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ISO 9001:2000
The Quality
Management Process

Colophon

Foreword

Although many books have already been published on ISO 9001:2000, 'ISO 9001:2000 - The Quality Management Process' (first published as 'Aide Mémoire to ISO 9001:2000') is unique in being directly aimed at those professionally involved in the actual use of the standard.

It cuts out all the lengthy explanations, hypothesis and discussions about ISO 9001:2000 and just provides the reader with the bare details of the standard, covering essential questions, including: What does the actual standard say? What needs to be checked? Where is a particular requirement covered in the standard?

This book will prove invaluable to all quality managers, internal auditors and those involved in the management and understanding of ISO 9001:2000. It will also serve as a ready reference for professional auditors to the requirements for auditing ISO 9001:2000 systems, and contains what is probably the most complete set of ISO 9001:2000 audit checksheets commercially available today.

Contents

Preface

The aim of this title, first published as 'Aide mémoire to ISO 9001:2000', is to provide a quick reference source to the background and requirements of the standard and simply to present the reader with the bare details of the standard. For example, *What does the standard actually say? What needs to be checked? Where is a particular requirement covered in the standard? What will an auditor be looking for?*

'ISO 9001:2000 - The Quality Management Process' contains full details of ISO 9001-2000 (i.e. its requirements and recommendations) and provides answers to the most common questions asked by organisations who are being audited. It also contains a complete cross-index to the contents of each clause of the standard, and provides the reader with reminders of the implications for achieving conformance.

For convenience, the book is divided into four parts with *Part One* providing notes concerning the background to the standard, its content and structure, a summary of its requirements and a brief description of ISO 9001:2000's process approach to quality.

Part Two is intended to assist in the administration of quality management systems. It contains all of the requirements specified in ISO 9001:2000 and includes an explanation of how these might affect an organisation. It provides an explanation of the likely documentation an organisation will need to control these requirements and indicates some areas that could be investigated during an internal audit of an organisation's QMS against ISO 9001:2000.

Part Three is in the form of a detailed questionnaire covering all of the elements of ISO 9001:2000. The questionnaire is **not** intended to act as a complete check sheet for auditing a management system, but merely as an indication of areas of an organisation's QMS that could be looked at and possibly further investigated during internal, external and/or third party audits.

Part Four provides a detailed index to ISO 9001:2000 that enables the reader to find out quickly where a specific requirement, topic, subject or item is covered in the standard.

Ray Tricker
July 2006

PART ONE - The Standard

Part 1 provides a series of background reminders to the ISO 9001:2000 standard, its content, its structure, its requirements, and its compatibility with other management systems. It includes a brief description of the process approach to quality, the requirements for a documented Quality Management System and the interrelationship of process documentation.

Part one – background reminders

The current ISO 9001 is a far more generic standard than the earlier 20-element 1994 structure. It adopts the process management approach widely used in business today and more clearly addresses the Quality Management System (QMS) requirements for an organisation to show its capability for meeting customer requirements. It is compatible with the ISO 14000 series of standards for environmental management as well as national/international health and safety management standards. It forms the cornerstone for the integrated management of quality, environment, health and safety.

With the publication of ISO 9001:2000, there is now a single quality management **'requirements'** standard that is applicable to **all** organisations, products and services.

Note: Although not officially referred to as a requirements standard, ISO 9001:2000 does, nevertheless, contain 141 'shalls' and two 'musts' as opposed to four 'shoulds' and one 'could'.

A reduction in the scope of the ISO 9001:2000 requirements is permitted for organisations that have previously used ISO 9002:1994 and ISO 9003:1994 by omitting those requirements that do not apply to their particular organisation.

ISO 9001:2000 is the only standard that can be used for the certification of a QMS and its generic requirements can be used by **any** organisation to:
- address customer satisfaction
- meet customer and applicable regulatory requirements
- enable internal and external parties (including certification bodies) to assess the organisation's ability to meet these customer and regulatory requirements

For certification purposes, an organisation will have to possess a documented management system that takes the inputs and transforms them into targeted outputs. Something that (in an effective manner):
- says what they are going to do
- does what they have said they are going to do
- keeps records of everything that they do – especially when things go wrong

The basic process to achieve these targeted outputs will encompass:
- the clients' requirements
- the input from management and staff
- documented controls for any activities that are required to produce the finished article
- delivering a product or service that satisfies the customer's original requirements

