

ISO 9000 系列标准

# 质量管理和质量保证

(英文原文与参考译文)

中国电子元器件质量认证委员会组织译编

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## 出版说明

我国是国际电工委员会电子元器件质量评定体系(IECQ)的全权成员国。我国的电子元器件质量认证工作必须执行我国国务院颁布的产品质量认证管理条例的同时,还必须执行 IECQ 的一切规定。

IECQ 已将执行 ISO 9000 系列关于质量管理和质量保证的国际标准列入制造厂审查批准的要求。因此,在建立和完善质量管理和质量保证体系方面,我国认证合格的以及申请认证的电子元器件制造厂在必须执行我国 GB/T 10300 系列国家标准的同时,还必须执行 ISO 9000 系列标准。

为便于我国认证合格的以及申请认证的电子元器件制造厂执行 ISO 9000 系列国际标准,中国电子元器件质量认证委员会组织翻译了此参考译文。现与英文原文一并出版,以资对照。参考译文中有错误或不够准确之处,请以英文原文为准。

参考译文由中国电子元器件质量认证委员会副主席李蒙蔚、国家监督检查机构(机电部五所)伍大来、张善芳、张建、王卫因集体翻译,常务办公室秦川协助整理。

中国电子元器件质量认证委员会  
一九九二年四月

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INTERNATIONAL STANDARD

ISO  
9000

LINE 001  
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INTERNATIONAL ORGANIZATION FOR STANDARDIZATION  
ORGANISATION INTERNATIONALE DE NORMALISATION  
МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ

**Quality management and quality  
assurance standards — Guidelines  
for selection and use**

*Normes pour la gestion de la qualité et l'assurance de la  
qualité — Lignes directrices pour la sélection et l'utilisation*

**质量管理和质量保证标准**

**——选择和使用指南**

Reference number  
ISO 9000:1987 (E)

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## Quality management and quality assurance standards — Guidelines for selection and use

### 0 Introduction

A principal factor in the performance of an organization is the quality of its products or services. There is a world-wide trend towards more stringent customer expectations with regard to quality. Accompanying this trend has been a growing realization that continual improvements in quality are often necessary to achieve and sustain good economic performance.

Most organizations — industrial, commercial or governmental — produce a product or service intended to satisfy a user's needs or requirements. Such requirements are often incorporated in "specifications". However, technical specifications may not in themselves guarantee that a customer's requirements will be consistently met, if there happen to be any deficiencies in the specifications or in the organizational system to design and produce the product or service. Consequently, this has led to the development of quality system standards and guidelines that complement relevant product or service requirements given in the technical specifications. The series of International Standards (ISO 9000 to ISO 9004 inclusive) embodies a rationalization of the many and various national approaches in this sphere.

国际标准

ISO 9000: 1987 (E)

## 质量管理和质量保证标准

### ——选择和使用指南

#### 0. 绪言

一个单位的表现的主要因素是它的产品和服务的质量。世界范围的趋势是用户对于质量的期望越来越严格。伴随着这种趋势，人们日益认识到，持续不断地改进质量对于取得和保持优良的经济表现，是非常必要的。

大多数单位——工业的、商业的或政府部门的——都是生产产品或提供服务以谋求满足用户的需要或要求。这些要求往往体现在“规范”中。但是，如果在规范中或者在设计 and 生产产品中或提供服务的组织体系中一旦存在某些缺陷，技术规范本身也许就不能保证客户的要求始终如一地得到满足，这样就导致了质量体系标准和指南的制订，以补充在技术规范中给出的对有关产品或服务的要求。一系列的国际标准（包括从 ISO 9000 到 ISO 9004）是各国在这方面的许多做法的合理化体现。

The quality system of an organization is influenced by the objectives of the organization, by the product or service and by the practices specific to the organization, and, therefore, the quality system varies from one organization to another.

A cross-reference list of quality system elements is given in the annex for information.

## 1 Scope and field of application

The purposes of this International Standard are

- a) to clarify the distinctions and interrelationships among the principal quality concepts (see clause 4), and
- b) to provide guidelines for the selection and use of a series of International Standards on quality systems that can be used for internal quality management purposes (ISO 9004) and for external quality assurance purposes (ISO 9001, ISO 9002 and ISO 9003) (see clauses 5 to 8 inclusive).

NOTE — It is not the purpose of this series of International Standards (ISO 9000 to ISO 9004 inclusive) to standardize quality systems implemented by organizations.

## 2 References

ISO 8402, *Quality — Vocabulary*.

ISO 9001, *Quality systems — Model for quality assurance in design/development, production, installation and servicing*.

ISO 9002, *Quality systems — Model for quality assurance in production and installation*.

ISO 9003, *Quality systems — Model for quality assurance in final inspection and test*.

ISO 9004, *Quality management and quality system elements — Guidelines*.

一个单位的质量体系受其目标、产品或服务以及其特定的实践的影响，因此，各个单位的质量体系是不同的。

附录中列有一份质量体系要素对照表供参考。

## 1. 范围和应用领域

本国际标准的目的是：

a) 阐明主要质量概念（见第 4 条）之间的区别和相互关系，并

b) 为选择和使用可以用于内部质量管理目的的（ISO 9004）以及用于对外质量保证目的的（ISO 9001、ISO 9002 及 ISO 9003）一系列的质量体系国际标准提供指南（见第 5 到第 8 章）。

注——这一系列的国际标准（包括从 ISO 9000 到 ISO 9004）的目的，并不是要使各个单位所实施的质量体系标准化。

## 2. 参考标准

ISO 8402，质量——词汇表

ISO 9001，质量体系——设计 / 开发、生产、安装和服务中的质量保证模式

ISO 9002，质量体系——生产和安装中的质量保证模式

ISO 9003，质量体系——最终检验和试验中的质量保证模式

ISO 9004，质量管理和质量体系要素指南

### 3 Definitions

For the purposes of this International Standard, the definitions given in ISO 8402 apply. Five key terms and definitions have been taken from ISO 8402 and included in this International Standard because of their importance in the proper use of this International Standard.

