

ICS 03.120.10
CCS A 00



**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 19001-2016

**Quality management systems -- Requirements
(English Translation)**

Issued on: December 30, 2016

Implemented on: July 1, 2017

**Issued by: General Administration of Quality Supervision, Inspection and
Quarantine**

Table of Contents

Foreword...	5
Introduction...	7
1 Scope...	13
2 Normative References...	13
3 Terms and Definitions...	13
4 Context of the Organization...	14
4.1 Understanding the organization and its context...	14
4.2 Understanding the needs and expectations of interested parties...	14
4.3 Determining the scope of the quality management system...	14
4.4 Quality management system and its processes...	15
5 Leadership...	16
5.1 Leadership and commitment...	16
5.1.1 General...	16
5.1.2 Customer focus...	16
5.2 Policy...	17
5.2.1 Establishing the quality policy...	17
5.2.2 Communicating the quality policy...	17
5.3 Organizational roles, responsibilities and authorities...	17
6 Planning...	18
6.1 Actions to address risks and opportunities...	18
6.2 Quality objectives and planning to achieve them...	19
6.3 Planning of changes...	19
7 Support...	20
7.1 Resources...	20
7.1.1 General...	20
7.1.2 People...	20
7.1.3 Infrastructure...	20
7.1.4 Environment for the operation of processes...	20
7.1.5 Monitoring and measuring resources...	21
7.1.6 Organizational knowledge...	21
7.2 Competence...	22
7.3 Awareness...	22

7.4 Communication...	23
7.5 Documented information...	23
7.5.1 General...	23
7.5.2 Creating and updating...	23
7.5.3 Control of documented information...	24
8 Operation...	24
8.1 Operational planning and control...	24
8.2 Requirements for products and services...	25
8.2.1 Customer communication...	25
8.2.2 Determining the requirements for products and services...	25
8.2.3 Review of the requirements for products and services...	26
8.2.4 Changes to requirements for products and services...	26
8.3 Design and development of products and services...	27
8.3.1 General...	27
8.3.2 Design and development planning...	27
8.3.3 Design and development inputs...	27
8.3.4 Design and development controls...	28
8.3.5 Design and development outputs...	28
8.3.6 Design and development changes...	29
8.4 Control of externally provided processes, products and services...	29
8.4.1 General...	29
8.4.2 Type and extent of control...	30
8.4.3 Information for external providers...	30
8.5 Production and service provision...	31
8.5.1 Control of production and service provision...	31
8.5.2 Identification and traceability...	31
8.5.3 Property belonging to customers or external providers...	32
8.5.4 Preservation...	32
8.5.5 Post-delivery activities...	32
8.5.6 Control of changes...	33
8.6 Release of products and services...	33
8.7 Control of nonconforming outputs...	33
9 Performance Evaluation...	34
9.1 Monitoring, measurement, analysis and evaluation...	34
9.1.1 General...	34

9.1.2 Customer satisfaction...	34
9.1.3 Analysis and evaluation...	35
9.2 Internal audit...	35
9.3 Management review...	36
9.3.1 General...	36
9.3.2 Management review inputs...	36
9.3.3 Management review outputs...	37
10 Improvement...	37
10.1 General...	37
10.2 Nonconformity and corrective action...	37
10.3 Continual improvement...	38

Foreword

This Standard was drafted as per the rules specified in GB/T 1.1-2009.

This Standard was one of the core standards of GB/T 19000 family.

This Standard replaced GB/T 19001-2008 Quality Management Systems - Requirements.

Compared with GB/T 19001-2008, this Standard has the major technical changes besides the editorial modifications.

--- Adopt the high-level structure given in Annex SL of the ISO Supplementary Provisions of Part 1 in the ISO/IEC Guidelines;

--- Adopt risk-based thinking;

--- Fewer prescriptive requirements;

--- More flexible requirements for documented information;

--- Improve the applicability of the service industry;

--- More emphasis on the organizational environment;

--- Strengthen the requirements for leadership;

--- Pay more attention to achieving expected process results to enhance customer satisfaction.

Annex A gives a more detailed description of the changes relative to GB/T19001-2008.

This Standard uses translation method to equivalently adopt ISO 9001.2015 Quality Management Systems - Requirements (English Version).

This Standard was proposed by and under the jurisdiction of National Technical Committee for Standardization of Quality Management and Quality Assurance (SAC/TC 151).

Drafting organizations of this Standard. China National Institute of Standardization; Certification and Accreditation Administration of the People's Republic of China; Chinese Certification and Accreditation Association; China National Accreditation Center for Conformity Assessment; China Quality Certification Center; Tianjin Huacheng Certification Center; China Classification Society Certification Company; Shenzhen Huantong Attestation Center Co., Ltd.; China Xinshidai Certification Center; Fangyuan Sign Certification Group Co., Ltd.; Beijing New Century Inspection & Certification Co., Ltd.; Guopei Renzheng Training (Beijing) Center; China Certification Center Inc.; Shanghai Audit Center of Quality System; Quality Assurance Center of China Association for Quality; SAIC-GM-Wuling Automotive Co., Ltd.; Inner Mongolia North Hauler Joint Stock Co., Ltd.; Taixing Longyi Terminal Co., Ltd.; Shanghai Jianke Engineering Consulting Co., Ltd.; Inner Mongolia Yili Industrial Group Co., Ltd.; Tianjin Tiandy Technology Co., Ltd.; China Chang'an Automobile Group Co., Ltd.; Inner Mongolia Hotision and Monsod Drought-Resistance Greening Co., Ltd.; Nanjing Mint Co., Ltd.; China Railway Construction Corporation Limited; China Building Material Test & Certification Group Co., Ltd.; and Beijing Dongfang Yichu Standard Technology Co., Ltd.

Chief drafting staffs of this Standard. Tian Wu, Kang Jian, Zhang Huicai, Li Qiang, Ren Qingyue, Li Ming, Zheng Yuanhui, Huang Xueliang, Qu Xintian, Zheng Yan, Liang Ping, Wang Mei, Li Ping, Xia Fang, Wang Jinde, Cao Hua, Deng Xiangning, Pei Jie, Lin Chuang, Zhou Hongbo, Li Huaqiu, Li Chenxuan, Fang Yejuan, Xie Hui, Zhu Jiangtao, Wei Xiangyang, Liu Ye, Dong Xiaohong.

The historical editions replaced by this Standard are as follows.