

ISO 9001:2015 and beyond: Using The Standard to develop work systems for 21st Century

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By

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How ISO 9001:2015 standard helps improve organizational performance

- Productivity as an economic performance measure

Region	Labor Productivity (value add per hour)
Sub-Saharan Africa	USD 5.32
East Africa	USD 3.10
Russia, Central Asia and Southeast Europe	USD 23.94
Middle East & North Africa	USD 30.59
Latin America	USD 19.28
Other Developing Asian Countries	USD 10.64
Other Mature Economies	USD 47.88
Europe	USD 46.55
World Average	USD 19.29

Technology as driver of productivity

- Information Technology has made it possible to make information available to wider users, removed geographical space as a limitation and hence made us achieve more using fewer resources
- Other technologies have affected outputs of organizations significantly through time usage effectiveness, material usage effectiveness and in other ways
- Management technology concerns effective deployment of the other technologies and effective utilization of work resources to achieve greater value perception by consumers and greater productivity.

Your organization and its environment



The turbulent environment requires constant adjustment and realignment of the elements of this ship. Else, it will be disabled by lightening strikes and sea storms.

ISO 9001:2015 standard is built around systems thinking

Change in thinking is required

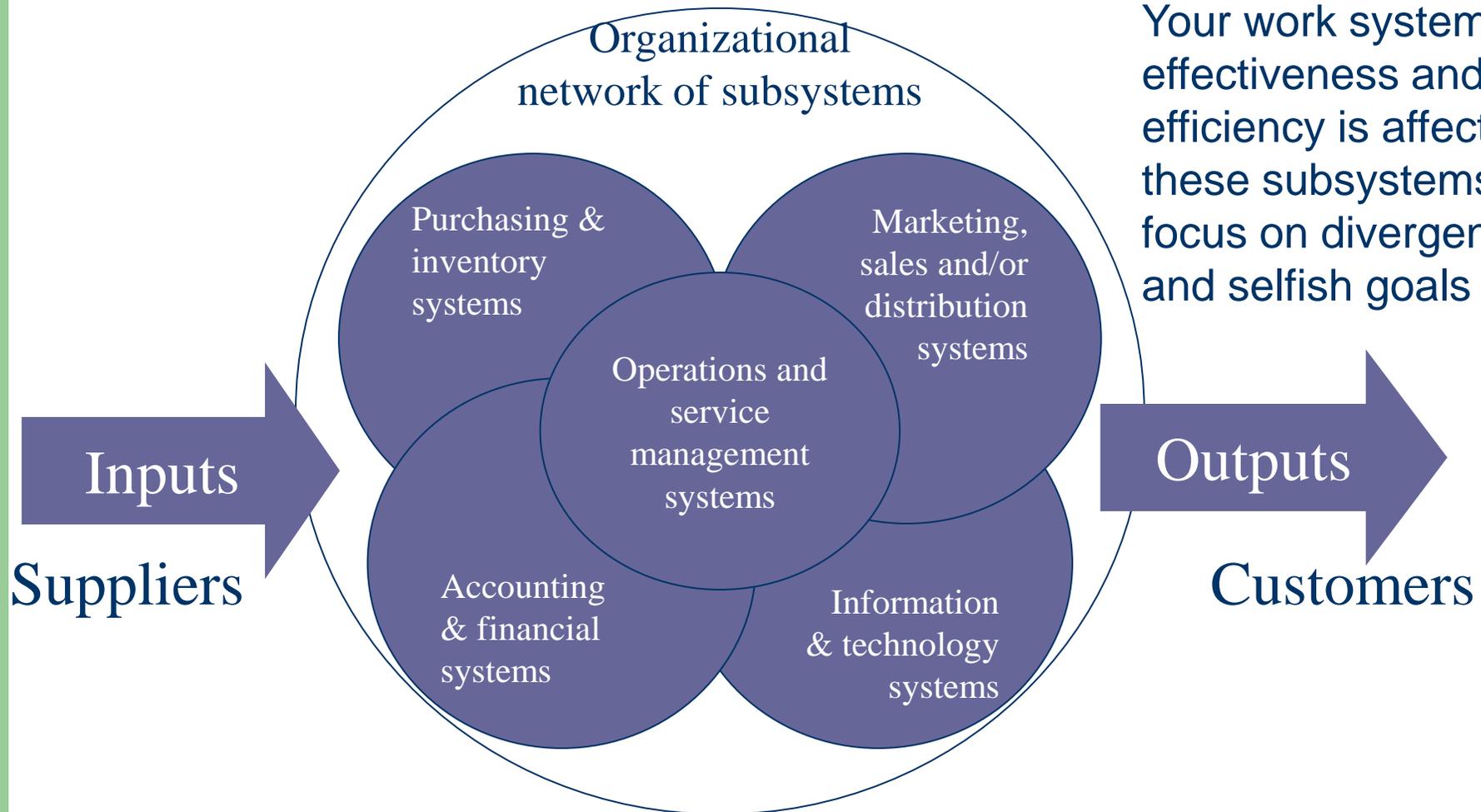


- It is important to note that before publication of a standard compromises often have to be made in order for a standard to be accepted by at least 75% of the member bodies.
- The standard lists 7 principles and Systems Approach to management IS NOT ONE OF THEM.
- Yet the Title of the standard is “Quality Management **System**” standard
- The “System” Signifies Systems thinking – which signifies a paradigm shift and systems approach is embedded on this thinking.
 - Clauses 4.1 to 4.4 of ISO 9001:2015 starts with the context just like crew of the ship in slide 4 would take account of lightening, storms, the nature of their cargo and destination

What Change in thinking entails

Old thinking	Systems Thinking
An individual delivers quality	Processes deliver quality
People are part of the process	People design and improve processes
Process requires external control	Workers who run the process control it
Managers have to control what people do	Managers obtain commitment of workers
Measures of profitability with no link to customer are used	Measures should be linked to customer value

Your Organizations as a Network of Subsystems



Your work system effectiveness and efficiency is affected if these subsystems focus on divergent and selfish goals

Management System is made up by set of procedures, structures and systems to maintain fit between sub-systems and with external environment

What to avoid when using ISO 9001:2015 standard



- Having a Quality Management System that is designed
 - For auditors
 - By auditors and
 - With auditors
- Perceiving the standard as addressing issues separate from the business of managing the organization
 - When documentation focuses on ISO 9001:2015 rather than organizational core operations hence necessitating parallel operating systems
 - Failure to take the standard as a vehicle for transfer of management technology intended to help achieve organizational goals

