Quality Management System Manual

ISO9001: 2008

质量管理体系手册

Wuxi Critical Mechanical Components Co., Ltd.

无锡科睿泰机械部件有限公司

Wuxi China 无锡中国

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1 Company Introduction 公司简介

Founded in 2010, Wuxi Critical Mechanical Components Co., Ltd. (CMC), is a wholly owned subsidiary of TechPrecision, positioned to meet the growing demand for a machining and distribution center in Asia. We provide both large-scale and small-scale component, equipment, and assembly manufacturing solutions for the region's solar and wind power challenges, as well as for nuclear, medical, and commercial challenges of business throughout the world. With access to one of the world's largest forges, CMC provides companies in demanding energy, medical, and commercial sectors with the sophisticated and experienced personnel to address their industries' specific needs.

无锡科睿泰机械元件有限公司（CMC）成立于年，是 TechPrecision 公司的全资子公司。公司定位于满足亚洲地区，尤其是中国在加工和配送方面不断增长的需求，为本地区不断增长的太阳能和风能发电，以及全球的核电，医疗和商业需求提供各种规模大小的元件、设备和组装制造解决方案。我们拥有世界上最大的锻造产能之一，还拥有一批在能源、医疗和商业等需求不断增长领域经验丰富的高级人才，能满足这些行业的特定需求。

2 Mission, Vision and Values 使命，愿景和价值观

Mission statement使命宣言

The Mission of WCMC (Wuxi Critical Mechanical Components, Co., Ltd) is to provide efficient and responsive customer service in facilitating the manufacturing of goods by developing a competitive and diversified vendor base that will provide the highest quality products and services to our customers.

通过打造独特而有竞争力的供应链，为顾客提供高品质、高效快速的产品和服务。

Vision Statement愿景宣言

Our vision acts as the backbone and guides every aspect of our business by describing what we need to accomplish in order to continue achieving sustainable

quality and productive growth. 作为核心支柱，愿景描述了持续发展的必要条件，它将指导我们工作的每个方面。

- **Profile**-Deliver a quality product that any customer would be proud to put their name on.
- **Partners**-Nurture a winning network of customers and suppliers.
- **Profit**-Maximize long term returns while being mindful of our overall responsibility.
- **Productivity**-To be a highly effective and productive organization.
- **Professional**- To be professional at all times ensuring healthy working relationships with customers and suppliers .

Values价值观

Our values serve as a compass for our actions and how we behave in the world.

价值观是我们的行动指南

- **Leadership**-The courage to shape a better future.
- **领导力- 改变世界的勇气**
- **Collaboration**-Leverage collective genius
- **合作-利用集体的力量**
- **Integrity**-Being honest, genuine and mindful.
- **正直- 诚实、诚恳、用心**
- **Accountability**-We are responsible for everything we do as individuals and a company.
- **责任- 对所有公司和个人行为负责**
- **Quality**-What we do we do well and stand behind our work
- **质量- 精益求精**

Quality Policy 质量方针

We are committed to continually improve and innovate our processes and system to provide end to end fabrication solutions to all our customers.

We shall:

- Focus on customer’s needs and expectation

- Manage with process and fact
- Develop people fully to maximize their potential
- Build partnership with customers and suppliers

我们承诺持续改进和革新系统和流程，为客户提供全方位的解决方案。

为们将：

- 关注顾客需求和期望
- 基于流程和事实进行管理
- 最大程度发挥员工潜能
- 和客户和供应商建立伙伴关系

2.1 Introduction 介绍

WCMC developed a quality management system to demonstrate its ability to consistently provide product that meets customer and regulatory requirements, and to address customer satisfaction, including continual improvement and the prevention of nonconformity.

科睿泰建立了一套质量管理体系，用以证明我们具备持续向客户提供符合客户和法律法规要求的产品的能力，及增强客户满意度，包括持续改进和不合格的预防。

The quality system complies with the international standard ISO 9001:2008.

质量体系遵守国际标准 ISO 9001:2008。

The manual is divided into eight sections modeled on the sectional organization of the ISO 9001:2008 standard. Sections are further divided into several subsections representing main quality system processes. Each subsection defines general policies and basic principles for the pertinent quality system process; summarizes responsibilities and methods; and references relevant quality procedures and other documents.

基于 ISO9001:2008 的章节，手册分为八个部分。另外进一步划分为一些子部分以阐述主要的质量系统进程。每一个子部分阐明了相关的质量系统进程的大纲政策和基本原则，统筹了责任及方法，另外给予相关的质量程序和其他文件提供指导。

The purpose of this manual is to define and describe the quality system, and to provide a general outline for WCMC's quality processes.

手册的宗旨在于定义和阐述质量体系，给 WCMC 的质量过程提供大概纲程。

2.2 Application 应用

The quality management system defined in this manual applies to the sales and service of pressure vessel and machinery.

手册中的质量管理体系可被应用于压力容器、机械的销售和服务。

2.3 Exclusions 豁免条款

The quality management system shall be relevant to the nature of our organization and products, and to customer and regulatory requirements. For this reason, those requirements of ISO 9001 that do not apply are excluded from the scope of our quality system.

质量管理系统应与生产组织的本性，顾客及规章要求息息相关。出于此因，那些不适用的 ISO9001 要求将会被排除出我们的质量系统的范围之外。

As the reason that the design is completed by WCMC's customer, so Quality Management System clause 7.3 which is Design and Development will be excluded in this manual.

因本公司产品的设计工作由客户完成，故本手册不包含于质量管理体系 7.3 条款设计和开发对本公司的要求。

As the reason that there is no special process to be validated, so the Quality Management System clause 7.5.2 will be excluded in this manual.

因公司没有特殊过程需要确认，故本手册删除质量体系 7.5.2 条款要求。

The Quality Manager is responsible for identifying those requirements of ISO 9001 that do not apply to our organization or products, and to propose to top management that such requirements be excluded from the scope of the quality system.

质量经理将负起识别那些对我们组织或生产不能够被应用的 ISO9001 要求的责任，同时还需对最高级管理阶层提出将该些要求排除出质量系统范畴的建议。

3 Quality Management System 质量管理体系

3.1 Quality System Processes 质量管理体系

3.1.1 The quality management system is designed as a system of interrelated processes. All main activities of the system are defined as Quality System Processes and are grouped into the following four categories (refer to the Quality System Processes Map on next page):

质量管理体系由相关联的过程构成.质量管理体系过程是指体系内所有主要活动, 分为以下 4 个范围:

- Management Responsibility Processes管理职责过程
- Resource Management Processes 资源管理过程
- Product Realization Processes 产品实现过程
- Measurement, Analysis and Improvement Processes 测量,分析和改进过程

3.1.2 The sequence and interrelation between the four groups and individual Quality System Processes are illustrated in the Processes Map diagram. Each Quality System Process is further broken down into its sub-processes, as defined in the Process Map Matrix included after the diagram.

