

FIFTH EDITION

DAVID HOYLE

ISO 9000

QUALITY SYSTEMS HANDBOOK



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ISO 9000
Quality Systems
Handbook

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ISO 9000 Quality Systems Handbook

Fifth Edition

David Hoyle



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Contents

Preface to the 5th edition	ix
Chapter 1 Basic concepts	1
Introduction	1
Principles or prescription	5
Needs, requirements and expectations	6
Quality	8
The interested parties or stakeholders	10
The characteristics of quality	15
Achieving, sustaining and improving quality	22
Summary	85
Basic concepts – Food for thought	86
Chapter 2 Perceptions of ISO 9000 and its derivatives	88
Introduction	88
How we think about certification	93
How ISO 9000 made us think about quality	99
How we think about reviews, inspections and audits	101
Is ISO 9000:2000 any different?	102
Misconceptions about the ISO 9000 family	104
Summary	105
Perceptions of ISO 9000 and its derivatives – Food for thought	106

Chapter 3	Role, origins and application of ISO 9000	108
	Why was ISO 9000 created?	108
	What does ISO 9000 apply to?	109
	Why would we need to use these standards?	109
	Origin of ISO 9000	110
	Using the ISO 9000 family of standards	119
	Exclusions	121
	Certification to ISO 9001:2000	125
	ISO 9000 derivatives	127
	Comparisons with other models	131
	Summary	135
	Role, origins and application – Food for thought	136
Chapter 4	Quality management system	138
	Summary of requirements	138
	Establishing a quality management system	139
	Identifying processes (4.1a)	141
	Sequence and interaction of processes (4.1b)	147
	Criteria and methods for effective operation and control (4.1c)	149
	Documenting a quality management system (4.1, 4.2.1)	151
	Documented procedures (4.2.1c)	155
	Documents that ensure effective planning, operation and control of processes (4.2.1d)	157
	Implementing a quality management system (4.1)	169
	Managing processes (4.1)	170
	Ensuring information availability (4.1d)	172
	Ensuring the availability of resources (4.1d)	173
	Measuring, monitoring and analysing processes (4.1e)	174
	Maintaining a quality management system (4.1)	177
	Continual improvement in the quality management system and its processes (4.1 and 4.1f)	178
	Outsourcing (4.1)	180
	Preparing the quality manual (4.2.1b)	181
	Control of documents (4.2.3)	188
	Control of records (4.2.1e and 4.2.4)	214
	Summary	223
	Quality management system requirements checklist	223
	Quality management system – Food for thought	225
Chapter 5	Management responsibility	227
	Summary of requirements	227
	Management commitment (5.1)	228

Customer focus (5.2)	241
Quality policy (5.3)	247
Quality objectives (5.4.1)	256
Quality management system planning (5.4.2)	267
Responsibility and authority (5.5.1)	272
Management representative (5.5.2)	278
Internal communication (5.5.3)	284
Management review (5.6)	288
Summary	301
Management responsibility requirement checklist	301
Management responsibility – Food for thought	303
Chapter 6 Resource management	305
Summary of requirements	305
Determining resources (6.2.1)	307
Providing resources (6.2.1)	310
Competence of personnel (6.2.1)	312
Training awareness and competence (6.2.2)	316
Infrastructure (6.3)	333
Work environment (6.4)	340
Summary	352
Resource management requirements summary	353
Resource management – Food for thought	354
Chapter 7 Product realization	356
Summary of requirements	356
Planning product realization processes (7.1)	358
Customer-related processes (7.2)	375
Design and development (7.3)	398
Purchasing (7.4)	444
Production and service provision (7.5)	467
Control of measuring and monitoring devices (7.6)	500
Summary	523
Product realization requirements checklist	524
Product realization – Food for thought	528
Chapter 8 Measurement, analysis and improvement	530
Summary of requirements	530
Monitoring, measurement, analysis and improvement processes (8.1)	533
Customer satisfaction (8.2.1)	543
Internal audit (8.2.2)	547

