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Processes and the QMS

Presented by:

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Agenda

- The Process Approach
- Process Sequence & Interaction
- SQA Comprehensive Requirements Workbook (CRW)
- Internal Audits
- Summary
- Questions

Applies to ALL ISO based QMS

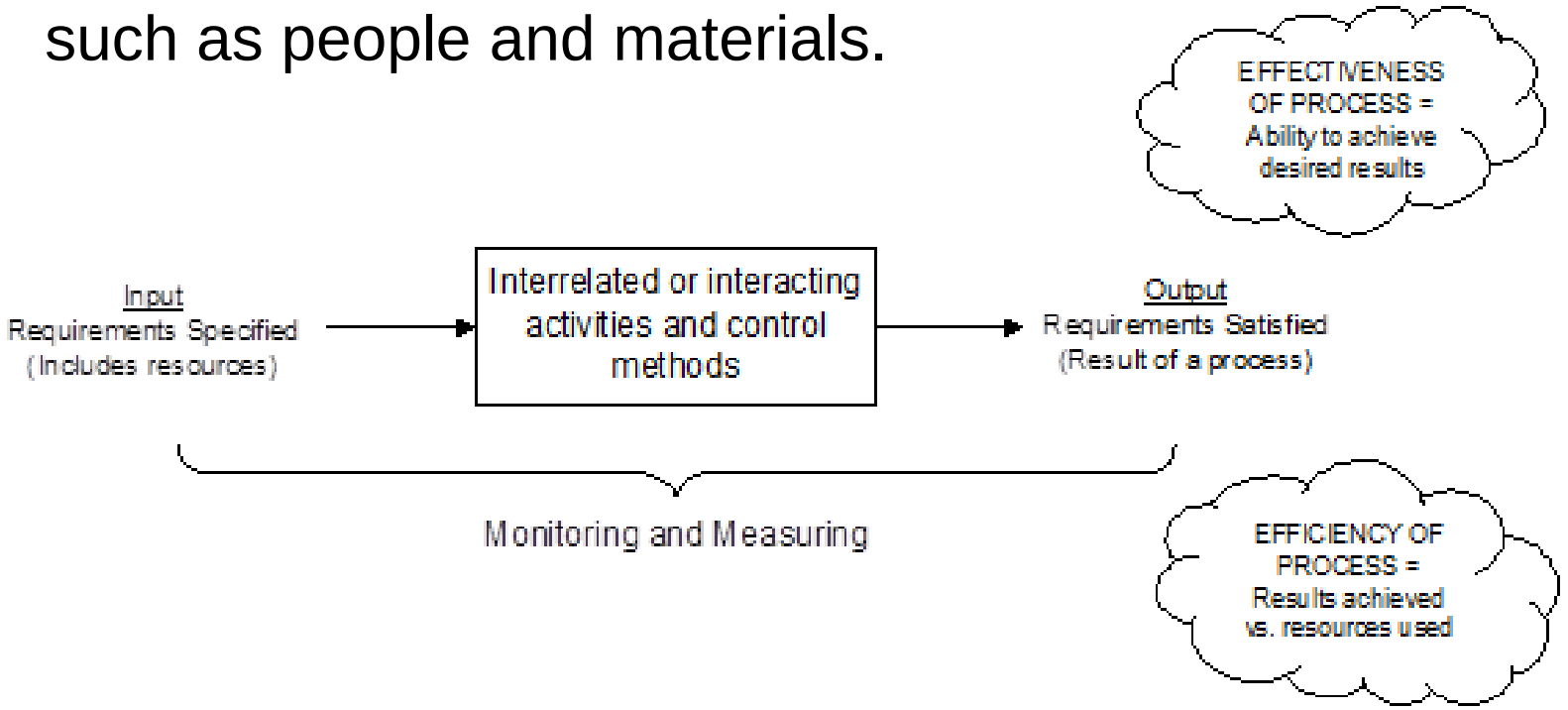
For Example:

- ISO 9001
- ISO/TS16949
- AS9100
- SN9001
- ISO 13485

The Process Approach

What is a Process

A “Process” can be defined as a “Set of interrelated or interacting activities, which transforms inputs into outputs”. These activities require allocation of resources such as people and materials.



