



PROFESSIONAL QUALITY
ASSESSMENTS INTERNATIONAL

Making ISO Make Sense™

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PQA International has specialized in working with ISO standards in small and mid-size organizations since 1986, providing training for internal auditors, management and staff. We are accredited to certify to ISO 9001, 13485, 14001 and OSHAS 18001. Our clients include a wide variety of manufacturing, sales, distribution, engineering, and service firms in the US, Canada and overseas.

The following is information to help in your understanding of the requirements of ISO 9001:2015. Let us know if we may be of service in your organization's pursuit of quality!

ISO 9001:2015 "Documented Information" references				
ISO 9001:2015 Requirement	Documented Info	Retained Info	"Determine" Or "Consider"	Business Purpose & Impact
4 - THE ORGANIZATION AND ITS CONTEXT				
4.1 The organization & its context			X	Clarify Identity, markets, and services
4.2 Needs & expectations of interested parties			X	Marketing arenas, regulatory environment, Supplier customer and community impacts
4.3 Defining the Scope of the QMS	X		X	Define services & boundaries
4.4 QMS system and its processes				Determine how to manage quality
4.4.1 Defining the QMS			X	Inputs, outputs, sequences, etc.
4.4.2 Control of documented & retained info	X	X		Commitment to a developing a controlled system to meet objectives
5 - LEADERSHIP				
5.1 Leadership & Commitment				Defining and taking responsibility
5.1.2 Customer focus				Ensure meeting their requirements
5.2 Quality Policy	X			Focus: How we will achieve quality, defines company philosophy and commitments
5.3 Organization roles, responsibilities, authorities				Focus: Who is responsible for what?
6.0 - PLANNING				
6.1 Actions to address Risks and Opportunities			X	Risk-based thinking to plan effectively and avoid sinkholes
6.2 Quality objectives, planning to achieve them	X		X	Strategic and objective-based thinking
6.3 Planning of changes			X	Avoiding unpleasant surprises
7.0 - SUPPORT				
7.1 Resources				Decide on Internal and External needs
7.1.1 General			X	
7.1.2 People			X	Plan staffing, skills, numbers.
7.1.3 Infrastructure			X	
7.1.4 Environment for the operation of processes			X	What physical, psychological, social factors?
7.1.5 Monitoring & measuring resources		X	X	Control of inspection & data collection tools
7.1.5.2 Measurement traceability	X	X	X	Certainty of measurements
7.1.6 Organizational knowledge			X	Retain trade secrets, best practices
7.2 Competence		X		Define, measure, train, increase
7.3 Awareness				Alignment, culture
7.4 Communication			X	Foster alignment
7.5 Documented Information				What and how to document, how to create and effectively control what's needed.
7.5.1 Documented information				
7.5.2 Create & update documented Info				
7.5.3 Control of documented info		X	X	



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8 - OPERATION				
8.1 Operation - Planning & control	X	X	X	Identify needed resources & controls
8.2.1 Customer communication				Emphasize customer service
8.2.2 Determining requirements for products & services			X	Can the organization meet the requirements?
8.2.3 Review of requirements for products & svcs		X		Bid = RFQ + Legal & regulatory?
8.2.4 Changes to requirements for products & services				Amending of docs, informing ppl
8.3.1 Design and development - General				Have a structured method for developing Goods or Services, from Concept to Production, includes reviews, verification of concept and prototype, and control of changes.
8.3.2 Design and development - planning			X	
8.3.3 Design and development - inputs		X	X	
8.3.4 Design and development - controls		X		
8.3.5 Design and development - outputs		X		
8.3.6 Design and development - changes		X		
8.4.1 Control of externally provided processes, products & services - General		X	X	Supply Chain Management
8.4.2 Type and extent of control			X	Supplier qualification and monitoring
8.4.3 Information for external providers				Ensure complete POs, T&C.
8.5.1 Production and service provision - Control	X			Controls for flow of operations
8.5.2 Production and service provision - Identification and traceability		X		Traceability ensures process quality & valid certificates of conformity
8.5.3 Production and service provision - Property belonging to customers or external providers		X		Tracking valuables of others to avoid loss & embarrassment
8.5.4 Production and service provision - Preservation				Ensure proper storage, preservation
8.5.5 Production and service provision - Post-delivery activities			X	Plan & prepare for on- or off-site service, warranty or repairs
8.5.6 Production and service provision - Control of changes		X		Plan for change without chaos
8.6 Release of products & services		X		Final inspection controls Plan shipping / documentation
8.7 Control of nonconforming outputs		X		Ensure rejects don't reach customers
9 - PERFORMANCE EVALUATION				
9.1 Monitoring, measurement, analysis & evaluation		X	X	Data analysis for strategic direction
9.1.2 Customer Satisfaction			X	Knowing customers' thinking
9.1.3 Analysis & evaluation				KPI data-crunching for key areas
9.2 Internal Audit		X		Regular checking on processes
9.3.1 Management review – General				Periodic review of performance and direction, to make adjustments
9.3.2 Management review - Inputs				
9.3.2 Management review - Outputs		X		
10 - IMPROVEMENT				
10.1 Improvement - General			X	An ongoing eye on ways to grow, increase effectiveness and keep employees engaged.
10.2 Nonconformity and corrective action		X		
10.3 Continual Improvement				