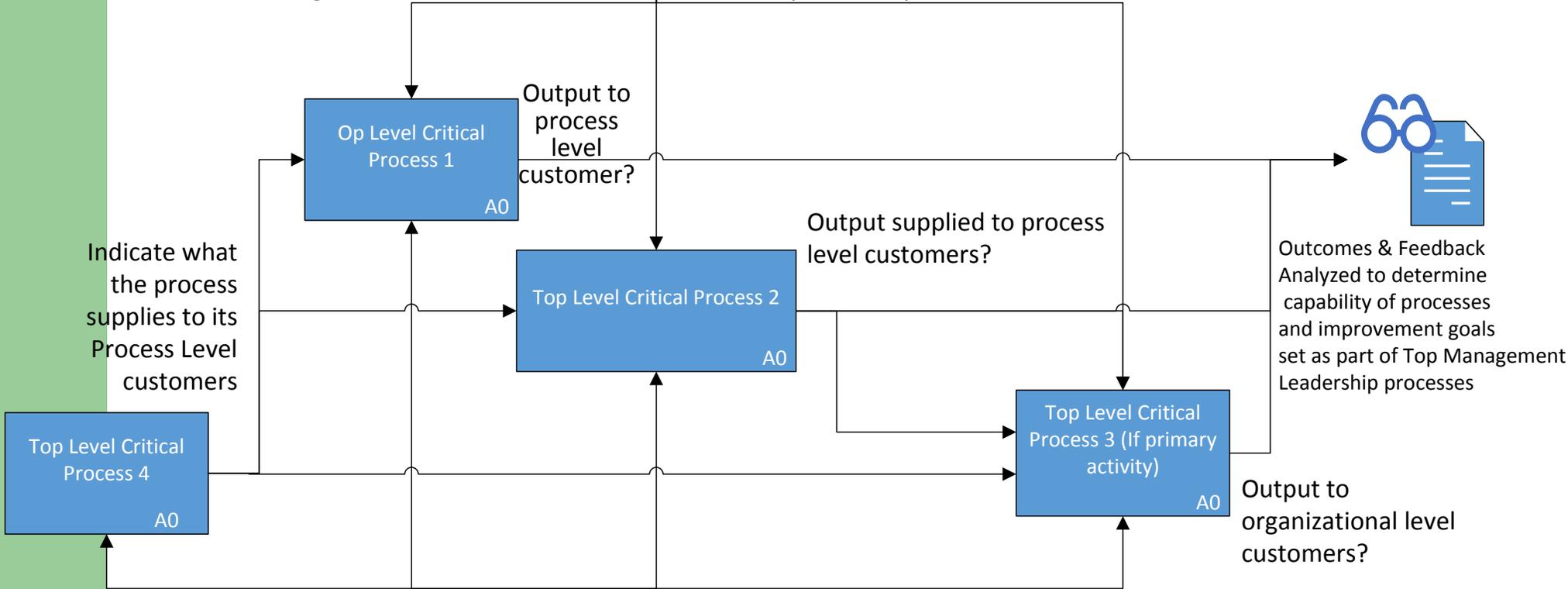
Designing Effective Work system

- Actions shall be guided by principles of:
 - Systems approach
 - Focus on organization's purpose, strategic direction and intended result when determining and reviewing issues in the external and internal contexts (ISO 9001:2015 clause 4.1)
 - Monitor and review information about organization's interested parties and their relevant requirements so as to keep alignment with the goals (ISO 9001:2015 clause 4.2)
 - Determine the boundaries and establish the system scope (ISO 9001:2015 clause 4.3)
 - Determine the processes needed, the inputs required and the outputs expected from them, and their application throughout the organization (ISO 9001:2015 clause 4.4).

Designing Effective Work system-2



Organizational Level customer and interested parties requirements,



Regulatory and Statutory Requirements as well as requirements to achieve strategic objectives

CONTROLS

Standards published by regulators

Acts of parliaments

Applicable Professional Associations Guidelines

Current Strategic Plan

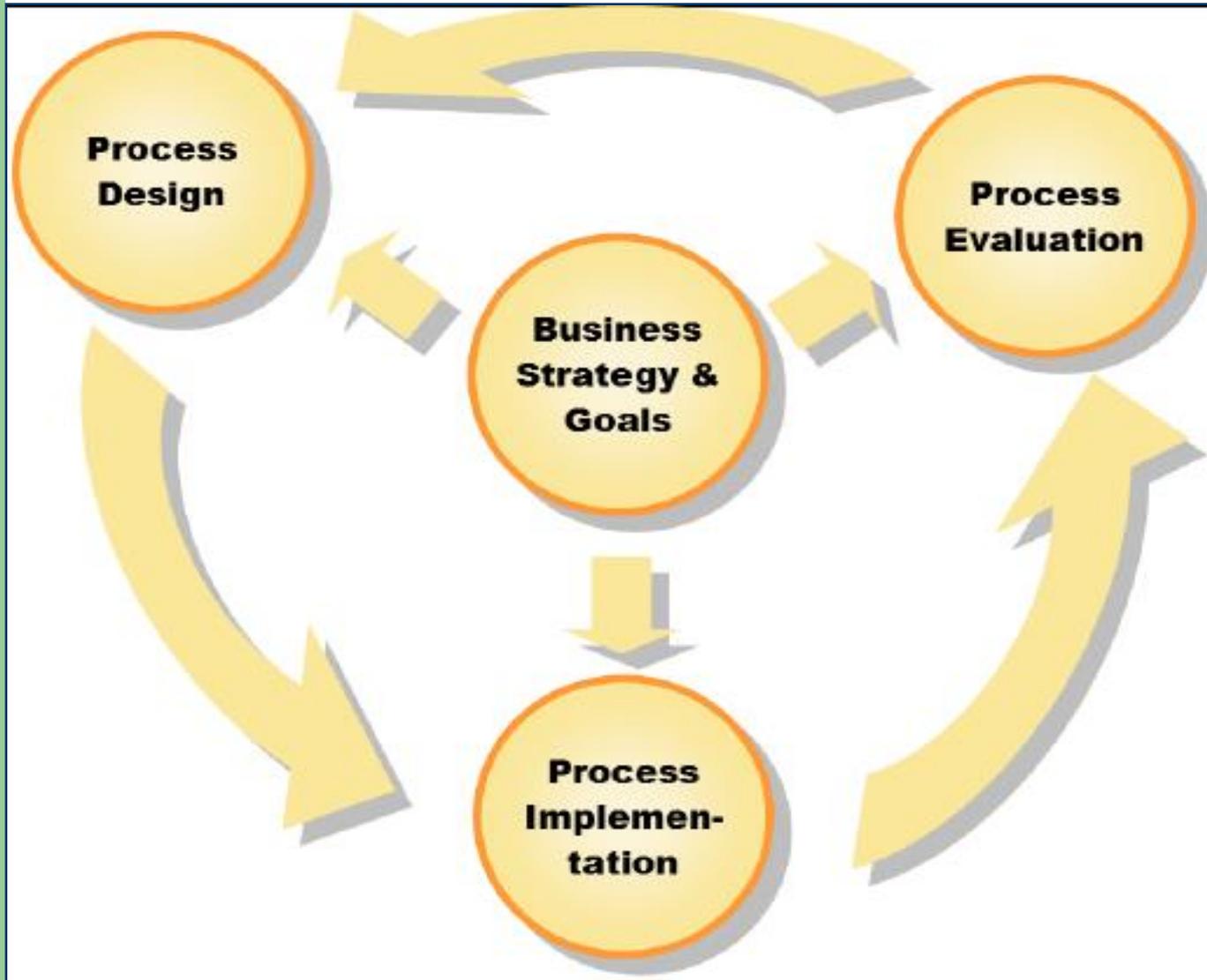
Safety and Health Act and Environmental Protection Laws

Designing Effective Work system 3



- Actions shall be guided by principles of:
 - Process Approach
 - Activities necessary to obtain a desired results are systematically defined, process performance measured and analyzed and the capability of key processes determined (ISO 9001:2015 clause 8 and consistent with 4.4.1 a, b, and c);
 - Control of the processes in accordance with the criteria and retention of documented information (ISO 9001:2015 clause 8.1d & e);
 - Customer focus (ISO 9001:2015 clause 5.1.2)
 - Customer & regulatory requirements determined
 - Risks and opportunities that can affect conformity determined
 - Focus on consistently meeting requirements

A 4-Phase Integrated Work-systems and Process Improvement



Support Resources Required:

- Work systems consulting services

● Strategy Mapping

- Vision statement: does your organization's vision statement capable of materializing into a climate and processes that focus prevention instead of correction, and capable of producing products and services that are fit for purpose and satisfies the customer's stated and implied needs?
- Have you determined the long term goals to be achieved?

