

Supplier Auditing Beyond the Standards

Mark Durivage, ASQ Fellow
Managing Principal Consultant
Quality Systems Compliance LLC

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Supplier Audits



ISO 9001:2015

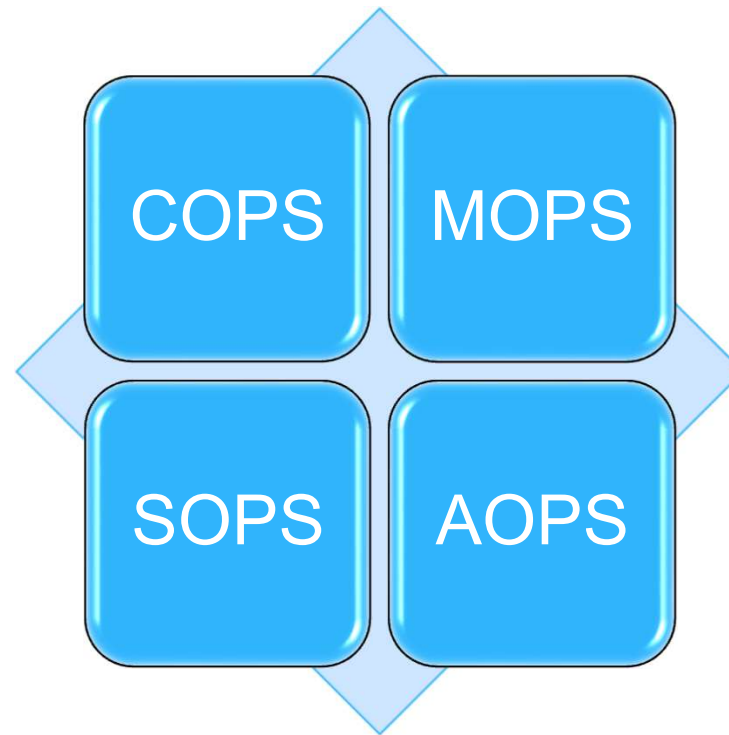
- 1 Scope
- 2 Normative references
- 3 Terms and definitions
- 4 Context of the organization
- 5 Leadership
- 6 Planning
- 7 Support
- 8 Operation
- 9 Performance evaluation
- 10 Improvement

ISO 9001:2015





QMS Processes



PLAN				DO	CHECK	ACT
4. Context of the organization	5. Leadership	6. Planning	7. Support	8. Operation	9. Performance evaluation	10. Improvement
4.1 Understanding the organization and its context	5.1 Leadership and commitment	6.1 Actions to address risks and opportunities	7.1 Resources	8.1 Operational planning and control	9.1 Monitoring, measurement, analysis and evaluation	10.1 General
4.2 Understanding the needs and expectations of interested parties	5.2 Quality policy	6.2 Quality objectives and planning to achieve them	7.2 Competence	8.2 Determination of requirements for products and services	9.2 Internal audit	10.2 Nonconformity and corrective action
4.3 Determining the scope of the QMS	5.3 Organizational roles, responsibilities and authorities	6.3 Planning of changes	7.3 Awareness	8.3 Design and development of products and services	9.3 Management review	10.3 Continual improvement
4.4 QMS and its processes			7.4 Communication	8.4 Control of externally provided products and services		
			7.5 Documented information	8.5 Production and service provision		
				8.6 Release of products and services		
				8.7 Control of nonconforming process outputs, products and services		

8.4 Control of externally provided processes, products and services

- ensure that externally provided processes, products and services conform to requirements
- determine the controls to be applied to externally provided processes, products and services
- determine and apply criteria for the **evaluation, selection, monitoring of performance, and re-evaluation** of external providers
- determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements

Other Supplier Audit Considerations



- * Change Notification
- * Quality Agreements
- * Contingency Plans
- * Capacity Utilization
- * Capability Assessment
- * Effectiveness
- * Efficiency

Change Notifications



Quality Agreements



Contingency Plans



Capacity Utilization



Capability Assessment



“Effectiveness is doing right things”