1   What are the three ISO 9000:2000 standards?
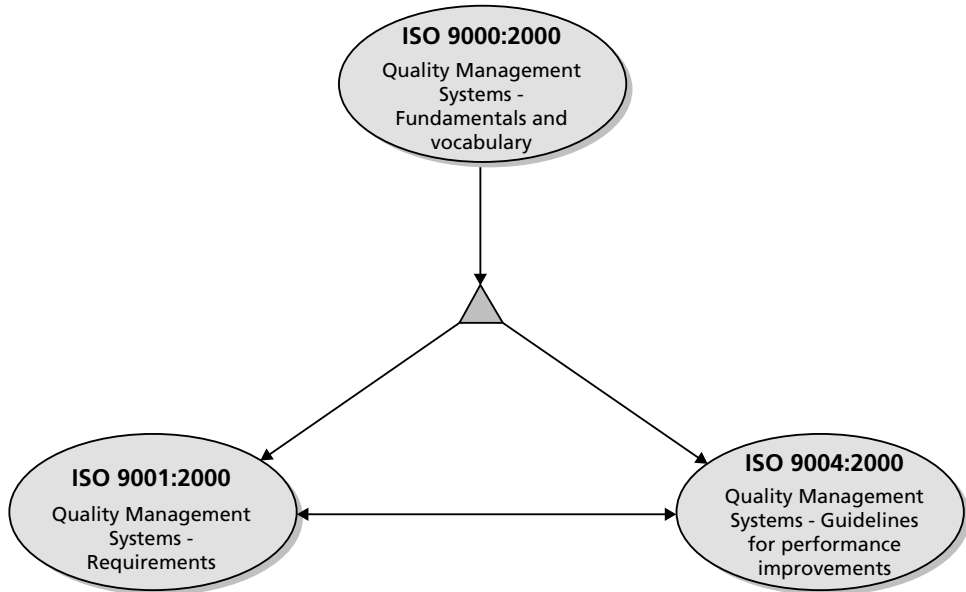
Figure 1.1 The ISO 9000:2000 series of standards

1.1   ISO 9000:2000 Quality Management Systems – Fundamentals and Vocabulary

Superseding ISO 8402:1995 (*Quality Management and Quality Assurance – Vocabulary*) and ISO 9000-1:1994 *(Quality Management and Quality Assurance Standards – Guidelines for selection and use).*

This standard describes the fundamentals of a QMS and specifies the terminology for QMSs.

1.2   ISO 9001:2000 Quality Management Systems – Requirements

Superseding ISO 9001:1994 *(Quality Systems – Model for quality assurance in design, development, production, installation and servicing)*, ISO 9002:1994 *(Quality Systems – Model for quality assurance in production, installation and servicing)* and ISO 9003:1994 *(Quality Systems – Model for quality assurance in final inspection and test)*.

This standard specifies the requirements for QMSs for use where an organisation's capability to provide products that meet customer and applicable regulatory requirements needs to be demonstrated.

1.3 ISO 9004:2000 Quality Management Systems – Guidelines for performance improvement

Superseding ISO 9004-1:1994 *(Quality Management and Quality System Elements – Guidelines).*

This standard provides guidance on the development of a QMS, including the processes for continual improvement that will contribute to the satisfaction of an organisation's customers and other interested parties. This guidance is generic and is applicable to all organisations, regardless of the type, size and the product provided. It is aimed at improving an organisation's overall quality performance and provides a stepping-stone to Total Quality Management (TQM).

ISO 9001:2000 and ISO 9004:2000 have been developed as a 'consistent pair' of QMS standards, based on eight quality management principles with a common process-oriented structure and harmonised terminology. They are designed to be used together, or may be used as stand-alone documents.