下面的过程图展示了质量体系的 4 个过程及过程之间的次序和相关性.每一过程被更深层次的划分成若干子过程, 如过程矩阵所列举的内容。

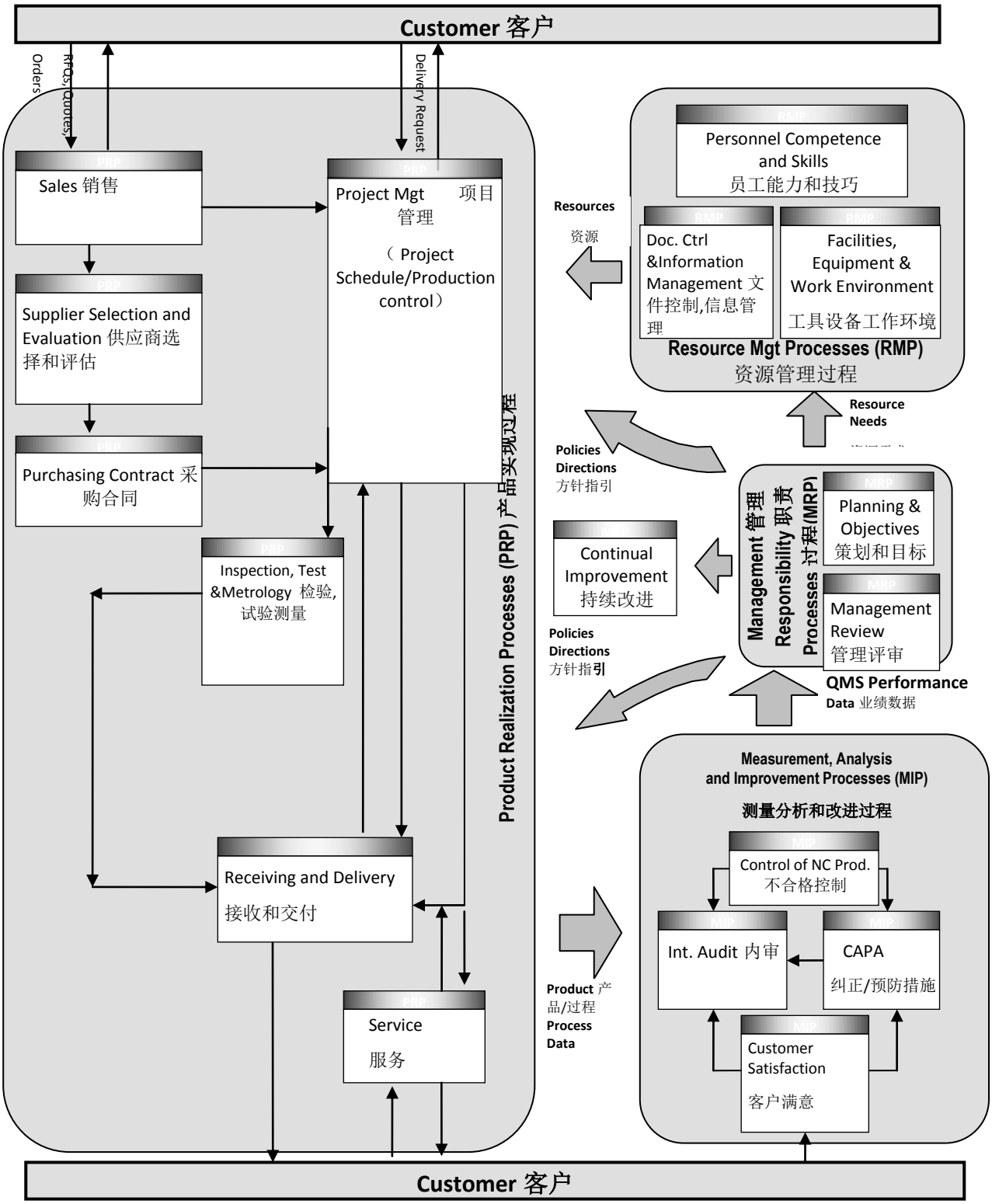
3.1.3 Quality System Processes and their sub-processes are documented in this Quality Manual and in associated Quality Procedures and Work Instructions. This documentation defines the quality system processes and their sequence and interaction, and instructs on how to implement and apply them throughout the organization.

质量手册,相关的质量程序及操作指引中都记录了质量体系的过程及子过程.本文件定义了质量体系过程和过程的顺序和相关性, 介绍了如何在组织内实施和开展这些过程。

3.1.4 Quality system documentation also defines criteria and methods needed to ensure that the operation and control of quality system processes are effective. This includes assignment of responsibilities and allocation of resources for the process, instructions on how to carry out (or operate) the process, and definition of methods for monitoring and/or measuring the effectiveness of the process.

质量体系文件也制定了若干标准和方法,来确保质量体系过程的控制和操作有效.包括: 职责的分配, 过程所需资源的配置, 如何开展过程的介绍。

Process Map 过程图



Process Map Matrix 过程图矩阵

PRODUCT REALIZATION PROCESSES (PRPs)产品实现过程	
Sales Process **销售流程**	
Purpose 目的	To determine customer requirements, take orders from, or enter into contracts with customers. 确定客户要求，得到订单，与客户接触.
Process Owner 流程责任人	GM/Sales dept. 总经理/销售部
Sub-Processes 子过程	• Determining product requirements • 确定产品要求 • Determining customer requirements • 确定客户要求 • Evaluating capability and capacity to meet requirements • 评估满足客户要求的能力 • Entering orders (or signing contracts) • 签定合同 • Receiving, entering and processing change orders • 接收，记录，处理定单更改 • Providing product information • 提供产品信息
Applicable Procedure documents 引用程序文件	• Quotation and Contract Handling Procedure 报价和合同管理程序
Supplier Selection and Evaluation **供应商选择和评估**	
Purpose 目的	To select the production sub-tier. 选择合适的制造供应商。
Process Owner 流程责任人	Quality / President 质量/总经理
Sub-Processes 子过程	• Sourcing potential supplier • 选择潜在供应商 • Potential supplier assessment • 潜在供应商审核
Applicable Procedure	• Supplier Selection and Evaluation Procedure

