



THIRD EDITION

FREE QMS
AVAILABLE

ISO 9001: 2000

for Small Businesses

- Top-selling ISO quality management handbook
- Supported by a customisable Quality Management System that could save thousands in consultancy fees

RAY TRICKER

Contents

<i>Foreword</i>	xi
<i>Preface</i>	xv
<i>Obtaining the customisable QMS and additional material</i>	xviii
Part One – The Background to ISO 9000	1
1 ISO 9000	3
1.1 ISO 9000	3
1.2 Interoperability of standards	6
1.3 The demand for standardisation of Quality Management Systems	9
1.4 The background to the ISO 9000 set of quality standards	10
1.4.1 What does the term ISO mean?	11
1.4.2 ISO 9000:1987	12
1.4.3 ISO 9000:1994	13
1.5 ISO 9001:2000	14
1.5.1 Background to the ISO 9001:2000 standard	14
1.5.2 The revision process	16
1.5.3 Factors considered during the revisions of the standards	17
1.5.4 Key changes in the standards	19
1.5.5 What are the aims, benefits, main changes and new requirements of ISO 9001:2000?	21
1.5.6 Certification registration and accreditation	24
1.5.7 The ‘consistent pair’	26
1.5.8 Quality management principles	26
1.5.9 What has happened to other standards previously based on ISO 9000:1994?	29
1.5.10 Are there any other standards based on ISO 9001:2000?	36

1.5.11	What is the ISO 9000 family?	37
1.5.12	Integrated Management Systems	41
1.5.13	ISO 9000:2000	42
1.5.14	ISO 9001:2000	43
1.5.15	Process approach	49
1.5.16	Planning an organisation's business processes	51
1.5.17	Brief summary of the ISO 9001:2000 standard	60
1.5.18	ISO 9004:2000 Quality Management Systems – guidelines for performance improvement	66
1.6	Certification	67
1.6.1	Who can certify an organisation?	67
1.6.2	What is required for certification?	68
1.6.3	Who will be responsible for quality within an organisation?	68
1.7	Assistance (in the UK) for obtaining a Quality Management System	69
1.7.1	Government assistance	69
1.7.2	Assistance for the smaller company	70
1.7.3	Assistance in setting up a Quality Management System in America	71
Appendix A	ISO 14001 – Environmental Management System	73
Part Two	The Structure of ISO 9001:2000	79
2	The structure of ISO 9001:2000	81
2.1	Section 1 – Scope	81
2.1.1	Section 1.1 General	81
2.1.2	Section 1.2 Application	81
2.2	Section 2 – Normative reference	82
2.3	Section 3 – Terms and definitions	82
2.4	Section 4 – Quality Management System	83
2.4.1	Section 4.1 General requirements	84
2.4.2	Section 4.2 Documentation requirements	85
2.5	Section 5 – Management responsibility	89
2.5.1	Section 5.1 Management commitment	91
2.5.2	Section 5.2 Customer focus	92
2.5.3	Section 5.3 Quality policy	93
2.5.4	Section 5.4 Planning	95
2.5.5	Section 5.5 Responsibility, authority and communication	97
2.5.6	Section 5.6 Management review	99

