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A PLUS AVIATION LIMITED

# 质量手册

Quality Manual

(依据 ISO 9001:2015 + AS 9120B:2016 编制)

(Reference: ISO 9001:2015 + AS9120B:2016)

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## 1. 范围 Scope

### 1.1. 手册说明 Manual Specification

依据 AS9120B《航空航天质量管理体系-销售商要求》和 ISO9001:2015《质量管理体系要求》，并结合公司实际情况，特编制本质量手册。适用于本公司业务在质量管理中的应用。

This quality manual is made as per AS9120B “Aviation and space quality management system - requirement of distributor” and ISO9001:2015 “Requirement of quality management system” with consideration of the actual situation of the company. It applies to the application of company's business in the quality management system.

本手册是本公司质量管理的纲领性、法规性文件,经总经理批准后生效,任何部门及个人必须遵照执行。为了将本手册中的规定落实到实际工作中去,本公司制订了一套程序文件及相应的作业指导书。

This manual is the programmatic and statutory document for the quality management in the company. It should be executed after being approved by the General Manager. It must be complied by every department or individual. In order to implement the terms and condition of this manual, the company has formulated a set of procedures and relevant work instructions.

质量手册每年应进行一次评审，若总经理认为有必要时也可随时组织评审。质量手册的管理按本公司《文件记录控制程序》执行。

The quality manual should be reviewed annually. Also, it may be reviewed at any time when the general manger deems it is necessary. The quality manual shall be managed in accordance with the “Document and Record Control Procedure”.

### 1.2. 质量手册声明 Statement of Quality Manual

本质量手册是本公司管理活动的纲领性文件，用来建立公司管理体系，并可作为客户或认证机构审核和评价本公司管理体系的依据。本质量手册是本公司对客户做出的管理承诺；是全体员工管理活动的准则。全体员工应认真学习和理解质量手册的规定，并严格贯彻实施。公司以顾客作为关注的焦点，确保本公司有能力稳定地提供满足客户要求和适用法律法规要求的产品和服务。

This ‘Quality Manual’ is the programmatic document of the management activities of the company. It is the special documents applied to establish the management system

internally. And it could act as the basis of the customer or certification authority to examine and evaluate the management system of the company. This ‘Quality Manual’ is the management commitments to the customer by the company; it is the criterion of the management activities to the staff. The staff shall learn and understand regulations of the ‘Quality Manual’ and implement it. The company focuses on customers’ requirements and ensures the sustainable and stable provision of products and services that meet the customer and applicable statutory and regulatory requirements.

本公司的质量方针与质量目标说明了我们企业的宗旨和方向，是企业最高管理者向顾客所作的质量承诺，是我们全体职工努力追求的目标和过程活动的准则。

The quality policy and objectives are the purpose and direction of the company. They are the commitments to the customers from the top management, and the targets for every employee to pursue and the criterion of processes in the company.

### **1.3. 公司简介 Company Introduction**

A PLUS AVIATION LIMITED 地址位于中国香港金钟夏悃道 12 号美国银行中心 25 层 2508A 室。公司致力于为客户提供航空电子件，消耗件和周转件的分销。我司以诚信和服务为准则，以质量优良，价格合理为经营宗旨，为客户提供满意的产品与服务。

The company has its registered address at Unit 2508A 25/F Bank of America Tower 12 Harcourt Road Central HONG KONG, China. The company is a professional enterprise that distributes aviation electronic parts, consumables and turnover parts. The company adheres to the principles of integrity and service, and regards quality and reasonable prices, providing customers with satisfactory products and services.

地址：中国香港金钟夏悃道 12 号美国银行中心 25 层 2508A 室  
Unit 2508A 25/F Bank of America Tower 12 Harcourt Road Central HONG KONG, China.

#### 1.4. 管理者代表授权书 Authorization of management representative

兹任命 *ALICE TONG* 为我公司管理者代表，负责 AS9120B 在我公司的实施与维护，并代表公司执行以下工作：

- a) 联络与协商 AS9100D 航空航天质量管理体系认证与追踪稽核相关事宜；
- b) 督导公司航空航天质量管理体系的有效运作与持续改进；
- c) 确保在公司内提高满足顾客要求的意识，推动以顾客为关注焦点；
- d) 确保公司满足相关方与法律法规的要求；
- e) 定期向公司最高管理者汇报质量体系业绩和任何改进的要求；
- f) 确保在策划和实施质量管理体系变更时保持其完整性；
- g) 确保各过程按预期输出。

Now, it appoints *Julia Zhu*, of the company as the management representative of our company, fully responsible for the implementation and maintenance of AS9120B in our company, and to carry on the following works on behalf of the company:

- a) Contact and negotiate related affairs of authentication and tracking and auditing on AS9120B;
- b) Supervise the effective operation and continual improvement of the quality management system in our company;
- c) Guarantee to improve the consciousness of satisfying customers in the company, ensuring the promotion of customer focus;
- d) Report regularly the performance and any requirements on improvement of quality system to the top management of the company;
- e) Report to the top management of the company about the performance of quality system and environmental system and requirements of any improvement;
- f) Ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented;
- g) Ensuring that the processes are delivering their intended outputs.

以上任命自签署之日开始生效执行。

The above appointment will take into effect and be executed since the date of signing.



总经理（General manager）：*ALICE TONG*

2024 年 3 月 5 日

## 2. 规范性引用文件 Normative References

ISO9000:2015 质量管理体系—基础和术语

ISO9000:2015 Quality management system - foundation and terms

AS 9120B:2016 航空航天质量管理体系-分销商要求

AS 9120B:2016 Aviation and space quality management system - requirement of distributor

本手册本公司依据 AS9120B 《航空航天质量管理体系-分销商要求》、ISO9001:2015《质量管理体系要求》及相关法律法规的要求编制。特别强调手册规定的质量管理体系要求是对客户要求和适用的法律法规要求的补充,而非替代。如果该标准与客户或法律法规有冲突,将以后者为准。

This Quality Manual is established per AS 9120B:2016 Aviation and space quality management system - requirement of distributor, ISO9001:2015 quality management system and the requirements of related statutory and regulations. It should be stressed that the requirements defined by the Quality Manual is the supplement to customer's requirements and statutory and regulations, but not replacement. If the Quality Manual conflicts with customer or law and regulation, the latter will prevail.

## 3. 术语和定义 Terms and Definitions

在本标准里,制造商的定义是指用来明确描述产品创建者和组织的关系。外部提供者和外部制造者可以是同一个意思。

外部提供者----组织----客户

(制造者/提供者)

In this standard, the definition of manufacturer is the relationship between the creator of the product and the organization. External provider and external manufacturer could mean the same.

External provider -- organization -- customer

(manufacturer / provider )

### 3.1. 件 Article

由设计组织列出的安装在产品上或包含在由局方批准的设计资料里的合格的材料、部件、零件、组件、或装置。

Qualified material, component, part, assemble or device which are illustrated by

the design organization and installed on the product or listed in the design data which is approved by authority.

### **3.2. 授权颁发的证书 Certificate issued by authority**

用来证明一个产品可以使用（如可以向服务放行或可以返回服务），且证明满足组织、法规和客户要求的活动已经实施，结果已经达成的文件。

To prove a product is serviceable (such as release to service or return to service), and to provide it satisfy the requirement of organization, regulation and customer and form as document.

### **3.3. 合格证书（一般是指符合性证书） Certificate(Certificate of Conformity in general)**

用来证明产品合格，规定过程、设计和规范要求符合性的文件化信息。

To prove a product that meets specified process, design and standard requirements in the form of compliance document.

### **3.4. 仿冒件 Counterfeit**

不是真正的来自于指定的原始或授权制造商，未经授权的复制、模仿、替换或修改的部件(如材料、部件、零件)。注:如仿冒件包括但不限于标记或标签、级别、系列号、生产日期、文件、性能特性的错误标识。

Item (such as material, component, part) that is not made by designated OEM or authorized manufacturer but is copied, imitated, replaced or modified without authorization. Counterfeit includes but not limit to incorrect identification of sign or label, grade, serial number, manufacturer date, document, performance feature.

### **3.5. 分销商 Distributor**

一个执行产品采购、储存、分装、或者销售，但不影响产品符合性的组织。在本标准中组织的定义即是指分销商。

The organization performs purchasing, storage, splitting or sales of the product but does not affect its conformance. The definition of organization in this standard means distributor.

### **3.6. 产品安全 Product Safety**

产品在实现其设计或预期用途时，会带来不可接受的影响人和财产安全的风

险的情况。

When achieving the design or expected purpose of the product, the risks occur to affect the safety of human and property.

### **3.7. 分装 Splitting**

通过物理或者数量上把产品分开，但是不影响产品的特性或者符合性。

To split the product physically or quantitatively without affecting its feature or conformance.

### **3.8. 疑似未批准件 Suspected Unapproved Part**

有客观或者可信证据表明部件疑似未批准件或者仿冒件的部件。

注：这个包括：没有经过批准的生产组织的直接交付授权的供应商提供的向最终用户发运的物品；不符合批准的设计或资料的新物品；不是由批准的来源进行的制造或维修的物品；物品信息故意不如实描述的，包括仿冒件；不完整或不适宜文件信息的物品。

Objective or authentic evidence to indicate that the part is suspected unapproved or counterfeit which includes unapproved manufacturer delivers the article which is originated from approved supplier; new article which does not meet the approved design or data; article which is not made or maintained by approved source; profile of the article is not truthfully described, such as counterfeit part; its certificate is incomplete or not applicable.

### **3.9. 测试报告 Testing Report**

用来表明由制造商或认可的测试机构提供的客观证据的文件化信息，这些客观证据表明了特定的设计要求、产品或性能特性的产品符合性。

The documented information indicating the objective evidence from manufacturer or accredited organization, such evidence indicates specific design requirement and conformity of product or performance feature.

### **3.10. 未批准件 Unapproved Part**

不是按照批准或可接受资料和适用的法规、规章和客户要求生产或维护的部件。

The part which is not produced or maintained in according with approved or acceptable data or applicable law, regulation, and customer's requirement.

## **4. 组织环境 Context of the Organization**

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

公司的质量管理体系应包括了客户和相关法律法规的质量管理体系要求。

The quality management system of the company shall include the quality management system requirements of customers and relevant statutory and regulations.

总经理应确定与本公司质量目标和战略方向相关并影响实现质量管理体系预期结果的各种内部因素（公司的价值观、文化、知识、绩效等相关因素）和外部因素（国际、国家、地区和当地的各种法律法规、技术、竞争、文化和社会因素等）。这些因素可以包括需要考虑的正面和负面因素或条件。

General Manager should determine various internal factor (core value, culture, knowledge, performance and etc.) and external factor (international, domestic, regional and local law and regulation, techniques, competition, culture, social factor and etc.) which are related to company's quality objectives and strategic direction and affect the expected result of the quality management system. Such factor could be positive and negative.