**3.1 quality policy :** The overall quality intentions and direction of an organization as regards quality, as formally expressed by top management.

**NOTE —** The quality policy forms one element of the corporate policy and is authorized by top management.

**3.2 quality management :** That aspect of the overall management function that determines and implements the quality policy.

#### NOTES

1 The attainment of desired quality requires the commitment and participation of all members of the organization whereas the responsibility for quality management belongs to top management.

2 Quality management includes strategic planning, allocation of resources and other systematic activities for quality, such as quality planning, operations and evaluations.

**3.3 quality system :** The organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

#### NOTES

1 The quality system should only be as comprehensive as needed to meet the quality objectives.

2 For contractual, mandatory and assessment purposes, demonstration of the implementation of identified elements in the system may be required.

### 3. 定义

为了本国际标准的目的，采用 ISO 8402 中的定义。从 ISO 8402 中摘出五项关键术语和定义，列入本国际标准，是由于它们在正确使用本国际标准中的重要性。

**3.1 质量方针 (quality policy):** 由最高领导正式表达的一个单位的关于质量的总的意图和方向。

注——质量方针是总方针的一个组成部分，由最高领导批准。

**3.2 质量管理 (quality management):** 全部管理职能中确定和执行质量方针的那一方面。

注:

1. 为达到所期望的质量，要求单位内全体成员的努力和参与，而质量管理的责任属于最高领导。
2. 质量管理包括质量方面的战略计划、资源分配和其他系统性的活动，例如质量计划、运作和评估。

**3.3 质量体系 (quality system):** 为实施质量管理而应有的组织结构、职责、程序、作业过程和资源。

注:

1. 质量体系所包括的内容只应以达到质量目标为度。
2. 为了执行合同和强制性规定以及进行评估，也许会要求对质量体系的指定的要素的实施进行证实。

**3.4 quality control :** The operational techniques and activities that are used to fulfil requirements for quality.

**NOTES**

1 In order to avoid confusion, care should be taken to include a modifying term when referring to a sub-set of quality control, such as "manufacturing quality control", or when referring to a broader concept, such as "company-wide quality control".

2 Quality control involves operational techniques and activities aimed both at monitoring a process and at eliminating causes of unsatisfactory performance at relevant stages of the quality loop (quality spiral) in order to result in economic effectiveness.

**3.5 quality assurance :** All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality.

**NOTES**

1 Unless given requirements fully reflect the needs of the user, quality assurance will not be complete.

2 For effectiveness, quality assurance usually requires a continuing evaluation of factors that affect the adequacy of the design or specification for intended applications as well as verifications and audits of production, installation and inspection operations. Providing confidence may involve producing evidence.

3 Within an organization, quality assurance serves as a management tool. In contractual situations, quality assurance also serves to provide confidence in the supplier.

## **4 Principal concepts**

An organization should seek to accomplish the following three objectives with regard to quality:

- a) The organization should achieve and sustain the quality of the product or service produced so as to meet continually the purchaser's stated or implied needs.

**3.4 质量控制 (quality control):** 用于满足质量要求的作业技术和活动。

注:

1. 为了避免混淆, 应注意引入有所限制的术语。当涉及局部质量控制时, 可使用如“制造质量控制”; 当涉及较广泛的概念时, 可使用如“公司范围的质量控制”。

2. 质量控制所包括的作业技术和活动, 旨在质量环 (质量螺旋) 的各个相关阶段上对作业过程进行监控, 并消除不良现象的原因, 以取得经济实效。

**3.5 质量保证 (quality assurance):** 为使人们确信产品或服务将会满足规定的质量要求所必需的所有的有计划的和系统性的行动。

注:

1. 如果规定的质量要求未能充分反映用户的需要, 质量保证则是不完全的。

2. 为了使质量保证行之有效, 通常需要不断地对各种因素进行评估, 这些因素影响到设计和规范对预期应用的适宜性, 并对生产、安装和检验工作进行验证和审核, 为取得信任可能包括提出证据。

3. 在单位内部, 质量保证是作为一种管理手段。在合同环境中, 质量保证也是作为对供方建立起信任的一种手段。

## **4. 主要概念**

一个单位必须在质量方面谋求达到下列三项目标:

a) 应该使其生产的产品或提供的服务, 达到和保持满足买方规定的或隐含的需要的质量。



b) The organization should provide confidence to its own management that the intended quality is being achieved and sustained.

c) The organization should provide confidence to the purchaser that the intended quality is being, or will be, achieved in the delivered product or service provided. When contractually required, this provision of confidence may involve agreed demonstration requirements.

The relationship of the concepts the definitions of which are quoted in clause 3 is illustrated in the figure; this figure should not, however, be interpreted as a rigid model.

## **5 Characteristics of quality system situations**

This series of International Standards on quality systems is intended to be used in two different situations: contractual and non-contractual.

In both these situations, the supplier's organization wants to install and maintain a quality system that will strengthen its own competitiveness and achieve the needed product quality in a cost-effective way.