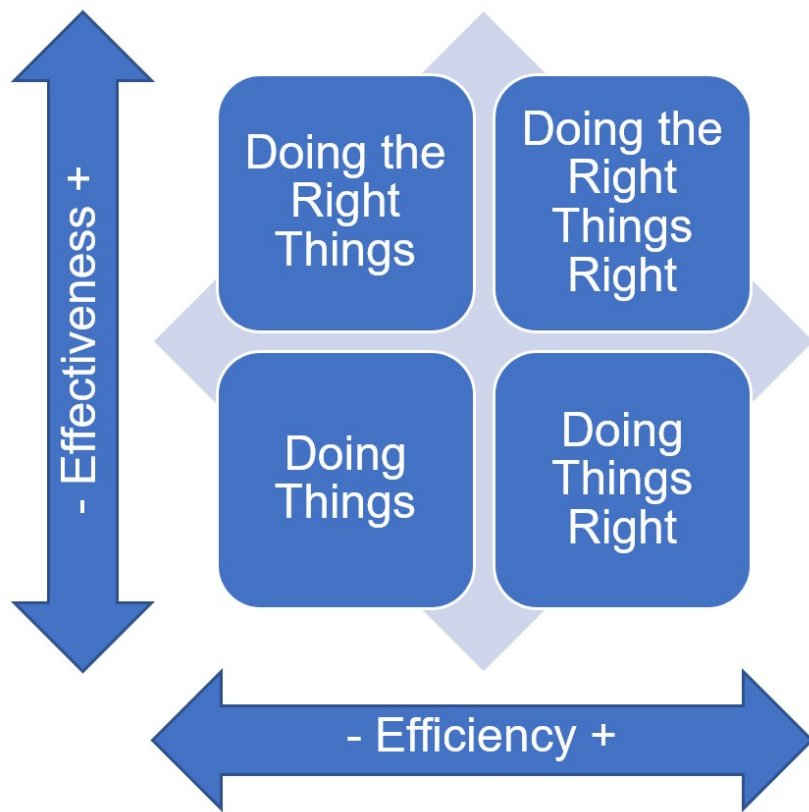
- Long term profits
- Sustainable growth
- Market performance

“Efficiency is doing things right”

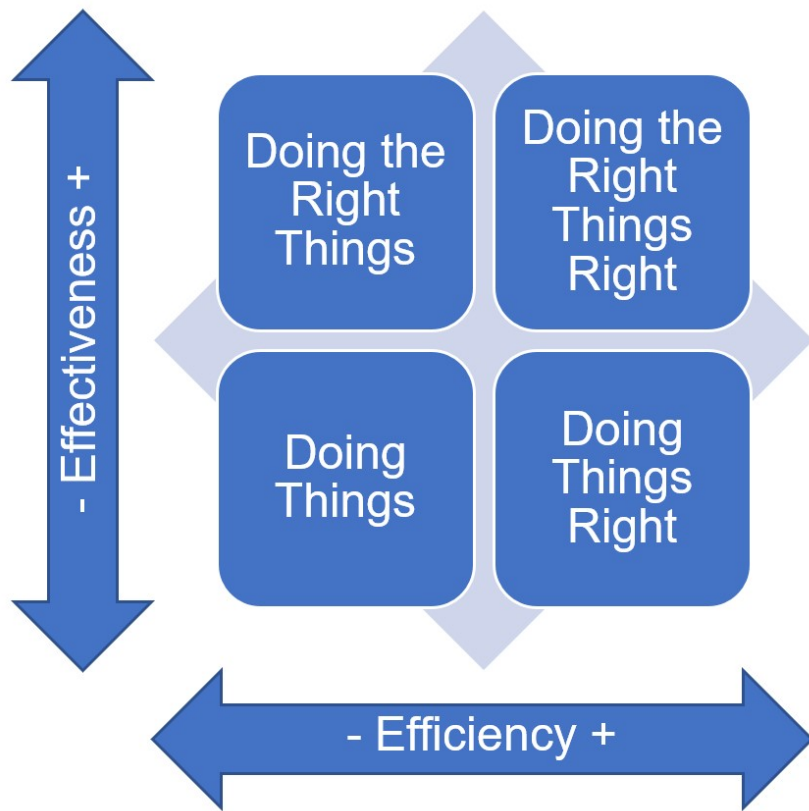


- Minimizing costs
- Short term goals
- Improving productivity

Effectiveness vs Efficiency



Effectiveness vs Efficiency



Summary

Supplier Auditing *should* consider:

- * requirements of standards and/or regulations
- * supplier capability
 - activities it can do (expertise)
 - capability of those activities
- * supplier capacity
- * contingency plans
- * effectiveness
- * efficiency

Wrapping Up



I cannot emphasize enough the importance of documenting the tools and methods used for the evaluation, selection, monitoring of performance, and re-evaluation of suppliers. Best practice includes providing rationale for your organization's supplier management program strategy.

The tools, methods, and strategies discussed in this presentation can and should be utilized based upon industry practice, guidance documents, regulatory, and statutory requirements.

Questions





Quality Systems Compliance LLC

mark.durivage@qscompliance.com

www.qscompliance.com

419-265-2862

www.linkedin.com/in/markdurivage