本公司定期对这些内部和外部因素的相关信息进行监视和评审，以确保其充分和适宜。

The company monitors and reviews the internal and external factors regularly, to ensure the sufficiency and suitability.

### **4.2. 理解相关方的需求和期望 Understanding the needs and expectations of interested parties**

公司应确定：The company should determine:

a) 与质量管理体系有关的相关方；

Parties related to quality management system;

b) 这些相关方的要求；

The requirement from these parties;

公司应对这些相关方及其要求的相关信息进行监视和评审，以便于理解和持续满足相关方的需求和期望。公司应考虑以下相关方：

The company should monitor and review the requirement from related parties in order to understand and continually satisfy these parties' demand and expectation. The

company should consider below related parties:

- 顾客； Customer;
- 最终用户或受益人； End user or beneficiary;
- 业主， 股东； Owner, stockholder;
- 银行； Bank;
- 外部供应商； External provider;
- 雇员及其他为组织工作者； Employee and the personnel worked for the

company;

- 法律法规及监管机关； Law, regulator and supervision department;
- 地方社区团体； Local community;
- 非政府组织。 Nongovernmental organization.

理解相关方的需求和期望可以帮助本公司更好的建立清晰的方针和目标。做到目的明确，满足相关方的要求并争取做到更高的期望值。

Understanding of the need and expectation from related parties could help the company to establish a clear policy and goal which could enable the company to satisfy related parties and achieve a higher expectation.

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

公司应明确质量管理体系的边界和适用性，以确定其范围。在确定质量管理体系范围时， 公司应考虑：

The Company should be distinct the border and applicability of the quality management system and determine its scope. When determine the scope of the QMS, the company should consider:

- 各种内部和外部因素， 见 4.1；  
Various internal and external factor, refer to 4.1;
- b) 相关方的要求， 见 4.2；  
Requirement from related parties, refer to 4.2;
- c) 公司的产品和服务。  
Company's product and service.

本公司为由供应商向客户直接发货， 公司无监视测量设备， 故 7.1.5 条款不适用。

The products would be delivered from vendors to customers directly, and there was no M&M equipment. Clause 7.1.5 is not applicable.

因公司业务为航空材料的销售，不涉及产品的设计与开发，故标准 8.3 条款不适用于本公司。

Since the company's business is the sales and supply of aviation parts and does not involve in the design and development of products, clause 8.3 of the standard is not applicable to the company.

对本公司的外包过程进行了识别，本公司无外包过程。

The company has identified the process of subcontract. Now there is no any process of subcontract needed.

本公司质量管理体系范围：电子件，消耗件和周转件的采购、销售。

Scope of AQMS: Procurement and sales of electronic parts, consumables and turnover parts.

地址：中国香港金钟夏慤道 12 号美国银行中心 25 层 2508A 室。

Address: Unit 2508A 25/F Bank of America Tower 12 Harcourt Road Central HONG KONG

#### **4.4. 质量管理体系及其过程 Quality Management System and Its Processes**

4.4.1 本公司确保按照本标准的要求，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。本公司应确定质量管理体系所需的过程及其在整个公司中的应用，且应：

The Company 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 Standard. Company shall determine the processes needed for the quality management system and their application throughout the company, and shall:

a)确定这些过程所需的输入和期望的输出；

Determine the inputs required and the outputs expected from these processes;

b)确定这些过程的顺序和相互作用；

Determine the sequence and interaction of these processes;

c) 确定和应用所需的准则和方法（包括监视、测量和相关的绩效指标），以

确保这些过程的运行和有效控制；

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;

d)确定并确保获得这些过程所需的资源；

Determine the resources needed for these processes and ensure their availability;

e) 规定与这些过程相关的责任和权限；

Assign the responsibilities and authorities for these processes;

f) 按照 6.1 的要求确定的风险和机遇；

Address the risks and opportunities as determined in accordance with the requirements of 6.1;

g) 评价这些过程并实施所需的变更，以确保实现这些过程的预期结果；

Evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;

h) 改进过程和质量管理体系。

Improve the processes and the quality management system.

本公司质量管理体系过程按类型分为：销售过程、采购过程、支持过程、管理过程。

The quality management system processes of the company are defined as sales process, procurement process, support process and management process.

过程流程图见附件 1.

The Quality Management System Process Flow Chart is included in the Appendix1.

职能分配表见附件 2

The Function allocation table is included in the Appendix2.

4.4.2 公司应建立和维持文件化的信息，包括：

The company should establish and maintain the necessary documented information, include:

相关的利益相关方的总体描述（参见 4.2）

General description of the related interested parties, refer to 4.2

质量管理体系范围，包括边界和适用性（参见 4.3）

The scope of quality management system, including border and applicability, refer



to 4.3

质量管理体系所需过程的描述和他们在公司内的应用

The description of the processes required by the quality management system and their applicability in the company.

这些过程的重要性和相互关系

Importance and relationship of processes

指定这些过程的职责和权限

To appoint responsibility and authority to the processes

注：上述质量管理体系的描述可以编制在一个文件化的信息里，通常作为质量手册

在必要的程度上，公司应：

Abovementioned description of quality management system could be formatted as document, usually as quality manual. When necessary, the company should:

保持形成文件的信息以支持过程运行；

Maintain documented information in order to support the operation of processes;

保留确认其过程按策划进行的形成文件的信息。

Maintain documented information to acknowledge the processes are operated as per planning.

## 5. 领导作用 Leadership

### 5.1. 领导作用和承诺 Leadership and commitment

#### 5.1.1 总则 General

总经理应证实其对质量管理体系的领导作用和承诺，通过：

General Manager should verify his leadership and commitment to the quality manage system by:

a)对质量管理体系的有效性承担责任；

Taking accountability for the effectiveness of the quality management system;

b) 确保制定质量管理体系的质量方针和质量目标，并与组织环境和战略方向相一致；

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;

c) 确保质量管理体系要求融入与公司的业务过程;

Ensure the integration of the quality management system requirements into the company's business processes;

d) 促进使用过程方法和基于风险的思维;

Promote the use of process approach and thinking of risk;

e) 确保获得质量管理体系所需的资源;

Ensuring that the resources needed for the quality management system are available;

f) 强调有效的质量管理和符合质量管理体系要求的重要性;

Communicating the importance of effective quality management and of conforming to the quality management system requirements;

g) 确保实现质量管理体系的预期结果;

Ensuring that the quality management system achieves its intended results;

h) 促使、指导和支持员工努力提高质量管理体系的有效性;

Engaging, directing, and supporting persons to contribute to the effectiveness of the quality management system;

i) 推动改进;

Promoting improvement;

j) 支持其他管理者履行其相关领域的职责。

Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

#### 5.1.2 以顾客为关注焦点 Customer focus

总经理应证实其以顾客为关注焦点的领导作用和承诺, 通过:

General Manager should play the leading role and commit to “customer focus” by:

a) 确定、理解并持续满足顾客要求以及适用的法律法规要求;

Customer and applicable statutory and regulatory requirements are determined, understood, and consistently met;

b) 确定和应对能够影响产品、服务符合性以及增强顾客满意能力的风险和机遇;

The risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;

c) 始终致力于增强顾客满意。

The focus on enhancing customer satisfaction is maintained;

d)产品和服务的符合性和准时交付的绩效应被监控，如果计划的结果没有或没有达到，则应采取适当的措施。

Product and service conformity and on-time delivery performance are measured and appropriate action is taken if planned results are not, or will not be, achieved.

## **5.2. 质量方针 Quality policy**

### **5.2.1 制定质量方针 Developing quality policy**

总经理应制定、实施和保持质量方针，方针应：

General Manager should develop, implement and maintain a quality policy. The policy should:

a)适应公司的宗旨和环境并支持其战略方向；

Is appropriate to the purpose and context of the company and supports its strategic direction;

b)为制定质量目标提供框架；

Provide the framework for setting quality objectives;

c)包括满足适用要求的承诺；

Includes the commitment to satisfy the applicable requirements;

d)包括持续改进质量管理体系的承诺。

Includes the commitment to continual improvement of the quality management system.

本公司质量方针为： 质量至上，客户满意，持续改进，追求卓越。

Quality policy is: Quality First, Customer Satisfaction, Continuous Improvement, Pursuit of Excellence.

### **5.2.2 沟通质量方针 Communication of the quality policy**

质量方针应： The quality policy should be:

a) 作为形成文件的信息，可获得并保持；

Be available and maintained as documented information;

b) 在公司内得到沟通、理解和应用；

Be communicated, understood and applied within the company;

c) 适宜时，可向有关相关方提供。

Be available to relevant interested parties, as appropriate.

### 5.3. 公司的角色、职责和权限 Company's roles, responsibilities and authorities

为了有效的实施质量管理，本公司确定了组织结构，并规定了各级各岗位人员职责、权限和相互关系，并在公司内对各级员工进行了必要的传达，各职能部门的职能分配表。

同时制定了岗位职责及权限，对本公司各主要岗位职责权限进行了确定。以：

In order to effectively implement quality management, the company has established an organizational chart that defines the responsibilities, authorities and interrelationships of personnel at all levels and carries out the necessary communication within the company as well as the functional distribution of each functional department for:

a) 确保质量管理体系符合本标准的要求；

Ensuring that the quality management system conforms to the requirements of this International Standard;

b) 确保各过程获得其预期输出；

Ensuring that the processes are delivering their intended outputs;

c) 报告质量管理体系绩效及其改进机遇（见 10.1），特别向总经理报告；

Reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;

d) 确保在整个公司推动以顾客为关注焦点；

Ensuring the promotion of customer focus throughout the company;

e) 确保在策划和实施质量管理体系变更时，保持其完整性。

Ensuring that the integrity of the quality management system is maintained when changes of the quality management system are planned and implemented.

总经理应任命公司管理层中的一名特定的成员作为管理者代表，管理者代表的职责和权限是监控上述要求的实施。从机构上保证能自主地解决质量有关的事务并直接向总经理通报。

注：管理者代表的职责可以包括与外部相关方质量管理体系方面的事宜的联络。

管理者代表授权书详见 1.4。

General Manager should appoint a specific member from management as management representative. The responsibility and authority of management

representative is to monitor and oversight the implementation of the abovementioned requirement. Within the company, he should be able to resolve the quality related matters independently and could report to General Manager directly.

Note: Management representative's responsibility could include the liaison with external interested parties for quality management system related matters.

Authorization of management representative see 1.4.

为了有效的实施公司的质量管理体系，本公司确定了公司结构（见图 1 组织结构图），规定了各级各岗位人员职责、权限和相互关系，并在公司内对各级员工进行了必要的传达，各职能部门的职能分配表见附件。规定各部门职责、权限。

To effectively implement the company's quality management system, the company has determined the company structure (see Figure 1), stipulated the responsibilities, authorities, and mutual relations of personnel at all levels and positions, and carried out necessary communication to employees at all levels within the company. See the appendix for the function allocation table of each functional department. The responsibilities and authorities of each department are specified.

