

FIFTH EDITION

DAVID HOYLE

ISO 9000

QUALITY SYSTEMS HANDBOOK



**B
H**

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