## ISO 9001:2000 Quality Management System Design

Jay Schlickman



	Preface	vii
	Acknowledgments	xiii
	Part I: QMS Design Fundamentals	1
1	QMS Foundations	3
	<ul> <li>1.1 The Relevance of Standards</li> <li>1.2 Core Competencies <ul> <li>1.2.1 Core Processes</li> <li>1.2.2 Strategy To Transform Documentation into an Operational System</li> </ul> </li> <li>1.3 Selection of a QMS Baseline <ul> <li>Endnotes</li> </ul> </li> </ul>	3 4 5 6 7 8
2	The ISO 9001:2000 QMS	11
	<ul> <li>2.1 The ISO 9000 QMS Design Context</li> <li>2.2 Effective QMS Processes</li> <li>2.3 The ISO 9000 QMS Process Model <ul> <li>2.3.1 Quality Management System Defined</li> <li>2.3.2 Operational Model for ISO 9001:2000</li> </ul> </li> <li>Endnotes</li> </ul>	11 12 14 14 14
3	QMS Continual Improvement Framework	17
	3.1 Continuous/Continual Improvement Is Inherent	17

viii Contents

	3.1.1	Continuous Versus Continual Improvement Concept	17
	3.1.2	Quality As a Philosophy	18
	3.1.3	Quality As a Scientific Measurement	19
	3.1.4	Continual Improvement Is Intrinsic Within the Standard	19
	3.1.5	Customer-Driven Orientation	19
	3.1.6	Shewhart Cycle	20
3.2	Cont	inuous Improvement Cycle Within Elements	23
	3.2.1	Other C/I	23
	3.2.2	Further Demonstration	23
	3.2.3	Continuous Improvement Cycle	24
	3.2.4	Continual Improvement Imperative	24
3.3	Man	datory Documentation Requirements	24
	3.3.1	Accreditation Impact on Guidelines	25
	3.3.2	QMS Design Methods To Be Presented	28
Endr	ıotes		30
Par	rt II:	QMS Documentation Design	. 33
Red	com	mended QMS Documentation	. 35
4.1	Over	view of Documentation Requirements	35
	4.1.1	Introduction	35
	4.1.2	Recommended Documentation Taxonomy	36
4.2	The 1	Four-Tier Pyramid Concept	37
	4.2.1	Matrix Format	38
	4.2.2	Operational Tiers	38
	4.2.3	Guidelines	38
	4.2.4	Four Tiers	38
	4.2.5	Navigation Is Key	40
	4.2.6	Clearly Link Lower Tiers from the Manual	40
	4.2.7	Waterfall Effect	40
	4.2.8	ISO 9000 Hierarchal Drivers	40
4.3	The l	ISO 9001:2000 QMS Is To Be Documented	
			42
	4.3.1	Information Channel Management	42 44
	4.3.1 4.3.2	Information Channel Management Mandatory Tier II Linkage Requirements	

Contents ix

5	Qu	ality	Manual Design	49
	5.1	A Qı	ıality Manual Is a Mandatory Document	49
		5.1.1	The Manual Should Be User Friendly	50
		5.1.2	A Quality Policy Statement Is a Mandatory Document	51
		5.1.3	Statements of Quality Objectives Are Mandatory Documents	51
		5.1.4	Example	51
		5.1.5	Performance Rate	54
	5.2	The	Quality Manual Controversy	54
		5.2.1	An Issue of Content	54
		5.2.2	Manual's Value	55
		5.2.3	Major Gate	56
		5.2.4	Competitive Advantage	57
		5.2.5	Rationale for an Ineffective Manual	58
		5.2.6	Conclusion	58
		5.2.7	Observed Root Causes	59
	5.3	Strat	egic Framework for the Manual	60
		5.3.1	Unified Approach—Integration of Enterprise Strategy with Quality Management	60
		5.3.2	Unified Business and Quality Policy	60
		5.3.3		63
		5.3.4		64
		5.3.5		65
		5.3.6	Prescriptive Versus Paraphrased Methods	65
	5.4	Cros	s-Functional Manual Action Teams	66
		5.4.1	Section Experts	66
		5.4.2	Ineffectiveness	66
	5.5	SHAL	L Analysis	67
		5.5.1	1	67
		5.5.2		67
		5.5.3	Scope of Effort	69
		5.5.4	Effective Number of SHALLS	69
		5.5.5	Method to Count SHALLS	71
	5.6	Man	ual Section Length	73
	5.7		comitance	73
		5.7.1	Requirement	74
		5.7.2	Training Example of Concomitance	74
		573	Annlication	80