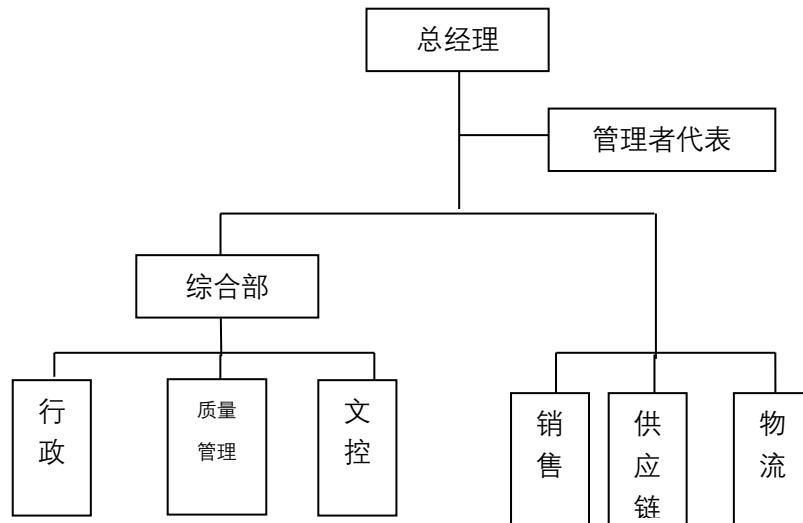


图 1 组织结构图

Figure 1 Organization Chart

### 5.3.1 总经理 General Manager

a) 根据的有关方针、政策和法律、法规的要求，负责制定本公司的总体发展战略和年度计划指标，并组织贯彻实施；

Be responsible for establishing and implementing the general strategy and annual

objective as per related requirement from related policy, law and regulation;

b) 加强员工对满足顾客和法律法规要求重要性的教育，确保本公司全体员工都能关注顾客的要求；

Strengthen the employee's awareness of meeting requirement from customer, law and regulation and ensure all employee are aware of customer's requirement;

c) 负责质量管理体系的建立、完善、实施和保持，并得到持续改进，负责组织制定质量方针和质量目标，并决定有关实施质量方针和质量目标的各项措施，批准颁布“质量手册”；

Be responsible for establishing, improving, implementing and maintaining the quality management system as well as keeping continual improvement) Be responsible for establishing quality policy and objectives and determining each measure for implementing the quality policy and objectives) He is also the approver of quality manual;

d) 确保本公司各个部门负责人员的职责、权限及其相互关系得到规定和沟通；

Determine the responsibility and authority of each department head and the interrelationship among the department and their communication;

e) 负责管理评审，批准管理评审报告，并按计划的时间间隔主持召开管理评审会议，评价质量体系的改进机会和变更需求，确保其适宜性、充分性和有效性；

Be responsible for management review, approving the management review report and conduct management review meeting per planned interval) By conducting such meeting, he should review the opportunity of improvement and the need of change for the quality system so as to ensure the suitability, sufficiency and effectiveness of the quality system;

f) 确保质量活动所必需的资源。

Ensure the availability of the resource required by quality activities.

### 5.3.2 管理者代表 Management Representative

a) 按照 ISO9001:2015、AS 9120B:2016 标准要求建立、实施质量管理体系并保证其有效运行；

Establish, implement and ensure the effective operation of the quality management system in accordance with the requirements of ISO9001:2015 and AS 9120B:2016 standards;

b) 定期公司管理层汇报质量管理体系、运行业绩和改进情况、组织内部质量管理体系、审核，批准内部审核报告；

Regularly report the quality management system, operation performance and improvement to the company's management, organize the internal quality management system and audit, and approve the internal audit report;

c) 负责审核质量管理体系管理手册和程序文件；

Review the quality management system management manual and procedure documents;

d) 在公司内强化满足顾客和法律法规要求的意识；

Promote the awareness of meeting the requirements of customers and statutory and regulations within the company;

e) 审核质量管理体系目标指标、管理方案；

Review quality management system objectives, indicators and management plans;

f) 主持质量事故的调查分析和处理；

Organize the investigation, analysis and handling of quality problems;

g) 负责就公司质量管理体系有关事宜与外部的联络工作；

Responsible for external liaison on matters related to the company's quality management system.

### 5.3.3 综合部 General Management Department

a) 负责公司的行政、财务管理工作，保障公司各项日常工作的进行；

Be responsible for managing the administration, finance and the daily operation activities;

b) 负责计算机、通讯和办公设备的采购和维护管理工作。

Be responsible for the purchasing and maintenance of computers, communication and office devices.

c) 组织执行内部审计并跟进整改及预防措施。

Arrange and conduct internal audit and follow up

d) 负责公司 ISO9001:2015 与 AS9120B:2016 质量体系的组织和管理的工作，包括：质量体系文件的编制、发布、更改和控制管理，质量记录的登记、整理、更改、过程的控制；

Be responsible for management of company's ISO9001:2015 and 与 AS9120B:2016 quality management system, including: formulating, publishing,

revising and controlling of the quality system documents and registering, sorting, revising of the quality records and process control.

#### 5.3.4 销售 Sales

a) 准确了解政策、产品信息，协助顾客做好采购前期的准备工作，并长期为其供应产品及服务；

Understand policy, product information correctly, assist customer on their purchasing preparation and provide them product and service in a long term;

b) 负责合同评审工作；)

Be responsible for conducting contract review;

c) 积极开拓业务市场、增加业务项目、扩大营业额；

Actively explore the market and business scope and boost the business volume;

d) 负责交付后的工作；

Be responsible for post-delivery activities;

e) 负责跟进及解决客户投诉。

Follow up and resolve customer's complaint.

#### 5.3.5 供应链管理 Supply Chain

a) 负责与原厂沟通并达成代理协议；

Be responsible for communicating with OEM and building up distribution-ship;

b) 服务搜寻客户需求的产品及服务并在市场部收到合同后采购；

Be responsible for sourcing the product and service required by customer and placing order after Marketing secures the contract;

c) 如产品及服务的符合性不满足要求，与供应商协商解决的改进方案；

When the conformity of product and service do not meet requirement, to negotiate with supplier for solution and improvement;

d) 负责合格证明材料检查，产品发运等活动。

Be responsible for inspection and receiving of incoming good, inventory management and shipping activities.

e) 协同供应链管理上游供应商并确保其符合性；

Cooperate with Supply Chain management Department to manage suppliers and ensure their conformity;

## 6. 策划 Planning



## **6.1. 应对风险和机遇的措施 Actions to address risks and opportunities**

6.1.1 策划质量管理体系，公司应考虑 4.1 和 4.2 的要求，确定需要应对的风险和机遇，以：

When planning for the quality management system, the company 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:

a) 确保质量管理体系能够实现其预期结果；

Give assurance that the quality management system can achieve its intended result(s);

b) 增强有利影响；

Enhance desirable effects;

c) 避免和减少不利影响；

Prevent, or reduce, undesired effects;

d) 实现改进。

Achieve improvement.

6.1.2 组织应策划：

The company shall plan:

a) 应对这些风险和机遇的措施；

Actions to address these risks and opportunities;

b) 如何：

How to:

1) 在质量管理体系过程中整合并实施这些措施（见 4.4）；

Integrate and implement the actions into its quality management system processes, refer to 4.4;

2) 评价这些措施的有效性。

Evaluate the effectiveness of these actions.

应对风险和机遇的措施应与其对产品和服务符合性的潜在影响相适应。

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

## **6.2. 质量目标及其实现的策划 Quality objectives and planning to achieve them**

6.2.1 公司应对质量管理体系所需的相关职能、层次和过程设定质量目标。  
质量目标应：

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

a) 与质量方针保持一致；

Be consistent with the quality policy;

b) 可测量；

Be Measurable;

c) 考虑适用的要求；

Take into account applicable requirements

d) 与提供合格产品和服务以及增强顾客满意相关；

Be relevant to conformity of products and services and to enhancement of customer satisfaction;

e) 予以监视；

Be monitored

f) 予以沟通；

Be communicated;

g) 适时更新。

Be updated, as appropriate

本公司的质量目标：

The company quality objectives are:

a) 顾客满意率 $\geq 90\%$ ；

Customer satisfactory $\geq 90\%$ ;

b) 投诉处理率=100%

Complaint handling rate=100%

c) 产品合格率 $\geq 95\%$ ；

Compliance ratio of products $\geq 95\%$ ;

d) 产品及时交付率 $\geq 90\%$ 。

Products On-time delivery $\geq 90\%$ 。

6.2.2 策划如何实现质量目标时，公司应确定：

Planning to achieve quality objectives, the company should clarify:

a) 采取的措施;

What will be done;

b) 需要的资源;

What resources will be required;

c) 由谁负责;

Who will be responsible;

d) 何时完成;

how the results will be evaluated.

e) 如何评价结果。

The method to evaluate the result.

### **6.3. 变更的策划 Changes of planning**

当公司确定需要对质量管理体系进行变更时, 此种变更应经策划并系统的实施 (见 4.4)。公司应考虑:

When the company determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4), the company should consider:

a) 变更目的及其潜在后果;

The purpose of the change and its potential consequence;

b) 质量管理体系的完整性;

Integrity of the quality management system;

c) 资源的可获得性;

Availability of the resources;

d) 责任和权限的分配与再分配。

Assignment and re-assignment of responsibility and authority.

## **7. 支持 Support**

### **7.1. 资源 Resources**

#### **7.1.1 总则 General**

公司应确定并提供为建立、实施、保持和持续改进质量管理体系所需的资源。  
公司应考虑:

The company should determine and provide the resources needed for the

establishment, implementation, maintenance and continual improvement of the quality management system. The company should consider:

a) 现有内部资源的能力和约束;

The capabilities of, and constraints on, existing internal resources;

需要从外部供方获取的资源。

b) What needs to be obtained from external providers.

#### 7.1.2 人员 People

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。

The company 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.

#### 7.1.3 基础设施 Infrastructure

组织应确定、提供和维护过程运行所需的基础设施, 以获得合格产品和服务。

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

基础设施可包括:

Include:

a) 建筑物和相关的设施;

Buildings and associated utilities;

b) 设备 (包括硬件和软件);

Equipment, including hardware and software;

c) 运输资源;

Transportation resources;

d) 信息和通讯技术。

The company has formulated “The infrastructure control procedure”.