2.6	Section 6 – Resource management	103
2.6.1	Section 6.1 Provision of resources	104
2.6.2	Section 6.2 Human resources	105
2.6.3	Section 6.3 Infrastructure	107
2.6.4	Section 6.4 Work environment	107
2.7	Section 7 – Product realisation	108
2.7.1	Section 7.1 Planning and realisation	109
2.7.2	Section 7.2 Customer-related processes	111
2.7.3	Section 7.3 Design and development	114
2.7.4	Section 7.4 Purchasing	126
2.7.5	Section 7.5 Production and service provision	131
2.7.6	Section 7.6 Control of measuring and monitoring devices	136
2.8	Section 8 – Measurement, analysis and improvement	139
2.8.1	Section 8.1 General	140
2.8.2	Section 8.2 Monitoring and measurement	140
2.8.3	Section 8.3 Control of non-conforming product	147
2.8.4	Section 8.4 Analysis of data	149
2.8.5	Section 8.5 Improvement	150
Part Three – The Importance of Quality Control and Quality Assurance		157
3	Quality control and quality assurance	159
3.1	Quality control	159
3.2	Quality assurance	160
3.3	Specifications	161
3.3.1	The significance of specifications	161
3.3.2	Types of specification	162
3.3.3	Manufacturer's responsibilities	163
3.3.4	Purchaser's responsibilities	165
3.4	Quality assurance during a product's life cycle	166
3.4.1	Design stage	166
3.4.2	Manufacturing stage	169
3.4.3	Acceptance stage	170
3.4.4	In-service stage	171
3.5	Benefits and costs of quality assurance	173
3.6	Costs of quality failure	174
3.6.1	The manufacturer	174
3.6.2	The purchaser	175

Part Four – Quality Management System	177
4 Quality Management System	179
4.1 Quality Management System – requirements	179
4.1.1 Basic requirements of a Quality Management System	180
4.2 Quality Management System principles	181
4.3 Quality Management System approach	183
4.3.1 What is a quality system?	185
4.3.2 What is the difference between a quality manual and a quality system?	185
4.4 Quality Management System structure	185
4.4.1 QMS documentation	186
4.5 Quality Manual	187
4.6 Processes	188
4.7 Quality Procedures	190
4.7.1 What documented procedures are required by ISO 9001:2000?	190
4.8 Work Instructions	191
4.8.1 What is the difference between a Work Instruction and a record?	192
4.9 Quality Plan	192
4.9.1 Management responsibility	194
4.9.2 Contract review	195
4.9.3 Design control	195
4.9.4 Document and data control	196
4.9.5 Purchasing	196
4.9.6 Customer supplied product	196
4.9.7 Product identification and traceability	196
4.9.8 Process control	196
4.9.9 Inspection and testing	197
4.9.10 Inspection, measuring and test equipment	197
4.9.11 Non-conforming service/product	197
4.9.12 Other considerations	198
4.10 Quality records	198
 Part Five – Quality Organisational Structure	 201
5 Quality organisational structure	203
5.1 Management	204

5.2	Quality assurance personnel	206
5.2.1	Quality manager	207
5.2.2	Chief Quality Assurance Inspector	209
5.2.3	Section Quality Assurance Inspectors	210
5.2.4	Quality assurance personnel	211
5.2.5	Quality assurance resources	212
Part Six	– Example Quality Management System	213
Part Seven	– Self-assessment	369
7	Self-assessment	371
7.1	How ISO 9000 can be used to check an organisation's Quality Management System	371
7.2	Internal audit	372
7.2.1	Audit plan	373
7.2.2	Internal audit program	374
7.3	External audit	382
7.3.1	Supplier evaluation	382
7.4	The surveillance or quality audit visit	386
7.4.1	Multiple evaluations and audits	387
7.4.2	Secondary audit	387
7.4.3	Third-party evaluation	387
7.4.4	Conformity assessment	387
7.5	ISO 9001:2000 checklist	388
7.5.1	ISO 9001:2000 headings	388
7.5.2	ISO 9001:2000 explanations and likely documentation	388
7.5.3	ISO 9001:2000 requirements of management	388
7.5.4	Example of an external auditor's checklist	389
7.5.5	Example stage audit checklist	389
7.5.6	Index for ISO 9001:2000	389
Appendix 7A	ISO 9001:2000 headings	390
Appendix 7B	ISO 9001:2000 – Explanations and likely documentation	392
Appendix 7C	Requirements of management	403
Appendix 7D	Example checklists for auditors	415
Appendix 7E	Example internal stage audit checks	429
Appendix 7F	Index for ISO 9001:2000	436
Annex A	Documentation requirements	453
Annex B	Customer satisfaction	459
Annex C	Guidance on non-conforming products	477

x Contents

References	483
Abbreviations and acronyms	491
Glossary of terms	493
Useful addresses	503
Index	507