

Contents

1	Introducing Quality Management System	1
1.1	Introduction	1
1.2	Relating Internal and End Customers	1
1.3	Understanding Quality	2
1.3.1	Needs and Expectations of Internal and End Customers	3
1.4	Quality Management System	4
	References.	4
2	Establishing ISO 9001 QMS Documentation	5
2.1	Documented QMS	5
2.1.1	Needs for Documentation	5
2.1.2	Basic Considerations	6
2.2	Process Approach	7
2.2.1	Defining Process Characterization	7
2.2.2	Monitoring and Measurement	7
2.3	Illustrating Process Characterization	9
2.3.1	Inputs	9
2.3.2	Process Procedure with Acceptance Criteria	9
2.3.3	Quality Needs of Internal Customer	10
2.3.4	Monitoring and Measurement	10
2.3.5	Outputs	10
2.4	Process Approach for Controlling Engineering Documents.	11
2.4.1	Inputs and Outputs	11
2.4.2	Quality Needs of Customers and Acceptance Criteria.	11
2.4.3	Monitoring and Measurement	12
2.5	QMS Processes.	12
2.5.1	Sequence and Interaction of QMS Processes.	12

2.6	QMS Documents	13
2.6.1	Quality Manual	14
2.6.2	Expertise for Preparing QMS Documents	14
	References.	15
3	Management Processes	17
3.1	Introduction	17
3.2	Organization and Its Context	18
3.2.1	Documentation Requirements	18
3.2.2	Monitoring External and Internal Issues	19
3.3	Needs and Expectations of Interested Parties	19
3.3.1	Interested Parties	20
3.3.2	Requirements of Interested Parties.	20
3.3.3	Determining, Monitoring and Reviewing.	21
3.4	Scope of Quality Management System	21
3.5	Quality Management System and Its Processes	22
3.5.1	Establishing QMS	23
3.5.2	Implementing, Maintaining and Improving QMS	24
3.5.3	Maintaining and Retaining Documented Information.	24
3.6	Leadership	24
3.6.1	Leadership and Commitment.	25
3.6.2	Customer Focus.	27
3.6.3	Establishing and Communicating Quality Policy.	28
3.6.4	Organizational Roles, Responsibilities and Authorities	29
3.7	Planning	29
3.7.1	Understanding Risks and Opportunities.	30
3.7.2	Practical Considerations.	31
3.7.3	Determining Risks and Opportunities	31
3.7.4	Planning Actions to Address Risks and Opportunities	32
3.8	Example-1: Risks and Opportunities in Design and Development	33
3.8.1	Risks and Their Causes.	34
3.8.2	Identifying the Actions to Address Opportunities	34
3.8.3	Integrating the Actions with QMS Process	35
3.9	Example-2: Risks and Opportunities in Customer Enquiries.	35
3.9.1	Risks and Their Causes.	36
3.9.2	Identifying the Actions to Address Opportunities	36
3.9.3	Integrating the Actions with QMS Process	36
3.10	Example-3: Risks and Opportunities in Production Processes.	37
3.10.1	Opportune Actions and Integrating Them with QMS Process	37

3.11	Quality Objectives	38
3.11.1	Requirements.	38
3.11.2	Planning to Achieve Quality Objectives	39
3.11.3	Planning Changes	40
	References.	40
4	Support Processes	43
4.1	Introduction	43
4.2	Resources	43
4.2.1	People, Infrastructure and Environment.	44
4.3	Monitoring and Measuring Resources.	45
4.3.1	Determining and Providing Resources for Measurement.	45
4.3.2	Fitness of Measuring Resources	47
4.3.3	Measurement Traceability	48
4.3.4	Calibration Against Measurement Standards	49
4.3.5	Verification Against Measurement Standards.	51
4.3.6	Non-existent of Measurement Standards	52
4.3.7	Calibration with Lower Accuracy Ratio Standards	53
4.3.8	Calibration Status and Safeguarding	53
4.4	Organizational Knowledge	54
4.5	Competence	55
4.5.1	Acquiring Competence and Evaluating Effectiveness	55
4.6	Awareness	55
4.7	Communication.	56
4.8	Documentation Requirements	56
4.8.1	Creating and Updating.	57
4.8.2	Control of Documented Information	58
	References.	59
5	Operational Processes	61
5.1	Operation	61
5.2	Operational Planning and Control.	62
5.2.1	Planning	62
5.2.2	Implementation, Control and Outputs	63
5.2.3	Addressing Planned and Unintended Changes.	64
5.3	Requirements for Products and Services.	65
5.3.1	Customer Communication	66
5.3.2	Determining the Requirements for Products	67
5.3.3	Review of Product Requirements	68
5.3.4	Changes to Requirements for Products	69
5.4	Design and Development of Products.	70
5.4.1	Design and Development Planning	70
5.4.2	Design and Development Inputs	73