documents **引用程序文件**	• 供应商选择和评估程序
Purchasing Contract **采购合同**	
Purpose 目的	Communicate purchasing information and come into agreement with supplier 沟通采购信息，与供应商达成协议
Process Owner 流程责任人	Purchasing Dept. 采购部
Sub-Processes 子过程	• Supplier quotation and contract • 供应商报价和合同 • PO handling • 采购订单处理
Applicable Procedure documents **引用程序文件**	• Supplier PO Handling • 供应商订单管理程序
Project Management **项目管理**	
Purpose 目的	To coordinate project team and monitor sub-tier manufacture 协调项目团队，监控供应商生产
Process Owner 流程责任人	Production Department 生产部
Sub-Processes 子过程	• Project scheduling and tracking • 项目计划和跟踪 • Drawing handling • 图纸管理 • Monitoring and controlling manufacturing processes of supplier • 监视和控制供应商制造过程 • Training supplier as necessary • 培训供应商
Applicable Procedure documents **引用程序文件**	• Project Schedule • 项目计划程序 • Project Control Procedure • 项目管理程序
Inspection, Test and Metrology **检验,测试和计量**	

Purpose 目的	To test products to meet customer and third party requirement. 测试产品，满足客户和第三方的需求
Process Owner 流程责任人	Quality Department 质量部
Sub-Processes 子过程	• Establish inspection and test plan • 建立检验和试验计划 • Monitor inspection and test plan implementation • 监控检验和试验计划的执行 • Maintaining testing documentation • 测试记录的维护
Applicable Procedure documents 引用程序文件	• Quality Inspection Procedure • 质量检验程序
Receiving and Delivery **接收和交付**	
Purpose 目的	To receive products from supplier and deliver to customers on time. 从供应商处接受产品并准时交付给客户。
Process Owner 流程责任人	Logistic Department 物流部
Sub-Processes 子过程	• Processing shipping orders • 执行发货 • Packaging and labeling product for shipping • 发货的包装和标识 • Dispatching or shipping product • 产品装运或调度 • Establishing and maintaining shipping and distribution records • 建立和维护发货记录
Applicable Procedure documents 引用程序文件	• Receiving and Delivery Procedure • 产品接受和发运程序
Service **服务**	
Purpose 目的	To handle customer feedback and provide customer service 处理客户 反馈并提供客户服务
Process Owner 流程责任人	Office 办公室

Sub-Processes 子过程	• Receive customer feedback and communicate to related function • 接收客户反馈，沟通到相关部门 • Handle complaints from customer • 处理客户投诉 • Provide customer service • 提供客户服务
Applicable Procedure documents 引用程序文件	Customer Service Procedure 客户服务程序

MEASUREMENT AND IMPROVEMENT PROCESSES (MIPs)测量和改进过程

Control of Nonconforming Product 不合格品的控制

Purpose 目的	To identify, control and disposition nonconforming products. 识别，控制和处理不合格品
Process Owner 流程责任人	Quality Department 质量部
Sub-Processes 子过程	• Identifying nonconforming products • 识别不合格品 • Making nonconforming product disposition decisions • 制定不合格品处理措施 • Reworking and verifying nonconforming products • 返工和验证不合格品
Applicable Procedure documents 引用程序文件	• Control of Nonconforming Product Procedure • 不合格品控制程序

Internal Audits and Analysis of Data 内部审核和数据分析

Purpose 目的	To verify conformity of the quality management system, and to evaluate its effectiveness and efficiency. 验证质量管理体系的符合性，评估质量管理体系的有效性和效益.
Process Owner 流程责任人	Quality Department 质量部
Sub-Processes 子过程	• Conducting internal audits of the quality system • 开展质量体系内部审核 • Analyzing and evaluating results of internal, third-party and customer audits • 分析和评估内部审核、第三方审核和客户审核的结果. • Collecting and analyzing quality performance data • 搜集和分析质量业绩数据.

Applicable Procedure documents 引用程序文件	• Internal Audits Procedure • 内部审核程序
Corrective and Preventive Action 纠正和预防措施	
Purpose 目的	To request, implement and follow up corrective and preventive (C&P) actions. 纠正和预防措施的要求、实施和跟踪检查.
Process Owner 流程责任人	Quality Department 质量部
Sub-Processes 子过程	• Evaluating the need for corrective and preventive (C&P) actions • 评估纠正和预防措施的需求 • Requesting and implementing C&P actions • 要求和实施纠正预防措施 • Verifying the implementation and effectiveness of C&P actions • 验证纠正和预防措施的效果
Applicable Procedure documents 引用程序文件	• Corrective and Preventive Action Procedure • 纠正预防措施程序
Customer Satisfaction 客户满意度	
Purpose 目的	To measure customer satisfaction. 客户满意度测量
Process Owner 流程责任人	Office 办公室
Sub-Processes 子过程	• Gathering of information and data about customer satisfaction • 搜集客户满意度信息和数据 • Analyzing, reporting and presenting customer satisfaction information and data • 分析、报告、陈述客户满意度信息和数据
Applicable Procedure documents 引用程序文件	• Customer Satisfaction Evaluation Procedure • 顾客满意度评估程序
MANAGEMENT RESPONSIBILITY PROCESSES (MRPs)管理职责过程	
Planning and Objectives 策划和目标	
Purpose 目的	To define the quality policy and quality objectives, to plan the quality management system (QMS), and to implement management commitments. 制定质量方针和质量目标，策划质量管理体系，实施管理承诺

Process Owner 流程责任人	Management 管理层
Sub-Processes 子过程	• Establishing quality policy • 制定质量方针 • Establishing and monitoring of quality objectives • 质量目标的制定和监测 • Planning the quality management system • 策划质量管理体系 • Defining responsibilities and authorities • 确定职责和权限 • Appointing Management Representative • 指定管理者代表
Applicable Procedure documents 引用程序文件	• KPI Planning Procedure • 业绩指标策划程序
Management Review 管理评审	
Purpose 目的	To review the suitability and effectiveness of the quality system; to consider changes to the quality system, quality policy and quality objectives; and to identify opportunities for improvement. 评审质量体系的适用性和效果，考虑质量体系的更改，质量方针和目标，寻求改进机会.
Process Owner 流程责任人	Top Management 管理层
Sub-Processes 子过程	• Presentation, discussion and evaluation of review input information • 陈述、讨论、评估评审输入信息 • Determining changes required (if any) for the quality policy, quality objectives and the quality management system • 确定质量方针、质量目标、质量管理体系的更改， • Identifying opportunities for improvement and establishing quality objectives • 识别质量目标改进和建立的机会
Applicable Procedure documents 引用程序文件	• Management Review Procedure • 管理评审程序
Continual Improvement 持续改善	
Purpose 目的	To continually improve the quality management system, processes and products. 持续改善质量管理体系、过程和产品
Process Owner 流程责任人	Top Management 领导高层
Sub-Processes 子过程	• Monitoring performance of the quality management system • 监测质量管理体系的业绩 • Requesting and implementing corrective and preventive actions