#### 7.1.4 过程运行环境 Environment for operating the process

组织应确定、提供并维护过程运行所需的环境, 以获得合格产品和服务。适当的过程运行环境可能是人文因素和物理因素的组合, 例如:

The company shall determine, provide, and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services. A proper environment for the operation of the process could be the combination of

humanity and physical factor, such as:

a) 社会因素（如不歧视、和谐稳定、不对抗）；

Social factor (such as nondiscrimination, harmony and nonresistance)

b) 心理因素（如降低压力、倦怠预防、情感保护）；

Psychology factor (such as lowering down pressure, preventing tiredness and emotional protection)

c) 物理因素（温度、热度、湿度、照明、空气流通、卫生、噪音）

Physical factor (temperature, humidity, illumination, air ventilation, sanitation and noise)

根据公司产品服务和营运特点，运营过程无法律法规的特殊环境要求，公司应保持运行环境良好，如：工作环境管理有序，物料摆放整齐，标识清晰，保持工作环境清洁卫生。

As per the feature of company's product, service and operation, there is no special environmental requirement for its operation. The company shall maintain a good environment for its operation, such as keeping everything in order, maintaining clear signs and labels and clean working environment.

各部门负责各所属区域环境安全的管理，确保工作环境安全得到控制。

All departments are responsible for the management of the environment in their respective areas to ensure that the safety of the working environment is controlled.

公司为产品采购、销售、销售服务等提供适宜的作业条件，并应对其进行管理；同时包括产品、职工劳动保护、安全等场所配备适宜的温度、湿度、照明条件等。确保了工作环境满足工作要求。

The company shall provide appropriate operating environment including suitable temperature, humidity and lighting conditions provided for products and , safety and other places provided for labor protection of employees for product procurement, sales and sales services, and manage them.

#### 7.1.5 监视和测量资源 Monitoring and measuring resources

Not Applicable.

#### 7.1.6 组织知识 Organizational knowledge

公司应确定运行过程所需的知识，以获得合格产品和服务。 这些知识应予以保持，并在需要范围内可得到。为应对不断变化的需求和发展趋势，组织应考虑现有的知识，确定如何获取更多必要的知识，并进行更新。公司的知识是从其

经验中获得的特定知识，是实现组织目标所使用的共享信息。知识可以基于：

The company should determine the knowledge required for operating the processes to achieve qualified product and service. The knowledge should be maintained and accessible within the company. To meet the changing requirements and developing trend, the company should review current knowledge and determine how to obtain more necessary knowledge from improving. The company's knowledge is specially obtained from its experience. It could be shared for achieving the objectives. The knowledge could be basis on:

内部资源（如：知识产权、从经验获得的知识、从失败和成功项目中获得的教训、获取和分享未形成文件的知识和经验、过程、产品和服务的改进结果）；

Internal resources (such as property right, knowledge from experience, lesson from loss or win projects, undocumented knowledge and experience, processes, improvement result of product and service);

外部资源（如：标准、学术交流、专业会议以及从顾客和外部供方收集的知识）。

External resource (such as standard, academic exchange, the knowledge from congress, customer and external provider).

## **7.2. 能力 Competence**

公司对所聘用人员考虑其职位职责及工作内容应有对应的能力要求：

The company shall have corresponding ability requirements for the employees considering their job responsibilities and work contents:

a) 确定其控制范围内的人员所具备的能力，工作适应岗位能力，明确这些人员从事工作影响质量管理体系绩效有效性；

Determine the ability of the personnel within the control scope and their ability to adapt to the job, and make it clear that the work of these personnel will affect the performance effectiveness of the quality management system;

b) 执行《岗位说明书》的要求，配备具备相应学历、技能、经历要求的人员上岗。确保全体员工意识到自身贡献的重要性及其在公司中的角色；

Implement the requirements of the job description, and allocate personnel with corresponding educational background, skills and experience requirements to work;

c) 综合部确定年度培训计划，总经理批准后，协助主办部门组织人员培训。

培训做到需求明确、有计划、采取灵活多样的方式进行,必要的时候可实施考核,以检验培训成果,以满足岗位要求;

General Management Department General Management Department shall determine the annual training plan and assist each department to organize personnel training after the approval of the general manager. The training shall be carried out in a clear, planned, and flexible manner, and assessment can be carried out when necessary to test the training results to meet the requirements of the post.

d)考虑必要的的能力,并对这些能力的符合性每年组织一次审查。

Determine necessary capability and review the conformity of this capability once a year.

e) 保留适当的形成文件的信息,作为人员能力的证据。

Retain necessary documented information as the evidence of employee's capability.

### 7.3. 意识 Awareness

公司应确保其控制范围内的相关工作人员知晓:

The company should ensure that the employee within its control is aware of below:

a) 质量方针;

The quality policy

b) 相关的质量目标;

The quality objectives;

c) 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;

Their contribution to the effectiveness of the quality management system, including the benefits of the quality performance;

d) 不符合质量管理体系要求的后果;

The implications of not conforming with the quality management system requirements;

e) 与其相关的质量管理体系文件及随后的变更;

Relevant quality management system documented information and changes thereto;

f) 对产品和服务一致性的贡献

Their contribution to product or service conformity;

g) 对产品安全的贡献;

Their contribution to product safety;

h) 道德行为的重要性。

The importance of ethical behavior.

#### **7.4. 沟通 Communication**

公司应确定与质量管理体系相关的内部和外部沟通, 确保产品质量得到有效的保障, 增强顾客满意。

The company shall determine the internal and external communication related to the quality management system to ensure that the product quality is effectively guaranteed and promote customer satisfaction.

通过早会、例会、培训、宣导、看板管理、相关方告知书等沟通手段提升内外部沟通的有效性。制定相关规定, 明确沟通什么、何时沟通、与谁沟通、如何沟通、由谁负责等。

Improve the effectiveness of internal and external communication through morning meetings, regular meetings, training, publicity, Kanban management, notification to interested parties and other communication methods. Formulate relevant regulations to clarify what to communicate, when to communicate, with whom, how to communicate and who is responsible for it.

#### **7.5. 形成文件的信息 Documented information**

##### **7.5.1 总则 General**

公司建立、实施、保持和持续改进的质量管理体系, 应用体系管理的方式包括标准要求的形成成文信息(如质量管理体系质量手册、程序文件、作业指导书、技术资料、记录等)。这些成文信息可采取多种形式体现(如电子文档、照片、书面文件、资料等)。

The company establishes, implements, maintains, and continuously improves the quality management system, and the adopts the management by system method to manage company's documented information, including Quality Manual, Procedure Documents, Work Instructions, Technical Information, Records etc.). The documented information can take various forms, such as electronic documents, photos, written documents, materials, etc.

##### **7.5.2 创建和更新 Establish and update**



在创建和更新形成文件的信息时，组织应确保适当的：

When establish or update documented information, the company should determine:

a) 标识和说明（例如：标题、日期、作者、索引编号等）；

Identification and description (such as title, date, originator, index number and etc.);

b) 格式（例如：语言、软件版本、图示）和媒介（例如：纸质、电子格式）；

Format (such as language, software version, chart) and media (such as hard copy, soft copy);

c) 评审和批准，以确保适宜性和充分性，批准的权责和方法。

Review and approval to ensure its applicability and sufficiency.

公司制定了《文件和记录控制程序》

The company has formulated “The control of documents and records procedure”.

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

#### 7.5.3.1 应控制质量管理体系和标准所要求的形成文件的信息，以确保：

The documented information required by quality management system and this standard should be controlled so as to:

a) 无论何时何处需要这些信息，均可获得并使用；

The information is available and suitable for use, where and when it is needed;

b) 予以妥善保护（如防止失密、不当使用或不完整）。

The information shall be adequately protected (e.g., from loss of confidentiality, improper use, or loss of integrity).

#### 7.5.3.2 为控制形成文件的信息，适用时，组织应关注下列活动：

The company should consider followings to control the documented information:

a) 分发、访问、检索和使用；

Distribution, access, retrieval, and use;

b) 储存和防护，包括保持可读性；

Storage and prevention, including preservation of legibility;

c) 变更控制（如：版本控制）；

Control of changes (e.g., version control )

d) 保留和处置。

Retention and disposition.

防止作废文件的非预期使用，若因任何原因而保留作废文件时，对这些文件

进行清楚的标识。

Prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.

当文件化的信息以电子形式进行管理时，数据保护过程应建立（如丢失保护、非授权变更、非预期修改、损坏、物理破坏）。

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.

给产品来源、符合性和装运提供证据的文件化信息应被存档。

Documented information such as resource of product, conformity and shipping evidence should be kept in file.

注：保留的文件化信息举例，可能包括但不限于：

Documented information could include:

——制造商、分销商、维修站的测试和检验报告；

Test and inspection report from manufacturer, distributor and maintenance station;

——采购订单或合同；

Purchase Order or contract;

——符合性证书（制造商、下一级分销商）、授权放行证书的复印件；

Certificate of conformity (manufacturer, distributor of next level), certificate copy of authorized release to service;

——不符合项、让步放行、和纠正措施；

Nonconformity, use as is and rectify measure;

——批追溯的文件化信息；

Traceability document;

——储存、防护、货架寿命条件（如时间、温度、湿度）的文件化信息

Condition of storage, prevention and shelf-life.

对策划和运行质量管理体系所必需的来自外部的原始的形成文件的信息，组织应进行适当识别和控制。具体见《文件和记录控制程序》

The company should properly identify and control the necessary external documented information for planning and operating the quality management system. See “Control of Human Resources”.

## **8. 运行 Operation**

## 8.1. 运行策划和控制 Operational planning and control

组织应通过采取下列措施，策划、实施和控制满足产品和服务要求所需的过程（见 4.4），并实施第 6 章确定的措施：

The company should plan, implement and control the processes required(refer to 4.4) to meet product and service requirements by implementing the following measures and implementing planning and response measures in section 6 that address risks and process management.

a) 确定产品和服务的要求，应包括确定以下内容：

Determine the requirement of product and service should include:

1) 人员和产品安全；

Safety for people and product;

2) 可获得性和可检验性；

Obtainability and detectability;

3) 产品废弃 ；

Scrap of the product;

4) 外来物的预防、检测和移除；

Prevention, inspection and removal of FOD;

5) 处置、包装和防护；

Disposal, package and protection;

6) 产品在寿命周期的再循环或处置。

Disposal and recycling of the product within the lifespan.

b) 建立以下准则：

Establish below standards:

1) 过程； Process;

2) 产品和服务接收。

The acceptance of product and service.

可选用一下合适的统计技术：

Statistical technique can be used to support:

A.过程控制（包括过程能力测量，统计过程控制，实验设计）

Process control, including process capability measurements; statistical process control; design of experiments;

B.验证。

Verification.

c)确定符合产品和服务要求所需的资源，并满足按时交付产品和服务所需要

的资源；

Determine the resource which meets the conformity of product and service and on time delivery;

d) 按照准则实施过程控制；

Implement process control as per standard;

e) 在需要的范围和程度上，确定并保持、保留形成文件的信息；

Determine and maintain documented information within required scope and degree:

1) 证实过程已经按策划进行；

Prove that the process is operated as per planning;

2) 证明产品和服务符合要求；

Product and service conform to requirement;

f) 各相关部门积极参与运行的策划和控制；

Engaging representatives of affected organization functions for operational planning and control;

g) 确定需要从外部获得的产品和服务；

Determining the products and services to be obtained from external providers;

h) 建立防止不合格产品和服务交付给客户的控制方法。

Establish a control method to prevent delivering nonconforming product and service to customer.

