

7.2 Competence能力

The organization shall:

组织应：

a) Determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;
确定其控制下工作的人员所需具备的能力，这些人员从事的工作影响质量管理体系绩效和有效性；

b) Ensure that these persons are competent on the basis of appropriate education, training, or experience;
基于适当的教育、培训或经验，确保这些人员是胜任的；

c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
适用时，采取措施以获得所需的能力，并评价措施的有效性；

d) retain appropriate documented information as evidence of competence.
保留适当的形成文件的信息，作为人员能力的证据。

NOTE :Applicable actions can include, for example, the provision of training to, the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons.

注：适当措施可包括对在职人员进行培训、辅导或重新分配工作，或者聘用、外包胜任的人员。

7.2.1Competence – supplemental能力-补充

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.

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。

7.2.2Competence — on-the-job training能力-在职培训

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.

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。在职培训的详细程序应与人员的教育程序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人员应被告知不符合顾客要求的后果。

7.2.3Internal auditor competency内部审核员能力

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.

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ISO19011.组织应保持一份合格内部审核员名单。

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

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) Understanding of the automotive process approach for auditing ，including risk-based thinking;
   了解汽车审核过程方法，包括基于风险的思维；
b) Understanding of applicable customer-specific requirements;
   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;
   了解ISO9001和IATF16949中适用的与审核范围有关的要求；
d) Understanding of applicable core tool requirements related to the scope of the audit;
   了解与审核范围有关的适用的核心工具要求；
e) Understanding how to plan，conduct ，report，and close out audit findings
   了解如何计划审核、实施审核、报告审核以及关闭审核发现。

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.

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（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。

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

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。

Maintenance of and improvement in internal auditor competence shall be demonstrated through:
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) Executing a minimum number of audits per year ，as defined by the organization; and
每年执行组织规定的最小数量的审核，并且

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)
基于内部更改（如：过程技术、产品技术）和外部更改（如：ISO9001、IATF 16949、核心工具及顾客特定要求）对相关要求的认知。

7.2.4Second-party auditor competency第二方审核员能力

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:
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) The automotive process approach to auditing ，including risk based thinking;
汽车审核过程方法，包括基于风险的思维；

b) Applicable customer and organization specific requirements;
适用的顾客特定和组织特定的要求；

c) Applicable ISO 9001 and IATF 16949 requirements related to the scope of the audit;
ISO9001和IATF16949中适用的与审核范围有关的要求；

d) Applicable manufacturing process(es) to be audited ，including PFMEA and control plan;
适用的待审核制造过程，包括PFMEA和控制计划；

e) Applicable core tool requirements related to the scope of the audit;
与审核范围有关的适用的核心工具要求；

f) How to plan，conduct，prepare audit reports，and close out audit findings.
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意识

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

7.3 Awareness意识

The organization shall ensure that persons doing work under the organization's control are aware of:
组织应确保在其控制下工作人员知晓

a) The quality policy;
质量方针

b) Relevant quality objectives;
相关的质量目标

c) Their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
他们对质量管理体系有效性的贡献，包括改进质量绩效的益处

d) The implications of not conforming with the quality management system requirements.
不符合质量管理体系要求的后果

7.3.1Awareness–supplemental意识—补充

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.

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。

7.3.2Employee motivation and empowerment员工激励和授权

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.

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。

7.4Communication沟通

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

7.4Communication沟通

The organization shall determine the internal and external communications relevant to the quality management system, including:

组织应确定与质量管理体系相关的内部和外部沟通，包括：

a) On what it will communicate;
   沟通什么；
b) When to communicate;
   何时沟通；
c) With whom to communicate;
   与谁沟通；
d) How to communicate;
   怎么沟通；
e) Who communicates?
   由谁沟通。

7.5Documented information形成文件的信息

7.5.1 General总则

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

7.5.1 General总则

The organization's quality management system shall include:

组织的质量管理体系应包括：

a) Documented information required by this International Standard;
   本标准要求的形成文件的信息；
b) Documented information determined by the organization as being necessary for the effectiveness of the quality management system.
   组织确定的为确保质量管理体系有效性所需的形成文件的信息；

NOTE：The extent of documented information for a quality management system can differfromone organization to another due to:

注：对于不同组织，质量管理体系形成文件的信息的多少与详略程度可以不同，取决于：

— The size of organization and its type of activities, processes, products and services;
组织的规模，以及活动、过程、产品和服务的类型；

— The complexity of processes and their interactions;
过程及其相互作用的复杂程序；

— The competence of persons.
人员的能力。

7.5.1.1Quality management system documentation质量管理体系文件

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)

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）文件构成的。

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.

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清单。

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

质量手册应至少包括以下内容：

a) Thescopeofthequalitymanagementsystem， including detailsofandjustificationforany exclusions;
质量管理体系范围，包括任何删减的细节和正当的理由；
b) Documented processes established for the quality management system ，or reference to them;
为质量管理体系建立的形成文件的过程或对其引用；
c) The organization's processes and their sequence and interactions (inputs and outputs) ，including type and extent of control of any outsourced processes;
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) A document (i.e., matrix) indicating where within the organization’s quality management system their customer-specific requirements are addressed.
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

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之间建立联系。

7.5.2Creatingandupdating编制和更新

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

7.5.2Creating and updating编制和更新

When creating and updating documented information, the organization shall ensure appropriate:

在创建和更新形成文件的信息时，组织应确保适当的：

a) Identification and description (e.g. A title, date, author, or reference number);
标识和说明（如：标题、日期、作者、索引编号）；

b) Format (e.g. Language, software version, graphics) and media (e.g. Paper, electronic);
形式（如语言、软件版本、图表）和载体（如纸质的、电子的）；

c) Review and approval for suitability and adequacy.
评审和批准，以确保适宜性和充分性。

7.5.3Control of documented information形成文件的信息的控制

7.5.3.1 and 7.5.3.2

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

7.5.3.1 Documented information required by the quality management system and by this International Standard shall be controlled to ensure:

应控制质量管理体系和本标准所要求的形成文件的信息，以确保:

a) it is available and suitable for use, where and when it is needed;
在需求的场合和时机，均可获得并适用；

b) itis adequately protected(e.g. from loss of confidentiality, improper use, or loss of integrity).
予以妥善保护（如防止泄密、不当使用或缺失）。

7.5.3.2 For the control of documented information, the organization shall address the following activities, as applicable:

为控制形成文件的信息，适用时，组织应进行下列活动：

a) Distribution, access, retrieval and use;
分发、访问、检索和使用；

b) Storage and preservation, including preservation of legibility;
存储和防护，包括保持可读性；

c) Control of changes(e.g. Version control);
变更控制（如版本控制）；

d) Retention and disposition.
保留和处置。

Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled.

对于组织确定的策划和运行质量管理体系所必需的来自外部的形成文件的信息，组织应进行适当识别，并予以控制。

Documented information retained as evidence of conformity shall be protected from unintended alterations.

对所保留的、作为符合性证据的形成文件的信息应予以保护，防止非预期的更改。

NOTE：Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

注：对成为信息的“访问”可能意味着仅允许查阅，或者意味着允许查阅并授权修改。

7.5.3.2.1Record retention记录保存

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

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。

Production part approvals, tooling records (including maintenance and ownership),productandprocess designrecords， purchaseorders(if applicable) ,or contractsand amendmentsshallbe retained for the length of time that theproductis active forproduction and servicerequirements , plus one calendar year, unlessotherwisespecifiedby thecustomerorregulatoryagency

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。

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

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 Engineering specifications工程规范

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.

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。

When an engineering standard/specification change results in a product design change ，refer to the requirements in ISO9001, 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.