● Metric Framework Development

- How would you know the goals are being achieved?
 - Performance measures

● Identification of Critical Success Factors

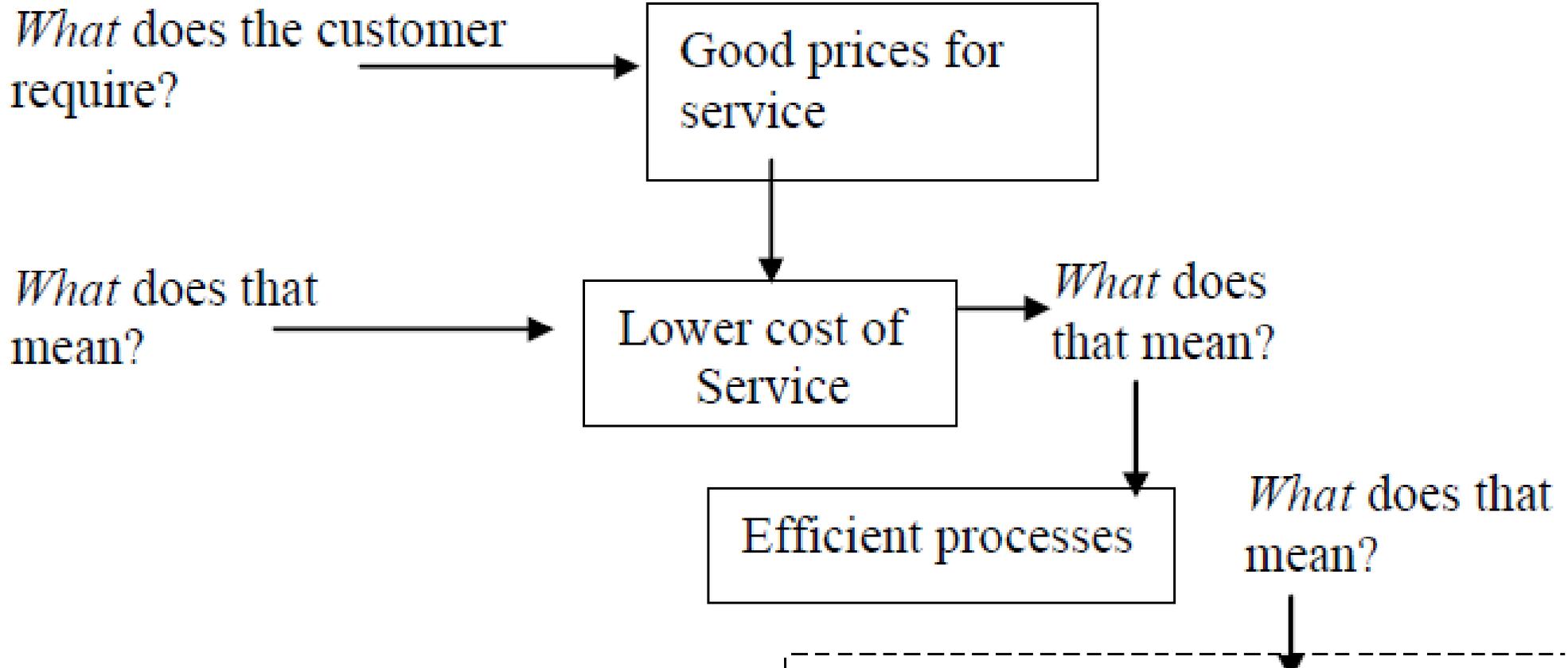
- What must be done exceedingly well to achieve long term goals?

- **Metric Framework Development**

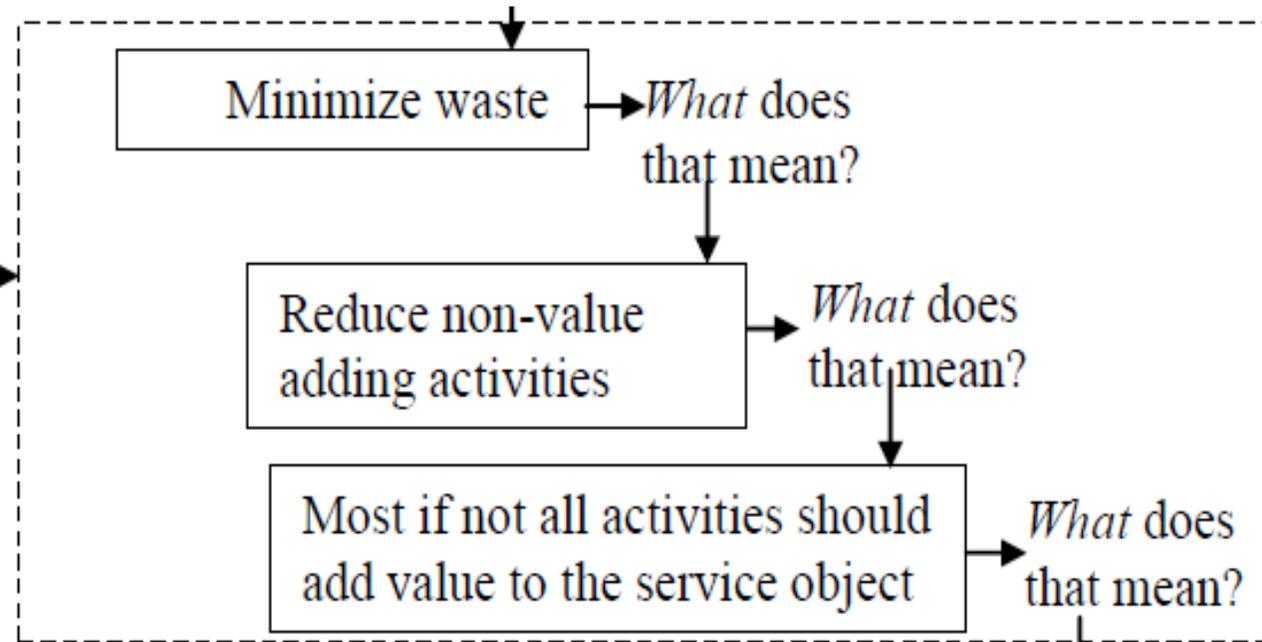
- How would you know the goals are being achieved?
 - Use performance measures
 - Quantitative measures of process performance must be relevant to the customer
 - Use Five Whats Framework to identify critical success factors and organization's internal process specifications for each customer requirement.

Business Strategy & Goals phase: Critical Success Factors and Metrics Development

Requirement 1: Good price



Makes up the 5th "what"?



The question:

What internal measures do we have or can we create that will help us monitor how well we have achieved the capability to meet the requirement of good price?

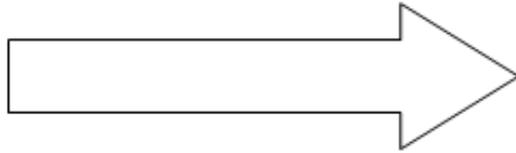
Cost performance metrics/indicators

1. Ratio of value adding (operating) steps to non-value adding steps.
2. Ratio of value-adding costs to total costs
3. Ratio of value adding cycle time to non-value adding cycle time

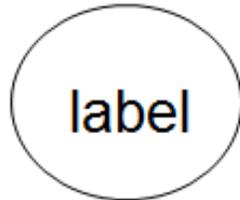
Process Design phase

- A “Process” any activity or group of activities that takes an input, adds value to it by changing it in some way, and gives out an output to an internal or external customer
 - There can be no product or service without a process and a process cannot exist unless there is a product or service to be produced
- Process Design starts with “As-Is” modelling and analysis to identify improvement opportunities
 - Build in intelligence using process symbols
 - Analyse the process for effectiveness

Process Design phase: Process symbols



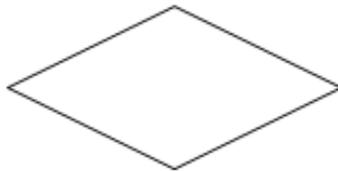
- * Movement of output object between locations