策划的输出应适合组织的运行需要。组织应控制策划的变更，评审非预期变更的后果，必要时，采取措施消除不利影响。组织应确保外包过程得到控制（见 8.4）。

The planning outputs should fit with company's operation. The company should control the planned changes, review the result of unexpected change, whenever necessary, it should take action to eliminate unfavorable influence. The company should ensure the subcontract is under control. Refer to 8.4

对本公司的外包过程进行了识别，本公司无外包过程。

The company has identified the process of subcontract. Now there is no any process of subcontract needed.

8.1.1 运行的风险管理(不适用) Operational risk management

Not applicable

### 8.1.2 技术状态管理 Configuration management

如果组织或产品适用时，组织应策划、实施和控制一个适用于组织和其产品的技术状态管理过程，以确保物理和功能属性在整个产品生命周期的可标识性。这个过程应：

When applicable to the company or its product, the company should plan, implement and control a configuration management process which is suitable for its own so as to ensure the physics and functional property are identified for its whole lifespan. Such process should:

- a) 按要求控制产品的标识和可追溯性，包括标识变更的实施控制；

Control the identification and traceability of the product, including change of identification;

- b) 确保文件化的信息（如要求、设计、验证、确认和可接受的文件）是符合实际产品和服务的属性。

Ensure the documented information (such as requirement, design, examination, acknowledgement, and acceptable file) is tallied with the character of product and service.

### 8.1.3 产品安全(不适用) Product safety

Not applicable

### 8.1.4 预防假冒产品 Prevention of counterfeit part

组织编制实施《预防假冒产品控制程序》，防止使用伪造嫌疑产品交付给客户。为确保有效实施考虑了以下方面：

The company should plan and implement “Prevention of counterfeit part” to prevent deliver the counterfeit product to customer. In order to implement the procedure effectively, the company should consider:

- 在年度培训计划中确定假冒伪劣产品危害意识和识别假冒伪劣产品知识的培训；

Conduct a yearly training;

- 从严控制供应商，所有材料必须进行可追溯性控制，防止供应商提供的产品为假冒产品；

Strictly control and manage suppliers, all material should be traceable and prevent from obtaining counterfeit part from supplier;

- 供应链管理负责进行假冒产品的确认，在规范中确定假冒产品识别方法。

Supply chain mangement Department should verify the counterfeit part and determine the identification method in the standard.

### 8.1.5 疑似未批准件的预防 Prevention of Suspected Unapproved Parts

公司应策划、实施和控制一个适宜于组织及其产品的过程，以识别与预防未批准件和疑似未批准件的放行。

The company shall plan, implement, and control a process appropriate to the company and the product that identifies and prevents the release of unapproved and suspected unapproved parts.

注：疑似未批准件预防过程应考虑：

Note: Suspected unapproved parts prevention processes should consider:

——对适宜人员进行培训，以提升其疑似未批准件意识和识别能力；

Training of appropriate persons in the awareness and identification of suspected unapproved parts to improve their awareness and identification ability;

——保证来自授权资源的部件和零件的追溯要求；

Ensure the traceability requirements of components and parts from authorized resources;

——检验过程以探测疑似未批准件；

Inspection processes to detect suspected unapproved parts;

——来自外部资源的疑似未批准件的监控；

Monitoring of suspected unapproved parts reporting from external sources;

——如果需要，按照零部件批准方或客户的适用要求，向他们保证和报告疑似未批准件。

Quarantine and reporting of suspected unapproved parts in accordance with applicable requirements from the competent authority or customers, as required.

## 8.2. 产品和服务要求 Requirements for products and services

### 8.2.1 顾客沟通 Customer communication

与顾客沟通应包括：

Communication with customers should include:

a) 提供公司产品的信息；

Providing information relating to company's products;

b) 问询，合同或订单的处理，包括更改；

handling enquiries, contracts or orders, including changes;

c) 获取顾客关于产品和服务的反馈，包括顾客抱怨；

handling enquiries, contracts or orders, including changes;

d) 顾客财产的处理和控制；

Handling and controlling of customer's property;

e) 关系重大时，制定有关应急措施的特定要求。

Establishing specific requirements for contingency actions.

销售在整个产品实现过程中，通过与顾客沟通确定顾客的要求，并及时向顾客对顾客提出的问题给予解答。

Within the whole product realization process, the Marketing & Sales Department shall determine the customer's requirements through communication with customers, and timely answer the customer's questions.

8.2.2 与产品和服务有关的要求的确定 Determining the requirements related to products and services

由销售代表公司组织对顾客提出的要求进行分析、评价；负责拟订合同草案。若采用投标方式，由营销部组织对合同进行投标；

The Sales Department shall, on behalf of the company, organize the analysis and evaluation of customers' requirements; Responsible for drafting the contract draft. If the bidding method is adopted, the Marketing & Sales Department shall organize the tender for the contract;

在确定提供给顾客的产品和服务的要求时，组织应确保：

When determining the requirement related to products and services, the company should ensure:

a) 产品和服务要求得到确定，包括：

The requirement of product and service is acknowledged, including:

1) 适用的法律法规要求；

Applicable requirements of statutory and regulation;

2) 组织认为必要的要求。

Requirements that the company considers necessary.

b) 对其所提供的产品和服务，能够满足组织所声称的要求。

The product and service meet the requirement committed by the company.

8.2.3 与产品和服务有关的要求的评审 Review of requirements related to

## products and services

对与产品有关要求的评审在提供产品承诺之前进行。评审的对象包括合同草案、技术协议、投标书、口头订单等。

The review of product related requirements shall be conducted before providing product commitment. The review objects include contract draft, technical agreement, tender, oral order, etc.

评审应确保产品要求得到规定，组织有能力满足顾客要求，与以往表述不一致的要求已经解决，风险（如新技术、短交货期）得到识别和控制。如果按照评审的结果，一些客户的要求不能满足或只能部分满足，组织应与客户商定一个双方可以接受的要求。

The review shall ensure that the product requirements are specified; the organization can meet the customer requirements; the requirements inconsistent with the previous statements have been solved, and the risks (such as new technology and short delivery period) have been identified and controlled. If, according to the results of the review, some customer requirements cannot be met or can only be partially met, the organization shall negotiate a mutually acceptable requirement with the customer.

评审内容包括：

The review includes:

a) 顾客规定的要求，包括交付和交付后活动的要求；

Customer's requirement, during delivery and after post-delivery;

b) 顾客虽然没有明示，但规定用途或已知的预期用途所必需的要求；

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

c) 公司规定的要求；

Company's requirement;

d) 适用于产品和服务的法律法规要求；

Applicable statutory and regulation;

e) 与以前表述不一致的合同或订单的要求。

For the requirements which is different with previous contract or order.

若顾客没有提供形成文件的要求，公司应在接受顾客要求前应对顾客要求进行确认。

If there is not documented information from customer, the company should



acknowledge the requirement before committing to customer.

8.2.3.2 公司应保留以下方面的记录:

The company shall maintain below records:

a) 评审结果;

Result of review;

b) 产品和服务的任何新要求。

Any new requirement for the product and service.

8.2.4 产品和服务要求的变更 Changes to requirements for products and services

若产品和服务要求发生变更, 公司应确保相关的文件化信息得到修改, 并确保相关人员知道已变更的要求。

If the requirement for product and service changes, the company shall ensure the related documented information is modified and relevant people is aware of the change.

**8.3. 产品和服务的设计和开发 (不适用) Design and development of products and services**

Not applicable.

**8.4. 外部提供过程、产品和服务的控制 Control of externally provided processes, products and services**

8.4.1 总则 General

为了确保所采购的产品符合规定要求, 公司结合实际建立了外部提供过程、产品和服务的控制过程, 确保外部提供的过程、产品和服务符合预期的要求。为了确保所采购的产品符合规定要求。公司采购由供应链管理负责。

To ensure that the purchased products meet the specified requirements, the company has established the control process of externally provided processes, products and services in combination with the actual situation to ensure that the externally provided processes, products and services meet the expected requirements. In order to ensure that the purchased products meet the specified requirements. The company's procurement is in the charge of the Supply chain management Department.

公司对供方采取不同的控制方式。通过制定供方选择、评价和重新评价的准则, 实施对供方的控制和管理。

The company adopts different control methods for suppliers. Implement supplier

control and management by formulating criteria for supplier selection, evaluation and reevaluation.

a) 供应链管理负责组织对供方的产品质量、资质、供货能力等进行调查和评价；

The Supply chain management Department is responsible for organizing the investigation and evaluation of the supplier's product quality, qualification, supply capacity, etc

b) 保持一份批准的外部提供方的登记表，里面包括批准的状态（例如被批准，有条件批准，不批准）和批准范围（例如产品种类，所属过程等），由总经理批准；

Maintain an approved registration form of external providers, including the approval status (such as approved, conditionally approved, not approved) and approval scope (such as product type, process, approval of distribution authorization, etc.), which shall be approved by the general manager;

c) 供应链管理定期评审外部提供方的绩效，包括过程、产品和服务的符合性、准时交付绩效。供应链管理保存供方评价结果及评价所引起的任何必要措施的记录。

The Supply chain management Department regularly reviews the performance of external providers, including the compliance of processes, products and services, and on-time delivery performance. The Supply chain management Department shall keep records of the supplier evaluation results and any necessary measures arising from the evaluation;

d) 供应链管理应识别和管理由外部提供的过程、产品和服务相关的风险。产生风险根据需求，由办公室组织各部门配合针对相应情况处理。

The Supply chain management Department shall identify and manage risks related to externally provided processes, products and services. In case of any risk, the office shall organize all departments to deal with it according to the needs.

e) 由供应链管理负责和供应商沟通其产生或保留的文件化信息的控制要求。

The Supply chain management Department is responsible for communicating the control requirements of the documented information generated or retained with the supplier

当进行外部提供方的评估和选择时，可以使用来自客观和可信赖的外部资源

的质量数据（如被认可的质量管理体系，如已获得 ISO 9001, AS 9100, AS 9120 认证，特殊过程有获得如 NADCAP 认证，供应商有获得局方或顾客批准等）。使用这些数据只是组织对其外部提供方控制的一个因素，我公司仍然保留确认外部提供的过程、产品和服务符合特定要求的责任。

When evaluating and selecting external suppliers, quality data from objective and reliable external resources can be used (such as recognized quality management system, such as ISO 9001, as 9100, as 9120 certification, NADCAP certification for special processes, CAAC or customer approval for suppliers, etc.). The use of these data is only a factor of the organization's control over its external providers. Our company still retains the responsibility to confirm that the externally provided processes, products and services meet specific requirements.