当工程标准/规范更改导致产品设计更改时，请参见ISO9001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。

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

应当在收到工程标准/更改通知后10个工作日内完成评审。

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：当设计记录引用了这些规范，或这些规范影响了生产批准过程的文件，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 运行

8.1 Operational planning and control 运行策划和控制

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:

为满足产品和服务提供的要求，并实施第6章所确定的措施，组织应通过以下措施对所需的过程（见4.4）进行策划、实施和控制：

a) Determining the requirements for the products and services;
确定产品和服务的要求；

b) Establishing criteria for:
建立下列内容的准则：

1) The processes;
过程；

2) The acceptance of products and services;
产品和服务的接收。

c) Determining the resources needed to achieve conformity to the product and service requirements;
确定所需的资源以使产品和服务符合要求

d) Implementing control of the processes in accordance with the criteria;
按照准则实施过程控制；

e) Determining, maintaining and retaining documented information to the extent necessary:
在必要的范围和程度上，确定并保持、保留形成文件的信息，以：

1) To have confidence that the processes have been carried out as planned;
确信过程已经按策划进行；

2) To demonstrate the conformity of products and services to their requirements.
证明产品和服务符合要求。

The output of this planning shall be suitable for the organization's operations.
策划的输出应适于组织的运行。

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.
组织应控制策划的变更，评审非预期变更的后果，必要时，采取措施减轻不利影响。

The organization shall ensure that outsourced processes are controlled (see 8.4).
组织应确保外包过程受控（见8.4）。

8.1.1 Operational planning and control- supplemental 运行策划和控制-补充

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

在对产品实现进行策划时，应包含以下主题：

a) Customer product requirements and technical specifications;
   顾客产品要求和技术规范；
b) Logistics requirements;
   物流要求；
c) Manufacturing feasibility
   制造可行性；
d) Project planning (refer to ISO 9001, Section 8.3.2)
   项目策划（参见ISO9001第8.3.2条）；
e) Acceptance criteria
   接收准则。

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.

ISO9001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 Confidentiality 保密

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

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 Customer communication 产品和服务的要求

8.2.1 customers Communication顾客沟通

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

8.2.1 customers Communication顾客沟通

Communication with customers shall include 与顾客沟通的内容应包括：

a) Providing information relating to products and services;
   提供有关产品和服务的信息；
b) Handling enquiries, contracts or orders, including changes;
   处理问询、合同或订单，包括更改；
c) Obtaining customer feedback relating to products and services, including customer complaints;
   获取有关产品和服务的顾客反馈，包括顾客投诉；
d) Handling or controlling customer property;
   处置或控制顾客财产；
e) Establishing specific requirements for contingency actions, when relevant.
   关系重大时，制定有关应急措施的特定要求。

8.2.1.1 Customer communication –supplemental 顾客沟通-补充

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).

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 Determining the requirements for products and services 产品和服务要求的确定

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

8.2.2 Determining the requirements for products and services 产品和服务要求的确定

When determining the requirements for the products and services to be offered to customers, the organization shall ensure that:

在确定向顾客提供的产品和服务的要求时，组织应确保：

a) The requirements for the products and services are defined, including:

产品和服务的要求得到规定，包括

1) Any applicable statutory and regulatory requirements;

适用的法律法规要求；

2) Those considered necessary by the organization;

组织认为的必要要求。

b) The organization can meet the claims for the products and services it offers.

提供的产品和服务能够满足所声明的要求。

8.2.2.1 Determining the requirements for products and services ® supplemental

产品和服务要求的确定-补充

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:

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ISO9001第8.2.2条a)1）项的要求应包括但不限于：

All applicable government, safety, and environmental regulations related to acquisition, storage, handling, recycling, elimination, or disposal of material.

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、安全和环境法规。

8.2.3 Review of the requirements for products and services 产品和服务要求的评审

8.2.3.1

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

8.2.3.1 The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer, to include:

组织应确保有能力向顾客提供满足要求的产品和服务。在承诺向顾客提供产品和服务之前，组织应对如下各项要求进行评审：

a) Requirements specified by the customer, including the requirements for delivery and post-delivery activities;

顾客规定的要求，包括对交付及交付后活动的要求；

b) Requirements not stated by the customer, but necessary for the specified or intended use, when known;

顾客虽然没有明示，但规定的用途或已知的预期用途所必需的要求；

c) Requirements specified by the organization;

组织规定的要求；

d) Statutory and regulatory requirements applicable to the products and services;

适用于产品和服务的法律法规要求；

e) Contract or order requirements differing from those previously expressed.

与以前表述不一致的合同或订单要求。

The organization shall ensure that contract or order requirements differing from those previously defined are resolved.

组织应确保与以前规定不一致的合同或订单要求已得到解决

The customer's requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.

若顾客没有提供成文的要求，组织在接受顾客要求前应对顾客要求进行确认。

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues.

注：在某些情况下，如网上销售，对每一个订单进行正式的评审可能是不实际的，作为替代方法，可评审有关的产品信息，如产品目录。

8.2.3.1.1 Review of the requirements for products and services — supplemental
产品和服务要求的评审-补充

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.

组织应保留形成文件的证据，证明对ISO9001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 Customer-designated special characteristics 顾客指定的特殊特性

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

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 Organization manufacturing feasibility 组织制造可行性

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.

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可行性分析。

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.

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 The organization shall retain documented information, as applicable:
适用时，组织应保留与下列方面有关的形成文件的信息：

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求.

8.2.3.2 The organization shall retain documented information, as applicable:
适用时，组织应保留与下列方面有关的形成文件的信息：

a) On the results of the review;
评审结果；

b) On any new requirements for the products and services.
产品和服务的新要求。

8.2.4 Changes to requirements for products and services 产品和服务要求的更改

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求.

8.2.4 Changes to requirements for products and services 产品和服务要求的更改

The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

若产品和服务要求发生更改 ,组织应确保相关的形成文件的信息得到修改 ,并确保相关人员知道已更改的要求。

8.3Design and development of products and services 产品和服务的设计和开发

8.3.1 General 总则

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求.

8.3.1 General 总则

The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.

组织应建立、实施和保持适当的设计和开发过程，以确保后续的产品和服务的提供。

8.3.1.1 Design and development of products and services — supplemental 产品和服务的设计和开发-补充

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.

ISO9001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。

The organization shall document the design and development process.

组织应对设计和开发过程形成文件。

8.3.2 Design and development planning 设计和开发策划

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求.

8.3.2 Design and development planning 设计和开发策划

In determining the stages and controls for design and development, the organization shall consider:

在确定设计和开发的各个阶段和控制时，组织应考虑：

a) The nature, duration and complexity of the design and development activities;
   设计和开发活动的性质、持续时间和复杂程度；
b) The required process stages, including applicable design and development reviews;
   所需的过程阶段，包括适用的设计和开发评审；
c) The required design and development verification and validation activities;
   所需的设计和开发验证及确认活动；

d) The responsibilities and authorities involved in the design and development process;
设计和开发过程涉及的职责和权限；

e) The internal and external resource needs for the design and development of products and services;
产品和服务的设计和开发所需的内部和外部资源：

f) The need to control interfaces between persons involved in the design and development process;
设计和开发过程参与人员之间接口的控制需求；

g) The need for involvement of customers and users in the design and development process;
顾客和使用者参与设计和开发过程的需求；

h) The requirements for subsequent provision of products and services;
对后续产品和服务提供的要求；

i) The level of control expected for the design and development process by customers and other relevant interested parties;
顾客和其他相关方期望的设计和开发过程的控制水平；

j) The documented information needed to demonstrate that design and development requirements have been met.
证实已经满足设计和开发要求所需的形成文件的信息。

8.3.2.1 Design and development planning — supplemental 设计和开发策划-补充

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;
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法包括但不限于：

a) Project management (for example, APQP or VDA-RGA);
项目管理（例如APQP或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;
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) Development and review of product design risk analysis (FMEAs), including actions to reduce potential risks;
产品设计风险分析（FEMA）的开发和评审，包括降低潜在风险的措施；

d) Development and review of manufacturing process risk analysis (for example, FMEAs, process flows, control plans, and standard work instructions).
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。

NOTE A multidisciplinary approach typically includes the organization's design, manufacturing, engineering, quality, production, purchasing, supplier, maintenance, and other appropriate functions.
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、维护和其它适当职能。

8.3.2.2 Product design skills 产品设计技能

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.
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。

NOTE An example of product design skills is the application of digitized mathematically based data.
注：基于数学的数学化数据的应用便是一种产品设计技能。

8.3.2.3 Development of products with embedded software 带有嵌入式软件的产品的开发

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.
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).
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 Design and development inputs 设计和开发输入

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求.