- * Inspection



Process of several activities



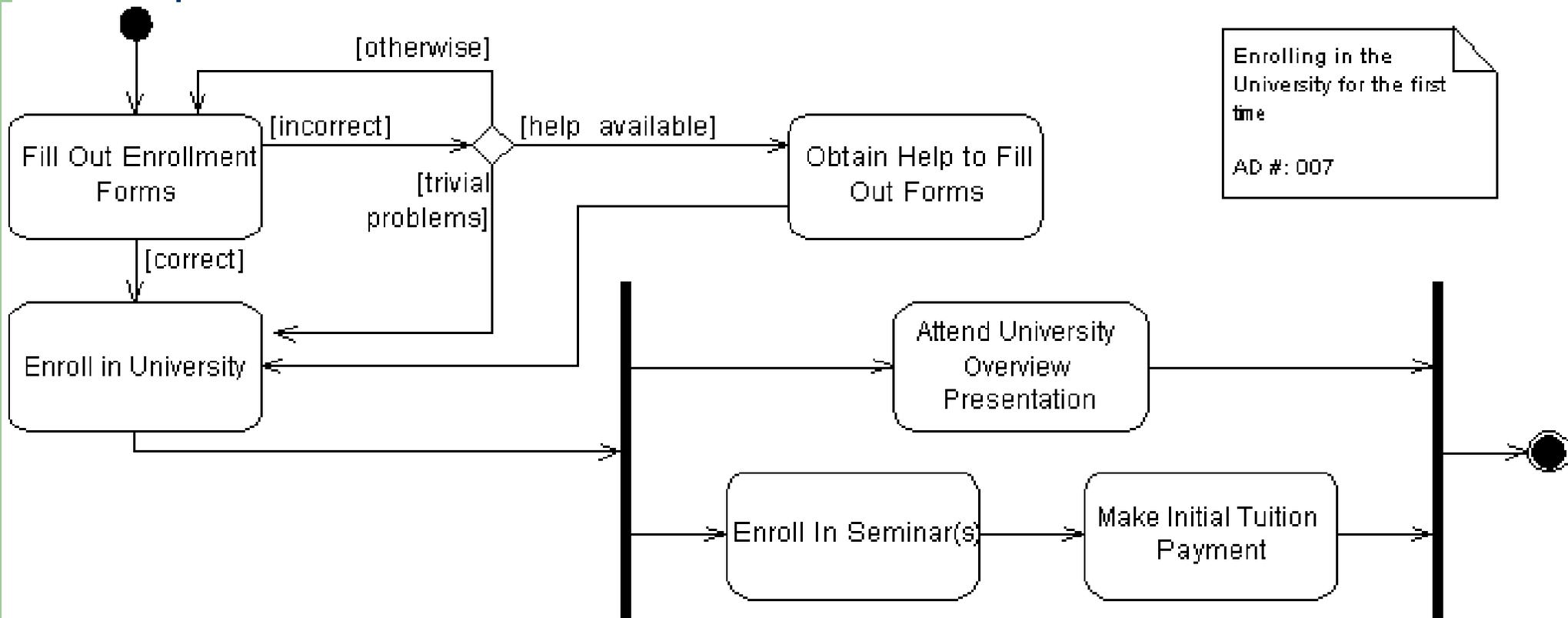
- * Decision is made depending on outcome of evaluation



- * Activity work object recorded on paper

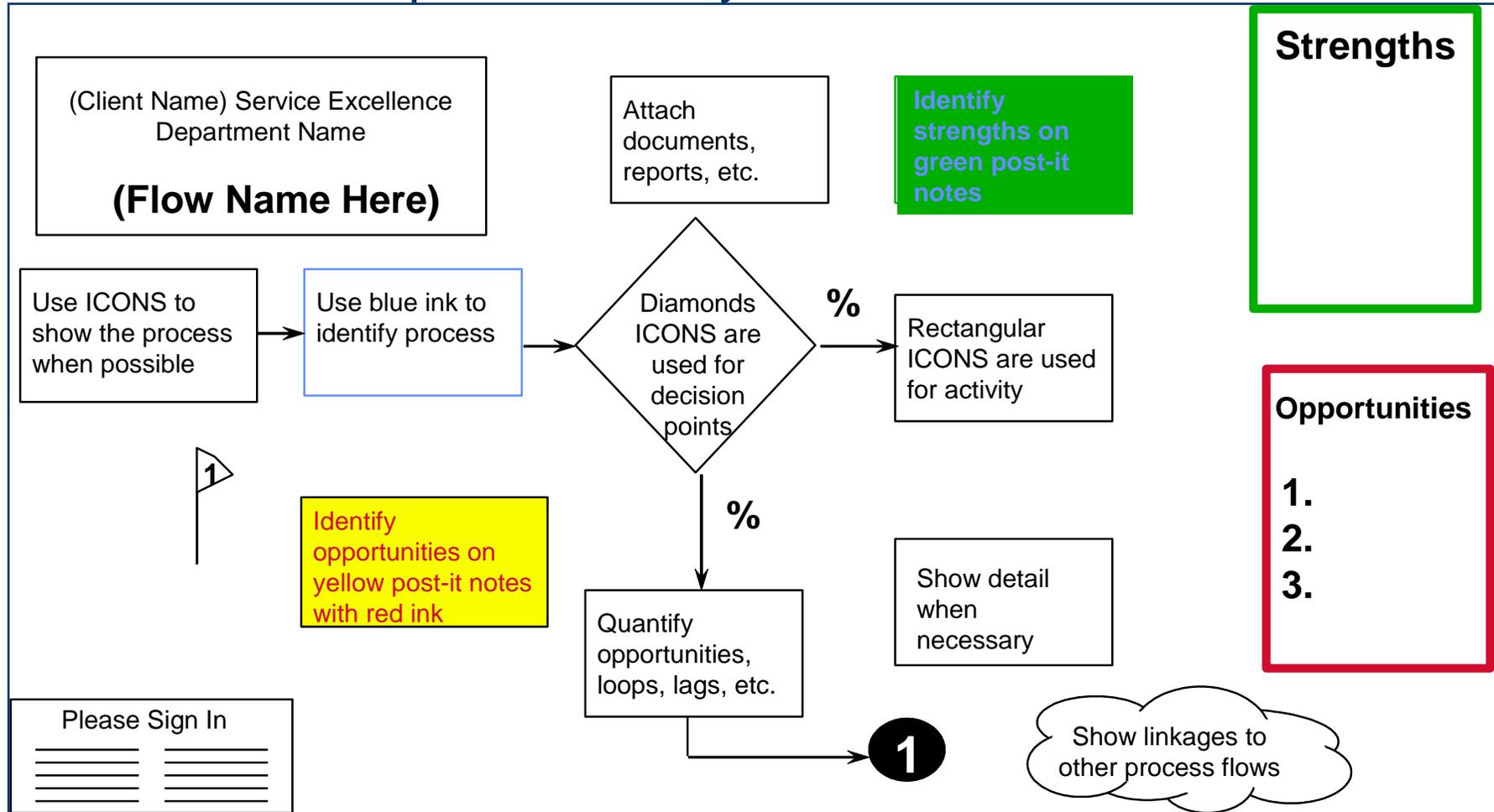
Process Design phase: Varying details in a process

- Depends on the detail level at which it is mapped
 - A simple graphical illustration could meet needs of small operation



Process Design phase: Varying details in a process - 2

- Depends on the detail level at which it is mapped (3)
 - A more detail map allows analysis for effectiveness