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

公司确定并实施对采购产品的验证，以确保采购产品符合规定要求。

The company shall determine and implement the verification of purchased products to ensure that the purchased products meet the specified requirements.

a) 物流负责按规范对采购产品实施进货检验，当存在不合格包括仿冒件的高风险时，实施性能测试，并保存相关检验记录；

The Logistics Department is responsible for the incoming inspection of purchased products according to the specifications. When there is a high risk of nonconformity, including counterfeit parts, the Logistics Department shall carry out performance tests and retain relevant inspection records;

b) 当收到供应商提供的测试报告或者材质报告时，应评估测试报告中的数据以确认产品是否符合要求。如果原材料为重要的风险时，还应去验证测试报告的准确性；

When receiving the test reports or material reports provided by the suppliers, the data in the test reports shall be evaluated to confirm whether the product meets the requirements. If the raw material is an important risk, the accuracy of the test report shall also be verified;

c) 对采购产品验证中发现的不合格品，按照《不合格品控制程序》的规定要求进行处置；

The nonconforming products found in the verification of purchased products shall be disposed according to the requirements specified in the “Nonconforming Product

Control Procedure”.

#### 8.4.3 外部供方信息 Information for external providers

采购信息发出前应履行审批手续，以确保采购要求是充分与适宜的。

The approval procedures shall be performed before the procurement information is sent to ensure that the procurement requirements are sufficient and appropriate.

采购文件应包括以下采购产品的信息，以确保采购信息对于采购是足够的：

The procurement documents shall include the following information of purchased products to ensure that the procurement information is sufficient for procurement:

a) 将要提供的过程、产品和服务；

Process, product and service to be provided by external provider;

b) 对产品的要求，如产品的名称、规格、型号、数量、质量标准、金额等；

Requirements for products, such as product name, specification, model, quantity, quality standard, amount, etc.;

c) 产品的验收要求或其它要求，如产品验收方式和条件、交货期、现场验收要求以及付款方式和违约责任等。如有特殊要求需要另外说明。

Product acceptance requirements or other requirements, such as product acceptance method and conditions, delivery date, on-site acceptance requirements, payment method and liability for breach of contract, etc. If there are special requirements, it needs to be explained separately.

d) 对供方的产品、程序、过程 and 设备的批准要求，人员资格的要求及质量管理体系的要求。

When appropriate, the procurement information may also include approval requirements for the supplier's products, procedures, processes and equipment, personnel qualification requirements and quality management system requirements.

e) 组织使用的产品接收统计技术和相关的接收指导书；

The use of statistical techniques for product acceptance and related instructions for acceptance by the company;

f) 向公司通报不合格的过程、产品和服务，并且得到处置这些不合格的批准。

Notify the company of nonconforming processes, products, or services and obtain approval by the company;

g) 使用顾客指定或批准的供方；

Use customer-designated or approved external providers;

h) 防止使用疑似未批准件、未批准件及仿冒件；

Prevent the use of suspected unapproved, unapproved, and counterfeit parts;

i) 通报任何过程、产品和服务的变更，包括其外部提供方、制造地点的变更，并且得到组织的批准；

Notify the company of changes to processes, products, or services, including changes of their external providers or location of manufacture;

j) 向其下级外部提供方传递相关的要求，包括客户的要求；

Flow down to external providers applicable requirements including customer requirements;

k) 适当时，提供合格证书、测试报告，获授权的放行证书；

Provide a certificate of conformity, test report, or authorized release certificate, as applicable;

l) 保留文件化的信息，包括保留时间和处置要求

Retain documented information, including retention periods and disposition requirements;

m) 公司人员、客户和局方有权进入采购订单所涉及供应链的任何层级的相关设施场所和查看相关记录；

The right of access by the company, the company's customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain;

n) 保证供应商人员意识到：

Ensuring that persons are aware of:

——他们对产品和服务符合性的贡献；

Their contribution to product or service conformity;

——他们对产品安全的贡献；

Their contribution to the product safety;

——道德行为守则的重要性。

The importance of the ethical behavior.

## **8.5. 产品和服务的提供 Products and service provision**

### **8.5.1 产品和服务控制 Control of Products and service provision**

公司确保生产和服务提供过程在受控状态下进行，包括：

The company ensures that each production and service provision process is under controlled conditions, including:

a) 提供的产品和服务活动的特性：如订单，物料清单、产品规范等；

The characteristics of the products to be produced, the services to be provided, or the activities to be performed, such as Purchase Orders, BOM, product specifications, etc.;

b) 拟达到的结果，如产品名称、规格/型号、数量、质量要求、完成时间等。

The results to be achieved, such as product name, specification / model, quantity, quality, lead time, etc.

c. 在适当阶段进行监视和测量，以验证产品和服务要求及接收准则已得到满足。

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.

1.确保接收产品的监视测量活动的成文信息包括：

Ensuring that documented information for monitoring and measurement activity for product acceptance includes:

——接受或拒收准则；

Criteria for acceptance and rejection;

——进行验证操作的顺序；

Where in the sequence verification operations are to be performed;

——保留测量结果（至少包括接受与拒收）；

Measurement results to be retained (at a minimum an indication of acceptance or rejection) .

2.当使用抽样作为产品接受的方法时，抽样计划应在统计原理上是可行的，并适合于使用。

Ensuring that when sampling is used as a means of product acceptance, the sampling plan is justified on the basis of recognized statistical principles and appropriate for use.

d) 为过程的运行提供适宜的基础设施和环境；

The use of suitable infrastructure and environment for the operation of processes;

e) 配备具备能力的人员，包括所要求的资格；

The appointment of competent persons, including any required qualification;

f) 采取措施防止人为错误;

The implementation of actions to prevent human error;

g) 实施放行、交付和交付后活动;

The implementation of release, delivery, and post-delivery activities;

h) 建立技艺准则 (如书面标准、样件、图示);

The establishment of criteria for workmanship (e.g., written standards, representative samples, illustrations);

i) 对所有产品负责 (如零件数量、分作业指令、不合格品)

The accountability for all products (e.g., parts quantities, split orders, nonconforming product);

j) 可获得所有生产和检验/验证操作已按计划、文件或授权完成的证据;

The availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;

#### 8.5.1.1 生产设备、工具 Control of Equipment and Tools

生产设备、工具、量具、产品自动控制程序以及监控的软件, 在使用前需要验证, 定期维护。

Equipment, and tools shall be validated and maintained.

对贮存的生产设备或工装应确定储存要求, 包括定期防护与状态检查。

Storage requirements shall be defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks.

#### 8.5.2 标识和可追溯性 Identification and traceability

需要时, 公司应采用适当的方法识别输出, 以确保产品和服务合格。标识可以是产品铭牌、标牌、标签、色标等方式。

The company shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services. The identification can be in the form of product nameplate, label, tag, color code, etc.

公司应保持产品和服务的技术状态标识, 以识别产品实际状态与要求状态的任何区别。

The company shall maintain the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration.

公司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。所有需要实施检验试验的产品均需对其状态（如检验结果的合格、不合格等）进行标识。

The company shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision. All products requiring inspection and test shall be marked with their status (such as qualified and unqualified inspection results).

当使用接收授权媒介时，公司将建立适当的授权媒介的控制。若要求可追溯，公司应控制输出的唯一性标识，且应保留实现可追溯性所需的形成文件的信息。不可投入服务使用的产品应得到控制并与可投入使用的产品进行物理隔离。

When acceptance authority media are used, the company shall establish controls for the media. The company shall control the unique identification of the outputs when traceability is a requirement and shall retain the documented information necessary to enable traceability. Unserviceable product shall be controlled and physically segregated from serviceable product.

公司应在拆分批次、仓储、包装盒防护的过程中通过适当的方式维持产品在供应商发货清单上列出的标识与可追溯性。上述要求也适用于分包给外部供应商的拿取与包装活动上。

The organization shall maintain product identification and traceability by suitable means from receipt; during splitting, storage, packaging, and preservation operations and until delivery. This includes handling or packing operations outsourced to external providers.

在产分批次交付产品时，下列信息应被保存：

When delivering split product, the following information shall be retained:

——从外部供应商处得到的数量与交付出去的数量；

Amount delivered relative to amount received from external provider;

——采购订单编号；

PO number;

——顾客名称。

Customer's name.

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



公司在控制或使用顾客或外部供方的财产期间，应对其进行妥善管理。对公司使用的或构成产品和服务一部分的顾客和外部供方财产，应予以识别、验证、保护和维护。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，公司应向顾客或外部供方报告，并保留相关形成文件的信息。

When the company controls or uses the property belongs to customer or external provider, such property should be safe kept. The company should identify, verify, protect and maintain the property belongs to customer and external provider which is part of its product and service. If the property is damaged, lost or inapplicable, the company should report to customer or external provider and maintain documented information.

本公司涉及的顾客财产为标准规范、文件、客户信息等。

The customer properties involved by the company include standard specifications, documents, customer information, etc.

#### 8.5.4 防护 Preservation

组织应在提供生产和服务的期间对输出进行必要的防护，以确保符合要求。

The organization shall provide necessary preservation to output during the provision of production and services to ensure compliance with requirements.

#### 8.5.5 交付后活动 Post-delivery activities

组织应满足与产品和服务相关的交付后活动的要求。在确定交付后活动的覆盖范围和程度时，组织应考虑：

The company shall meet requirements for post-delivery activities associated with the products and services. In determining the extent of post-delivery activities that are required, the organization shall consider:

a) 法律法规要求；

Statutory and regulatory requirements;

b) 与产品和服务有关的潜在不良的后果；

The potential undesired consequences associated with its products and services;

c) 产品和服务的性质、用途和预期寿命；

The nature, use, and intended lifetime of its products and services;

d) 顾客要求；

Customer's requirement;

e) 顾客反馈；

Customer's feedback;

f) 产品和客户支持（如询问、培训、质保、维护、部件替换、资源、作废）在交付后发现了问题，组织应采取适当的措施，包括调查与报告。

Product/customer support (e.g., queries, training, warranties, maintenance, replacement parts, resources, obsolescence). When problems are detected after delivery, the organization shall take appropriate action including investigation and reporting.

注：交付后活动可能包括担保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。

Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

#### 8.5.6 更改控制 Changes of control

公司应对生产和服务提供的更改进行必要的评审和控制，以确保稳定的符合要求。

The company shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

公司应识别批准生产和服务更改的授权人员。

Persons authorized to approve production or service provision changes shall be identified by the company.

公司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、批准生产变更和服务提供变更的授权人员应识别。

The company 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.

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

组织应在适当阶段实施策划的安排，以验证产品和服务的要求已被满足。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。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：

The organization shall implement planned arrangements, at appropriate stages, to

verify that the product and service requirements have been met. 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. The organization shall retain documented information on the release of products and services. The documented information shall include:

a) 符合接收准则的证据;

Evidence of conformity with the acceptance criteria;

b) 授权放行人员的可追溯性信息。

Traceability to the person(s) authorizing the release.

公司应保证所有要求的成文信息与产品和服务一并交付。

The company shall ensure that all documented information required to accompany the products and services are present at delivery.