8.3.3 Design and development inputs 设计和开发输入

The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider:
组织应针对所设计和开发的具体类型的产品和服务，确定必需的要求。要求应考虑：

a) Functional and performance requirements;
功能和性能要求；
b) Information derived from previous similar design and development activities;
来源于以前类似设计和开发活动的信息；
c) Statutory and regulatory requirements;
法律法规要求；
d) Standards or codes of practice that the organization has committed to implement;
组织承诺实施的标准或行业规范；
e) Potential consequences of failure due to the nature of the products and services.
由产品和服务性质所导致的潜在失效后果。

Inputs shall be adequate for design and development purposes, complete and unambiguous.
针对设计和开发的目的，输入应是充分和适宜的，且应完整、清楚。

Conflicting design and development inputs shall be resolved.
相互矛盾的设计和开发输入应得到解决。

The organization shall retain documented information on design and development inputs.
组织应保留有关设计和开发输入的形成文件的信息。

8.3.3.1 Product design input产品设计输入

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:

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) Product specifications including but not limited to special characteristics (see Section 8.3.3.3);
产品规范，包括但不限于特殊特性（见第8.3.3.3条）；

b) Boundary and interface requirements;
边界和对接要求；

c) Identification, traceability, and packaging;
标识、可追溯性和包装；

d) Consideration of design alternatives;
对设计的替代选择的考虑；

e) Assessment of risks with the input requirements and the organization's ability to mitigate/manage the risks, including from the feasibility analysis;
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) Targets for conformity to product requirements including preservation, reliability, durability, serviceability, health, safety, environmental, development timing, and cost;
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) Applicable statutory and regulatory requirements of the customer-identified country of destination, if provided;
顾客确定的目的国（如有提供）的适用法律法规要求；

h) Embedded software requirements.
嵌入式软件要求。

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.

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、使用现场数据和其他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。

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

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 Manufacturing process design input 制造过程设计输入

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

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) Product design output data including special characteristics;
产品设计输出的数据，包括特殊特性；

b) Targets for productivity, process capability, timing, and cost;
生产力、过程能力、时程安排及成本的目标；

c) Manufacturing technology alternatives;
制造技术替代选择；

d) Customer requirements, if any;
顾客要求，如有；

e) Experience from previous developments;
以往的开发经验；

f) New materials;
新材料；

g) Product handling and ergonomic requirements; and
产品搬运和人体工学要求；以及

h) Design for manufacturing and design for assembly.
制造设计和装配设计。

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.
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 特殊特性

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:
组织应采用多方认证方法来建立、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) 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;
将所有特殊特性记录进图纸（按要求）、风险分析（例如FEMA）、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) Development of control and monitoring strategies for special characteristics of products and production processes;
为产品和生产过程的特殊特性开发控制和监视策略；

c) Customer-specified approvals, when required;
顾客规定的批准，如有要求；

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.
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 Design and development controls 设计和开发控制

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

The organization shall apply controls to the design and development process to ensure that:

组织应对设计和开发过程进行控制，以确保：

a) The results to be achieved are defined;
   规定拟获得的结果；
b) Reviews are conducted to evaluate the ability of the results of design and development to meet requirements;
   实施评审活动，以评价设计和开发的结果满足要求的能力；
c) Verification activities are conducted to ensure that the design and development outputs meet the input requirements;
   实施验证活动，以确保设计和开发输出满足输入的要求；
d) Validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;
   实施确认活动，以确保产品和服务能够满足规定的使用要求或预期用途；
e) Any necessary actions are taken on problems determined during the reviews, or verification and validation activities;
   针对评审、验证和确认过程中确定的问题采取必要措施；
f) Documented information of these activities is retained.
   保留这些活动的形成文件的信息。

NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.

注：设计和开发的评审、验证和确认具有不同目的。根据组织的产品和服务的具体情况，可单独或以任意组合的方式进行。

8.3.4.1 Monitoring 监视

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).

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）。

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.

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。

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

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 Design and development validation 设计和开发确认

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.
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。

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.
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 Prototype programme 原型样件方案

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.
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同、工装和制造过程。

All performance-testing activities shall be monitored for timely completion and conformity to requirements.
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).
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ISO9001第8.4条）。

8.3.4.4 Product approval process 产品批准过程

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

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.
在向顾客提交其零件批准之前，组织应根据ISO9001第8.4.3条，对外部提供的产品和服务进行审批。

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

NOTE Product approval should be subsequent to the verification of the manufacturing process.
注：产品的批准应当是制造过程验证的后续步骤。

8.3.5 Design and development outputs 设计和开发输出

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

8.3.5 Design and development outputs 设计和开发输出

The organization shall ensure that design and development outputs:
组织应确保满足设计和开发输出：

a) Meet the input requirements;
满足输入的要求；

b) Are adequate for the subsequent processes for the provision of products and services;
对于后续的产品和服务的提供过程是充分的；

c) Include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;
包括或引用监视和测量的要求，适当时，包括接收准则；

d) Specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.
规定对于预期目的、安全和正确提供的产品和服务的基本特征。

The organization shall retain documented information on design and development outputs.
组织应保留设计和开发输出的形成文件的信息。

8.3.5.1 Design and development outputs — supplemental 设计和开发输出-补充

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:
产品设计输出的陈述方式应适合地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) Design risk analysis (FMEA);
设计风险分析（FMEA）；

b) Reliability study results;
可靠性研究结果；

c) Product special characteristics;
产品特殊特性；

d) Results of product design error-proofing, such as DFSS, DFMA, and FTA;
产品设计防错结果，例如：DFSS、DFMEA和FTA；

e) Product definition including 3D models, technical data packages, product manufacturing information, and geometric dimensioning & tolerancing (GD&T);
产品定义，包括三维模型、技术数据包、产品制造信息，以及几何尺寸和公差（GD&T）；

f) 2D drawings, product manufacturing information, and geometric dimensioning & tolerancing (GD&T);
二维图纸、产品制造信息以及几何尺寸和公差（GD&T）；

g) Product design review results;
产品设计评审结果；

h) Service diagnostic guidelines and repair and serviceability instructions;
服务诊断指南及修理和可服务性说明；

i) Service part requirements;
服务件要求；

j) Packaging and labeling requirements for shipping.
运输的包装和标签要求。

NOTE Interim design outputs should include any engineering problems being resolved through a trade-off process.
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 Manufacturing process design output 制造过程设计输出

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:

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;
   规范的图纸；
b) Special characteristics for product and manufacturing process;
   产品和制造过程的特殊特性；
c) Identification of process input variables that impact characteristics;
   对影响特性的过程输入变量的识别；
d) Tooling and equipment for production and control, including capability studies of equipmentand process(es);
   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) Manufacturing process flow charts/layout, including linkage of product, process, and tooling;
   制造过程流程图/制造过程平面布置图，包括产品、过程和工装的联系；
f) Capacity analysis;
   产能分析；
g) Manufacturing process fmea;
   制造过程FMEA；
h) Maintenance plans and instructions;
   维护计划和说明；
i) Control plan (see annex a);
   控制计划（见附录a）；
j) Standard work and work instructions;
   标准作业和工作指导书；
k) Process approval acceptance criteria;
   过程批准的接收准则；
l) Data for quality, reliability, maintainability, and measurability;
   质量、可靠性、可维护性和可测量性的数据；
m) Results of error-proofing identification and verification, as appropriate;
   适用时，防错识别和验证的结果；
n) Methods of rapid detection, feedback, and correction of product/manufacturing process nonconformities.
   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 Design and development changes 设计和开发更改

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

8.3.6 Design and development changes 设计和开发更改

The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

组织应对产品和服务设计和开发期间以及后续所做的更改进行适当的识别、评审和控制，以确保这些更改对满足要求不会产生不利影响。

The organization shall retain documented information on:
组织应保留下列方面的形成文件的信息：

a) Design and development changes;
   设计和开发更改；
b) The results of reviews;
   评审的结果；
c) The authorization of the changes;
   更改的授权；
d) The actions taken to prevent adverse impacts.
   为防止不利影响而采取的措施。

8.3.6.1 Design and development changes — supplemental 设计和开发更改-补充

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.
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。

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

For products with embedded software, the organization shall document the revision level of software and hardware as part of the change record.
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
外部提供的过程、产品和服务的控制

8.4.1 General 总则

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

8.4.1 General 总则

The organization shall ensure that externally provided processes, products and services conform to requirements.
组织应确保外部提供的过程、产品和服务符合要求。
The organization shall determine the controls to be applied to externally provided processes, products and services when:**在下列情况下，组织应确定对外部提供的过程、产品和服务实施的控制：**

a) products and services from external providers are intended for incorporation into the organization's own products and services;
   外部供方的产品和服务将构成组织自身的产品和服务的一部分；
b) products and services are provided directly to the customer(s) by external providers on behalf of the organization;
   外部供方代表组织直接将产品和服务提供给顾客；
c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization.
   组织决定由外部供方提供过程或部分过程。

The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.