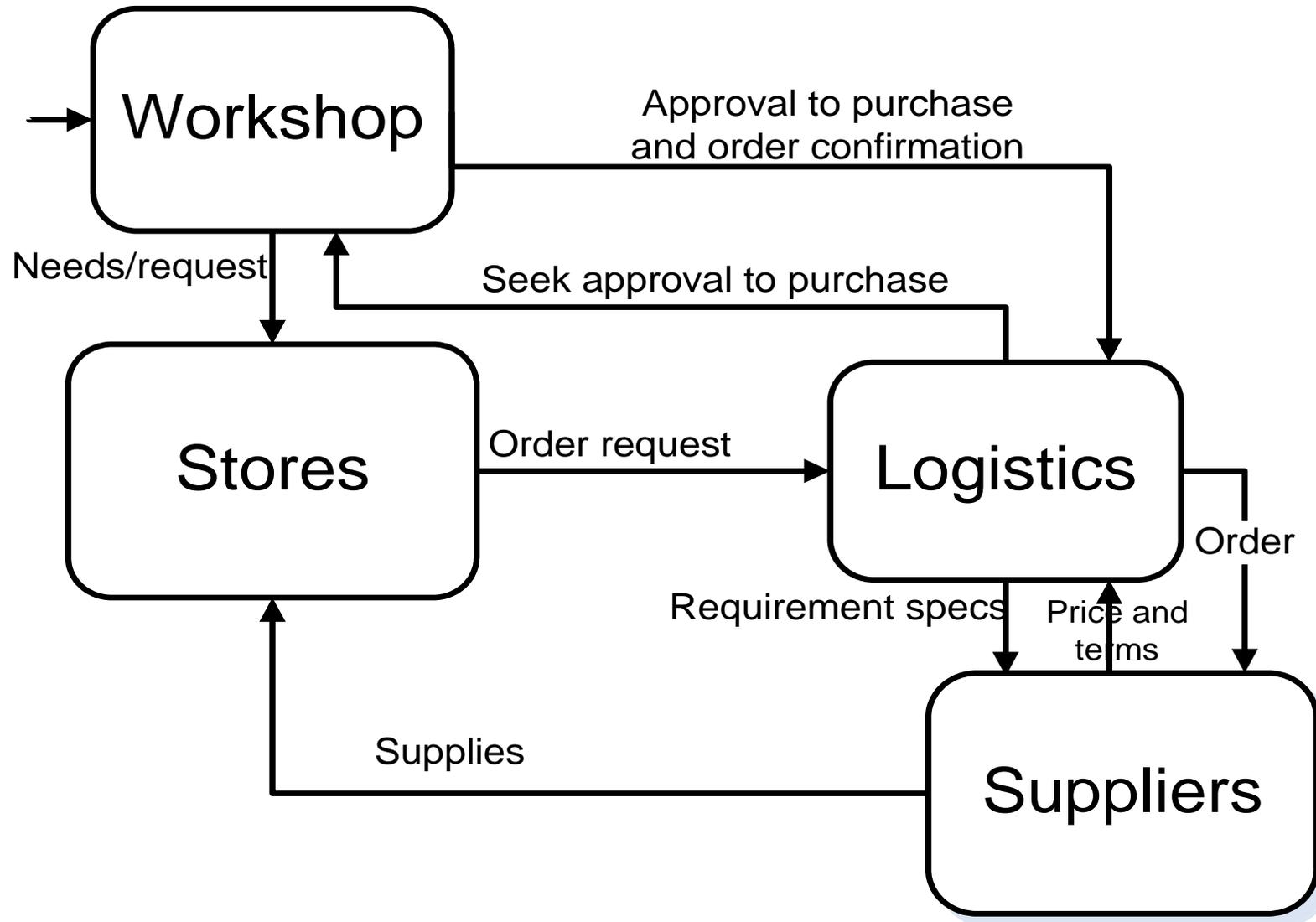
“As Is” model of Parts Order Process in a hypothetical firm

- To make an order for required parts needed for use in a Transport division of a hypothetical firm would be as follows:

No. of activity steps	8
Total time to complete ordering process	62 minutes

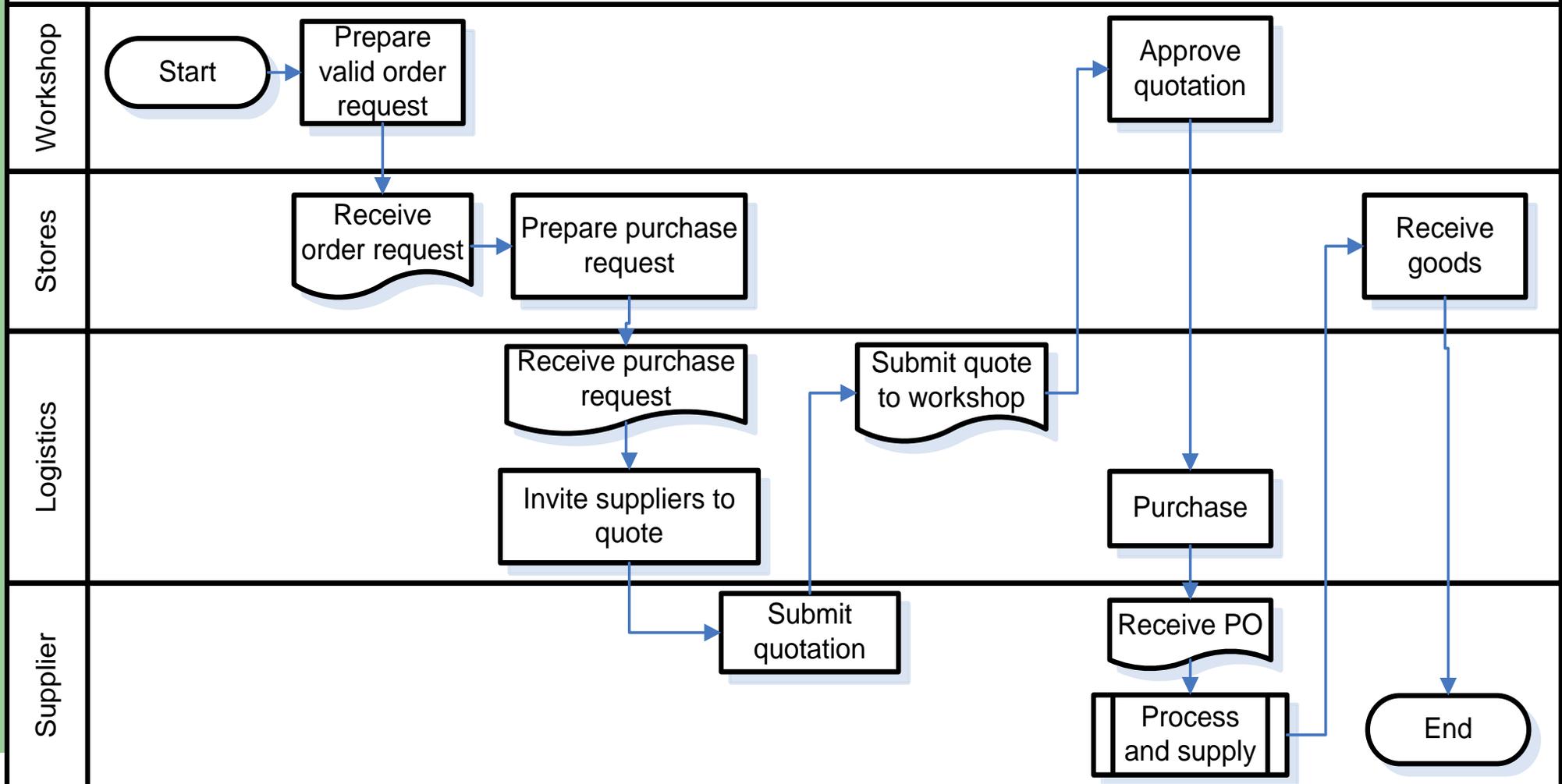
How effective is this process?