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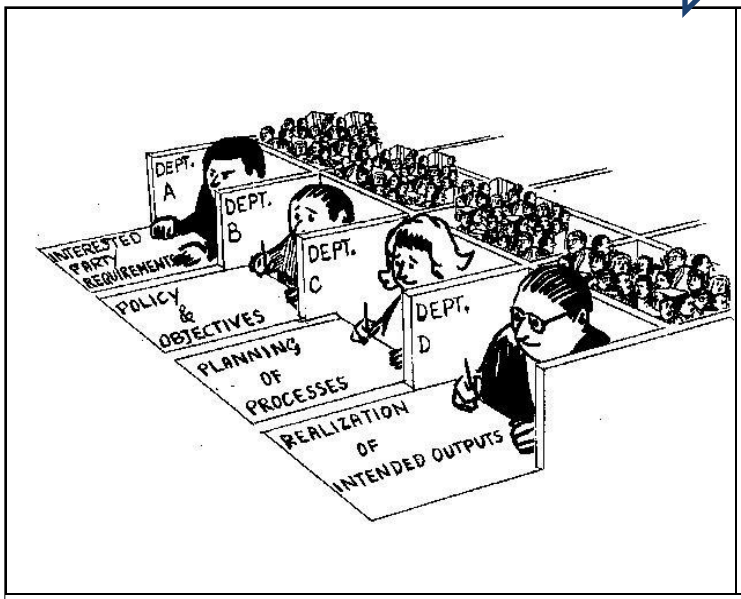
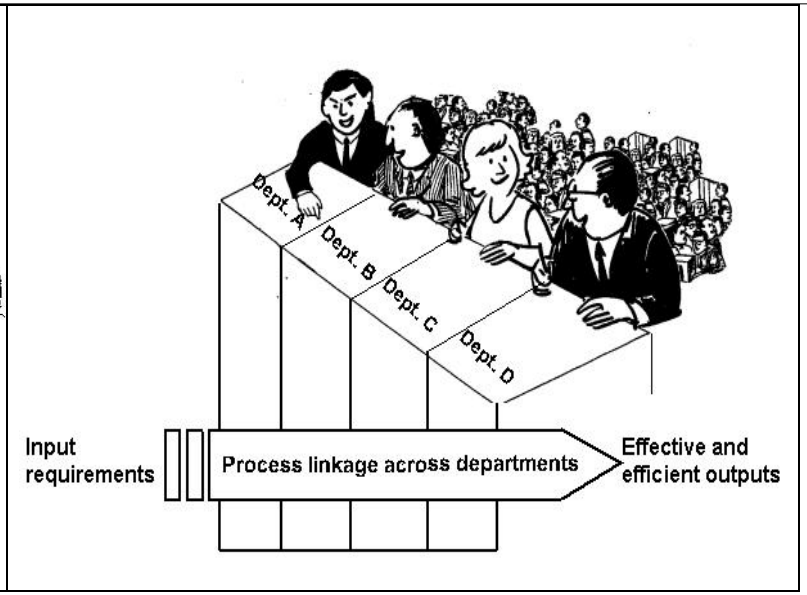
Understanding the process approach

- A process approach is a powerful way of organizing and managing how work activities create value for the customer and other interested parties.
- Problems that occur at the process interfaces are often given less priority than the processes themselves.
- This leads to little or no improvement to the interested party, as actions are usually focused on the functions, rather than overall benefit to the organization.

Vertical versus Process Approach

- The process approach introduces horizontal management, crossing the barriers between different functional units and unifying their focus to the main goals of the organization. It also improves management of process interfaces ⇒ System Approach





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Benefits of the process approach

- Integration and alignment of processes (interfaces) to enable achievement of planned results.
- Ability to focus effort on process effectiveness and efficiency.
- Provision of confidence to customers, and other interested parties, about the consistent performance of the organization.
- Transparency of operations within the organization.