5.8	Nona	pplicability of Specific SHALLS	81						
5.9	Appropriate Detail Level								
	5.9.1	An ISO 9000–Certified Vendor	82						
	5.9.2	Example #1—On Work Environment	82						
	5.9.3	Example #2—On Control of Monitoring							
		and Measuring Devices (Clause 7.6)	83						
	5.9.4	Example #3—On Internal Audits (Clause 8.2.2)	83						
	5.9.5	Suggested Rule	84						
5.10	Leve	el of Detail in Practice	85						
	5.10.1	Summary of Quality Policy Statement Attributes	85						
	5.10.2	Electronic Media Solutions	86						
5.11	Pyra	amid for a Manual	87						
	5.11.1	Quality Policy	88						
	5.11.2	Total Quality Policy	88						
	5.11.3	Elemental Policies and Specific ISO 9001:2000 Requirements	88						
	5.11.4	Quality Policy Statement Examples	88						
5.12	Qua	llity Manual Sequences	89						
	5.12.1	Four Possible Quality Manual Sequences	89						
	5.12.2	Direct Sequences	90						
	5.12.3	Shewhart Sequence	112						
	5.12.4	Operational Sequence	114						
	5.12.5	According to Another Standard's Sequence	117						
	5.12.6	Comparison of Sequences	121						
5.13	Mar	nual Configurations	123						
	5.13.1		123						
	5.13.2	The Stand-Alone Configuration—Model I	123						
	5.13.3	The Integrated Manual Configuration—Model II	126						
5.14	Mul	tidivisional Manuals	129						
	5.14.1	ISO Management Review—Example of Labels	130						
	5.14.2	Summary and Conclusion	131						
5.15	Sect	or-Specific Manuals	132						
	5.15.1	The Accreditation Board Requirements	132						
	5.15.2	Sector-Specific Quality Policy Statements	133						
	5.15.3	Current Good Manufacturing Practices Example	134						
	5.15.4	EN46001/ISO 13485 Example	136						
5.16	Pote	ential Manual Readership	138						
5.17		nual Objectives	140						
Endn			142						

6	Pro	ocess Document Design	. 147
	6.1	The Process Document	147
		6.1.1 The Critical Development of Processes	147
		6.1.2 Process Document Application	148
	6.2	The Trouble with Tier II	151
	6.3	ISO 9000 Quality Plans—Optional	156
		6.3.1 Sounds Like a Process	156
		6.3.2 Device Master Record Technique	158
	6.4	Process Flow Charts	160
	Endi	notes	162
7	Pro	ocedure Design	. 163
	7.1	Some Procedures Are Mandatory Documents	163
	7.2	The Special Case of Work Instructions—Optional	164
	Endi	note	165
8	Fo	rms and the Control of Records	. 167
	8.1	Forms Versus Records	167
		8.1.1 Formats	167
		8.1.2 Analytical Linkage	167
		8.1.3 Bypasses for Forms	168
	8.2	Records Are Mandatory Documents	170
		8.2.1 Records As Historical Documents	174
		8.2.2 Records As Objective Evidence	174
	8.3	The Records Master List	175
		8.3.1 Specific Records	175
		8.3.2 Records Quantity	177
	Endi	notes	177
9	Ot	her Mandatory Documents	. 179
	9.1	SHALL Analysis of Other Mandatory Documents	179
	9.2	The Special Case of Product Characteristics	180
	9.3	Mandatory Organizational Requirements	181
		9.3.1 Mandatory Requirements from the Registrar	181