2   Is ISO 9001:2000 compatible with other management systems?
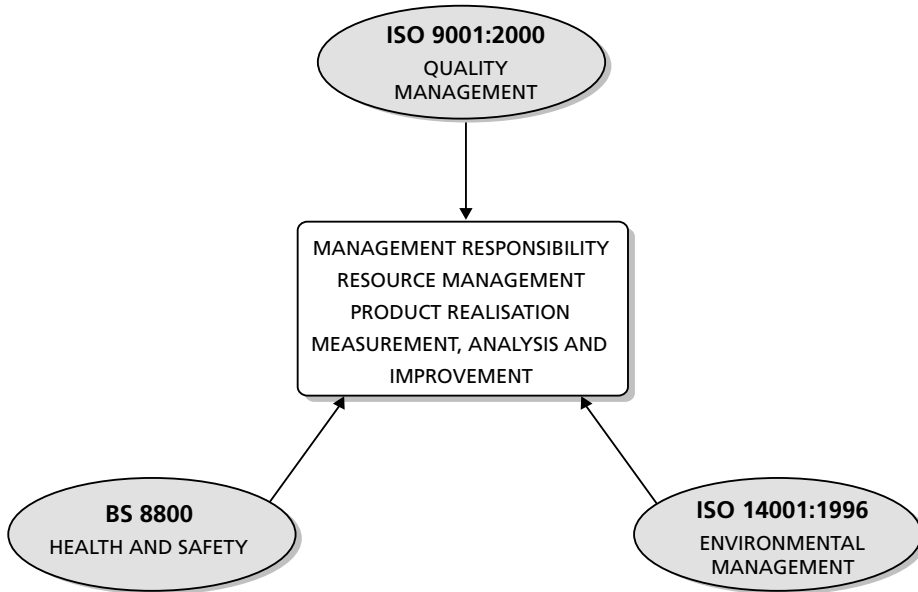
Figure 1.2 Compatibility with other management systems

- ISO 9001:2000 is intended to be compatible with other internationally recognised management system standards, in particular, those relating to environmental management, and occupational health and safety.
- Whilst ISO 9001:2000 does not, however, include any requirements that are specific to any of these other management systems, it does, nevertheless, allow an organisation to align and integrate its own QMS with other (related) management system requirements.
- In many cases, it may even be possible for an organisation to adapt its existing environmental, health and/or safety management system(s) in order to establish a QMS that complies with the requirements of ISO 9001:2000.

3 What is the difference between ISO 9000 and ISO 14000?

ISO 9001:2000 has been closely aligned with ISO 14001:1996 *(Environmental Management Systems – Specification with guidance for use)* to *'enhance the compatibility of these two standards for the benefit of the user community'.*

Whilst both of these standards are effectively 'generic management system standards', the ISO 9000 family is primarily concerned with 'quality management' and:
• what the organisation does to fulfil the customer's quality requirements
• how it meets the applicable regulatory requirements
• how it enhances customer satisfaction
• how it achieves continual improvement of its performance, product and/or service

On the other hand, the ISO 14000 family is an Environmental Management System. (EMS) that is aimed at continually reducing pollution (through the more efficient and responsible use of raw materials) and the minimisation of energy usage and waste. It is concerned with how an organisation:
• minimises harmful effects on the environment caused by its activities
• achieves continual improvement of its environmental performance

4   What other standards are based on ISO 9001:2000?

During its lifetime, the 1994 version of ISO 9000 was frequently used as the generic template for other industry management system standards. Currently, although there are still a number of these other industry standards available, they are all gradually being rewritten around the requirements and recommendations of ISO 9001:2000 and the following are a selection of some of the most important ones.

Telecommunications Industry

TL 9000 *(Quality management standard for the telecommunication sector)* is a set of quality system requirements for the telecommunications industry which were originally developed by the QuEST Forum (Quality Excellence for Suppliers of Telecommunications Leadership) and was first published in November 1999. It has now been updated to conform to ISO 9001:2000.

Automotive industry

ISO/TS 16949:2002 *(Quality System Requirements QS-9000)* is the minimum qualifying standard for suppliers to vehicle manufacturers.

Medical Devices

ISO 13485:2003 *(Medical devices -- Quality management systems -- Requirements for regulatory purposes)* specifies the requirements for a QMS that is aimed at ensuring that all medical devices manufactured and/or provided by an organisation continue to meet customer and regulatory requirements applicable to those medical devices.

Note: As patient safety is involved, **all** of the requirements of ISO 13485:2003 are mandatory.

Testing and calibration laboratories

ISO/IEC 17025:2000 *(General requirements for the competence of testing and calibration laboratories)* is applicable to all laboratories (regardless of size) and laboratories meeting this standard are then certified as being capable of producing test and calibration results which are mutually acceptable between countries.

This standard is currently being updated to comply with the basic management system requirements of ISO 9001:2000.

Petroleum, petrochemical and natural gas industries

PD ISO/TS 29001: 2003 *(Petroleum, petrochemical and natural gas industries – Sector specific quality management systems – Requirements for product and service supply organisations)* is another new technical specification that has recently been developed by ISO as a QMS for these particular industries.