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

8.7.1 公司规定对不符合的输出进行识别和控制的要求，以防止其非预期使用或交付。

The company shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

根据不合格的性质及其对产品和服务的影响采取适当的措施。这也适用于产品交付后、服务提供期间或之后发现的不合格产品和服务。

The company 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.

公司编制《不合格品控制程序》，对不合格品的判定、标识、记录、评审和处置做出规定。

The company has prepared “The Control Procedure for Nonconforming Products”, which specifies the determination, identification, recording, review and disposal of nonconforming products.

公司通过以下一种或几种途径处置不合格的输出

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

a) 纠正;

Correction;

b) 隔离、限制、退货或暂停提供产品和服务；

segregation, containment, return, or suspension of provision of products and services;

c) 告知顾客；

Informing customer;

d) 获得让步接收的授权。

Obtain authorization for acceptance under concession.

对不合格品的处置方式仅限于以下几种：

Dispositions of nonconforming product shall be limited to:

——报废；

Scrap;

——拒收，退回供应商处；

Rejection for return to the external provider;

——拒收，返回生产商进行再确认

Rejection for revalidation by the manufacturer;

——适用时，提交给客户或设计单位两方中的一方，由其作出“原样使用”的处理决定。

Submittal to either the customer or design authority for use-as-is disposition, as applicable.

处置为报废的产品必须作醒目和永久的标记或处于绝对控制之中,直到物理上的不可用。

Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

控制假冒件或疑似假冒件，防止其再次进入供应链。

Counterfeit, or suspect counterfeit, parts shall be controlled to prevent reentry into the supply chain.

对不合格输出进行纠正之后应验证其是否符合要求。

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

对不合格品的处理结论，只对当时被审理的不合格品有效，不作为以后审理不合格品的依据，也不影响顾客对产品的判定。

The treatment conclusion of nonconforming products is only valid for the nonconforming products reviewed at that time and will not be used as the basis for the subsequent review of nonconforming products, nor will it affect the customer's judgment of products.

8.7.2 公司应保留下列成文信息：

The company should retain documented information:

a) 有关不合格的描述；

Describes the nonconformity

b) 所采取措施的描述；

Describes the actions taken;

c) 获得让步的描述；

Describes any concessions obtained;

d) 处置不合格的授权标识。

Identifies the authority deciding the action in respect of the nonconformity.

## 9. 绩效评价 Performance Evaluation

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

#### 9.1.1 总则 General

公司应确定：

The company should determine:

a) 需要监视和测量的对象；

The objects need to be monitored and measured;

b) 确保有效结果所需要的监视、测量、分析和评价方法；

The methods for monitoring, measurement, analysis and evaluation needed for the valid results;

c) 实施监视和测量的时机；

When the monitoring and measurement shall be performed;

d) 分析和评价监视和测量的结果的时机。

When the results from monitoring and measurement shall be analyzed and evaluated.

公司通过分析数据评价质量绩效和质量管理体系的有效性，并保留适当的形成文件的信息作为结果的证据。对发现存在的问题，采取纠正措施和预防措施，

分析的结果作为管理评审的输入。

The company evaluates the quality performance and the effectiveness of the quality management system by analyzing data, and retains appropriate documented information as evidence of the results. Corrective and preventive measures shall be taken for the problems found, and the analysis results shall be used as the input of management review.

#### 9.1.2 顾客满意 Customer satisfaction

本公司规定了销售为该过程的主要负责部门。作为对质量管理体系的业绩的一种测量，本公司编写了《顾客满意程度调查表》以监视顾客对本公司的产品和服务是否满意。《顾客满意程度调查表》由销售负责实施。

The company has specified the Marketing & Sales Department as the main department responsible for this process. As a measure of the performance of the quality management system, the company has prepared the “Customer Satisfaction Questionnaire” to monitor whether customers are satisfied with the company's products and services. The “Customer Satisfaction Questionnaire” shall be implemented by the marketing department.

销售负责收集顾客投诉的信息，质量处负责组织顾客投诉的处理。

The Marketing & Sales Department is responsible for collecting the information of customer complaints, and the Sales Department is responsible for organizing the handling of customer complaints.

#### 9.1.3 分析和评价 Analysis and evaluation

组织应分析、评价通过监视和测量获得的适宜数据和信息，包括外部来源报告的产品和服务问题的信息（例如：政府、行业警示、公告等）

The company should analyze and evaluate appropriate data and information, including the information from external report about products and services ( such as: government, industrial warnings, announcement and etc. )

应利用分析结果评价：

The result of analyze should be used to evaluate:

a) 产品和服务的符合性；

Conformity of products and services;

b) 顾客满意程度；

The degree of customer satisfaction;

- c) 质量管理体系绩效和有效性;  
The performance and effectiveness of the QMS;
- d) 策划是否得到有效实施;  
Whether the planning has been implemented effectively;
- e) 针对风险和机遇所采取措施的有效性;  
The effectiveness of actions taken to address risks and opportunities;
- f) 外部供方的绩效;  
The performance of external providers;
- g) 质量管理体系改进的需求。 注: 分析数据的方法可以包括统计技术。  
The need for improvements to the quality management system.
- 各部门统计分析内容见表 1  
See Table 1 for the statistical analysis contents of each department.

表 1 各部门数据收集和分析记录表

Table 1 Records of data collection and analysis of each department

数据来源		数据内容	收集部门
外部 External	顾客满意 Customer satisfaction	顾客满意、产品质量（退货记录）、用户满意度调查、流失业务分析、顾客赞扬、索赔等; Customer satisfaction, product quality (return records), user satisfaction survey, loss business analysis, customer praise, claims, etc;	销售 Sales Dept.
		合同履约率 Contract performance rate	销售 Sales Dept.

数据来源		数据内容	收集部门
内部 Internal	产品符合性 Conformity of products	供方评价率; Supplier evaluation rate 采购产品合格率; Compliance ratio of purchased products 采购产品及时到货率 OTR	供应链管理 Supply chain management Dept.
		交付产品合格率; Compliance ratio of delivery products 产品交付及时率 OTD	供应链管理 Supply chain management Dept.
		顾客投诉处理 Customer complaint handling	销售 Sales Dept.
	质量成本 Quality Cost	内、外部质量成本 Internal and external quality cost	综合部 General Management Dept.
	质量管理体系 QMS	不合格数量及分布; 纠正、预防措施有效率等; 质量目标的完成率等 Quantity and distribution of nonconformities; Effectiveness of corrective and preventive measures; Completion rate of quality objectives, etc	综合部 General Management Dept.

## 9.2. 内部审核 Internal audit

9.2.1 公司制定并执行《内部审核控制程序》，按照策划的时间间隔进行内部审核。以确定公司的质量管理体系是否符合产品实现策划的安排，是否符合标准的要求以及公司的确定质量管理体系要求；是否得到有效的实施和保持。综合部负责内部审核工作。

The company shall formulate and implement “The Internal Audit Control Procedure” and conduct internal audit according to the planned time interval. To determine whether the company's quality management system conforms to the arrangement of product realization planning, whether it conforms to the requirements of standards and the requirements of the company's determined quality management system; Whether it is effectively implemented and maintained. The General Management Department is responsible for internal audit.

9.2.2 根据公司质量管理体系过程、部门状况和重要性，客户的特定要求，以及以往审核结果，管理者代表组织对审核方案进行策划，在每年年初制定本年度的内部审核计划，明确内审的准则、范围、频次和方式，确保质量管理体系涉



及的部门和过程的质量活动至少审核一次，年度审核计划经管理者代表批准后实施。

According to the process, Department status and importance of the company's quality management system, the specific requirements of customers and the previous audit results, the management representative shall organize the planning of the audit scheme, formulate the internal audit plan of the current year at the beginning of each year, define the criteria, scope, frequency and method of internal audit, and ensure that the quality activities of the departments and processes involved in the quality management system are audited at least once, The annual audit plan shall be implemented after being approved by the management representative.

内审员应具有资格，并由管理者代表授权后，方可从事内审工作。内审员不应审核自己的工作。

Internal auditors shall be qualified and authorized by the management representative before engaging in internal audit. Internal auditors should not audit their own work.

每次内审应由审核组长编制本次内审的实施计划，内审员编制检查表，按内审程序及检查表策划的内容和方式进行内审。收集审核证据，记录审核结果，内审结束后，内审组应评价质量管理体系，开出不符合项报告，编制内审报告。实施内部审核时，需要关注绩效参数来确定质量管理体系是否得到有效地实施和维护。

For each internal audit, the audit team leader shall prepare the implementation plan of the internal audit, and the internal auditor shall prepare the checklist, and conduct the internal audit according to the internal audit procedures and the contents and methods of the checklist planning. Collect audit evidence and record audit results. After the internal audit, the internal audit team shall evaluate the quality management system, issue a nonconformance report and prepare an internal audit report. When implementing internal audit, it is necessary to pay attention to performance parameters to determine whether the quality management system is effectively implemented and maintained.

不符合项的责任部门，对其不符合项及时进行纠正，并进行原因分析，采取纠正措施。

The Department responsible for the nonconformities shall timely correct the

nonconformities, analyze the causes and take corrective measures.

内审员应对不合格项的纠正措施的有效性进行跟踪验证，并做好记录。

The internal auditor shall track and verify the effectiveness of corrective measures for nonconforming items and make records.

综合部保存内审各项记录。

The General Management Department shall keep all internal audit records.

### 9.3. 管理评审

#### 9.3.1 总则 General

本公司制定了《管理评审程序》。总经理应按照策划的时间间隔对组织的质量管理体系进行评审，以确保其持续的保持适宜性、充分性和有效性，并与组织的战略方向相一致。产品和服务发生重大质量事故，组织的质量管理体系发生重大变化，组织应及时进行专题管理评审。

The company has formulated “The Management Review Procedure”. The General Manager shall review the quality management system of the organization according to the planned time interval to ensure that it continues to maintain its suitability, sufficiency and effectiveness, and is consistent with the strategic direction of the organization. In case of major quality accidents of products and services and major changes in the organization's quality management system, the organization shall conduct special management review

#### 9.3.2 管理评审输入 Management review inputs

策划和实施管理评审时应考虑下列内容：

When planning and implementing management review, followings should be taken into consideration:

a) 以往管理评审所采取措施的实施情况；

The status of actions from previous management review;

b) 与质量管理体系相关的内外部因素的变化；

Changes in external and internal issues that are relevant to the quality management system;

c) 有关质量管理体系绩效和有效性的信息，包括下列趋势性信息：

Information on the performance and effectiveness of the quality management system, including trends in:

1) 顾客满意和相关方的反馈;

Customer satisfaction and feedback from relevant interested parties;

2) 质量目标的实现程度;

The extent to which quality objectives have been met;

3) 过程绩效以及产品和服务的符合性;

Process performance and conformity of products and services;

4) 不合格以及纠正措施;

Nonconformities and corrective actions;

5) 监视和测量结果;

Monitoring and measurement results;

6) 审核结果;

Audit results;

7) 外部供方的绩效。

The performance of external provider;

8) 准时交付的绩效。

On-time- delivery performance.

d) 资源的充分性;

The adequacy of resources;

e) 应对风险和机遇所采取的措施的有效性;

The effectiveness of actions taken to address risks and opportunities;

f) 改进的机会。

Opportunity for improvement.