组织应基于外部供方按照要求提供过程、产品或服务的能力，确定并实施外部供方的评价、选择、绩效监视以及再评价的准则。对于这些活动和由评价引发的任何必要的措施，组织应保留形成文件的信息。

8.4.1.1 General — supplemental 总则-补充

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.

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 Supplier selection process 供应商选择过程

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

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) an assessment of the selected supplier's risk to product conformity and uninterrupted supply of the organization's product to their customers;

对所选择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) relevant quality and delivery performance;

相关质量和交付绩效；

c) an evaluation of the supplier's quality management system;

对供应商质量管理体系的评价；

d) multidisciplinary decision making; and

多方论证决策；以及

e) an assessment of software development capabilities, if applicable.

对软件开发能力的评估，如适用。

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

应当考虑的其它供应商选择准则包括：

— Volume of automotive business (absolute and as a percentage of total business);

汽车业务量（绝对值，以及占总业务量的百分比）；

— Financial stability;

财务稳定性；

— Purchased product, material, or service complexity;

采购的产品、材料或服务的复杂性；

— Required technology (product or process);

所需技术（产品或过程）；

— Adequacy of available resources (e.g., people, infrastructure);

可用资源（如：人员、基础设施）的充分性；

— Design and development capabilities (including project management);

设计和开发能力（包括项目管理）；

— Manufacturing capability;

制造能力；

— Change management process;
更改管理过程；
— Business continuity planning (e.g., disaster preparedness, contingency planning);
业务连续性规划（如：防灾准备、应急计划）；
— Logistics process;
物流过程；
— Customer service. 8.4.1.3 Customer-directed sources (also known as "Directed—Buy")
顾客服务。

8.4.1.3 Customer-directed sources (also known as "Directed—Buy")
顾客指定的货源（亦称"指向性购买"）

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

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.
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 控制类型和程度

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

8.4.2 Type and extent of control 控制类型和程度

The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers.
组织应确保外部提供的过程、产品和服务不会对组织持续地向顾客交付合格产品和服务的能力产生不利影响。
The organization shall:**组织应：**

a) ensure that externally provided processes remain within the control of its quality management system;
确保外部提供的过程保持在其质量管理体系的控制之中；
b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
规定对外部供方的控制及其输出结果的控制；
c) take into consideration:
考虑：
1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;
外部提供的过程、产品和服务对组织持续地满足顾客要求和适用的法律法规要求的能力的潜在影响；
2) the effectiveness of the controls applied by the external provider;
由外部供方实施控制的有效性。
d) Determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.
确定必要的验证和其他活动，以确保外部提供的过程、产品和服务满足要求。

8.4.2.1 Type and extent of control supplemental 控制的类型和程序-补充

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.

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。

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.

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序以及开发活动的准则和措施。

8.4.2.2 Statutory and regulatory requirements 法律法规要求

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.

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。

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.

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 Supplier quality management system development 供应商质量管理体系开发

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:

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ISO9001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) Compliance to ISO 9001 through second-party audits;
   经由第二方审核符合ISO9001；
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 1AF MLA (International Accreditation Forum Multilateral Recognition Arrangement) member and where the accreditation body's main scope includes management system certification to ISO/IEC 17021;
   经由第三方审核通过ISO9001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ISO9001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/IEC17021管理体系认证；
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;
   经由第二方审核通过ISO9001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[MSQMSR]或等效要求）；

d) Certification to I809001 with compliance to IATF 16949 through second-party audits;
通过ISO9001认证，同时经由第二方审核符合IATF16949；

e) Certification to 16949 through third-party audits (valid third-party certification of the supplier to IATF 16949 by an IATF-recognized certification body).
经由第三方审核通过IATF16949认证（IATF认可的认证机构进行的有效的供应商IATF16949第三方认证）。

8.4.2.3.1 Automotive product-related software or automotive products with embedded software
汽车产品相关软件或带有嵌入式软件的汽车产品

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.
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.
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评估保存形成文件的信息。

8.4.2.4 Supplier monitoring 供应商监视

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.
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。

At a minimum, the following supplier performance indicators shall be monitored:
至少应监视以下供应商绩效指标：

a) Delivered product conformity to requirements;
已交付产品对要求的符合性；

b) Customer disruptions at the receiving plant, including yard holds and stop ships;
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) Delivery schedule performance;
交付排程的绩效；

d) Number of occurrences of premium freight.
超额运费发生次数。

If provided by the customer, the organization shall also include the following, as appropriate, in their supplier performance monitoring:
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) Special status customer notifications related to quality or delivery issues;
与质量或交付有关的特殊状态顾客通知；

f) Dealer returns, warranty, field actions, and recalls.
经销商退货、保修、使用现场措施和召回。

8.4.2.4.1 Second-party audits　第二方审核

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

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) Supplier risk assessment;
   供应商风险评估；
b) Supplier monitoring;
   供应商监视；
c) Supplier qms development;
   供应商质量管理体系开发；
d) Product audits;
   产品审核；
e) Process audits.
   过程审核。

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.

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。

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

组织应保留第二方审核报告的记录。

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.

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。

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

注：可从IATF审核员指南和ISO19011获得指导。

8.4.2.5 Supplier development　供应商开发

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:

组织应为现行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);
   通过供应商监视（见第8.4.2.4条）识别的绩效问题；
b) second-party audit findings (see Section 8.4.2.4.1);
   第二方审核发现（见第8.4.2.4.1条）；
c) third-party quality management system certification status;
   第三方质量管理体系认证状态；
d) risk analysis.
   风险分析。

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

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 Information for external providers 外部供方的信息

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

8.4.3 Information for external providers 外部供方的信息

The organization shall ensure the adequacy of requirements prior to their communication to the externalprovider.

组织应确保在与外部供方沟通之前所确定的要求是充分的。

The organization shall communicate to external providers its requirements for:

组织应与外部供方沟通以下要求：

a) The processes, products and services to be provided;
   拟提供的过程、产品和服务；
b) The approval of:
   对下列内容的批准：
   1) Products and services;
      产品和服务；
   2) Methods, processes and equipment;
      方法、过程和设备；
   3) The release of products and services;
      产品和服务的放行。
c) Competence, including any required qualification of persons;
   能力，包括所要求的人员资格；
d) The external providers' interactions with the organization;
   外部供方与组织的互动；
e) Control and monitoring of the external providers' performance to be applied by the organization;
   被组织所用的外部供方绩效的控制和监视；
f) Verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.
   组织或其顾客拟在外部供方现场实施的验证或确认活动。

8.4.3.1 Information for external providers — supplemental 外部供方的信息—补充

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.

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 Production and service provision 生产和服务提供

8.5.1 Control of production and service provision 生产和服务提供的控制

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

8.5.1 Control of production and service provision 生产和服务提供的控制

The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable:

组织应在受控条件下进行生产和服务提供。适用时，受控条件应包括：

a) The availability of documented information that defines:
   可获得形成文件的信息，以规定以下内容：
   1) The characteristics of the products to be produced, the services to be provided, or the activities to be performed;
      所生产的产品、提供的服务或进行的活动的特征；
   2) The results to be achieved;
      拟获得的结果。
b) The availability and use of suitable monitoring and measuring resources;
   可获得和使用适宜的监视和测量资源；
c) The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;
   在适当阶段实施监视和测量活动，以验证是否符合过程或输出的控制准则以及产品和服务的接收准则；
d) The use of suitable infrastructure and environment for the operation of processes;
   为过程的运行提供适宜的基础设施和环境；
e) The appointment of competent persons, including any required qualification;
   配备具备能力的人员，包括所要求的资格；
f) The validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
   若输出结果不能由后续的监视或测量加以验证，应对生产和服务提供过程实现策划结果的能力进行确认，并定期再确认；
g) The implementation of actions to prevent human error;
   采取措施防范人为错误；
h) The implementation of release, delivery and post-delivery activities.
   实施放行、交付和交付后的活动。

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.

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 Control plan 控制计划

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.

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。

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).