Benefits of the process approach (cont'd)

- Lower costs and creates shorter cycle times, through the effective use of resources.
- Improved, consistent and predictable results.
- Provision of opportunities for focused and prioritized improvement initiatives.
- Encouragement of the involvement of people and the clarification of their responsibilities.

Process Approach Summary

- A major advantage of the process approach, when compared to other approaches, is in the management and control of the interactions between these processes and the interfaces between the functional hierarchy of the organization

Process Approach Summary

- The purpose of the process approach is to enhance an organization's effectiveness and efficiency in achieving its defined objectives.

Process Sequence & Interaction per ISO 9001

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Definitions- see section 4.1

- ISO 9001:2008 section 4.1….
  - a: ***determine*** processes and application throughout the organization

  “determine” means “move forward, impel, to use”, the intent is that top management will use the processes to operate the business.

Definitions- see section 4.1

- ISO 9001:2008 section 4.1….
  - b: **determine** the sequence and interaction of these processes

The sequences of the processes must be described in the Quality Manual (4.2.2.c) “description of the interactions between the processes”.

Definitions- see section 4.1

In a nut shell section 4.1 requires the following:

- Processes defined

  Organizations define processes; not auditors!

- Sequence of processes
- Interactions of processes (inputs/ outputs)
  - Outsourced processes, sub-contracted processes, support activities (may be an additional location), etc.

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Definitions- see section 4.1

- ISO 9001:2008 section 4.1….

  Depth of processes should be based on:

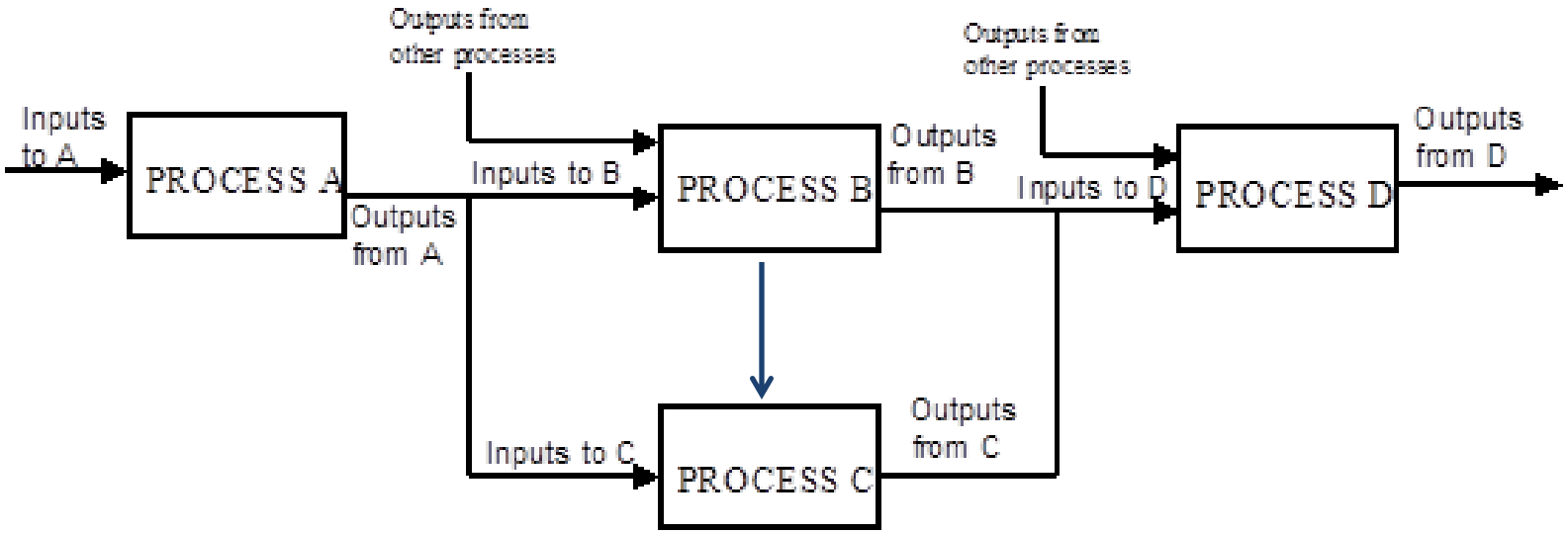
  – Customer and applicable regulatory/ statutory requirements
  – Nature of the organizations activities
  – Overall business strategy