Measurement and monitoring of processes (8.2.3)	565
Measurement and monitoring of product (8.2.4)	570
Control of nonconforming product (8.3)	577
Analysis of data (8.4)	589
Improvement (8.5)	601
Summary	641
Measurement, analysis and improvement requirements checklist	643
Measurement, analysis and improvement – Food for thought	645
Appendix A Glossary	647
Appendix B Related web sites	661
Bibliography	664
Index	669

Preface to the 5th edition

The basic purpose of the book is to provide a source of reference not only for those seeking and maintaining ISO 9001 certification but also to provide the reader with the fundamental concepts of quality management so that use of the standard becomes a quest for improving quality in all operations and is not limited to simply getting and keeping a certificate.

In addressing the standards the book provides the reader with an understanding of each requirement of ISO 9001:2000 through explanation, examples, lists, tables and diagrams. As there are over 250 requirements in ISO 9001:2000, this has led to a book of considerable size – it was not intended as a quick read! I make no apologies for the layout. If I were to explain how a management system would be developed, the chapters and sections would be presented in an entirely different order to that of the standard. But I have chosen to explain the requirements of the standard and therefore they are addressed in the sequence they are presented in the standard itself, adding Clause numbers to the headings to make it user friendly. The summaries at the beginning of Chapters 4, 5, 6, 7 and 8 do attempt to link together the requirements in a cycle but they are hampered by the headings ascribed to the Clauses in the standard.

At the end of each chapter there is a Summary of Requirements that will act as a checklist for system developers and auditors. However, it is not intended that the list be used by auditors during a system audit but used afterwards in order to test the completeness of the system. I have included a section on *Food for Thought*. This is intended to cause the reader to reflect on the previous chapter, perhaps even change perceptions but mostly confirm understanding.

In this edition I have maintained a structured approach with each requirement covered by three basic questions: *What does it mean? Why is it important? How is it demonstrated?* (I changed the question *How is it implemented* to *How is it demonstrated* to reflect the approach promoted in this book that ISO 9001 is an assessment standard not a design standard).

The interpretations are those of the author and should not be deemed to be those of the International Organization for Standardization, any National Standards Body or Certification Body.

New in the 5th edition

- A number of case studies illustrating interpretations, solutions and auditing practices
- A section putting ISO 9000 in context and summarizing the key attributes
- Material putting the various tools, techniques and models associated with quality management in context
- A section on quality planning completing Juran's Quality Trilogy
- Difference between function and processes
- Revision of the section on standard deviation, a new section on the Six-Sigma methodology in Chapter 1 and additional material on statistical techniques in Chapter 8
- Rationalization of core business processes
- Introduction to process management principles
- A section on developing an effective process-based management system
- A section on ISO 9001 derivatives such as AS9100, ISO/TS 16949 etc.
- Comparisons between ISO 9000 and Six-Sigma methodology
- Revision of the process identification methods
- Simplification of documentation control
- Replacement of questionnaires with numbered requirements checklists
- Examples of matching quality policy to objectives
- Reference to the published interpretations from ISO/TC 176
- Addition of techniques used in the automotive industry
- Revision of material on measuring the effectiveness of training
- Removal of ISO 9001:1994 material
- Process decomposition refined
- Revision of product requirement review material
- Addition of requirement linkages in Section 8 of the standard
- Addition of outline improvement processes
- Addition of product and process auditing material
- Addition of 8D method of problem resolution
- Several forms have been added such as Change Requests, Corrective Action, FMEA, Nonconformity Report
- The addition of several Japanese terms associated with quality management

Structure and style of the handbook

The first three chapters provide background information with the subsequent five chapters dealing with the sections of ISO 9001 that contain the requirements. In this way the chapter numbers of the book mirror the section headings of ISO 9001.

Other than for comparisons between the 1994 and the 2000 version of the standard, all references to ISO 9000, ISO 9001 and ISO 9004 refer to the 2000 version. In view of the differing perceptions, when the term ISO 9000 is used in

this book it means the standard and not its attendant infrastructure. Comment on any aspect of the infrastructure will be referred to it by its usual name – auditing, consulting, certification, training or accreditation.