Aerospace

AS/EN/JIS Q 9100: 2001 *(Quality Management Systems – Aerospace – Requirements)* is an international aerospace standard for quality assurance in design, development, production, installation and servicing.

Computer software

ISO/IEC 90003:2004 *(Software engineering - Guidelines for the application of ISO 9001:2000 to computer software)* provides guidance for organisations using ISO 9001:2000 to purchase, supply, develop, operate and maintain computer software and related support services.

Note: TickIT procedures relate directly to the requirements set out in ISO 9001:2000 and similar to this standard, certification is conducted by an independent third party certification body using specialist auditors trained by the International Register of Certificated Auditors (IRCA) with the support of the British Computer Society.

Food and drink industry

ISO 15161:2001 *(Guidelines on the application of ISO 9001:2000 for the food and drink industry)* is aimed at organisations involved in all aspects of this industry sector, including sourcing, processing and packaging of food and drink products.

Education

IWA 2:2003 *(Quality management systems – Guidelines for the application of ISO 9001:2000 in education)* provides guidelines for the application of ISO 9001:2000 in educational organisations providing educational products.

Iron ore industry

ISO/TR 13352:1997 *(Guidelines for interpretation of ISO 9000 series for application within the iron ore industry)* was written around the old procedural based 1994 version of ISO 9000 with certain additions that were specific for the mining and quarrying (iron ore) industry.

It is currently being updated to comply with the basic management system requirements of ISO 9001:2000.

5   What about auditing ISO 9001:2000?

ISO 19011:2002 *(Guidelines on auditing quality and environmental management systems)*, provides guidance on managing and conducting environmental and quality audits and supersedes:
- ISO 10011-1:1990 (*Guidelines for Auditing Quality Systems – Auditing*)
- ISO 10011-2:1991 (*Guidelines for Auditing Quality Systems – Qualification criteria for quality system auditors*)
- ISO 10011-3:1991 (*Guidelines for Auditing Quality Systems – Management of audit programmes*)
- ISO 14010:1996 (*Guidelines for Environmental Auditing – General principles*)
- ISO 14011:1996 (*Guidelines for Environmental Auditing – Audit procedures – Auditing of environmental management systems*)
- ISO 14012:1996 (*Guidelines for Environmental Auditing – Qualification criteria for environmental auditor*)

It is intended that, by using this new standard, organisations can save time, effort and money by:
- avoiding confusion about the objectives of the audit programme
- conducting a combined environmental/quality audit
- ensuring audit reports follow the best format and contain all the relevant information
- evaluating the competence of audit team members against the appropriate criteria

6 What about registration to ISO 9001:2000?

For certification purposes, an organisation will have to possess a documented management system that takes the inputs and transforms them into targeted outputs.

Something that (in an effective manner):
• says what they are going to do
• does what they have said they are going to do
• keeps records of everything that they do – especially when things go wrong

6.1 What is the difference between being certified and being registered?

Actually there is no difference! In some countries organisations will say that they are 'certified', in others they will say that they are 'registered' – but it means the same thing.

6.2 What is the difference being certified and being compliant?

When an organisation claims that they are ISO 9000 'certified' or 'registered', they mean that a notified body (that is, an independent registrar) has audited their QMS, certified that it meets the requirements of ISO 9001:2000, given them a written assurance that ISO's quality management system standard has been met and registered their organisation as having been certified.

On the other hand, when an organisation says that they are ISO 9000 'compliant', they usually mean that they have met ISO's quality system requirements, but have not been formally certified by an independent registrar. In effect, they are self-certified and whilst this is perfectly acceptable for many organisations, especially the smaller ones, an official certificate issued by an independent register does tend to carry more weight in the market place.

Note: As ISO 9001:2000 is a process standard (and not a product standard), when a company says that they are certified or compliant, they are not saying that their products and/or services meet the ISO 9000 requirements.

6.3 What is the difference between being certified and being accredited?

Registrars (such as BSI and TÜV) audit and certify organisations who wish to become ISO 9000 registered. Accreditation bodies like UKAS (United Kingdom Accreditation Service) on the other hand, evaluate and accredit the registrars. In effect, accreditation bodies audit the auditors and certify that the registrars are competent and authorised to issue ISO 9001:2000 certificates in specified business sectors.

Throughout ISO 9001:2000, the requirement for continuous improvement is frequently (and heavily) emphasised. 'Continual improvement' (i.e. in the context of ISO 9001:2000) requires an organisation to concentrate on continually increasing the effectiveness and efficiency of its business processes whilst carrying out the policies and objectives of that organisation.