Process Design phase: A Relationship Process Map for Parts Order



Process Design phase: A Cross Functional Process Map for parts order process

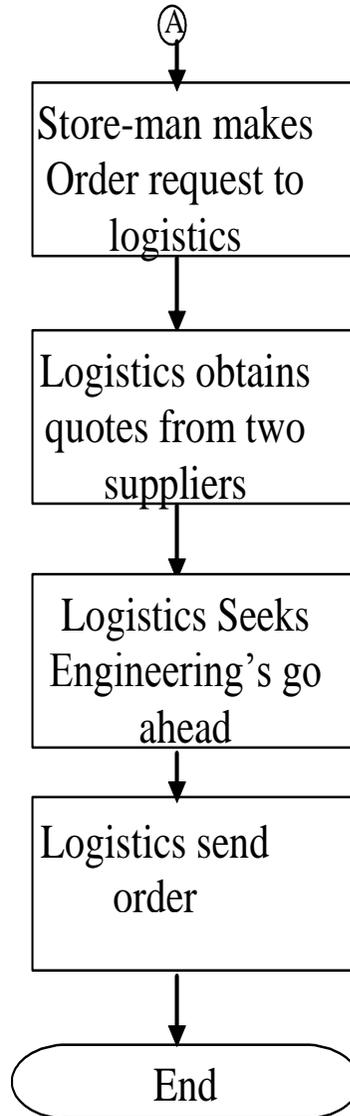
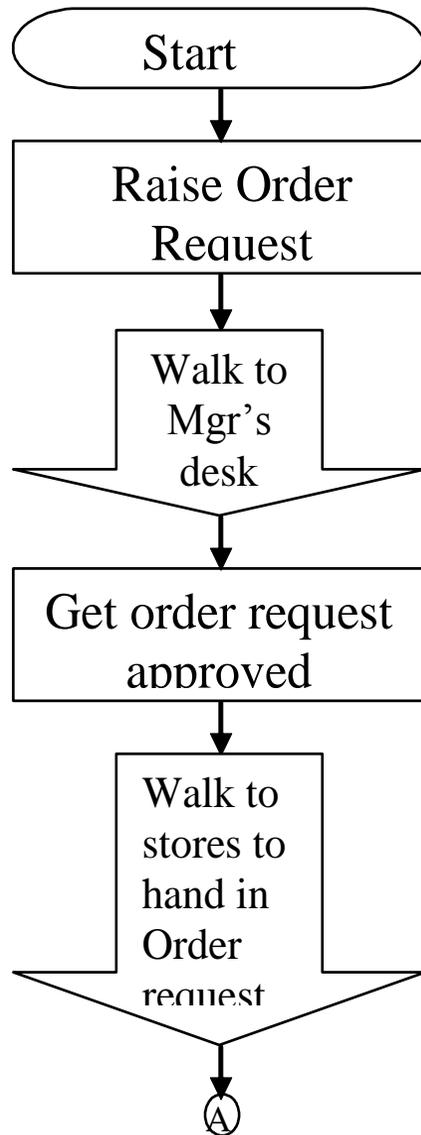
Parts Order Process



Process Design phase: A Detailed process map to allow analysis

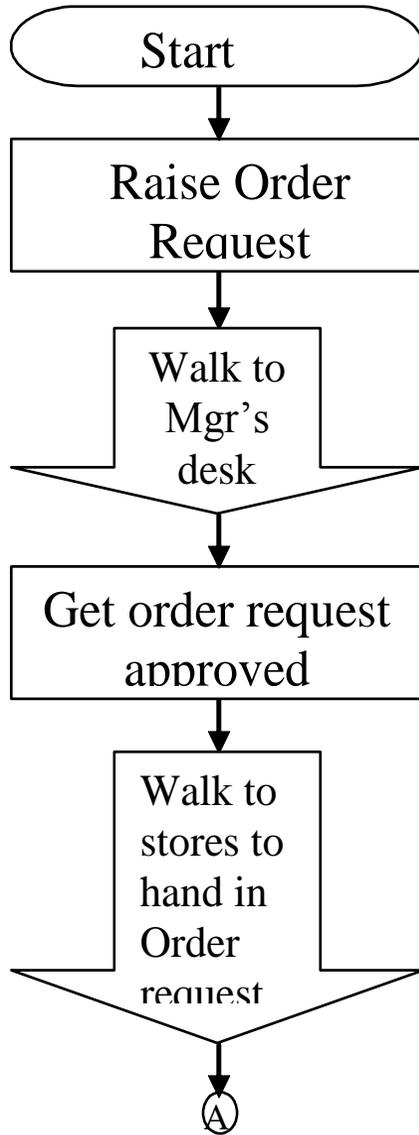
Parts order request (process flowchart 2)

Parts order request

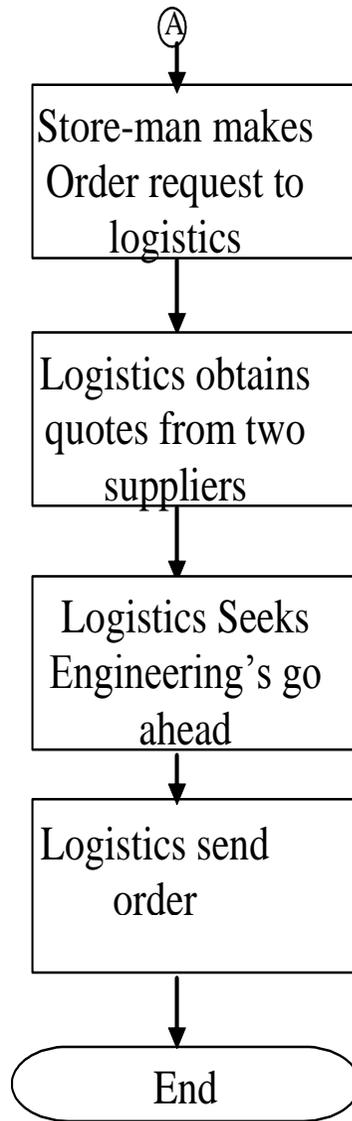


Process Design phase: A Detailed process map to allow analysis

Parts order request

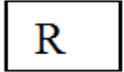


Parts order request (process flowchart 2)



Process Design phase: Task Analysis to determine effectiveness

Task analysis sheet for Parts Order process

#	Step description	Flow	Time (min)	Resource	Notes
1	Raise Order Request		5	CE	After failing to get a spare part at the stores..
2	Walk to manager's desk to get approval		2	CE	Manager approves by signing
3	Approve order request		1	Manager	Inspection step. CE waits while manager is doing the step.
4	Take order request to stores		4	CE	To walk to stores, hand in form and explain, walk back to work bench.
5	Make order request to logistics		5	Stores man	A rework step.
6	Obtain quotes from at-least 2 suppliers		15	Logistics	
7	Seek engineering's go ahead to order		20	Logistics Eng. Mgr	A rework inspection step.
8	Prepare and dispatch order to selected supplier		10	Logistics	
	TOTAL	8	62		

Process Design phase: Task Analysis to determine effectiveness

A data summary chart for Parts Order process

Flow type	# of steps	Minutes	steps
Operation (value-adding)	3	30	5, 15, 10
Transport	2	6	2 and 4
Rework	2	25	5 and 7
Inspection	1	1	3
Delay			
Storage			
Total	8	62	

Process Design phase: Task Analysis to determine effectiveness

Flow type	% of steps	% of processing time
Operation (value-adding)	37.5	48.4
Transport	25	9.7
Rework	25	40.3
Inspection	12.5	1.6
Delay & Storage		
Total	100	100

Process Design phase: Implication of the distributions

- The cost to the organization of the parts to be ordered in the example process = Sourcing cost + administrative cost of ordering
- Time implies cost
 - Administrative cost of ordering in the parts order process instance
- Non-value add steps add to cost without adding to the work object value
- Non-value add steps lengthen the cycle time hence reduce the value to the customer
 - Reduced satisfaction
 - Reduced value perception
 - Reduces amount customer is willing to pay

A 4-Phase Integrated Work-systems and Process Improvement (cont 3)