Process Sequence & Interaction Importance

- Sets the framework/definition for your entire system
- Drives your process approach
- Sets your organization up to get ALL the value from the process approach
- Clarifies audit path for Internal Audits

Process Sequence & Interaction Example

- Process A- Management Activities
- Process B- Resource Management
- Process C- Product Realization
- Process D- Measurement & Monitoring



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SQA Expectations

SQA expects to see a process model that explains the key processes of the business and how each relates and links to the others. The depth of this model is up to the organization to choose, however it must be based on several factors.

The SQA CRW

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CRW Example

Basic ISO 9001 System Requirements (Also applies to ISO/TS 16949)		LIST of					
		Business & Program Development	Management	Manufacturing/ Production	Testing	Design	Pruchasing & Supply Chain
4.1	Quality management. system – general requirements		x	x			
4.2.1	General – documentation requirements		x				
4.2.2	Quality manual		x				
4.2.3	Control of documents	x	x	x	x	x	x
4.3	Configuration Management (AS9100 Only)						
4.2.4	Control of records	x	x	x	x	x	x
5.1	Management commitment		x				
5.2	Customer focus	x	x	x	x	x	
5.3	Quality policy	x	x	x	x	x	x
5.4.1	Quality objectives		x				
5.4.2	Quality management system planning		x				
5.5.1	Responsibility & authority		x	x			
5.5.2	Management representative		x	x			
5.5.3	Internal communication		x	x			
5.6.1	Management review – general		x				
5.6.2	Management Review – review input		x	x			
5.6.3	Management Review – review output		x				
6.1	Provision of resources	x	x	x			
6.2.1	Human resources – general		x				
6.2.2	Human Resources – competence, awareness and training		x				
6.3	Infrastructure		x	x			
6.4	Work environment		x	x			
7.1	Planning of product realization	x	x	x		x	
7.2.1	Determination of requirements related to the product	x				x	
7.2.2	Review of requirements related to the product	x			x	x	
7.2.3	Customer communication	x				x	
7.3.1	Design and development – planning			x		x	
7.3.2	Design and development – inputs			x		x	
7.3.3	Design and development – outputs			x	x	x	
7.3.4	Design and development – review			x		x	
7.3.5	Design and development - verification			x	x	x	
7.3.6	Design and development – validation			x	x	x	
7.3.7	Design and development – control of changes			x		x	
7.4.1	Purchasing process			x			x
7.4.2	Purchasing information			x			x
7.4.3	Verification of purchased product			x			x

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Processes versus Sub-processes

AS 9100 QMS Processes		Realization					Improvement				Management							
		Product Realization Planning	Design Control	Purchasing	Risk Management	Process Control	Audits	Preventive Action and Continual Improvement	Corrective Action	Customer Satisfaction	Management Review	Human Resources	Measuring Devices	Document Control	Record Control	Non-Conforming Product	Customer Specific Requirements	Configuration Management
4.1	General Requirements										X							
4.2.1	Documentation Requirements - General										X			X				
4.2.2	Quailty Manual										X			X				
4.2.3	Control of documents													X				
4.2.4	Control of records														X			
5.1	Management commitment										X							
5.2	Customer focus									X	X						X	
5.3	Quality policy										X							
5.4.1	Quality objectives										X							
5.4.2	QMS Planning										X							
5.4.3	Safety Objectives ***(9110 only)***																	
5.5.1	Responsibility & authority ***(including 5.5.1.1-2 for 9110 only)***																	
5.5.2	Management representative										X							
5.5.3	Internal communication										X							
5.6	Management Review										X							
5.6.1	General										X							
5.6.2	Review Input										X							
5.6.3	Review Output																	
5.7	Safety Policy ***(9110 only)***										X							
6.1	Provision of resources										X							