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。

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:

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) Controls used for the manufacturing process control, including verification of job set-ups;
   用于制造过程的控制手段，包括作业准备的验证；
b) First-off/last-off, part validation, as applicable;
   首件/末件确认，如适用；
c) Methods for monitoring of control exercised over special characteristics (see Annex A) defined by both the customer and the organization;
   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) The customer-required information, if any;
   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.
   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。

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

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) The organization determines it has shipped nonconforming product to the customer;
   当组织确定其已经向顾客发运了不合格品；
g) When any change occurs affecting product, manufacturing process, measurement, logistics, supply sources, production volume changes, or risk analysis (FMEA) (see Annex A);
   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) After a customer complaint and implementation of the associated corrective action, when applicable;
   在收到顾客投诉并实施了相关纠正措施之后，当适用时；
i) At a set frequency based on a risk analysis.
   以基于风险分析的设定频率。

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

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 Standardised work—operator instructions and visual standards*标准化作业-操作指导书和目视标准

The organization shall ensure that standardised work documents are:

组织应确保标准化作业文件：

a) Communicated to and understood by the employees who are responsible for performing the work;
被传达给负责相关工作的员工，并被员工理解；

b) Legible,
是清晰易读的；

c) Presented in the language(s) understood by the personnel responsible to follow them;
用有责任遵守这些文件的人员能够理解的语言表述；

d) Accessible for use at the designated work area(s).
在指定的工作区域易于得到。

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

标准化作业文件还应包含作业员安全规则。

8.5.1.3 Verification of job set-ups作业准备的验证

The organization shall:

组织应：

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;
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) Maintain documented information for set-up personnel;
保持有关准备人员的形成文件的信息；

c) Use statistical methods of verification, where applicable;
适用时采用统计的验证方法；

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;
进行首件/末件确认，如适用；适当时，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) Retain records of process and product approval following set-up and first-off/last-off part validations.
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 Verification after shutdown 停工后的验证

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

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 全面生产维护

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

At a minimum, the system shall include the following:
该系统应至少包含：

a) Identification of process equipment necessary to produce conforming product at the required volume,
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) Availability of replacement parts for the equipment identified in item a);
a)项中被识别设备的替换件的可用性；
c) Provision of resource for machine, equipment, and facility maintenance;
机器、设备和设施维护的资源提供；
d) Packaging and preservation of equipment, tooling, and gauging;
设备、工装和量具的包装和防护；
e) Applicable customer-specific requirements;
适用的顾客特定要求；
f) Documented maintenance objectives, for example: []ee (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);
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ISO9001第9.3条）；
g) Regular review of maintenance plan and objectives and a documented action plan to address corrective actions where objectives are not achieved;
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) Use of preventive maintenance methods;
对预防性维护方法的使用；
i) Use of predictive maintenance methods, as applicable;
对预测性维护方法的使用，如适用；
j) Periodic overhaul.
周期性检修。

8.5.1.6 Management of production tooling and manufacturing, test, inspection tooling and equipment生产工装及制造、试验、检验工装和设备的管理

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.
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。

The organization shall establish and implement a system for production tooling management, whether owned by the organization or the customer, including:
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) Maintenance and repair facilities and personnel;
维护、维修设施与人员；
b) Storage and recovery;]
存储和修复；

c) Set-up;
工装准备；

d) Tool-change programmes for perishable tools;
易损工具的工具更换方案；

e) Tool design modification documentation, including engineering change level of the product;
工具设计修改的文件，包括产品的工程变更等级；

f) Tool modification and revision to documentation;
工具的修改和文件的修订；

g) Tool identification, such as serial or asset number; the status, such as production, repair or disposal; ownership; and location.
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。

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.
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.
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 Production scheduling 生产排程

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.
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。

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.
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、预防性维护和校准。

8.5.2 Identification and traceability 标识和可追溯性

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

8.5.2 Identification and traceability 标识和可追溯性

The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.
需要时，组织应采用适当的方法识别输出，以确保产品和服务合格。

The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.
组织应在生产和服务提供的整个过程中按照监视和测量要求识别输出状态。

The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.
当有可追溯要求时，组织应控制输出的唯一性标识，且应保留所需的形成文件的信息以实现可追溯。

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.
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（如有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 Identification and traceability — supplemental 标识和可追溯性-补充

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.
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。

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:
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) Enable the organization to identify nonconforming and/or suspect product;
使组织能够识别不合格品和/或可疑产品；
b) Enable the organization to segregate nonconforming and/or suspect product;
使组织能够隔离不合格品和/或可疑产品；
c) Ensure the ability to meet the customer and/or regulatory response time requirements;
确保能够满足顾客要求和/或法规对响应时间的要求；
d) Ensure documented information is retained in the format (electronic, hardcopy, archive) that enables the organization to meet the response time requirements;
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) Ensure serialized identification of individual products, if specified by the customer or regulatory standards;
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) Ensure the identification and traceability requirements are extended to externally provided products with safety/regulatory characteristics.
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 Property belonging to customers or external providers 顾客或外部供方的财产

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

8.5.3 Property belonging to customers or external providers 顾客或外部供方的财产

The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.
组织应爱护在组织控制下或组织使用的顾客或外部供方的财产。

The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.
对组织使用的或构成产品和服务一部分的顾客和外部供方财产，组织应予以识别、验证、保护和防护。

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred.
若顾客或外部供方的财产发生丢失、损坏或发现不适用情况，组织应向顾客或外部供方报告，并保留所发生情况的形成文件的信息。

NOTE A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.
注：顾客或外部供方的财产可能包括材料、零部件、工具和设备，顾客的场所，知识产权和个人资料。

8.5.4 Preservation 防护

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

8.5.4 Preservation 防护

The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.
组织应在生产和服务提供期间对输出进行必要防护，以确保符合要求。

NOTE Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.
注：防护可包括标识、处置、污染控制、包装、储存、传输或运输以及保护。

8.5.4.1 Preservation — supplemental 防护-补充

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

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.
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。

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.
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。

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).
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）”。

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

Organizations shall comply with preservation, packaging, shipping, and labeling requirements as provided by their customers.
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 Post-delivery activities 交付后的活动

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

8.5.5 Post-delivery activities 交付后的活动

The organization shall meet requirements for post-delivery activities associated with the products and services.
组织应满足与产品和服务相关的交付后活动的要求。

In determining the extent of post-delivery activities that are required, the organization shall consider:
在确定所要求的交付后活动的覆盖范围和程度时，组织应考虑：

a) Statutory and regulatory requirements;
   法律法规要求；
b) The potential undesired consequences associated with its products and services;
   与产品和服务相关的潜在不期望的后果；
c) The nature, use and intended lifetime of its products and services;
   产品和服务的性质、用途和预期寿命；
d) Customer requirements;
   顾客要求；
e) Customer feedback.
   顾客反馈。

NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.
注：交付后活动可能包括保证条款所规定的相关活动，诸如合同规定的维护服务，以及回收或最终报废处置等附加服务等。

8.5.5.1 Feedback of information from service服务信息的反馈

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.

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的过程。

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.

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

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

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 Service agreement with customer与顾客的服务协议

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

当与顾客达成服务协议时，组织应：

a) Verify that the relevant service centres comply with applicable requirements;
   验证相关服务中心满足适用要求；
b) Verify the effectiveness of any special purpose tools or measurement equipment;
   验证任何特殊用途的工具或测试设备的有效性；
c) Ensure that all service personnel are trained in applicable requirements.
   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 更改控制

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

> ## 8.5.6 Control of changes 更改控制
>
> The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.
>
> **组织应对生产和服务提供的更改进行必要的评审和控制，以确保持续地符合要求。**
>
> The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.
>
> **组织应保留形成文件的信息，包括有关更改评审结果、授权进行更改的人员以及根据评审所采取的必要措施。**

8.5.6.1 Control of changes — supplemental 更改的控制-补充

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.