	• 要求和实施纠正预防措施 • Establishing, reviewing and updating the quality policy • 建立、评审和更新质量方针 • Establishing, implementing and monitoring quality objectives • 建立、实施和检测质量目标 • Improving the Quality Management System • 改进质量管理体系
Applicable Procedure documents 引用程序文件	• KPI Planning Procedure • 业绩指标策划程序、 • Management Review Procedure • 管理评审程序 • Corrective and Preventive Action Procedure • 纠正预防措施程序
RESOURCE MANAGEMENT PROCESSES (RMPs)资源管理过程	
Personnel Competence and Skills 员工能力和技巧	
Purpose 目的	To define competency requirements, provide training, and ensure awareness about quality-related issues. 制定能力要求、提供培训确保员工质量相关意识
Process Owner 流程责任人	Human Resources Department 人力资源部
Sub-Processes 子过程	• Determining competency requirements for jobs/positions affecting product quality • 确定影响产品质量的工作/岗位的能力要求 • Providing training and/or taking other actions to satisfy competency requirements • 提供培训和/或采取其它措施满足能力要求 • Evaluating the effectiveness of training • 评估培训效果 • Providing awareness programs to ensure employee motivation, empowerment, and knowledge of quality-related issues • 为确保员工质量相关方面的动力，灌能和知识提供意识方案
Applicable Procedure documents 引用程序文件	• Recruiting Procedure • 招聘程序 • Training Procedure • 培训程序
Document Control and Information Management 文件控制和信息管理	
Purpose 目的	To control documents related to products, manufacturing processes and the quality system; and to control quality records. 控制与产品、制造、质量体系相关的记录，控制质量记录
Process Owner	Quality Department 质量部

流程责任人	
Sub-Processes 子过程	• Establishing documents needed by the organization • 建立组织需要的文件 • Reviewing and approving documents • 文件的审核和批准 • Controlling document revisions and distribution (availability) • 控制文件的修改和发放（可利用） • Managing retention, storage, and disposition of records • 管理记录的保留、保存和处理
Applicable Procedure documents 引用程序文件	• Documents Control Procedure • 文件控制程序 • Records Control Procedure • 记录控制程序
Facilities, Equipment and Work Environment 设施、设备和工作环境	
Purpose 目的	To ensure appropriate and adequate facilities and supporting services. 确保适当和足够的设施和服务支持
Process Owner 流程责任人	Related dept. 相关部门
Sub-Processes 子过程	• facility and equipment planning • 设施、工具和设备策划 • Maintaining facilities and supporting service • 设施、辅助服务的维护
Applicable Procedure documents 引用程序文件	• Monitoring and Measuring Equipment Control Procedure • 监视测量设备管理程序

3.2 Documentation and Records 文件和记录

3.2.1 Documentation 文件

3.2.1.1 Quality system documentation comprises the following categories of documents 质量体系文件包含以下范围的文件:

- Quality system manual;质量体系手册
- Quality procedures;质量程序
- Quality system forms and record;质量体系表格和记录
- Drawing; 图纸
- Standards and codes.标准和法规

3.2.2 Document Control 文件控制

3.2.2.1 Both electronic and paper documents are used, and are defined in ***Control of Documents***.
文件包括电子和书面文件,定义在***文件控制程序***中。

3.2.2.2 The document control system defined in ***Control of Documents*** ensures that all documents, including those supplied by the customer, are:
质量程序***文件控制*** 中规定的文件控制体系应当确保所有的文件，包括客户提供的文件被：

- Reviewed and are approved;
- 审核和批准
- Updated as necessary;
- 必要时进行更新
- Identified, to include their current revision status;
- 识别，包括当前的版本状态
- Distributed to,
- 分发
- Available at locations where they are used, and are controlled;
- 文件在使用处可获得，受控
- Withdrawn from points of use when obsolete.
- 废弃版本的回收

3.2.3 Control of Records 记录控制

3.2.3.1 Records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.
记录建立和维护的目的是为提供符合质量管理体系的要求和体系的有效实施提供证据。

3.2.3.2 Records are organized into the following 3 categories:
记录分为以下3种类型:

- Production and Product Quality Records
- 生产和产品质量记录,
- Distribution Records
- 发货记录,

- Other Quality System Records
- 其他质量体系记录

3.2.3.3 Quality Procedure ***Control of Records*** defines more specifically what records are maintained in each category and designates their storage locations and retention periods. It also defines the process for ensuring that records are clearly identified, are stored in appropriate locations and conditions, are adequately protected, and are easily retrievable.

质量程序*记录控制*明确规定了每种类型的记录中应保存的部分和保存的地点和期限.也提供了能够确保记录清晰识别，应保存的地点和条件, 充分被保护, 便于回收的过程方法。

4 Management Commitment *管理承诺*

4.1 Management Commitment 管理承诺

4.1.1 Purpose & Objectives 目的和目标

Management defines the purpose and objectives for the quality management system. Objectives are documented and communicated in ***QM Section 5.2 Quality System planning***, and are further detailed in Quality Procedure ***Management Review***.

管理定义了质量管理体系的目的和目标。目标记录和传达在*质量手册第 5.2 节质量体系策划*中，更多的细节记录在质量程序*管理评审*中。

4.1.2 Reviews 评审

Management periodically reviews the quality management system to ensure its continuing suitability, adequacy, and effectiveness. The process for conducting management reviews is defined in Quality Procedure ***Management Review***.

质量管理体系的定期评审用来确保体系的持续适宜性，充足性和有效性。质量程序*管理评审程序*规定了开展管理评审的流程。

4.1.3 Commitment 承诺

Management is committed to providing resources necessary for establishing, implementing, and improving the quality management system. ***QM Section 6.1 Provision of Resources*** defines processes for identifying resource requirements and allocation of resources for specific activities and projects.