xii Contents

		9.3.2	Respo	nsibility	y and Ai	uthority	y Req	uired	by th	e Stai	ıdara	ł		182
		9.3.3	Job D	escriptic	ons									184
	9.3.4 Registrar Mandatory Interface Issues												184	
	9.4 Mandatory Effective Implementation Requirement													185
	9.5 Nonmandatory Sensible Requirements													186
	9.6	Specia	al Ma	ndato	ry Req	uiren	nent	S						187
		9.6.1	Custon	ner Con	nplaints	As a N	1and	atory	Requ	ireme	nt			187
	9.6.2 Registrar-Mandated Factored-Items Requirement													187
	9.7	Mand	lated	Stand	ards ar	nd Co	des 1	Requ	ıiren	nent				188
	Endn	otes												189
	Par	t III:	Q	MS I	Imple	eme	nta	itio	n					191
10	The	e Qua	ality	7 Ma	nual	Sco	ре	of	Eff	ort				193
	10.1	Estir	nates											193
	10.2		ussio											194
	10.2	2150	45510											
11	Hul	b Do	cun	ents	s .									197
	11.1	Defi	nitior	1										197
	11.2	Hub	Tem	plate										197
_														
12	Qua	ality	Ma	nual	Issu	es								201
	12.1	Harc	d-Cop	y Mar	nual Iss	sues								201
		12.1.1	Man	ual Cor	ıtrol									201
		12.1.2	Man	ual Rev	risions									201
		12.1.3	Man	ual Dis	tributior	1								202
	12.2	Onli	ne M	anual	Issues									202
		12.2.1	Ітро	ict of th	e Online	Manu	ıal							202
		12.2.2	Key	Factors	;									202
	Endn	otes												204
13	Lea	ders	ship											205
	13.1	ISO	9000	Stewa	ardship	)								205
	13.2				ake Ou		nper	atur	e					207
							-							

	13.3 Tean	n Leaders							211
	13.3.1	Cross-Functional Team	Organization						212
	13.3.2	Organizations Without	Explicit Design or (	Qualit	v-Assi	uranc	e Fun	ıctions	215
	13.3.3	Team Effectiveness							217
	13.3.4	Typical Real-Time Action	on Team Plan						219
	13.4 Certi	fication Audits							220
	13.4.1	You Cannot Fail							220
	13.4.2	Audit Focus							221
	13.4.3	Assessor Role							222
	13.4.4	Structure of the Audit							223
	13.4.5	Audit Plan for Sector-Sp	pecific Requirement	S					225
	13.4.6	Tip of the Iceberg							229
	13.4.7	Dynamics of the Initial	Assessment						229
	Endnotes								230
	Part IV:	QMS Effective	veness .						233
14		gest Change i D 9001:1994  .	n ISO 9001 	:200	00				235
15	Quality	Objectives .							237
	15.1 Qual	ity Objectives Issue							237
	15.2 The	Components of a Qu	uality Objective						238
	15.3 The	Framework for Qual	lity Objectives						241
	15.4 Univ	ersal Quality Object	ives Process						242
	Endnotes	- 1							244
	Part V:	QMS Styles .							245
16	Readers	ship and Form							247
	16.1 Whi	ch Comes First? The	Manual, the Pr	ocess	ses,				
	or th	ne Procedures?							247
	16.2 Par.	4.2.1 of the Standar	d						248
	16.2.1	Linear Estimate							249
	16.2.2	Conclusion							250
	Endnote								250