5.4.3	Design and Development Controls	74
5.4.4	Design and Development Outputs	76
5.4.5	Design and Development Changes	77
5.5	Control of Externally Provided Processes and Products	77
5.5.1	Applicability of Controls	77
5.5.2	Evaluation of External Providers	78
5.5.3	Selection and Monitoring	80
5.5.4	Re-evaluation of External Providers	80
5.5.5	Type and Extent of Control.	81
5.6	Information for External Providers	83
5.6.1	Practical Considerations.	84
5.6.2	Requirements of Processes, Products and Services	84
5.6.3	Approval of Products and Services	84
5.6.4	Approval of Methods, Processes and Equipment.	85
5.6.5	Approval of the Release of Products and Services	85
5.6.6	Competence and Qualification of Personnel	86
5.6.7	Interactions, Controls and Monitoring	86
5.6.8	Verification and Validation	86
5.7	Control of Production and Service Provision	87
5.7.1	Availability of Documented Information	87
5.7.2	Monitoring and Measuring Resources and Activities.	87
5.7.3	Infrastructure, Environment and Competence of Personnel.	88
5.7.4	Validation and Revalidation of Processes	88
5.7.5	Preventing Human Errors	91
5.7.6	Release, Delivery and Post-delivery Activities.	91
5.8	Identification and Traceability.	92
5.8.1	Product Identification.	92
5.8.2	Product Status Identification	92
5.8.3	Traceability Requirements	92
5.9	Property of Customers and External Providers	93
5.9.1	Discrepancies in Property	93
5.10	Preservation of Product.	93
5.11	Post-delivery Activities.	94
5.11.1	Extent of Post-delivery Activities	94
5.12	Control of Changes.	95
5.13	Release of Products and Services	96
5.14	Control of Nonconforming Outputs	96
5.14.1	Actions on Nonconforming Products.	96
5.14.2	Documentary Evidences	98
	References.	98

6	Performance Evaluation and Improvement	101
6.1	Introduction	101
6.2	Monitoring, Measurement, Analysis and Evaluation	102
6.2.1	General Requirements	102
6.2.2	Needs to Be Monitored and Measured	103
6.2.3	Key Performance Indicator	104
6.2.4	Key Performance Indicators for QMS Processes	105
6.2.5	Methods for Monitoring and Measuring KPIs	107
6.2.6	Methods for Analyzing Data on KPIs and Evaluation	108
6.2.7	Periodicity of Monitoring and Measuring KPIs	109
6.2.8	Periodicity for Analyzing Data on KPIs and Evaluation	109
6.3	Customer Satisfaction	109
6.3.1	Needs and Expectations of Customers	110
6.3.2	Proactive Methods	111
6.3.3	Monitoring and Measuring Customers' Perception	111
6.3.4	Methods for Analysis and Evaluation	112
6.3.5	Practical Considerations	112
6.4	Analysis and Evaluation	113
6.5	Internal Audit	113
6.5.1	QMS Conformance to ISO 9001 Requirements	114
6.5.2	QMS Conformance to Organization's Own Requirements	115
6.5.3	Audit for Effective Implementation and Maintenance of QMS	116
6.5.4	Audit Program	117
6.5.5	Planning Audit Program	118
6.5.6	Responsibilities, Frequency and Methods	118
6.5.7	Planning Requirements and Reporting	120
6.5.8	Impartiality and Objectivity in Conducting Audits	121
6.5.9	Corrections and Corrective Actions	122
6.5.10	Quality Records	122
6.6	Management Review	123
6.6.1	Management Review Inputs	123
6.6.2	Management Review Outputs	124
6.7	Improvement	125
6.7.1	Improvement Actions	125
6.8	Nonconformity and Corrective Action	126
6.8.1	Corrections	126
6.8.2	Corrective Actions	127
6.8.3	Quality Records	127

6.9	Continual Improvement	128
	References.	128
7	Implementing QMS with ERP Software	129
7.1	Understanding Integrated Approach	129
7.1.1	Benefits of Integrated Approach	130
7.1.2	Feasibility of Integration with ERP Software	130
7.2	Software System Engineering	131
7.2.1	Requirements and Acceptance Testing of Software	131
7.3	Integrating QMS Requirements with ERP Software	132
7.3.1	Requirements Analysis	132
7.3.2	System Functional Analysis.	132
7.3.3	Illustrations with QMS Processes	133
7.4	Software for the Control of Measuring Resources	133
7.4.1	Requirements Analysis for Operational Needs.	133
7.4.2	Requirements Analysis for Monitoring Needs	134
7.4.3	Requirements Analysis for Output Needs	135
7.4.4	Acceptance Test Plan	136
	References.	137
8	Operational Processes with ERP Software	139
8.1	Integrating Operational Processes	139
8.1.1	Illustrations for Operational Processes.	139
8.2	Requirements for Products and Services.	140
8.2.1	Process Flow Diagram.	140
8.2.2	Requirements Analysis	141
8.3	Operational Planning and Control.	143
8.3.1	Process Flow Diagram.	144
8.3.2	Acceptance Test Plan	146
8.4	Production and Service Provision.	146
8.4.1	Process Flow Diagram.	146
8.4.2	Requirements Analysis	147
8.4.3	Acceptance Test Plan	148
8.5	Design and Development of Products.	148
	Reference	148
9	QMS Planning with Indian Classic, Thirukkural	149
9.1	Indian Classic, Thirukkural	149
9.1.1	Contents of Thirukkural.	149
9.1.2	Translations of Thirukkural	150
9.1.3	Thirukkural for ISO 9001 QMS Planning	150
9.2	QMS Planning Requirements	151
9.3	Planning Actions to Address Risks and Opportunities	151
9.3.1	Thirukkural for Planning the Actions	152

9.4 Design and Development Planning 154

9.4.1 Thirukkural for Design and Development Planning 154

9.5 Production Planning 156

9.5.1 Thirukkural for Preparing Work Instructions 156

References. 158

Index 159



<http://www.springer.com/978-3-319-54382-6>

ISO 9001 Quality Management Systems

Natarajan, D.

2017, XXI, 160 p. 35 illus., Hardcover

ISBN: 978-3-319-54382-6