管理层致力于为建立，实施和改进质量体系提供必须的资源。*质量手册 6.1 资源提供*规定了识别特定活动和项目的资源需求和资源分配过程。

4.2 Quality Systems Planning 质量体系策划

4.2.1 Quality Objectives 质量目标

Quality objectives are established by general manager and will be reviewed at the management reviews of the quality system. These processes for establishing, implementing and monitoring quality objectives are defined in Quality Procedure ***KPI Planning Procedure***. 公司总经理确定质量目标，质量目标在管理评审会议时进行评审.质量程序***KPI 策划程序***中规定了建立、实施和监测质量目标的过程。

4.2.2 Quality System Planning 质量体系策划

4.2.2.1 Quality system processes are planned to ensure that the system is appropriate for its intended purpose, and that it is effective and efficient. The purpose of the quality system is to:

质量体系的策划用来确保体系能够达到预期的目的，质量体系适用、有效. 质量体系的目的是：

- Achieve the quality policy;
- 实现质量方针；
- Ensure and demonstrate our ability to provide electrical devices and related services that consistently meet customer requirements and applicable regulatory requirements;
- 确保和证明我们提供的电气设施和相关服务能够与客户要求相一致，同时满足相应的法律法规；
- Ensure high level of customer satisfaction;
- 确保高水平的客户满意度；
- Facilitate continual improvement;
- 推动持续改善；
- Comply with requirements of the ISO 9001 standard and other applicable requirements for quality management systems.
- 遵从ISO9001标准要求和质量管理体系其它适用要求。

4.2.2.2 The output of quality system planning is documented in this quality manual, in associated operational procedures, and in other referenced documents. These documents identify and define all processes of the quality system (refer to ***QM Section 4.1.1 Quality System Processes***).

本手册包含了质量体系策划输出和其它相关的操作程序及参考文件.这些文件识别和定义了质量体系所有的过程。（参照***质量手***

册4.1.1节质量体系过程）。

4.3 Organization and Communication 组织和沟通

4.3.1 Responsibility and Authority 职责和权限

4.3.1.1 Departments under Quality Management System are identified in the Organizational Chart. Management ensures that departments have sufficient independence and authority to perform those tasks that could affect Quality Management System.
组织架构图确定了本公司质量管理体系下各部门之间的联系。管理层确保各部门开展影响质量体系工作时具有充分的独立性和权限。

4.3.1.2 Authorities and responsibilities for specific processes of the quality management system are defined throughout this quality manual and in procedures where the specific quality system process or activity is documented.
质量管理体系特定过程的职责和权限定义为本质量手册和每个操作程序记录的特定的质量体系过程和活动。

4.3.2 Management Representative 管理者代表

WCMC appoints the Quality Manager as the Management Representative for the quality management system. The Management Representative has the authority and responsibility to:

WCMC公司任命质量经理为质量管理体系的管理者代表.管理者代表具有以下职责和权限：

- Ensure that the quality management system is implemented, maintained and continually improved;
- 确保质量管理体系得到实施、维护和持续改善；
- Promote awareness of regulatory and customer requirements throughout the organization;
- 在组织内推动满足法律法规和客户要求的意识；
- Report to management on the efficiency and performance of the quality system;
- 向管理层汇报质量管理体系的适宜性和绩效；
- Coordinate communication with external parties on matters relating to the quality system and ISO 9001 registration.
- 与外部相关方就质量管理体系和 ISO9001 注册展开合作交流。

4.4 Management Review 管理评审

Management reviews of the quality management system are conducted at least once a year. They are chaired by the general manager and are attended by other managers responsible for, and/or affected by the quality management system. The processes for initiating and conducting management reviews are defined in Quality Procedure ***Management Review***.

质量管理体系的管理评审至少每年开展一次。由总经理主持，与质量管理体系有关的部门经理需参加。质量程序*管理评审程序*规定了发起和开展管理评审的流程。

5 Resource Management 资源管理

5.1 Provision of Resources 资源提供

5.1.1 Resources required for maintaining and improving the quality management system, and for addressing customer satisfaction, include:
质量管理体系的维护、改进和增强客户满意度必需的资源包括：

- Personnel人力资源
- Infrastructure设施
- Work environment工作环境
- Process equipment过程设备
- Training培训
- Information, and信息
- Financial Resources财务资源

5.1.2 Depending on the type and nature of the process, operation, or activity, resource requirements are defined in relevant procedures.
根据过程、操作、活动的类型和特点，资源需求定义在相关程序中描述。

5.2 Human Resources 人力资源

5.2.1 General 总则

5.2.1.1 Personnel performing work affecting product quality are competent. Competency is determined on the basis of appropriate education, training, skills and experience.
员工有能力执行影响产品质量的工作. 能力由以下几部分为基础

确定：适当的教育程度，培训，技能和经验。

5.2.1.2 Human Resources Department is responsible for training and awareness programs for company-wide participation.
人力资源部负责公司范围内的能力和意识培训。

5.2.1.3 Departmental Managers and area supervisors are responsible for identifying competency requirements and for providing training in their areas.
各部门经理和主管负责识别部门员工的能力需求和提供相应的培训。

5.2.2 Competence, Awareness, and Training 能力、意识和培训

5.2.2.1 The objective of our training is to ensure that employees possess the required knowledge and skills for performing their jobs; and that they are familiar with relevant requirements of the quality system pertaining to their job functions.
培训的目的是确保员工在开展工作时具备必需的知识和技能，以及熟悉与岗位工作相关的质量体系要求。

5.2.2.2 Processes for ensuring adequate competency and awareness of personnel are defined in ***HR Procedure***. The procedure addresses issues related to:
人力资源管理程序规定了确保员工具备充分的能力和意识所需要的过程.程序涉及到的内容包括：

- Determining competency requirements,
- 确定能力要求；
- Identifying training needs,
- 识别培训需求；
- Providing training,
- 提供培训
- Evaluating the effectiveness of training,
- 评估培训效果
- Ensuring quality awareness, and
- 确保质量意识
- Maintaining training records.
- 保存培训记录

6 Product Realization 产品实现

6.1 Planning of Product Realization 产品实现策划

6.1.1 Production and Quality Planning

Production processes and product verification activities are planned to determine: 对生产过程和产品验证进行策划，以确定：