### 9.3.3 管理评审输出 Management review outputs

管理评审的输出应包括与以下方面有关的决定和措施:

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

a) 改进的机会;

Opportunities for improvement;

b) 质量管理体系变更的需求;

Any need for changes of the quality management system;

c) 资源需求;

Resource needs;

d) 识别的风险。

Risks identified.

组织应保留作为管理评审结果证据的形成文件的信息。

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

## **10. 改进 Improvement**

### **10.1. 总则 General**

组织应确定并选择改进机会，采取必要措施，满足顾客要求和增强顾客满意。这些应包括：

The company shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction, including:

a) 改进产品和服务，以满足要求并关注未来的需求和期望；

Improving products and services to meet requirements as well as to address future needs and expectations;

b) 纠正、预防或减少不利影响；

Correcting, preventing or reducing undesired effects;

c) 改进质量管理体系绩效和有效性。

Improving the performance and effectiveness of the QMS.

改进的示例可以包括纠正、纠正措施、持续改进、突变、创新或重组。

Examples of improvement include correction, corrective actions, continual improvement, breakthrough change, innovation, or reorganization.

### **10.2. 不合格与纠正措施 Nonconformity and corrective action**

10.2.1 对于出现的不符合，包括投诉所引起的不合格，公司建立了《不合格品控制程序》进行处置，包括：

For the nonconformities, including those caused by complaints, the company has established “The Nonconforming Product Control Procedure” for disposal, including:

a) 对不符合做出应对，适用时：

Company reacts to the nonconformity and, as applicable:

1) 采取措施予以控制和纠正

Take action to control and correct it;

2) 处置产生的后果

Deal with the consequences;

b) 相关部门应通过下列活动，评价是否需要采取措施：

Relevant departments shall evaluate the need for action, by:

1) 评审和分析不合格；

Reviewing and analyzing the nonconformity;

2) 确定不合格的原因；包括与人为因素有关的原因；

Determining the causes of the nonconformity, including those related to human factors;

3) 确定是否存在或可能发生类似的不合格；

Determining if similar nonconformities exist, or could potentially occur;

d) 相关部门将依据评价结论采取纠正措施以消除不符合的原因，避免其再次发生或者在其他场合发生。

Relevant departments will take corrective measures according to the evaluation conclusion to eliminate the causes of nonconformities and avoid their recurrence or occurrence in other occasions.

d) 评审所采取的纠正措施的有效性；

Review the effectiveness of corrective action taken;

e) 需要时，更新策划期间确定的风险和机遇；

Update risks and opportunities determined during planning, if necessary;

f) 需要时，对质量管理体系进行变更；

Make changes to the quality management system, if necessary;

g) 当确定不合格是供方的责任时，应向供方传递纠正措施的要求；

Convey the requirement of corrective action to the external provider when the nonconformity is attributed to the external provider;

h) 当不能及时、有效的事先纠正措施时，应采取专门的措施；

Take specific actions when timely and effective corrective actions are not achieved;

纠正措施应与所产生的不合格的影响相适应，并且应保持描述不合格和纠正措施管理过程的形成文件的信息。

Corrective actions shall be appropriate to the effects of the nonconformities

encountered. The company shall maintain documented information that defines the nonconformity and corrective action management processes.

10.2.2 组织应保留形成文件的信息，作为以下方面的证据：

The company shall maintain documented information as evidence of followings:

a) 不合格的性质以及随后所采取的措施；

The nature of the nonconformities and any subsequent actions taken;

b) 纠正措施的结果。

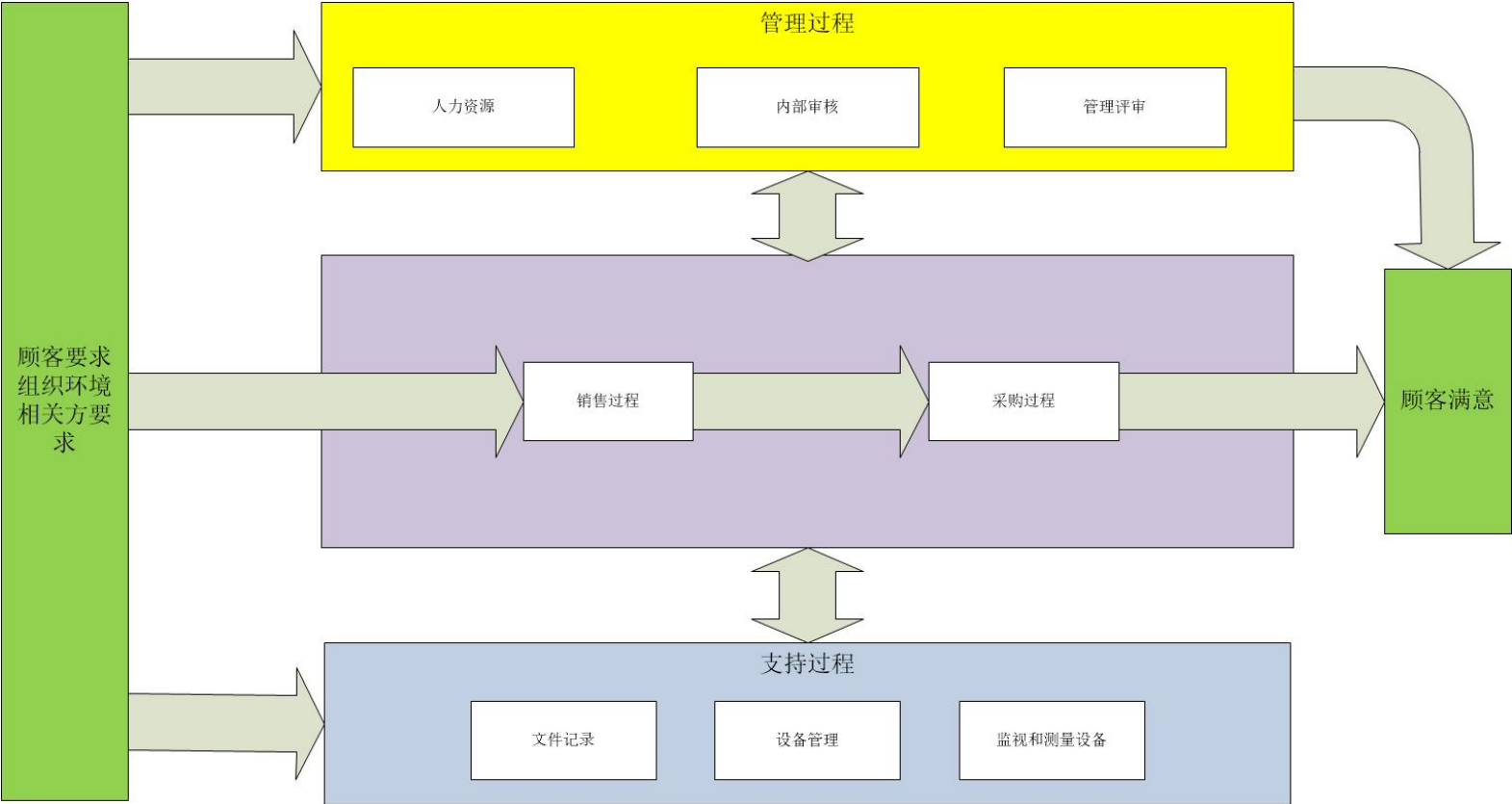
The results of any corrective action.

### 10.3. 持续改进 Continual Improvement

公司将运用自我完善机制，及时识别过程产品符合性以及质量管理体系中存在的问题，包括潜在的问题，制定有效措施，加以改进。公司应持续改进质量管理体系的适宜性、充分性和有效性。公司应考虑管理评审的分析、评价结果以及管理评审的输出，确定是否存在持续改进的需求和机会。组织应监视改进活动的实施并评价其结果的有效性。持续改进的机会可以来自于经验教训、问题解决和最佳实践标杆。

The company will use the self-improvement mechanism to timely identify the process product conformity and problems in the quality management system, including potential problems, and formulate effective measures for improvement. The company shall continually improve the suitability, adequacy and effectiveness of the QMS. Company should consider the management review analysis, the evaluation results, and the management review output to determine if there is a continuous need for improvement and opportunity. The company shall monitor the implementation of improvement activities and evaluate the effectiveness of the results. The opportunity of continual improvement could come from experiences and lessons, problem solving and best practices.

附表 1 Appendix1



过程流程图

## 附表 2 Appendix2

## 职能分配表

## Function allocation table

标准条款	管理层	综合部	商务部
4.1 理解组织及其环境	▲	△	△
4.2 理解相关方的需求和期望	▲	△	△
4.3 确定质量管理体系的范围	▲	△	△
4.4 质量管理体系及其过程	▲	△	△
5.1 领导作用和承诺	▲	△	△
5.2 质量方针	▲	△	△
5.3 组织的角色、职责的权限	▲	△	△
6.1 应对风险和机遇的措施	▲	△	△
6.2 质量目标及其实现的策划	▲	△	△
6.3 变更的策划	▲	△	△
7.1.1 资源 总则	▲	△	△
7.1.2 人员	△	▲	△
7.1.3 基础设施	△	▲	△
7.1.4 过程运行环境	△	▲	△
7.1.5 监视和测量资源	不适用		
7.1.6 组织知识	△	▲	△
7.2 能力	△	▲	△
7.3 意识	△	▲	△
7.4 沟通	△	▲	△
7.5 形成文件的信息	△	▲	△
8.1 运行策划和控制	△	△	▲



标准条款	管理层	综合部	商务部
8.2 产品和服务的要求	△	△	▲
8.3 研发	不适用		
8.4 外部提供过程、产品和服务的控制	▲	△	△
8.5.1 生产和服务提供	△	△	▲
8.5.2 标识和可追溯性	△	△	▲
8.5.3 顾客或外部供方的财产	△	△	▲
8.5.4 防护	△	△	▲
8.5.5 交付后活动	△	△	▲
8.5.6 变更的控制	△	△	▲
8.6 产品和服务的放行	△	△	▲
8.7 不合格输出的控制	△	△	▲
9.1.1 监视、测量、分析和评价总则	△	△	▲
9.1.2 顾客满意	△	△	▲
9.1.3 分析与评价	△	△	▲
9.2 内审审核	△	▲	△
9.3 管理评审	▲	△	△
10.1 改进 总则	▲	△	△
10.2 不合格与纠正措施	△	△	▲
10.3 改进	▲	△	△

注：▲：主管部门      △：配合部门