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SQA CRW

The CRW's purpose is to ensure that you have identified where each element is addressed within your QMS (required for some standards).

The SQA CRW (Comprehensive Requirements Workbook) provides the relationship between the processes and the requirements of the standard; however it **DOES NOT** show the interaction of the processes.

SQA Expectations

- SQA expects the processes identified on the CRW to MATCH the processes you identify on YOUR Sequence & Interaction document.
- It is critical that you update the CRW to reflect any updates to YOUR Sequence & Interaction document.
  - Failure to do so may cause improper planning

Monitor, Measure & Analyze

Definitions- see section 4.1

- ISO 9001:2008 section 4.1….
  - e: monitor, measure and analyze these processes

Each process should have established, measurable objectives (5.4.1)

Additional reference material on The Concept and Use of the Process Approach for Management Systems can be found at www.bsi.org.uk/iso-tc176-sc2

26

SQA Expectations

All identified processes need to be monitored, measured (as applicable) and analyzed for needed improvement

- Critical for product realization processes
- Optional for support/ management processes (HR, accounting, administration, etc.)

Monitor, Measure & Analyze

When your organization defines a “process” then it shall be monitored for effectiveness (4.1, 8.4, 8.2.3).

Some examples of monitoring a process includes:

- Scrap rate
- Efficiency
- Time/temperature
- Delivery
- Inspection
- First pass yield/ first time quality

SQA Expectations

SQA expects to see a processes monitored, measured and analyzed on some specified frequency. The depth of this process is up to the organization to choose, however it must be based on several factors.

Depth of this process should be based on:

- Customer and applicable regulatory/ statutory requirements
- Nature of the organizations activities
- Overall business strategy (meeting goals/objectives)

Monitor, Measure & Analyze

A system should be used to gather data, which can be analyzed to provide information about process performance and to determine the need for corrective action or improvement.

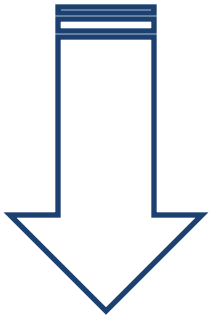
Monitor, Measure & Analyze

- Based on the results of the monitored, measured and analyzed, action should be taken to:
  - Correct the process (corrective)
  - Improve the process (preventive)

  This may be evidenced through allocation of resources (people, equipment, methods, etc.), corrective actions being taken, preventive action being taken

Next Steps

Now that your processes and interactions are defined, process measurements and appropriate actions are occurring…. Now what?



Internal Audits

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Internal Audits

Benefit from Internal Audits

- Audit schedule needs to be process based, not clause based
- Audit schedule needs to be based on the status and importance of processes (how are they doing meeting the objectives).

- Please attend the class “Effective Internal Auditing” presented by Paula Fyda & Steve Sabo for additional information on Process Audits

34

FAQ

- We get asked this question a lot…. Do my internal audits have to be process based?
  - Not a requirement of the standard, however, why would you not want to do Process Audits?

Summary

Summary

- These should MATCH
  - YOUR Sequence & Interaction document
  - CRW
  - Internal Audit Schedule

The purpose of the process approach is to enhance an organization's effectiveness and efficiency in achieving its defined objectives.

37

Parting Thoughts

- When evaluating your QMS, there are four basic questions that should be asked for every process
- Is the process identified and appropriately defined?
- Are responsibilities assigned?
- Are the processes implemented and maintained?
- Is the process effective in achieving the required results?

Questions?

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