- Requirements and quality objectives for products and processes;
- 产品质量目标和过程要求；
- The need to develop production processes; establish process specifications, operator instructions and other such documentation in supplier; and provide training to process operators of supplier;
- 开发生产过程的需求；建立供应商过程规范，操作指引和其它文件；为供应商提供培训；
- Required product verification, inspection and test activities, and the criteria for product acceptance;
- 必需的产品验证、检验和测试活动，产品接受标准；
- Records needed to provide evidence of product and process conformity.
- 提供产品和过程符合要求的记录证明。

6.2 Customer-Related Processes 与客户相关的过程

6.2.1 Product Requirement Definition 确定产品要求

Product requirements are determined, to include:

确定产品要求，包括

- Requirements specified by the customer;
- 客户规定的要求
- Requirements not stated by the customer, but necessary for intended use
- 客户未规定，但达到预期使用效果必需的要求；
- Statutory and regulatory requirements;
- 法律法规要求；
- Any additional requirements determined by the company.
- 公司确定的其它附加要求

6.2.2 Review of Requirements Related to the Product 产品相关的评审要求

6.2.2.1 Prior to the commitment to supply a product to the customer, orders are reviewed to ensure that:

承诺客户提供符合要求的产品之前，对定单进行评审，以确保：

- Product requirements are defined;
- 产品要求已明确；
- Any ambiguities and conflicts in contract or order requirements are resolved;
- 合同或定单中所有不明确或冲突的问题已解决；
- WCMC is able to meet customer requirements.
- WCMC具备满足客户要求的能力。

The details refer to the quality procedure **Quotation and Contract Handling Procedure.**

细节请参考质量程序***报价和合同处理程序***。

6.3 Design and Development 设计和开发 **(excluded 删除)**

6.4 Purchasing 采购

6.4.1 Supplier Selection and Evaluation 供应商选择和评估

There is a process for supplier selection and evaluation in WCMC to ensure all suppliers have the ability to meet the technical and commercial requirements. The performance of qualified supplier shall also be evaluated during the cooperation process to ensure the sustainable supplier conformity. The quality procedure ***Supplier Selection and Evaluation Procedure*** defines the details.

为了确保所有供应商有能力满足技术和商务要求，应对供应商进行选择和评价。为了确保供应商持续的满足要求的能力，还应对合格供应商进行业绩评估。质量程序***供应商选择和评估程序***规定了以上要求。

6.4.2 Purchasing Control 采购控制

Purchasing documents are reviewed and approved prior to release. The processes for the preparation, review and approval of purchasing documents are defined in Quality Procedure ***Supplier PO and Contract Handling***.

采购文件应在下发前得到审核和批准.质量程序 ***供应商订单和合同管理***规定了采购文件的准备、审核和批准的流程。

6.5 Production and Service Provision 生产和服务的提供

6.5.1 Control of Production and Service Provision 生产和服务提供的控制

Production process is controlled by CMC's supplier. CMC's focus is on additional process and product monitoring. So before the production, CMC shall confirm the drawings, quality criteria and process instructions together with supplier. These shall be defined in procedure **Production Control Procedure.**

供应商控制生产过程。CMC 负责对供应商的生产过和产品实施额外的监控。因此在生产前，CMC 应和供应商一起确认图纸、质量规范和工艺文件。 这些要求在***生产过程控制程序***中定义。

6.5.2 Validation of production and service provision 生产和服务提供的确认

（Excluded 删除）

6.5.3 Identification and traceability 标识和可追溯性

WCMC shall ensure the identification of finished products and traceability in supplier's production process.

WCMC 确保供应商交付品的标识符合顾客要求，并确保在供应商处产品的可追溯性。

6.5.4 Preservation of Product 产品防护

WCMC shall endure the preservation of product at supplier's location and preservation during delivery.

WCMC 应确保在供方处和交付过程中产品的防护。

*6.6 Control of Monitoring and Measuring Equipments*监视和测量设备控制

6.6.1 General 总则

6.6.1.1 Appropriate measuring and monitoring devices are selected to ensure that measurement requirements can be met. Quality Procedure ***Measuring and Monitoring Equipment*** defines the calibration and control system.

选择合适的监视和测量设施以满足测量的要求.质量程序***监视和测量设备*** 规定了设施的校验和控制流程。

7 Measurement, Analysis and Improvement 测量，分析和改进

7.1 General 总则

7.1.1 Planning 策划

7.1.1.1 Measurement and monitoring activities to ensure and verify product conformity are defined in engineering specifications and drawings, production work orders, inspection and testing procedures, and process control procedures. These activities are further defined in Quality Procedure ***Quality Inspections***. The conformity and effectiveness of the quality system are monitored by internal audits and by measuring quality performance and customer satisfaction. Results of these activities are reported to the management and are used to identify opportunities for improvement. Activities related to internal audits and to measuring customer satisfaction and quality performance are defined in Quality Procedures ***Quality Audits*** and from any customer feedback.

工程规范、图纸、生产流程、检验和测试程序中规定了为确保和验证产品符合性的测量和监测活动。质量程序，***质量检验***进一步规定了测量和检测活动开展的细节。质量体系的有效性和符合性通过内部审核、质量体系业绩测量和客户满意度进行测量，并向管理层汇报，以寻求持续改进的机会。质量程序***内部审核***和顾客反馈的信息规定了与内部审核、 客户满意度和质量业绩相关的活动。

7.2 Monitoring and Measurement 监视和测量

7.2.1 Customer Satisfaction 客户满意度

7.2.1.1 Quality Department is responsible for developing suitable indicators of customer satisfaction, and for defining methods for collecting and analyzing the pertinent information.

质量部负责开发客户满意度恰当的指标，制定客户满意度相关信息的搜集和分析方法。

7.2.1.2 For this purpose, customer satisfaction information is reported to, and evaluated by the management review of the quality system, as defined in Quality Procedure ***Customer Satisfaction Evaluation Procedure.***

质量管理体系评审时进行客户满意度信息的汇报和评估，具体流程参照程序文件***顾客满意度评估程序***。

7.2.2 Internal Audit 内部审核

7.2.2.1 The Quality Manager is responsible for conducting internal audits of the quality management system to determine whether the quality system:

质量经理负责开展质量管理体系内部审核，以确定质量体系：

- Conforms to management system requirements and to the requirements of the ISO 9001 standard;
- 是否满足质量管理体系和ISO9001的要求和标准；
- Is effectively implemented and maintained.
- 得到了有效实施和保持。

7.2.2.2 Quality Procedure ***Quality Audits*** defines the processes for planning, conducting and reporting internal audits, as well as taking corrective actions and follow-ups.