I have retained the direct style of writing referring to the reader as “you”. You may be a manager, an auditor, a consultant, an instructor, a member of staff, a student or simply an interested reader. You may not have the power to do what is recommended in this book but may know of someone who does whom you can influence. There will be readers who feel I have laboured topics too much but it never ceases to amaze me how many different ways a certain word, phrase or requirement might be interpreted.

How to use this handbook

As stated previously this is a reference book for users of the ISO 9000 family of standards and as such it contains concepts as well as details.

If you are new to the field of quality management you might start by reading Chapter 1 in order to gain an appreciation of the fundamental principles and the broader perspective of quality management. You could skip Chapter 2 because you won't have any preconceived ideas about the standard and move onto Chapter 3. To obtain an overview of the ISO 9001, you could then read the requirement summaries at the start of each chapter from Chapters 4 through 8 and then seek out particular requirements of interest.

If you have experience of using ISO 9000 and are charged with improving your management system you might start with Chapter 2 where you will gain an insight into how the standard has been used, misused and misunderstood. If you then dip into Chapter 1 especially the last sections on process management and developing an effective quality management system, you might begin changing your perceptions so that when you begin browsing Chapters 4 through 8 which deal with the requirements you will see them within an entirely different framework. Finally you might use the requirement lists at the end of Chapters 4 through 8 to help check that your system addresses all relevant requirements.

If you have a problem with interpreting a particular requirement, simply go to the heading carrying the Clause number about which you are interested.

If you have to prepare a case for seeking ISO 9000 certification, you might study Chapter 2 to gain an awareness of the arguments for and against certification then skim Chapter 3 to gain an appreciation of the origins of the standard and how to respond to the requirements.

If you are auditing management systems against ISO 9001 you certainly need to read Chapter 2 to gain an appreciation of the problems that have been caused by its inappropriate use. You should then study Chapter 1 to appreciate the concepts and principles, especially the sections on quality management principles and process management. In preparing for the audit you might consult the appropriate sections in Chapters 4 through 8 in order to gain an insight into

what evidence you should be looking for when you examine the organization's processes. After completing the audit you might use the requirement lists at the end of Chapters 4 through 8 to help check that you have covered all relevant requirements.

I have recognized that although many organizations are using the latest information technology there are many that are not and will continue to use labour intensive ways of generating, maintaining and distributing information. Therefore, if the solutions appear outdated, simply skip over these and remember that more and more of the organizations that are using ISO 9001 are in developing countries.

Whatever your purpose you would benefit from studying the Glossary of terms because the meaning given might well differ from that which you may have assumed the term to mean and thus it will affect your judgement.

Acknowledgements

I am grateful to the many clients and associates I have talked with before, during and after the transition to ISO 9001:2000 on related consultancy and training assignments; to my business partner John Thompson whose ideas and insight provided the clarity needed to explain the requirements in the wider context of business management and for his teachings on process management; to my wife Angela for her constructive comment and editing of the manuscript and to Jonathan Simpson of Elsevier who commissioned the work.

The teachings of P. F. Drucker have been a constant inspiration particularly in clarifying issues on strategic management. The teachings of W. E. Deming have been particularly useful in clarifying the theory of variation and confirming my ideas on systems theory. The techniques used by Taiichi Ohno in developing the Toyota Production System have provided a basis for contrast and comparison. The teachings of J. M. Juran have also been a constant inspiration particularly concerning breakthrough and control principles and quality planning. The treatment of *competence* in Chapter 6 was enhanced and clarified by the teachings of Shirley Fletcher and contributions from my business partner John Thompson.

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This book is written for those who want to improve the performance of their organization and whether or not certification is a goal or indeed required, it is hoped that the book will continue to provide a source of inspiration in the years ahead.

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Chapter 1

Basic concepts

By three methods we may learn wisdom: First, by reflection, which is noblest; second, by imitation, which is easiest; and third, by experience, which is the bitterest.