xiv Contents

17	The .	Adverse Effects of Paraphrasing	. 251
	17.1	The Two Classes of Paraphrasing	251
	1	7.1.1 The Issue	251
	1	7.1.2 Classes	251
	17.2	Paraphrased Class I Characteristics	252
	1	7.2.1 ISO 10013:1995	252
	1	7.2.2 Discussion on the Direct Method of Paraphrasing—Class I	252
	17.3	Paraphrased Class II Characteristics	253
		7.3.1 Discussion of the TOC Approach to Paraphrasing—Class II	254
		7.3.2 Comment	255
	17.4	Conclusions	255
18	Publ	ication Media	. 259
		Selection of a Publication Media (Hard-Copy	
		Electronic)	259
		8.1.1 Media Types	259
		8.1.2 What Should Be the Exact Form of the Documentation System?	260
		8.1.3 Control Issue	260
		8.1.4 An Example of How to Choose What Is Best for You	261
	18.2 Endnote	Generic Numbering System	262 263
19	Writ	ing Style	. 265
	19.1	Contain Paragraphs and Sentences That Are Variable	
		in Length, but Short	265
	19.2	Use Simple Declarative Sentences	265
	19.3	Avoid Redundancy <del>, i.e., repeated material</del>	266
	19.4	Stress the Active Voice (Subject, Verb, Object)	266
	19.5	Clearly Label Section Content	266
	19.6	Build a Useful Table of Contents (TOC)	266
	19.7	Minimize Organizational Jargon, but	
		Keep the Industry Language	267
	19.8	Write To Be Understood, Not to Impress	268
	19.9	Clearly Define Terms	268
	19.10	Effectively Link the Reader to Referenced Documents	268

	19.11 Use Bullets or Equivalent Symbols Wherever Possible		268
	19.12 Avoid Words That End in "ing"		269
	19.13 Use the Spell Checker, and Then Don't Believe It		269
	19.14 Use Graphics Whenever Possible for Tables,		
	Figures, and Flow Charts		269
	19.15 Avoid the Future Tense—Stay with the Present Tense		269
	Endnotes		270
	Part VI: QMS Design Rule Summary		271
20	Issue Resolution		273
	20.1 Proposal		273
	20.2 Benefits		276
	Endnote		278
21	OMS Desumentation and Implementation		
41	QMS Documentation and Implementation Design Rules		279
	21.1 Design Rule Tables		279
	21.2 Closing Invitation to the Case Studies		283
	Endnotes		284
	Part VII: Two Case Studies		285
22	Case Study #1: The Growth Corporation		
	Upgrades to ISO 9001:2000		287
	22.1 Choice Point		287
	22.1.1 Author's Introduction		287
	22.1.2 An Upgrade Decision		288
	22.1.3 The Staff Meets		289
	22.1.4 The Upgrade Assessment		290
	22.2 Application Notes to the Upgraded Quality Manual		291
	22.3 The Upgraded ISO 9001:2000 Quality Manual: Cover Pa	ige	
	and Table of Contents		292
	22.4 Quality Management System (QMS)		295
	22.5 Management Responsibility		306
	22.6 Resource Management		317

	22.7	Product R	ealizatio	n									320
	22.8	Measuren	nent, An	alysi	is, an	d Im	prov	veme	ent				337
23		e Study 9001:20								or l	Jp		349
	23.1	The Phon	e Call										349
	23.2	The Certif	ication I	Plan	from	the	Gro	und !	Floo	r Up			350
		endix <i>I</i> Team L						dsl	nip				355
		endix E cy State			Ex	am	ple	es o	f Q	ual	ity		357
	Eler	endix ( ment 4.2	2.3: C	onti	rol	of I	Doc	um			00		
	Qua	lity Ma	nual R	.eqı	uire	eme	ents	5.					359
	Ann	endix I	) · An 1	Eva	mn	ا ما	of F	'vc	211ء	nt'	c		
		cess Flo											361
	Abo	out the A	Luthor	٠.				•					363
	Inde	ex .											365