质量程序***内部质量审核***规定了内部审核的策划、 开展、汇报流程以及纠正措施和跟踪检查流程。

7.2.3 Monitoring and Measurement of Processes and Products 监视和测量过程和产品

7.2.3.1 When a quality system process does not conform to requirements, a corrective action request to address the problem is initiated. The process for requesting and implementing corrective actions is defined in Quality Procedure ***Corrective and Preventive Action***.

当质量体系某一过程不符合体系要求时，质量经理应发起一项纠正措施要求对问题进行解决。质量程序***纠正和预防措施***规定了纠正措施的要求和实施流程。

7.2.3.2 **Verification of incoming material:** All purchased material at supplier are visually inspected or verified by WCMC. Processes for performing these inspections are defined in ***Quality Inspections***.

来料的验证：所有供应商采购产品应进行目视检验。某些指定的产品应进行更仔细的技术质量检验。质量程序***质量检验***规定了开展这些检验的流程。

7.2.3.3 **In process monitoring: WCMC** shall monitor the whole process of product manufacturing in supplier as per quality plan.

过程监控：WCMC 应根据质量计划监控供应商的整个生产过程。

7.2.3.4 **Final acceptance inspection:** Finished products are subjected to the final QC inspection. Inspectors perform inspections and tests necessary to complete the product and ensure that it conforms to the specified requirements. Quality Procedure ***Quality Inspections*** defines these activities.

最终接收检验：成品应进行最终质量检验。检验员应执行保证产品完成所必须的检验和测试，确保产品符合所有的规定要求。质量程序***质量检验***规定了开展这些活动的流程。

7.3 Control of Nonconforming Product 不合格品控制

7.3.1 Identification and Documentation 识别和记录

7.3.1.1 Nonconforming products are documented in the Nonconformance Report Form (NCR). The use of the NCR and its processing are explained in Quality Procedure***Control of Nonconforming Product***.
不合格品记录在不合格报告表(NCR)中。不合格报告表的使用和处理流程参照质量程序***不合格品控制。***

7.4 Analysis of Data 数据分析

7.4.1 General 总则

7.4.1.1 Data and information recorded in quality records are compiled and analyzed periodically to determine trends in the performance of the quality system and to identify opportunities for improvement.
质量记录中记载的数据和信息应定期地进行整理和分析，以确定质量体系业绩和有效性的趋势以及寻求持续改进机会。

7.4.1.2 The Quality Manager is responsible for coordinating these activities, and for reporting conclusions and trends to management. This is usually done within the framework of management reviews of the quality system, in accordance with Quality Procedure ***Management Review***. 质量经理负责以上活动的协调，并向管理层汇报质量体系的分析结果和趋势。这些内容通常是在质量体系管理评审框架内部完成的，与质量程序***管理评审***规定的流程相一致。

7.5 Improvement 改进

7.5.1 Continual Improvement 持续改进

7.5.1.1 Electronic Power Design China Group, LTD. continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.
易倍得中国有限公司通过使用质量方针，质量目标，审核结果，数据分析，纠正预防措施和管理评审对质量管理体系的有效性进

行持续改善。

7.5.1.2 Improvement projects are defined either as corrective and preventive actions or as quality objectives. These processes are defined in Quality Procedures ***Corrective and Preventive Action***, and ***Management Review***, respectively.
改善计划以纠正预防措施或质量目标的形式制定。质量程序*纠正预防措施*和*管理评审*中分别规定了改善计划的制定流程。

7.5.2 Customer Input 客户输入

7.5.2.1 Customer complaints that allege deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a product are logged and documented.
对不符合产品标识、质量、寿命、可靠性、安全、有效性、性能等相关要求的投诉进行记录并形成文件；

7.5.2.2 Complaints that involve a possible failure of a product, labeling, or packaging to meet any of its specifications are always investigated, and the results of the investigation are documented.
对可能发生不符合规范的产品质量、标识、包装问题投诉进行调查，并记录调查的结果。

7.5.3 Corrective and Preventive Action 纠正和预防措施

7.5.3.1 Corrective actions are taken to eliminate causes of actual nonconformities in order to prevent their recurrence.
纠正措施是指为消除已发现的不合格，防止不合格再次发生而采取的措施。

7.5.3.2 Preventive actions are implemented to eliminate causes of potential nonconformities in order to prevent their occurrence.
纠正措施是指为消除潜在的不合格，防止不合格发生而采取的措施。

7.5.3.3 The process for taking corrective and preventive actions is defined in Quality Procedure ***Corrective and Preventive Action***.
质量程序*纠正和预防措施*规定了采取纠正和预防措施的流程。

Appendix 1：

Management Representative Appointment Letter

管理者代表任命书

WCMC appoints **Manuel Teall** as the Management Representative for the quality management system. The Management Representative has the authority and responsibility to:

WCMC 任命**Manuel Teall**为质量管理体系的管理者代表.管理者代表具有以下职责和权限：

- Ensure that the quality management system is established, implemented, maintained and continually improved;
- 确保质量管理体系得到建立、实施、维护和持续改善；
- Promote awareness of regulatory and customer requirements throughout the organization
- 在组织内推动满足法律法规和客户要求的意识；
- Report to top management on the performance of the quality system and needs for improvement;
- 向管理层汇报质量管理体系的绩效以及改进需求；
- Coordinate communication with external parties on matters relating to the quality system and ISO 9001 registration.
- 与外部相关方就质量管理体系和 ISO9001 注册展开合作交流。

