

# **ISO 9001:2000 - A Process Interaction Matrix - A Case Study**

By Mark Kaganov

## **Abstract**

This article presents a case study of development and implementation of a process interaction matrix to address one of the requirements of ISO 9001:2000 standard [1]. Going beyond a simple case study model, this tool may also be used for quality management systems (QMS) compliant with ISO 13485:2003 standard [2]. This article will be of interest to companies developing or improving their QMS for such standards.

## **Introduction**

One of the new requirements of ISO 9001:2000, specified in the paragraph 4.2.2 c), requires a company to develop a quality manual that, among other attributes, shall contain “a description of the interaction between the processes of the quality management system.” Through my experience, as a professional auditor, with dozens of companies around the world, I found that very few businesses had developed practical approaches to address this requirement. Attempts to document process interactions range from busy and hard to read flow charts to establishing cross-reference tables in the quality manual. I observed one of the best tools to address process interaction requirement at Quality Works, a small on-line publishing company.

## **Initiation of the project**

Quality Works, a small Internet-based publishing company, has set a goal to establish compliance with ISO 9001:2000 standard. The Management Team assigned the company’s Business Manager to develop and implement documentation to address new requirements of the standard. While most of the new requirements were simply addressed through preparation of the corresponding procedures and work instructions, documentation of the interaction of the processes created some difficulties. Attempts to document interaction of processes through traditional flow-chart resulted in a hard to read busy document that did not impress the management team.

## **Brainstorming**

To address this issue, the management group conducted a brainstorming session to search for a new tool. The group determined that there were two types of the processes: processes related to product realization and processes related to the management system as follows:

Business management processes:

- Documentation management
- Management review
- Internal audit program
- Non-conformity and Corrective & Preventive Action (NC-CAPA) System
- Communication
- Resource management
- Record management
- Information technology

Product realization processes:

- Market analysis
- Product design
- Verification
- Validation
- Product release
- Order processing
- Product delivery
- Customer satisfaction
- Continual improvement

## **Identification of process interactions**

Analyzing system and product realization processes, the management team concluded that virtually all system processes are interrelated. For example, management review may receive inputs from corrective actions, communication, internal audits, etc. Internal audit process receives inputs from all processes within the company and provides feedback or input into all those processes.

Product realization process was found to be more linear than system processes. For example, results of the market analysis initiate product design. Product design leads to verification. If verification is successful, validation of the product takes place. Validation of the product results in product release and finally communication regarding availability of the product. Customer satisfaction and continual improvement close this sequence with a possibility of providing inputs into Product delivery, Order processing, Product release, etc.

To document process interactions, the company elected two tools. The first, top-level definition of the process interaction was documented in the Process Interaction Matrix shown in Figure 1. The second tool was a well-known technique of flow-charting for those processes that required graphical illustration.

## **Afterword**

Use of the Process Interaction Matrix at Quality Works proved that it is a helpful concise method of defining and documenting interaction of processes for an ISO 9001:2000 quality management system. Based on our experience, we also realized that the same matrix might be successfully used for other standards requiring definition of the interaction of the processes, such as ISO 13485:2003, ISO/TS 16949 [3] and others.

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## **About the author**

Mark Kaganov is a Director of Operations with Quality Works. He is an IRCA certified QMS lead auditor and RAB certified EMS lead auditor. He earned a master's degree in design and technology of electronic equipment from Moscow University of Radio-Electronics and Automation.

## **References**

- [1] ISO 9001:2000 Quality management systems – Requirements
- [2] ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes
- [3] ISO/TS 16949 Quality management systems – particular requirements for the application of ISO 9001:2000 for automotive production and relevant service part organizations

**Figure 1 - Process Interaction Matrix**

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		Processes Type >		System processes									Product realization																	
		Process No. >		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19								
Process Type	Process No.	Quality-Works.com Interaction between the processes matrix																												
			Documentation management	NC-CAPA	Management review	Internal audits	Communication	Record management	Resource management	Information technology			Market analysis	Product design	Verification	Validation	Product release	Order processing	Product delivery	Customer satisfaction	Continual improvement									
System processes	1	Documentation management		∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧									
	2	NC-CAPA			∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧								
	3	Management review				∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧							
	4	Internal audits					∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧						
	5	Communication						∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧					
	6	Record management							∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧				
	7	Resource management								∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧			
	8	Information technology									∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧		
	9											∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	
Product realization	10	Market analysis										∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	
	11	Product design												∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	
	12	Design verification														∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	
	13	Design validation															∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧
	14	Product release																∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	
	15	Order processing																	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	∨	∧
	16	Product delivery																		∨	∧	∨	∧	∨	∧	∨	∧	∨	∧	
	17	Customer satisfaction																			∨	∧	∨	∧	∨	∧	∨	∧	∨	∧
	18	Continual improvement																				∨	∧	∨	∧	∨	∧	∨	∧	∨
19																														

**Legend:**

		5	6	7
1	Process	∨		
2	Process		∧	
3	Process			∨ ∧

- Process No.
- Process 1 provides input into the process 5
- Process 6 provides input into the process 2
- Process 3 provides input into the process 7 and **MAY** receive input from process 7