7   How does ISO 9001:2000 compare with ISO 9000:1994?

The 20 elements contained in section four of ISO 9001:1994 have been replaced by four major generic business processes covering the management of resources, the quality of the product, the maintenance of quality records and the requirements for continual improvement.

ISO 9001:1994
4.1 Management responsibility
4.2 Quality system
4.3 Contract review
4.4 Design control
4.5 Document and data control
4.6 Purchasing
4.7 Control of customer supplied product
4.8 Product identification and tracability
4.9 Process control
4.10 Inspection and testing
4.11 Control of inspection, measuring and
      test equipment
4.12 Inspection and test status
4.13 Control of non conforming product
4.14 Corrective and preventative action
4.15 Handling and storage, packaging,
      preservation and delivery
4.16 Control of quality records
4.17 Internal quality audits
4.18 Training
4.19 Servicing
4.20 Statistical techniques

QUALITY MANAGEMENT SYSTEM
MANAGEMENT RESPONSIBILITY
RESOURCE MANAGEMENT
PRODUCT REALISATION
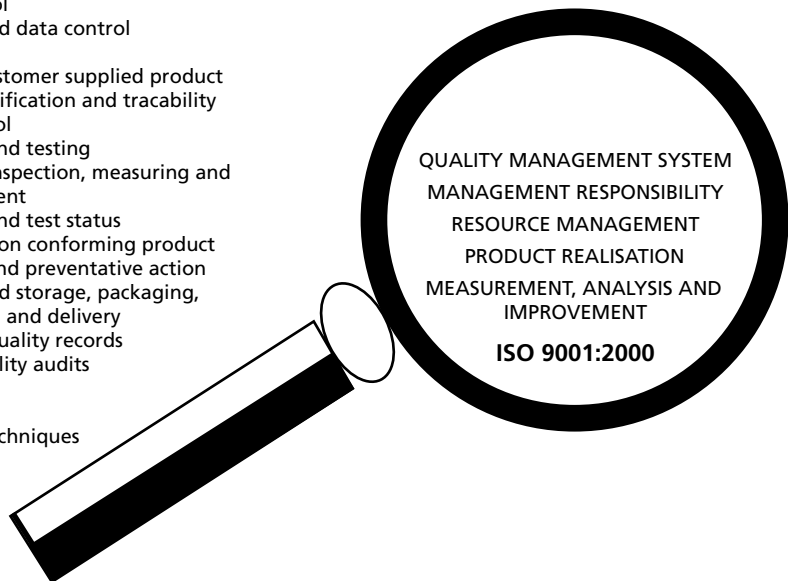MEASUREMENT, ANALYSIS AND
IMPROVEMENT
ISO 9001:2000

Figure 1.3 How 20 went into 4

Each of the three main standards (i.e. ISO 9000:2000, ISO 9001:2000 and ISO 9004:2000) now have a revised title, which no longer includes the term 'quality assurance'. This has been done in order to reflect the fact that the system requirements specified in these standards address the quality assurance of a product **as well as** customer satisfaction.

In addition, ISO 9000:2000 now includes a description of the basic approach to quality management, as well as a revised vocabulary to reflect the usage of new and revised terms and associated definitions contained in ISO 9001:2000 and ISO 9004:2000.

8   What is the future evolution of ISO 9000

Similar to other ISO standards, ISO 9000:2000 is reviewed every five years and so a new version might well be published during 2008 (i.e. 5 years after ISO 9001:2000 became the mandatory standard for quality management).

9   What is the aim of ISO 9001:2000?

The aim of ISO 9001:2000 is to assist users in producing a QMS that is capable of being:

Flexible:
- flexible enough to fit any sort organisation
- flexible approach to quality documentation
- includes quality planning similar to other management standards (e.g. ISO 13484:2004)
- is in line with other management systems

Structured:
- no longer consists of 20 isolated elements
- has a new quality process management model
- includes process capability studies
- relies on process measurements and process audits
- includes design control based on project management
- includes expanded validation of design requirements
- requires configuration management
- documents how a product is measured and evaluated using a quality (control) plan

Customer orientated:
- has a new emphasis on the identification of stakeholders and how the organisation plans to meet their needs
- emphasises close communications with customers
- requires a formal system of measuring customer satisfaction
- emphasises the need to identify and review customer requirements and expectations
- replaces service requirements with delivery and post delivery service requirements