组织应有一个形成文件的过程，对影响产品实现的进行控制和反应。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。

The organization shall:**组织应：**

a) Define verification and validation activities to ensure compliance with customer requirements;
   明确验证和确认活动，以确保与顾客要求相一致；

b) Validate changes before implementation;
在实施前对更改予以确认；
c) Document the evidence of related risk analysis;
对相关风险分析的证据形成文件；
d) Retain records of verification and validation.
保留验证和确认的记录；

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.
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。

When required by the customer, the organization shall:
当顾客要求时，组织应：
e) Notify the customer of any planned product realization changes after the most recent product approval;
向顾客通知最后一次产品批准之后任何计划产品实现的更改；
f) Obtain documented approval, prior to implementation of the change;
在实施更改之前获得形成文件的批准；
g) Complete additional verification or identification requirements, such as production trial run and new product validation.
达成额外验证或标识要求，例如：试生产和新产品确认。

8.5.6.1.1Temporary change of process controls 过程控制的临时更改

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.
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，清单包括主要过程控制和经批准的备用或替代方法。

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.
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FEMA）和严重程度，在本过程中包含要在生产中实施控制方法之前获得的内部批准。

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.
在发运采用替代方法检验或试验的产品之前，如有要求，组织应获得顾客的批准。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。

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:
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) Daily quality focused audits (e.g,, layered process audits, as applicable);
以质量为关注的每日审核（如：分层过程审核，如适用）；
b) Daily leadership meetings.
每日领导会议。

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.
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。

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).
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 Release of products and services 产品和服务的放行

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

8.6 Release of products and services 产品和服务的放行

The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.
组织应在适当的阶段实施策划的安排，以验证产品和服务的要求已得到满足。

The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.
除非得到有关授权人员的批准，适用时得到顾客的批准，否则在策划的安排已圆满完成之前，不应向顾客放行产品和交付服务。

The organization shall retain documented information on the release of products and services. The documented information shall include:
组织应保留有关产品和服务放行的形成文件的信息。形成文件的信息应包括：

a) Evidence of conformity with the acceptance criteria;
   符合接收准则的证据。
b) Traceability to the person(s) authorizing the release.
   授权放行人员的可追溯信息。

8.6.1 Release of products and services — supplemental 产品和服务的放行—补充

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).
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）。

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

The organization shall ensure that product or service approval is accomplished after changes following initial release, according to ISO 9001, Section 8,5.6.
根据ISO9001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 Layout inspection and functional testing 全尺寸检验和功能性试验

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.
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。

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

NOTE 2 The frequency of layout inspection is determined by the customer.
注2：全尺寸检验频率由顾客确定。

8.6.3 Appearance items 外观项目

For organizations manufacturing parts designated by the customer as "appearance items," the organization shall provide the following:
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) Appropriate resources, including lighting, for evaluation;
适当的资源，包括评价用的照明；
b) Masters for colour, grain, gloss, metallic brilliance, texture, distinctness of image (doi), and haptic technology, as appropriate;
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) Maintenance and control of appearance masters and evaluation equipment;
外观原版样件及评价设备的维护和控制；
d) Verification that personnel making appearance evaluations are competent and qualified to do so.
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外部提供的产品和服务符合性的验证和接受

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:
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) Receipt and evaluation of statistical data provided by the supplier to the organization;
接收并评价组织供应商提供的统计数据；
b) Receiving inspection and/or testing, such as sampling based on performance;
接收检验和/或试验，例如基于绩效的抽样检查；
c) Second-party or third-party assessments or audits of supplier sites when coupled with records of acceptable delivered product conformance to requirements;
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) Part evaluation by a designated laboratory;
指定实验室的零件评价；
e) Another method agreed with the customer.
顾客同意的其它方法。

8.6.5 Statutory and regulatory conformity 法律法规的符合性

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.

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标的国（如有提供）最新的适用法律、法规和其它要求。

8.6.6 Acceptance criteria 接收准则

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).

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

8.7 Control of nonconforming outputs不合格输出的控制

8.7.1

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

8.7.1 Theorganizationshallensurethatoutputsthatdonotconformtotheir requirements are identified and controlled to prevent their unintended use or delivery.

组织应确保对不符合的输出进行识别和控制，以防止非预期的使用或交付。

The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

组织应根据不合格的性质及其对产品和服务符合性的影响采取适当措施。这也适用于在产品交付之后，以及在服务提供期间或之后发现的不合格产品和服务。

The organization shall deal with nonconforming outputs in one or more of the following ways:

组织应通过下列一种或几种途径处置不合格输出：

a) Correction;
   纠正；
b) Segregation, containment, return or suspension of provision of products and services;
   隔离、限制、退货或暂停对产品和服务的提供；
c) Informing the customer;
   告知顾客；
d) Obtaining authorization for acceptance under concession.
   获得让步接收的授权；

Conformity to the requirements shall be verified when nonconforming outputs are corrected.

对不合格输出进行纠正之后验证其是否符合要求。

8.7.1.1 Customer authorization for concession 顾客的让步授权

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.

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

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.
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。

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.
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 Control of nonconforming product-- customer-specified process 不合格品控制-顾客规定的过程

The organization shall comply with applicable customer-specified controls for nonconforming product(s).
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 可疑产品的控制

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.
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 Control of reworked product 返工产品的控制

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.
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的风险。如顾客有所要求，组织应在产品开始返工之前获得顾客批准。

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.
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。

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

The organization shall retain documented information on the disposition of reworked product including quantity, disposition, disposition date, and applicable traceability information.
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 Control of repaired product 返修产品的控制

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.
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就获得顾客批准。

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

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

The organization shall obtain a documented customer authorization for concession for the product to be repaired.
组织应获得顾客对待返修产品的形成文件的让步授权。

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

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.
当不合格品被发运时，组织应立即通知顾客。初始通知应随附事件的详细文件。

8.7.1.7 Nonconforming product disposition 不合格品的处置

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.
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变得无用。

The organization shall not divert nonconforming product to service or other use without prior customer approval.
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 The organization shall retain documented information that:　组织应保留下列形成文件的信息，以：

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

8.7.2 The organization shall retain documented information that:　组织应保留下列形成文件的信息，以：

a) Describes the nonconformity;
描述不合格；
b) Describes the actions taken;
描述所采取的措施；
c) Describes any concessions obtained;
描述获得的让步；
d) Identifies the authority deciding the action in respect of the nonconformity.
识别处置不合格的授权；

9 Performance evaluations 绩效评价

9.1 Monitoring, measurement, analysis and evaluation
监视、测量、分析和评价

9.1.1 General总则

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

9.1.1 General总则

The organization shall determine:
组织应确定：

a) What needs to be monitored and measured;
需要监视和测量什么；
b) The methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
需要用什么方法进行监视、测量、分析和评价，以确保结果有效；
c) When the monitoring and measuring shall be performed;
何时实施监视和测量；
d) When the results from monitoring and measurement shall be analysed and evaluated.
何时对监视和测量的结果进行分析和评价

The organization shall evaluate the performance and the effectiveness of the quality management system.
组织应评价质量管理体系的绩效和有效性。
The organization shall retain appropriate documented information as evidence of the results.
组织应保留适当的形成文件的信息，以作为结果的证据。

9.1.1.1 Monitoring and measurement of manufacturing processes制造过程的监视和测量

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.
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。

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.
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。

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:
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) Measurement techniques;
测量技术；
b) Sampling plans;
抽样计划；
c) Acceptance criteria;
接收准则；

d) Records of actual measurement values and/or test results for variable data;
计量数据实际测量值和/或试验结果的记录；
e) Reaction plans and escalation process when acceptance criteria are not met.
当不满足接收准则时的反应计划和升级过程。

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

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.
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。

The organization shall maintain records of effective dates of process changes.
组织应保持过程变更生效日期的记录。

9.1.1.2 Identification of statistical tools统计工具的确定

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.
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统计概念的应用

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.
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 Customer satisfaction 顾客满意

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

9.1.2 Customer satisfaction顾客满意

The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring and reviewing this information.
组织应监视顾客对其需求和期望已得到满足的程度的感受。组织应确定获取、监视和评审该信息的方法。

NOTE: Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.
注：监视顾客感受的例子可包括顾客调查、顾客对交付产品或服务的反馈、顾客座谈、市场占有率分析、顾客赞扬、担保索赔和经销商报告。

9.1.2.1 Customer satisfaction — supplemental顾客满意——补充

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.
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。

Performances indicators shall be based on objective evidence and include but not be limited to the following:
绩效指标应基于客观证据，包括但不限于：

a) Delivered part quality performance;
已交付零件的质量绩效；
b) Customer disruptions;
对顾客造成的干扰；
c) Field returns, recalls, and warranty (where applicable);
使用现场退货、召回和保修（在适用情况下）；
d) Delivery schedule performance (including incidents of premium freight);
交付时间安排的绩效（包括超额运费的情况）；
e) Customer notifications related to quality or delivery issues, including special status.
与质量或交付问题有关的顾客通知，包括特殊状态。

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.
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 Analysis and evaluation 分析和评价

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

9.1.3 Analysis and evaluation分析和评价

The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement.