Confucius

Introduction

Making the link

Since the dawn of civilization the survival of communities has depended on trade. As communities grow they become more dependent on others providing goods and services they are unable to provide from their own resources. Trade continues to this day on the strength of the customer–supplier relationship. The relationship survives through trust and confidence. A reputation for delivering a product or a service to an agreed specification, at an agreed price on an agreed date is hard to win and organizations will protect their reputation against external threat at all costs. But reputations are often damaged not by those outside but by those inside the organization. Broken promises, whatever the cause, harm reputation and promises are broken when an organization does not do what it committed itself to do. This can arise either because the organization accepted a commitment it did not have the capability to meet or it had the capability but failed to manage it effectively.

This is what the ISO 9000 family of standards is all about. It is a set of criteria that, when applied correctly, will help organizations develop the capability to create and retain satisfied customers. It is not a product standard – there are no requirements for specific products or services – only criteria that apply to the management of an organization when determining customer needs and expectations and supplying products and services that are intended to satisfy those needs and expectations.

A quest for confidence

In a nutshell

The ISO 9000 family of standards will stop you making promises you can't fulfil and help you keep those you can.

Customers need confidence that their suppliers can meet their quality, cost and delivery requirements and have a choice as to how they acquire this confidence. They can select their suppliers:

- (a) Purely on the basis of past performance, reputation or recommendation
- (b) By assessing the capability of potential suppliers themselves

(c) On the basis of an assessment of capability performed by a third party

Most customers select their suppliers using option (a) or (b) but there will be cases where these options are not appropriate either because there is no evidence for using option (a) or resources are not available to use option (b) or its not economic. It is for these situations that a certification scheme was developed. Organizations submit to a third party audit that is performed by an accredited certification body independent of both customer and supplier. An audit is performed against the requirements of ISO 9001 and if no nonconformities are found, a certificate is awarded. This certificate provides evidence that the organization has the capability to meet customer and regulatory requirements relating to the supply of certain specified goods and services. Customers are now able to acquire the confidence they require simply by establishing whether a supplier holds an ISO 9001 certificate covering the type of products and services they are seeking. However, the credibility of the certificate rests on the competence of the auditor and the integrity of the certification body neither of which are guaranteed. (This is addressed further in Chapter 2.)

A quest for capability

Trading organizations need to create and retain satisfied customers to survive. This depends on their capability to:

- (a) Identify customer needs and expectations
- (b) Convert customer needs and expectations into products and services that will satisfy them
- (c) Attract customers to the organization
- (d) Supply the products and services that meet customer requirements

Many organizations develop their own ways of working and strive to satisfy their customers in the best way they know how. In choosing the best way for them, they can either go through a process of trial and error, select from the vast body of knowledge on management, or utilize one or more management models available that combine proven principles and concepts. ISO 9000 represents one

of these models. Others are the Business Excellence Model, Six Sigma, CMM and Process Management. (These are addressed later in this chapter.)

Having given the organization the capability to do (a) to (d) above, customer confidence can be built up by reputation, customer assessments or third party assessment. If a customer requires confidence to be demonstrated through an ISO 9001 assessment, the organization has no option but to seek ISO 9001 certification if it wishes to retain business from that particular customer or market sector. In the UK alone there are about 2.5 million trading organizations and less than 2.5% have been registered to ISO 9001. It is therefore reasonable to assume that over 95% of organizations in the UK are able to give their customers confidence in their capability without becoming registered to ISO 9001 but this should not be assumed to mean that the concepts embodied in the ISO 9000 family of standards are flawed. It simply means that in the majority of organizations many of these concepts are employed but perhaps not consistently. Nevertheless in the particular business-to-business relationship, confidence is developed by reputation rather than certification.

In B2B relationships where confidence in capability is developed by reputation there might be no need for certification.

However, it is important to recognize that there is no requirement in ISO 9000 for certification. The family of standards can be used in helping an organization discover the right things to do as well as assess for itself the extent to which its goals and processes meet international standards. Only where customers are imposing ISO 9001 in purchase orders and contracts would it be necessary to obtain ISO 9001 certification.