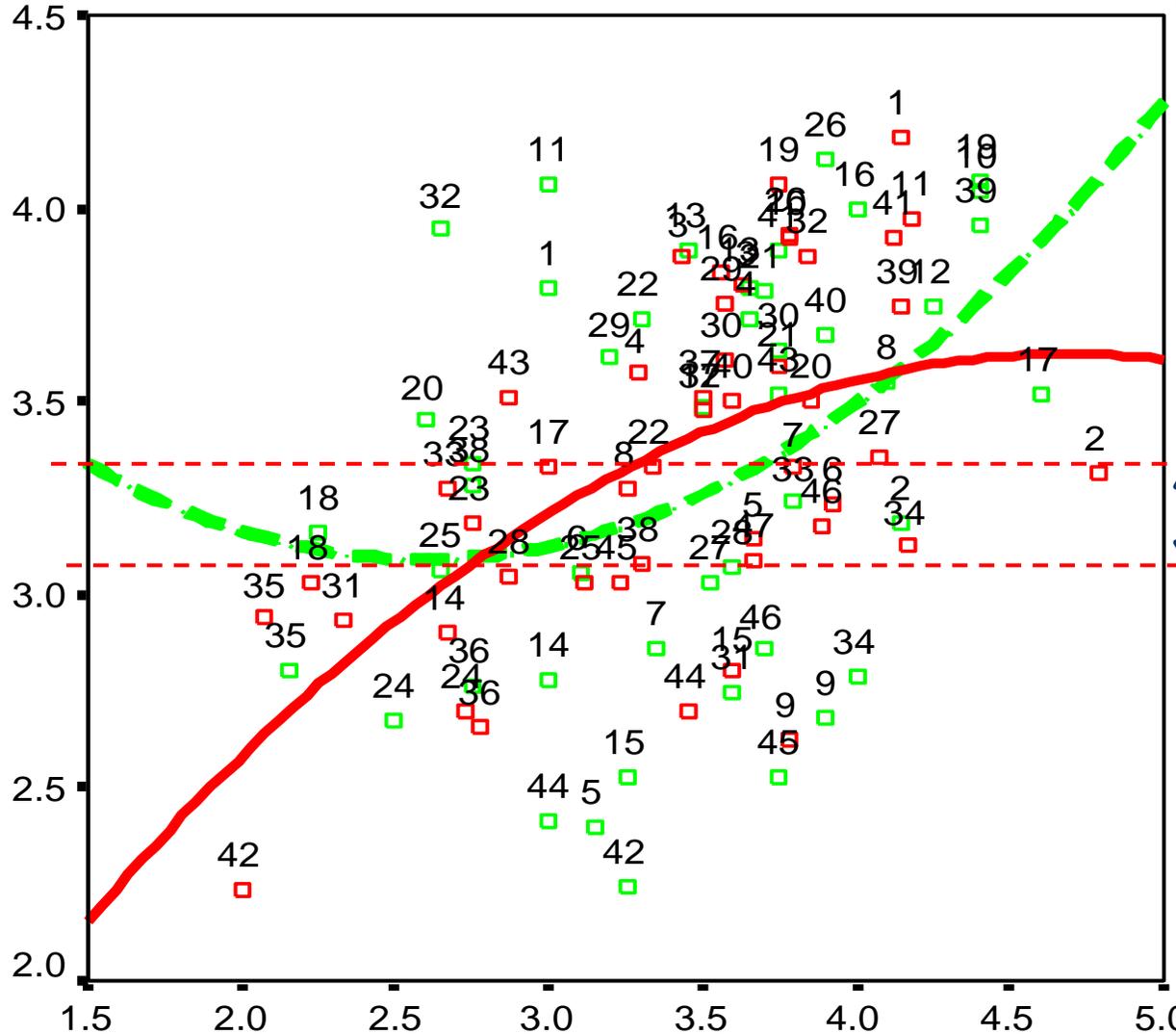
- **Process Implementation (D phase of PDCA)**
 1. Training
 2. Change management
 3. Tools & techniques improvements & Workflow implementation (ICT supported)
- **Process Evaluation (Check Phase of PDCA)**
 1. Metric gathering (manual & automated)
 2. Metric goal vs. actual analysis
 3. Issues identification
 4. Plan corrective action (for the Do phase of PDCA cycle)

- Self-generated
 - Draw the map from own knowledge of the activities
 - Then ask those who interact with the process to react
 - A much faster way but requires knowledge of the process
- Group interview
 - Group to include task performers, process suppliers, and process customers
 - Results in high sense of ownership but requires a facilitator with knowledge of process mapping conventions to help identify inputs, outputs and process steps
- One-on-one interview
 - Interviews with task performers, suppliers and customers to the process, circulate draft to interviewees and those with knowledge of the process

Why adopt Process Approach?

Quadratic curve model fit

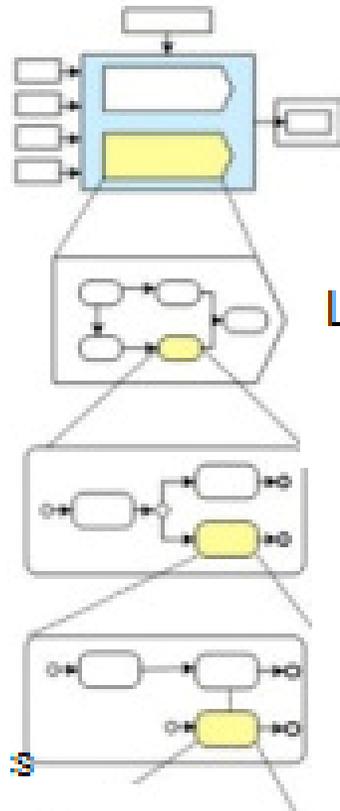
Source: Okwiri (2013)



How Process Approach adoption influences the outcome in Customer satisfaction dimension. Note the effect of minimalist pass/fail oriented actions

-  Process approach & Customer Satisfaction
 $R^2 = 0.1561$
-  Customer focus & Customer satisfaction
 $R^2 = 0.3423$

Process Hierarchy

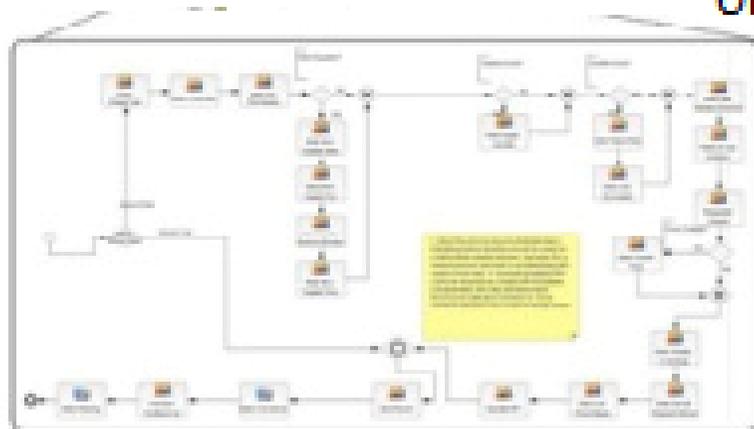


Strategic plan may identify Strategic Issues that constitute Critical Success Factors - No more than 6

Level 1 Processes - Mega Process are top level

Level 2 Processes are subprocesses of level 1 Processes.

Level 3 Processes are subprocesses of level 2 processes
Note: Lowest level depends on organization complexity



Each activity may require Standard Operating Procedure

Six Sigma and ISO 9001:2015 Standard: DMAIC Methodology

Mnemonic	Action	Source Concept	Organizational Context
D	Define requirements	Performance contracting	Source of measurable requirements.
	Define Processes for achieving	Internal Quality Assurance	Appropriately owned process based on systems thinking and process approach
M	Measure performance	Internal Quality Assurance	Process quality measured in: Mean cycle time & effectiveness %

Six Sigma and ISO 9001:2015 Standard: DMAIC Methodology

Mnemonic	Action	Source Concept	Organizational Context
A	Analyze to obtain information	Internal Quality Assurance	Analysis of the assessment data to reveal: Whether the process can or cannot be guaranteed to always meet requirements.
I	Improve process	Internal Quality Improvement	Plan of actions on the identified process to include removal of as much of non-value add steps as feasible.
C	Control process	ISO 9001:2015	Use ISO 9001:2015 QMS to institutionalize process approach and to prevent relapse after improvement.