组织应分析和评价通过监视和测量获得的适当的数据和信息。

The results of analysis shall be used to evaluate:

应利用分析结果评价：

a) Conformity of products and services;
   产品和服务的符合性；
b) The degree of customer satisfaction;
   顾客满意程度；
c) The performance and effectiveness of the quality management system;
   质量管理体系的绩效和有效性；
d) If planning has been implemented effectively;
   策划是否得到有效实施；
e) The effectiveness of actions taken to address risks and opportunities;
   应对风险和机遇所采取措施的有效性；
f) The performance of external providers;
   外部供方的绩效；
g) The need for improvements to the quality management system.
   质量管理体系改进的需求。

NOTE Methods to analyse data can include statistical techniques.

注：数据分析方法可包括统计技术。

9.1.3.1 Prioritization优先级

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.

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

9.2 Internal audit内部审核

9.2.1 AND 9.2.2

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

9.2.1 The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:

组织应按照策划的时间间隔进行内部审核，以提供有关质量管理体系的下列信息：

a) Conforms to:
   是否符合：

1) The organization's own requirements for its quality management system;
组织自身的质量管理体系要求；
2) The requirements of this international standard;
本标准的要求。

b) Is effectively implemented and maintained.
是否得到有效的实施和保持。

9.2.2The organization shall:组织应

a) Plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;
依据有关过程的重要性、对组织产生影响的变化和以往的审核结果，策划、制定、实施和保持审核方案，审核方案包括频次、方法、职责、策划要求和报告；
b) Define the audit criteria and scope for each audit;
规定每次审核的审核准则和范围；
c) Select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
选择审核员并实施审核，以确保审核过程客观公正；
d) Ensure that the results of the audits are reported to relevant management;
确保将审核结果报告给相关管理者；
e) Take appropriate correction and corrective actions without undue delay;
及时采取适当的纠正和纠正措施；
f) Retain documented information as evidence of the implementation of the audit programme and the audit results.
保留形成文件的信息，作为实施审核方案以及审核结果的证据。

NOTE SeeISO19011forguidance.
注：相关指南参见ISO 19011。

9.2.2.1 Internal audit programme内部审核方案

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.
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。

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

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

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.
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 Quality management system audit质量管理体系审核

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.

组织应根据年度审核方案，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 Manufacturing process audit制造过程审核

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.

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。

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.

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。

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.

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

9.2.2.4 Product audit产品审核

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.

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 Management review管理评审

9.3.1 General总则

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

9.3.1 General总则

Top management shall review the organization’s quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.

最高管理者应按照策划的时间间隔对组织的质量管理体系进行评审，以确保其持续的适宜性、充分性和有效性，并与组织的战略方向一致。

9.3.1.1 Management review — supplemental管理评审——补充

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.

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风险，提高管理评审的频率。

9.3.2 Management review inputs 管理评审输入

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

9.3.2 Management review inputs 管理评审输入

The management review shall be planned and carried out taking into consideration:

策划和实施管理评审时应考虑下列内容：

a) The status of actions from previous management reviews;
   以往管理评审所采取措施的情况；
b) Changes in external and internal issues that are relevant to the quality management system;
   与质量管理体系相关的内外部因素的变化；
c) Information on the performance and effectiveness of the quality management system, including trends in:
   下列有关质量管理体系绩效和有效性的信息，包括其趋势：
   1) Customer satisfaction and feedback from relevant interested parties;
      顾客满意和有关相关方的反馈；
   2) The extent to which quality objectives have been met;
      质量目标的实现程度；
   3) Process performance and conformity of products and services;
      过程绩效以及产品和服务的合格情况；
   4) Nonconformities and corrective actions;
      不合格及纠正措施；
   5) Monitoring and measurement results;
      监视和测量结果；
   6) Audit results;
      审核结果
   7) The performance of external providers;
      外部供方的绩效。
d) The adequacy of resources;
   资源的充分性；
e) The effectiveness of actions taken to address risks and opportunities(see 6.1);
   应对风险和机遇所采取措施的有效性（见 6.1）；
f) Opportunities for improvement.
   改进的机会。

9.3.2.1 Management review inputs — supplemental 管理评审输入

Input to management review shall include:

管理评审的输入应包括：

a) Cost of poor quality (cost of internal and external nonconformance);
不良质量成本（内部和外部不符合成本）；

b) Measures of process effectiveness;
过程有效性的衡量；

c) Measures of process efficiency;
过程效率的衡量；

d) Product conformance;
产品符合性；

e) Assessments of manufacturing feasibility made for changes to existing operations and for new facilities or new product (see section 7.1.3.1);
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) Customer satisfaction (see iso 9001, section 9.1.2);
顾客满意（见iso9001第9.1.2条）；

g) Review of performance against maintenance objectives;
对照维护目标的绩效评审；

h) Warranty performance (where applicable);
保修绩效（在适用情况下）；

i) Review of customer scorecards (where applicable);
顾客计分卡评审（在适用情况下）；

j) Identification of potential field failures identified through risk analysis (such as FMEA);
通过风险分析（如FMEA）识别的潜在使用现场失效标识；

k) Actual field failures and their impact on safety or the environment.
实际使用现场失效及其对安全或环境的影响。

9.3.3 Management review outputs管理评审输出

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

9.3.3 Management review outputs管理评审输出

The outputs of the management review shall include decisions and actions related to:

管理评审的输出应包括与下列事项相关的决定和措施：

a) opportunities for improvement;
改进的机会

b) any need for changes to the quality management system;
质量管理体系所需的变更；

c) Resource needs.
资源需求。

The organization shall retain documented information as evidence of the results of management reviews.

组织应保留形成文件的信息，作为管理评审结果的证据。

9.3.3.1 Management review outputs — supplemental管理评审输出——补充

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

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改进

10.1 General总则

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

10.1 General总则

The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

组织应确定和选择改进机会，并采取必要措施，以满足顾客要求和增强顾客满意。

These shall include:

这应包括：

a) Improving products and services to meet requirements as well as to address future needs and expectations;
改进产品和服务，以满足要求并应对未来的需求和期望；

b) Correcting, preventing or reducing undesired effects;
纠正、预防或减少不利影响；

c) Improving the performance and effectiveness of the quality management system.
改进质量管理体系的绩效和有效性。

NOTE：Examples of improvement can include correction, corrective action, and continual improvement, break through change, innovation and re-organization.

注：改进的例子可包括纠正、纠正措施、持续改进、突破性变革、创新和重组。

10.2 Nonconformity and corrective action 不符合和纠正措施

10.2.1 and 10.2.2

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

10.2.1 When a nonconformity occurs, including any arising from complaints, the organization shall:当出现不合格时，包括来自投诉的不合格，组织应：

a) React to the nonconformity and, as applicable:
对不合格做出应对，并在适用时：

1) Take action to control and correct it;
采取措施以控制和纠正不合格；

2) Deal with the consequences;
处置后果。

b) Evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
通过下列活动，评价是否需要采取措施，以消除产生不合格的原因，避免其再次发生或者在其他场合发生：

1) Reviewing and analyzing the nonconformity;
评审和分析不合格；

2) Determining the causes of the nonconformity;
确定不合格的原因；

3) Determining if similar nonconformities exist, or could potentially occur;
确定是否存在或可能发生类似的不合格。

c) Implement any action needed;
实施所需的措施；

d) Review the effectiveness of any corrective action taken;
评审所采取的纠正措施的有效性；

e) Update risks and opportunities determined during planning, if necessary;
需要时，更新策划期间确定的风险和机遇；

f) Make changes to the quality management system, if necessary.
需要时，变更质量管理体系。

Corrective actions shall be appropriate to the effects of the nonconformities encountered.
纠正措施应与不合格所产生的影响相适应。

10.2.2 The organization shall retain documented information as evidence of:

组织应保留形成文件的信息，作为下列事项的证据：

a) The nature of the nonconformities and any subsequent actions taken;
不合格的性质以及随后所采取的措施；

b) The results of any corrective action.
纠正措施的结果。

10.2.3 Problem solving/问题解决

The organization shall have a documented process(es) for problem solving including:
组织应有形成文件的问题解决过程，包括：

a) Defined approaches for various types and scale of problems (e.g., new product development, current manufacturing issues, field failures, audit findings);
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) Containment, interim actions, and related activities necessary for control of nonconforming outputs (see iso 9001, section 8.7);
控制不符合输出所必要的遏制、临时措施及相关活动（见iso9001第8.7条）；

c) Root cause analysis, methodology used, analysis, and results;
根本原因分析、采用的方法、分析及结果；

d) Implementation of systemic corrective actions, including consideration of the impact on similar processes and products;
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) Verification of the effectiveness of implemented corrective actions;
对已实施纠正措施有效性的验证；

f) Reviewing and, where necessary, updating the appropriate documented information (e.g., PFMEA, control plan).
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。

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.
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 Error-proofing防错

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.
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。

The process shall include 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.
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 Warranty management systems保修管理体系

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.
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顾客投诉和使用现场失效试验分析

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.
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。

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.
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。

The organization shall communicate the results of testing/analysis to the customer and also within the organization.
组织应向顾客并且在组织内部传达试验/分析的结果。

10.3 Continual improvement持续改进

See ISO 9001:2015 requirements.见 ISO 9001:2015的要求

10.3 Continual improvement持续改进

The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system.