Anatomy of the standards

There are three standards in the ISO 9000 family:

ISO 9000 Quality management systems – Fundamentals and vocabulary

ISO 9001 Quality management systems – Requirements

ISO 9004 Quality management systems – Guidelines for performance improvements

Each of the standards has a different purpose, intent, scope and applicability as indicated in Table 1.1.

These standards provide a vehicle for consolidating and communicating concepts in the field of quality management that have been approved by an international committee of representatives from national standards bodies. It is not their purpose to fuel the certification, consulting, training and publishing industries. The primary users of the standards are intended to be organizations acting as either customers or suppliers. But we should not forget that their primary purpose is to improve the capability of organizations to satisfy their customers and

Table 1.1 Overview of the ISO 9000 family of standards

<i>Attribute</i>	<i>ISO 9000 family</i>	<i>ISO 9000</i>	<i>ISO 9001</i>	<i>ISO 9004</i>
Purpose	To assist organizations operate effective quality management systems	To facilitate common understanding of the concepts and language used in the family of standards	To provide and equitable basis for assessing the capability of organizations to meet customer and applicable regulatory requirements	To assist organizations to satisfy the needs and expectations of all interested parties
Intent	To facilitate mutual understanding in national and international trade and help organizations achieve sustained success	To be used in conjunction with ISO 9001 and ISO 9004	To be used for contractual and certification purposes	To assist organizations purpose continual improvement. It is not intended as a guide to meeting the requirements of ISO 9001
Scope	The management of quality	Defines the principles and fundamental concepts and terms used in the ISO 9000 family	Defines the requirements of a quality management system, the purpose of which is to enable organizations to continually satisfy their customers	Provides guidelines for improving the performance of organizations and enabling them to satisfy all interested parties
Applicability	Applies to all organizations regardless of size or complexity	Applies to all terms used in the ISO 9000 family	Applies where an organization needs to demonstrate its ability to provide products and services that meet customer and regulatory requirements and aims to enhance customer satisfaction	Applies to organizations seeking guidance on developing quality management systems and improving their performance
Facts and figures	3 Standards	81 Definitions	8 Sections, 51 Clauses, 250+ Requirements	8 Sections, 64 Clauses, No requirements

other stakeholders. Broken promises create massive problems for society thus making quality key to survival and so we begin by looking at the meaning of the word “quality” and the principles and practices that have emerged to determine and manage it.

Principles or prescription

One of the great problems in our age is to impart understanding in the minds of those who have the ability and opportunity to make decisions that affect our lives. There is no shortage of information – in fact there is too much now we can search a world of information from the comfort of our armchair. We are bombarded with information but it is not knowledge – it does not necessarily lead to understanding. With so many conflicting messages from so many people, it is difficult to determine the right thing to do. There are those whose only need is a set of principles from which they are able to determine the right things to do. There are countless others who need a set of rules derived from principles that they can apply to what they do and indeed others who need a detailed prescription derived from the rules for a particular task. In the translation from principles to prescription, inconsistencies arise. Those translating the principles into rules or requirements are often not the same as those translating the rules into a detailed prescription. The principles in the field of quality management have not arisen out of academia but from life in the work place. Observations from the work place have been taken into academia, analysed, synthesized and refined to emerge as universal principles. These principles have been expressed in many ways and in their constant refreshment the language is modernized and simplified, but the essence is hardly changed.

Without a set of principles, achieving a common understanding in the field of quality management would be impossible. Since Juran, Deming and Feigenbaum wrote about quality management in the 1950s there has been considerable energy put into codifying the field of quality management and a set of principles from which we can derive useful rules, regulations and requirements has emerged. This chapter addresses these principles in a way that is intended to impart understanding not only in the minds of those who prefer principles to prescription, but also in the minds of those who prefer prescriptions. There is nothing intrinsically wrong with wanting a prescription. It saves time, it's repeatable, it's economic and it's the fastest way to get things done but it has to be right. The receivers of prescriptions need enough understanding to know whether what they are being asked to do is appropriate to the circumstances they are facing.