Verification and Validation:
- verifies purchased products
- validates the output of processes within an organisation
- includes the requirement for regular revalidation of products and/or services to ensure that they continue to meet customer expectations

Corrective action:
- gives a more assertive definition of corrective and preventive action

Continuous Improvement:
- provides for continually reviewing the work environment and its effect on quality

Workforce:
- defines responsibilities and authorities within the process areas
- enables an organisation to assure that its infrastructure is sufficient to meet its quality objectives

Reviews
- sets a requirement for the regular review of quality objectives
- requires a formal policy on continuous improvement

10 What are the advantages of ISO 9001:2000?

With the publication of ISO 9001:2000, there is now a single quality management **'requirements'** standard that is applicable to **all** organisations, products and services. It is the only standard that can be used for the certification of a QMS and its generic requirements can be used by **any** organisation to:
- address customer satisfaction
- meet customer and applicable regulatory requirements
- enable internal and external parties (including certification bodies) to assess the organisation's ability to meet these customer and regulatory requirements

11   What is the structure of ISO 9001:2000?

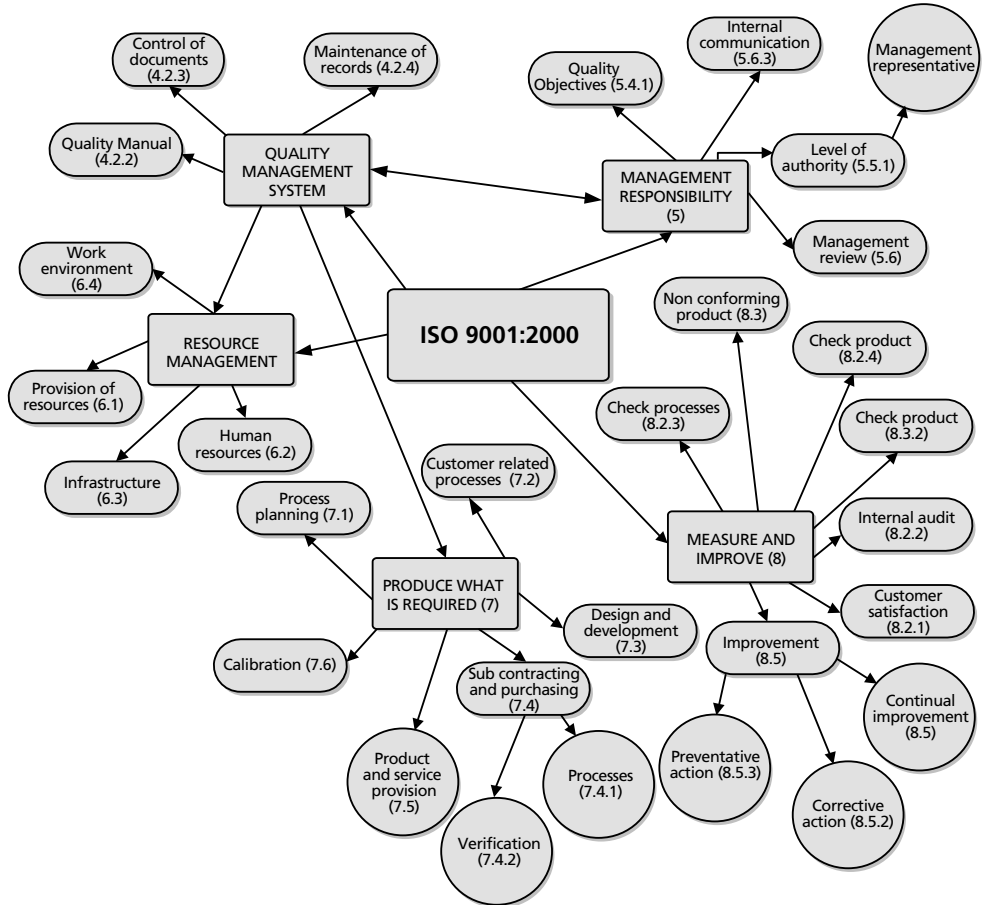In outline, the structure of the standard is in figure 1.4.

Figure 1.4 The structure of ISO 9001:2000

Section	Title
1	Scope
2	Normative reference
3	Terms and definitions
4	Quality Management System
5	Management responsibility
6	Resource management
7	Product realisation
8	Measurement, analysis and improvement

Table 1.1 The structure of ISO 9001:2000