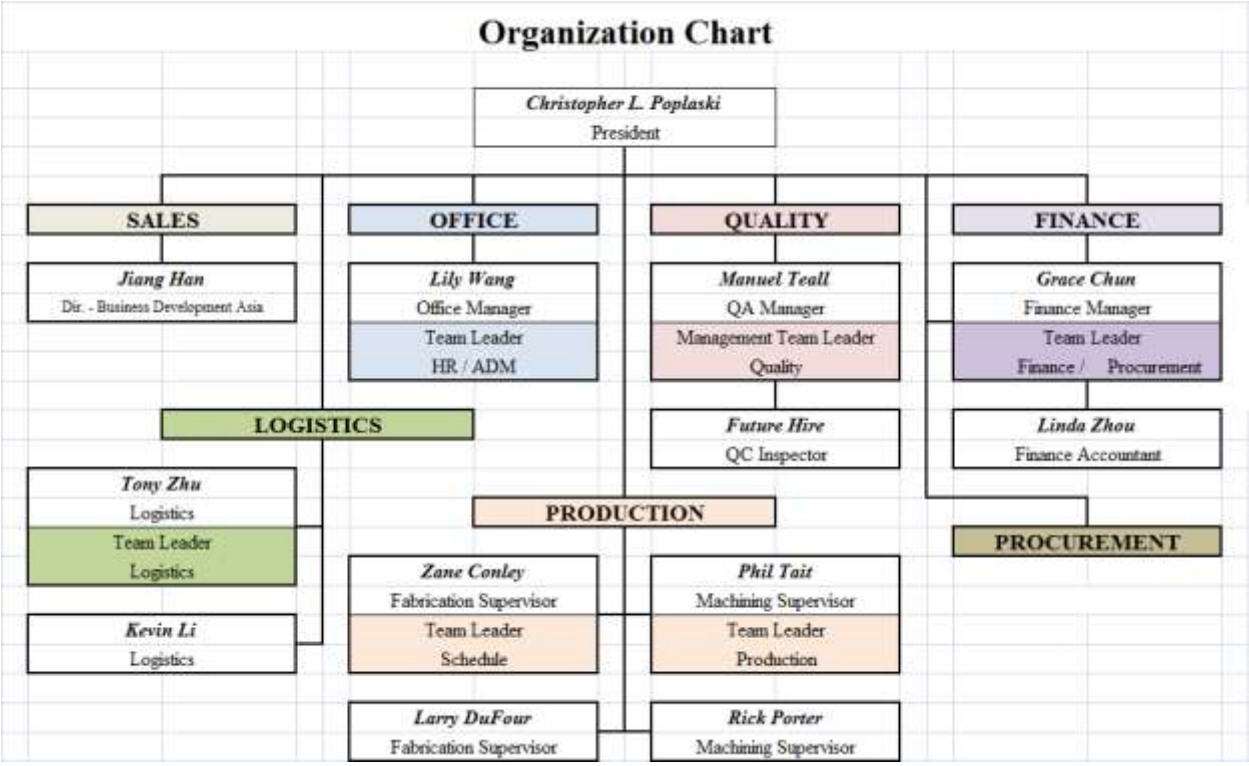
General Manager 总经理:

Date 日期:

Appendix 2：

Organizational Chart

组织架构图



Appendix 3：

Quality Management System Functions Distribution

质量体系职能分配表

Dep. / Clause	Top Mgt. 总经理	Mgt. Rep. 管代	Sales 销售	Purchase 采购	Quality 质量	Production 生产（项目）	Logistics 物流	OFFICE 办公室
4.1	▲	△	△	△	△	△	△	△
4.2.2	△	▲	△	△	△	△	△	△
4.2.3	△	△	△	△	▲	△	△	△
4.2.4	△	△	△	△	▲	△	△	△
5.1	▲	△						
5.2	▲	△	△	△	△	△	△	△
5.3	▲	△	△	△	△	△	△	△
5.4	▲	△	△	△	△	△	△	△
5.5	▲	△	△	△	△	△	△	△
5.6	▲	△	△	△	△	△	△	△
6.1	▲	△						
6.2			△	△	△	△	△	▲
6.3						△	△	▲
6.4	△	▲	△	△	△	△	△	▲
7.1	△	▲	△	△	△	△	△	△
7.2	△	△	▲	△	△	△	△	
7.4.1	△	△	△	△	▲	△		
7.4.2	△	△	△	▲	▲	△	△	
7.4.3	△	△	△	△	▲	△		
7.5.1			△	△	△	▲	△	
7.5.3				△	▲	△		
7.5.4				△	△	△	▲	
7.6					▲	△		
8.1	▲	△	△	△	△	△	△	△
8.2.1	△	△		△	▲			
8.2.2	△	▲	△	△	▲	△	△	△
8.2.3	△	△	△	△	△	△	△	△
8.2.4				△	▲	△		
8.3			△	△	▲	△	△	
8.4			△	△	▲	△	△	△
8.5.1	▲	△	△	△	△	△	△	△
8.5.2		△	△	△	▲	△	△	△
8.5.3		△	△	△	▲	△	△	△

Appendix 4： Process and procedure list

过程 Process	过程 (二级） Processes (level 2)		程序 (二级） Procedure (level 2)
PRODUCT REALIZATION PROCESSES (PRPs)产品实现过程			
	1	**Sales** **销售**	Quotation and Contract Handling Procedure 报价和合同管理程序
	2	**Purchasing** **采购**	Supplier Selection and Evaluation Procedure 供应商选择和评估程序
			Supplier PO Handling 供应商订单管理程序
	3	**Receiving and Delivery** **接收和交付**	Receiving and Delivery Procedure 产品接受和发运程序
	4	**Project Management** **项目管理**	Project Schedule 项目计划程序
			Project Control Procedure 项目管理程序
	5	**Inspection, Test and Metrology** **检验,测试和计量**	Quality Inspection Procedure 质量检验程序
			Monitoring and Measuring Equipment Control Procedure 监视测量设备管理程序
	6	**Service** **服务**	Customer Service Procedure 客户服务程序
RESOURCE MANAGEMENT PROCESSES (RMPs)资源管理过程	1	**Personnel Competence and Skills** **员工能力和技巧**	Recruiting Procedure 招聘程序
			Training Procedure 培训程序
	2	**Document Control and Information Management** **文件控制和信息管理**	Documents Control Procedure 文件控制程序
			Records Control Procedure 记录控制程序
MEASUREMENT AND IMPROVEMENT PROCESSES (MIPs)测量和改进过程	1	**Control of Nonconforming Product** **不合格品的控制**	Control of Nonconforming Product Procedure 不合格品控制程序
	2	**Internal Audits and Analysis of Data** **内部审核和数据分析**	Internal Audits Procedure 内部审核程序
	3	**Corrective and Preventive Action** **纠正和预防措施**	Corrective and Preventive Action Procedure 纠正预防措施程序
	4	**Customer Satisfaction** **客户满意度**	Customer Satisfaction Evaluation Procedure 顾客满意度评估程序
MANAGEMENT RESPONSIBILITY PROCESSES (MRPs)管理职责过程	1	**Planning and Objectives** **策划和目标**	KPI Planning Procedure 业绩指标策划程序
	2	**Management Review** **管理评审**	Management Review Procedure 管理评审程序