The concepts expressed in this chapter embody universal principles and have been selected and structured in a manner that is considered suitable for users of the ISO 9000 family of standards. It is not intended as a comprehensive guide to quality management – some further reading is given in the Bibliography. ISO 9000:2000 also contains concepts some of which are questionable but these will

be dealt with as they arise. The aim is to give the reader a balanced view and present a logical argument that is hoped will lead to greater understanding. As ISO 9000 is supposed to be about the achievement of quality, there is no better place to start than with an explanation of the word *quality*.

Needs, requirements and expectations

Organizations are created to achieve a goal, mission or objective but they will only do so if they satisfy the needs, requirements and expectations of their stakeholders. Their customers, as one of the stakeholders, will be satisfied only if they provide products and services that meet their needs, requirements and expectations. Their other stakeholders (shareholders, employees, suppliers and society) will only be satisfied if the products and services provided to customers are produced and supplied in a manner that satisfies their needs, requirements and expectations.

We all have needs, wants, requirements and expectations. Needs are essential for life, to maintain certain standards, or essential for products and services, to fulfil the purpose for which they have been acquired. According to Maslow¹, man is a wanting being; there is always some need he wants to satisfy. Once this is accomplished, that particular need no longer motivates him and he turns to another, again seeking satisfaction. Everyone has basic physiological needs that are necessary to sustain life (food, water, clothing and shelter). Maslow's research showed that once the physiological needs are fulfilled, the need for safety emerges. After safety come social needs followed by the need for esteem and finally the need for self-actualization or the need to realize one's full potential. Satisfaction of physiological needs is usually associated with money – not money itself but what it can buy. The hierarchy of needs is shown in Figure 1.1.

These needs are fulfilled by the individual purchasing, renting or leasing products or services. Corporate needs are not too dissimilar. The physiological



Figure 1.1 Hierarchy of needs

needs of organizations are those necessary to sustain survival. Often profit comes first because no organization can sustain a loss for too long but functionality is paramount – the product or service must do the job for which it is intended regardless of it being obtained cheaply. Corporate safety comes next in terms of the safety of employees and the safety and security of assets followed by social needs in the form of a concern for the environment and the community as well as forming links with other organizations and developing contacts. Esteem is represented in the corporate context by organizations purchasing luxury cars, winning awards, superior offices and infrastructures and possessing those things that give it power in the market place and government. Self-actualization is represented by an organization's preoccupation with growth, becoming bigger rather than better, seeking challenges and taking risks. However, it is not the specific product or service that is needed but the benefits that possession brings that is important. This concept of benefits is the most important and key to the achievement of quality. Unfortunately, ISO 9001 certification falls into the category of physiological needs simply because, for organizations in some supply chains, it has become a necessity for survival.

Requirements are what we request of others and may encompass our needs but often we don't fully realize what we need until after we have made our request. For example, now that we own a mobile telephone we discover we really need hands-free operation when using the phone while driving a vehicle. Our requirements at the moment of sale may or may not therefore express all our needs. By focusing on benefits resulting from products and services, needs can be converted into wants such that a need for food may be converted into a want for a particular brand of chocolate. Sometimes the *want* is not essential but the higher up the hierarchy of needs we go, the more a *want* becomes essential to maintain our social standing, esteem or to realize our personal goals. Our requirements may therefore include such wants – what we would like to have but are not essential for survival.

In growing their business organizations create a demand for their products and services but far from the demand arising from a want that is essential to maintain our social standing, it is based on an image created for us by media advertising. We don't need spring vegetables in the winter but because industry has created the organization to supply them, a demand is created that becomes an expectation. Spring vegetables have been available in the winter now for so long that we expect them to be available in the shops and will go elsewhere if they are not. But they are not essential to survival, to safety, to esteem or to realize our potential and their consumption may in fact harm our health because we are no longer absorbing the right chemicals to help us survive the cold winters. We might want it, even need it but it does us harm and there are plenty of organizations ready to supply us products that will harm us.

Expectations are *implied needs* or *requirements*. They have not been requested because we take them for granted – we regard them to be understood within