Auditing to the ISO 9001:2015 Standard

- If you were an auditor, what would you be looking for when auditing against ISO 9001:2015?
- What questions would you be asking?
- To be vindictive, you will probably try and catch the auditee out to show you know more than him/her and make yourself look good.
- To maintain a professional approach, you will probably focus on the continual improvement approach and appreciate that management systems change and improve over time.
 - You will be seeking objective evidence on.....

Understanding the organization and its context – clause 4.1

Information required	Evidence sought
<p>How the organization has determined the external and internal issues that are relevant to their business and its strategic direction.</p>	<p>A big business will have a strategic business plan BUT the auditee need not show the auditor all of the plan, but can just highlight the parts where it mentions the external forces that are impacting on it as well as its internal strengths and weaknesses</p>
	<p>Having Vision and Mission statements should demonstrate where a small business is heading – its strategic direction. A SWOT analysis is sufficient to show the external and internal issues for a small business.</p>

Note: ISO 9001:2015 uses the term “**determined**” **not documented**, **But related clause** require documented information as evidence of **management reviews** and these reviews have to include relevant changes in external and internal issues,

Actions to address risks and opportunities – clause 6.1

Information required	Evidence sought
<p>How the organization has determined the quality risks and opportunities that need to be addressed</p>	<p>A big business will most probably already have a risk manager or risk department, and they will be looking at the big picture risks to the business. The business plan will most likely be clear on the opportunities and where it could be growing. Some of the risks and opportunities are related to customer.</p>
	<p>A small business could have a risk register, (any safety system in place will certainly have one). A risk register can be created on a table or spreadsheet and will show that quality risks and opportunities have been identified; Risk is what you would not like if you were a customer; Opportunity is what you would like the business to be doing if you were a customer.</p>

Note: The term “**determined**” and **not documented is used, but related clause** require documented information as evidence of management reviews and these reviews have to include the effectiveness of actions taken to address risks and opportunities.

Planning of changes – clause 6.3

Information required	Evidence sought
How the organization has considered the purpose of any changes to the QMS and their potential consequences ,	A big business will probably be having changes occurring at many different levels. High level changes may already look at the possible consequences of the change. The lower level, day to day changes will most probably be captured in things like improvement registers, non-conformance reports, corrective action requests. Additional fields could be added to identify the consequences of the change.
	A small business will need to have non-conformance reports and some form of improvement or corrective action register. Columns to show what is expected to happen as a result of any change will meet the requirements. Include changes that result from meetings

Note: the term is “considered” **not documented, But related clauses 8.2.4, 8.3.6, 8.7.2, 9.3.3, 10.2.2,** require documented information as evidence if changes affect product, non-conformities and QMS

Quality management system and its processes – clause 4.4.1

Information required	Evidence sought
How the organization has determined the inputs required and outputs expected from your QMS processes.	A big business could be managing a number of different projects and activities within a matrix structure with many complex process maps. Simplifying and streamlining the organization's processes make identifying inputs and outputs easier and the QMS more effective. Having Relationship maps and cross-functional maps achieves this requirement but with added advantage of making work visible
	If small business will most probably have a relatively straight forward end to end process maps, making identification of the inputs and outputs reasonably easy.

Note: Process approach has been spelt out as a requirement since as from ISO 9001:200. When managing interrelated processes, output from one process is most likely the input to another process.

Organizational knowledge – clause

7.1.6

Information required	Evidence sought
How the organization has determined the knowledge necessary for the operation of its processes.	<p>An organizations is expected to have things like skills matrices, job or position descriptions, and performance review records. These represent competence which is ability to apply knowledge and skills to achieve intended results. Adjustment of these to include any knowledge requirements along with any actions to gain the knowledge where gaps appear will suffice.</p> <p>Consideration knowledge sources – internal is learnt from successes, failures, and experiences within the business whiles external source of knowledge is from customers, standards, conferences, and even the internet, employees as knowledge carriers</p>

Managing the Transition to the ISO 9001:2015 Standard

- Three years transition period to end in September 2018
- Transition is an opportunity
- Requires understanding of the now emphasized core concepts of processes, risk-based thinking and Plan-Do-Check-Act
 - Have been part of the requirements since 2000

Transition Activities.

Understand the differences in more detail, take fresh look at QMS and highlight the key changes

Implement NEW requirements on leadership, risk and context of organization

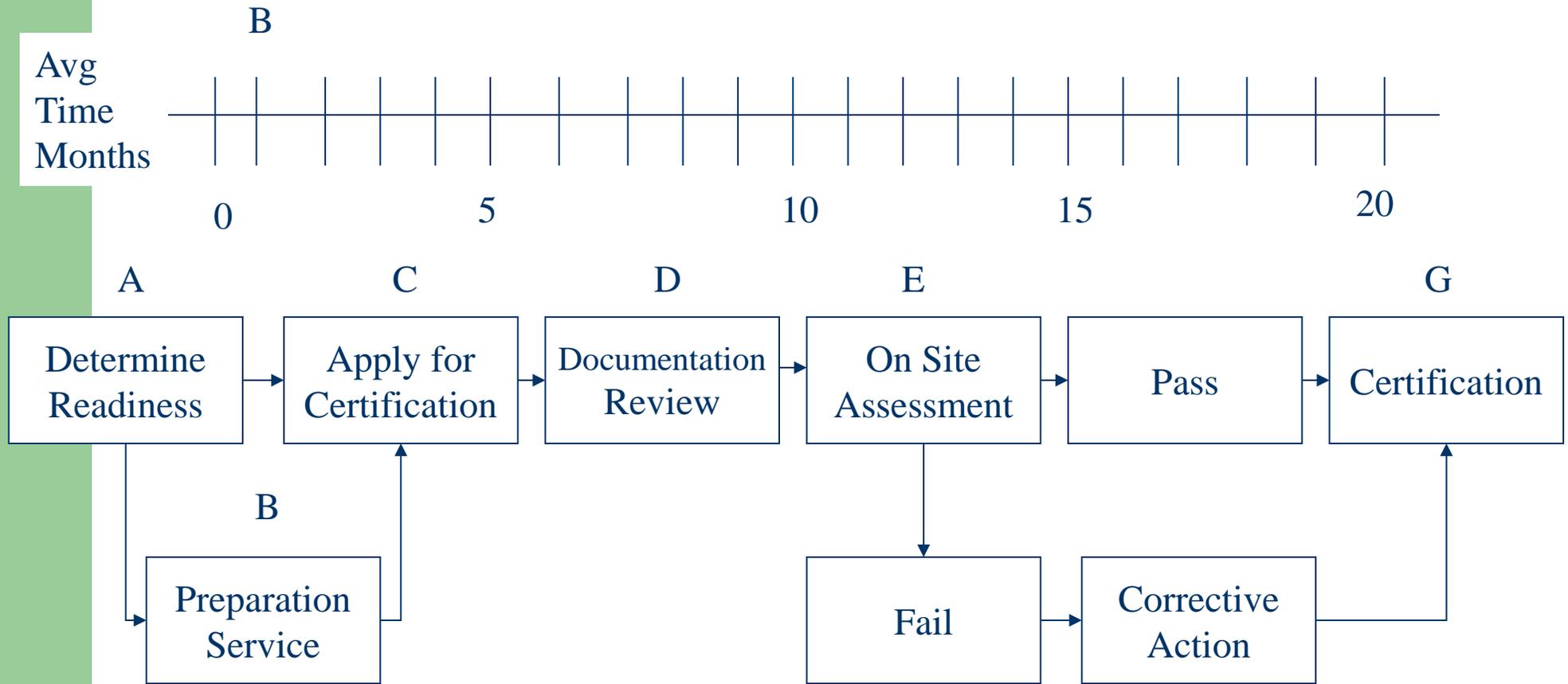
Carry out impact assessment

September 2018
Transition to ISO 9001:2015 complete



Training is Required
Use ISO 9001:2015 Readiness questionnaire

Certification Time Line



Thank you