组织应持续改进质量管理体系的适宜性、充分性和有效性。

The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

组织应考虑分析和评价的结果以及管理评审输出，以确定是否存在需求和机遇，这些需求或机遇应作为持续改进的一部分加以应对。

10.3.1 Continual improvement — supplemental持续改进——补充

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

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) Identification of the methodology used, objectives, measurement, effectiveness, and documented information;
   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) A manufacturing process improvement action plan with emphasis on the reduction of process variation and waste;
   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) Risk analysis (such as FMEA).
   风险分析（如FMEA）。

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

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附录A：控制计划

A.1Phases of the control plan控制计划的阶段

A control plan covers three distinct phases，as appropriate:

适当时，控制计划涵盖三个不同阶段

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，
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) 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.
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) Production: documentation of product/process characteristics, process controls, tests, and measurement systems that occur during mass production.
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。

Control plans are established at a pa叫 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.

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。

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

注1：建议组织要求其供应商满足本附录的要求。

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.

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.2Elements of the control plan控制计划的要素

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

控制计划至少包括以下内容：

General data综合资料

a) control plan number;
控制计划编号

b) issue date and revision date，if any;
发布日期和修订日期，如有;

c) customer information (see customer requirements);
顾客信息（见顾客要求）

d) organization’s name/site designation;
组织名称/现场的编号

e) part number(s);
零件编号

f) part name/description;
零件名称/描述

g) engineering change level;
工程更改等级

h) phase covered (prototype ，pre-Launch，production);
涵盖的阶段（原型样件制造、投产前、生产）

i) key contact;
关键联络人

j) part/process step number;
零件/过程步骤编号

k) process name/operation description;
过程名称/作业描述

l) functional group/area responsible
负责的功能组/区域

Product control产品控制

a) product-related special characteristics;
与产品有关的特殊特性

b) other characteristics for control (number ，product or process);
其它要控制的特性（编号、产品或过程）

c) specification/tolerance
规范/公差

Process control过程控制

a) process parameters (including process settings and tolerances);
过程参数

b) process-related special characteristics;
与过程有关的特殊特性

c) machines, jigs, fixtures, tools for manufacturing (including identifiers ，as appropriate);
制造用机器、卡具、夹具、工装（适当时还包括标识符）

Methods方法

a) evaluation measurement technique;
评价测量技术

b) error-proofing;
防错

c) sample size and frequency;
样本容量和抽样频次

d) control method
控制方法

Reaction plan反应计划

a) Reaction plan (include or reference).
反应计划（包括或引用）

ANNEX B: Bibliography - supplemental automotive

Internal audit内部审核

AIAG	CQI-8 Layered Process Audit	**CQI-8 分层过程审核**
	CQI-9 Special Process: Heat Treatment System Assessment	**CQI -9 特殊过程：热处理系统评估**
	CQI-11 Special Process: Plating System Assessment	**CQI -11 特殊过程：电镀系统评估**
	CQI-12 Special Process: Coating System Assessment	**CQI -12 特殊过程：涂装系统评估**
	CQI-15 Special Process: Welding System Assessment	**CQI -15 特殊过程：焊接系统评估**
	CQI-17 Special Process: Soldering System Assessment	**CQI -17 特殊过程：锡焊系统评估**
	CQI-23 Special Process: Molding System Assessment	**CQI -23 特殊过程：模塑系统评估**
	CQI-27 Special Process: Casting System Assessment	**CQI -27 特殊过程：铸造系统评估**
ANFIA	AQ 008 Process Audit	**AQ 008 过程审核**
FIEV	V2.0 Production Process Audit Manual	**《生产过程审核手册》2.0**
IATF	Auditor Guide for IATF 16949	**IATF 16949审核员指南**
VDA	Volume 6 part 3 Process Audit	**第6卷第3部分-过程审核**
	Volume 6 part 5 Product Audit	**第6卷第5部分-产品审核**

Nonconformity and corrective action不符合和纠正措施

AIAG	CQI-14 Automotive Warranty Management Guideline	**CQI -14 汽车保修管理指南**
	CQI-20 Effective Problem Solving Practitioner Guide	**CQI-20 有效解决问题的从业者指南**
VDA	Volume "Audit standard field failure analysis"	**"审核标准使用现场失效分析“卷**
	Volume "Field failures analysis"	**“使用现场失效分析”卷**

Measurement systems analysis测量系统分析

AIAG	Measurement Systems Analysis (MSA)	**测量系统分析MSA**
ANFIA	AQ 024 MSA Measurement Systems Analysis	**AQ 024 测量系统分析 MSA**
VDA	Volume 5 "Capability of Measuring Systems"	**第5卷：测量系统能力**

Product approval产品批准

AIAG	Production Part Approval Process (PPAP)	**生产件批准程序PPAP**
	Volume 2 Production process and product approval (PPA)	**第2卷“生产过程和产品批准**
VDA	Volume 19 Part 1 ("Inspection of Technical Cleanliness - Particulate Contamination of Functionally Relevant Automotive Components")	**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）**
	Volume 19 Part 2 ("Technical cleanliness in assembly - Environment ，Logistics，Personnel and Assembly Equipment")	**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）**

Product design产品设计

	APQP and Control Plan	**APQP和控制计划**
AIAG	CQ-24 Design Review Based on Failure Modes (DRBFM Reference Guide)	**CQI-24基于失效模式的设计审核（DRBFM参考指南）**
	Potential Failure Mode & Effects Analysis (FMEA)	**潜在失效模式及后果分析FMEA**
	AQ 009 FMEA	**AQ 009FMEA**
ANFIA	AQ 014 Manual of Experimental Design	**AQ 014 实验设计手册**
	AQ 025 Reliability Guide	**AQ 025 可靠性指南**
	Volume 4 Chapter Product and Process FMEA	**第4卷，产品和过程章**
VDA	Volume VDA-RGA "Maturity Level Assurance for New Parts"	**VDA-RGA卷新零件成熟度等级保证**
	Volume "Robust Production Process"	**稳健生产过程卷**
	Volume Special Characteristics (SC)	**特殊特性卷**

Production control生产控制

AIAG	MMOG/LE Materials Management Operational Guidelines / Logistics Evaluation	**材料管理操作指南/物流评价**
SMMT	Implementing Standardized Work	**实施标准化作业**

Quality management system administration质量管理体系管理

ANFIA	AQ 026 Managing and improving the process	**AQ 026过程的管理和改进**
IATF	Rules for achieving and maintaining IATF recognition	**获得并保持认可的规则**

Risk analysis风险分析

VDA	Volume 4 "Ring-binder" (elementary aids, risk analyses ， methods，and process models)	**第4卷“活页夹”（基本帮助、风险分析、方法和过程模型）**

Software Process Assessment软件过程评估

CMMI	Capability Maturity Model Integration (CMMI)	**能力成熟度模型集成CMMI**
VDA	Automotive SPICE@ (Software Process Improvement and Capability Determination)	**汽车SPICE（软件过程改进和能力测定）**

Statistical tools统计工具

AIAG	Statistical Process Control (SPC)	**SPC统计过程控制**
ANFIA	AQ 011 SPC	**AQ 011 SPC**

Supplier quality management供应商质量管理

AIAG	CQI-19 Sub-Tier Supplier Management Process Guideline	**CQI-19 次级供应商管理过程指南**
IATF	Minimum Automotive Quality Management System Requirements for Sub-Tier Suppliers (MAQMSR)	**次级供应商最低汽车质量管理体系要求**

Health and safety健康与安全

ISO	ISO 45001 Occupational health and safety management systems	**ISO45001职业健康安全管理体系**

International Automotive Task Force

IATF16949:2016 (C &E)