

## ISO9001 质量管理体系介绍

国际标准化组织(ISO)于 1979 年成立了质量管理 and 质量保证技术委员会(TC176), 负责制定质量管理 and 质量保证标准。ISO9000 系列标准自 1987 年发布以来, 经历了 1994 版、2000 版、2008 版的修改, 形成了现在的 ISO9001:2008 系列标准。

2008 版 ISO9000 族标准包括以下一组密切相关的质量管理体系核心标准:

- ISO9000 《质量管理体系基础和术语》
- ISO9001 《质量管理体系要求》
- ISO9004 《质量管理体系业绩改进指南》
- ISO19011 《质量和（或）环境管理体系审核指南》

ISO9000 族标准是世界上许多经济发达国家质量管理实践经验的科学总结, 且适用于各种类型, 不同规模和提供不同产品的组织。实施 ISO9000 族标准, 可以促进组织质量管理体系的改进和完善, 对提高组织的管理水平能够起到良好的作用。

### 标准特点

1. 以八项质量管理原则作为标准的理论基础, 体现了质量管理最普遍、适用的通用规律广泛应用于质量管理各领域。
2. 具有广泛的通用性, 适用于各类组织。
3. 适度简化, 经过三次修订, 使标准在内容和数量上得到简化, 对指令性文件要求大量减少, 标准的灵活性与操作指导性更好。
4. 用过程方法、PDCA 循环模式建立、实施和持续改进质量管理体系。
5. 提高了与环境、职业健康安全管理体系的相容性
6. 将 ISO9001 与 ISO9004 作为协调一致的一对标准使用, 可为组织带来更大效益。

### 实施意义

1. ISO9000 族标准的应用, 为组织增强顾客满意和改进组织业绩提供要求和指南, 使组织在激烈的市场竞争中, 提高产品/服务质量, 满足顾客不断变化的要求和法律法规要求。
2. 防止非关税贸易技术壁垒, 在质量方面与国际接轨, 成为进入国际市场的“通行证”
3. 建立质量管理体系, 可以有效提高组织的管理水平和整体业绩。
4. 有助于调动全体员工的积极性, 提高全员质量意识、守法意识。

## **Brief intro to ISO9001 (QMS)**

In 1979, International Standardization Organization (ISO) set up Quality Management and Quality Assurance Technical Committee (TC176), which is in charge of constituting standards for quality management and quality assurance. Since issued in 1987, a standard of ISO9000 series has gone through modification of 1994 edition and 2000 edition, and become today's standards of ISO9001: 2000 series.

ISO9000 series standard of 2000 edition includes the following suite of core standards of quality management system, which are closely related to each other.

-ISO9000 "Quality Management System---Fundamentals and vocabulary"

-ISO9001"Quality Management System---Requirements"

-ISO9004"Quality Management System---Guidelines for performance improvement"

-ISO19011"Quality/Environmental Management System Audit Guide"

ISO9000 series standard is the scientific sum-up of experiences of many developed countries' practice in quality management, and it applies to organizations of different types and sizes, and providing different products. Bringing ISO9000 series standard into effect can improve the management of an organization.

### **Specification**

1. On eight quality management principles as the standard theory, reflects the most common application of quality management, the general rule is widely used in quality management fields.
2. All requirements of this standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.
3. In accordance with process approach and PDCA cycle modeling, the quality management system shall be established, implemented and maintained and continually improved its effectiveness.
4. The compatibility with EMS and OHSMS is enhanced.
5. Using ISO9001 and ISO9004 as a couple of coordinated standards, it can bring greater benefits for the organization,

### **Significance**

1. Quality management systems can assist organizations in enhancing customer satisfaction and help organizations demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements and enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.
2. It will break through the prevention of non tariff trade technology barrier, in terms of quality and international standards, become the "pass" for international market.

3. The establishment of quality management system can effectively improve the management level and the overall performance of the organization.
4. Help to mobilize the enthusiasm of all staff, improve the quality of full consciousness, law consciousness.