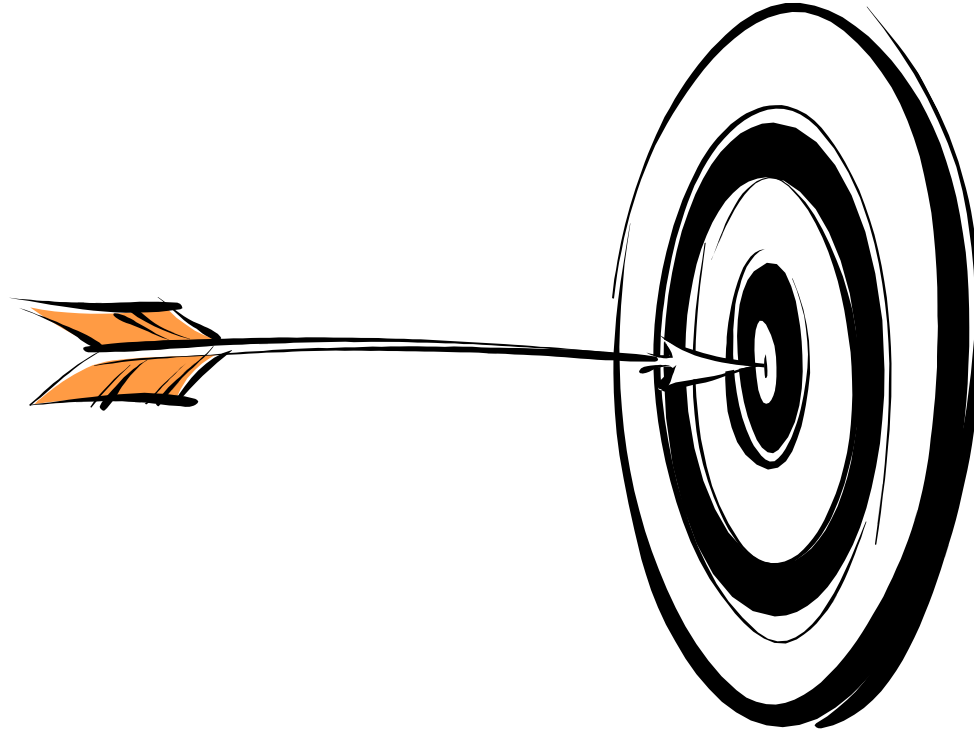


Process Approach to Internal Audits

ASQ – January 18, 2011

- **Douglas Phillips** - President of Phitelos Solutions Inc.
www.phitelos.com
- **Jim Moran** - President of the Learning Alliance, Inc.
www.simplifyISO.com

What are your targets for this workshop?



What the Standard says.....

1 Scope

1.1 General

This International Standard specifies requirements for a quality management system where an organization

- a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and
- b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

8.2.2 Internal audit

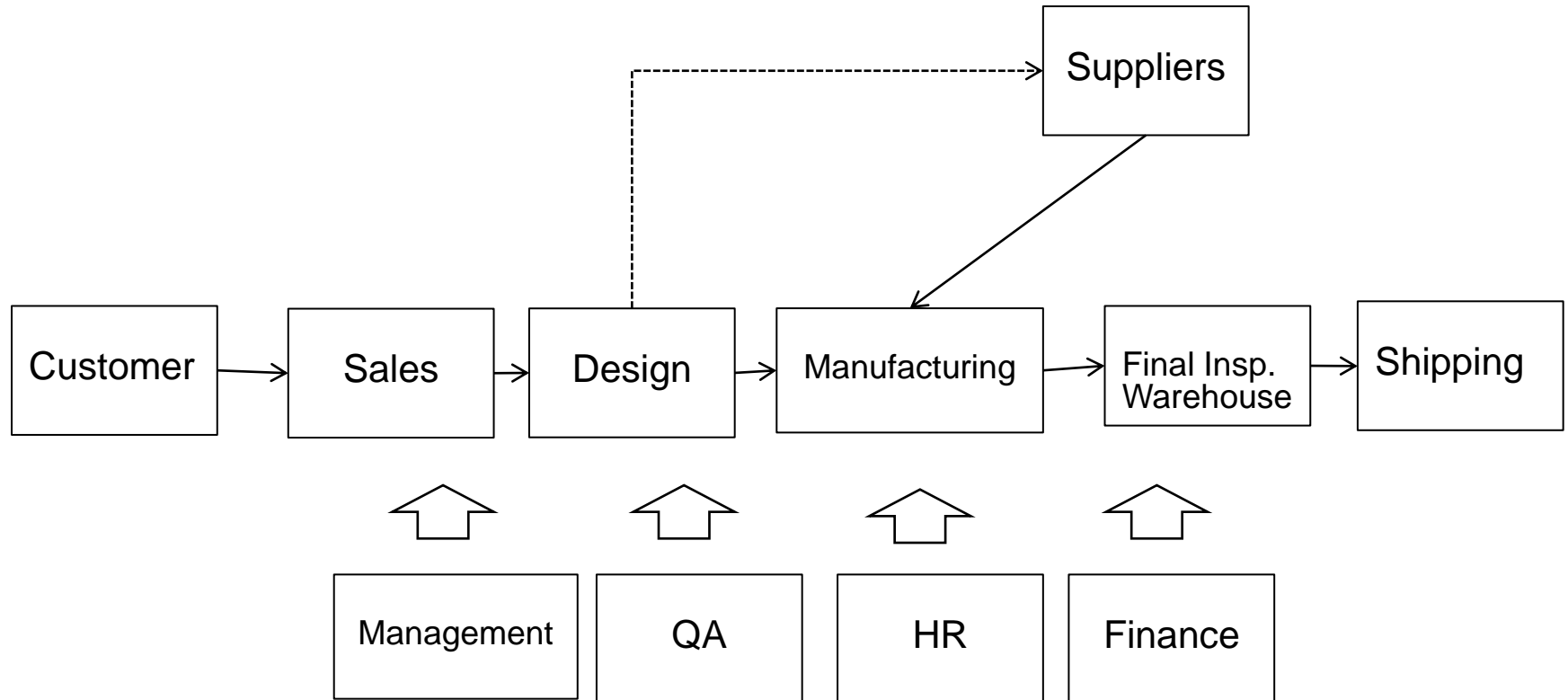
The organization shall conduct internal audits at planned intervals to determine whether the quality management system

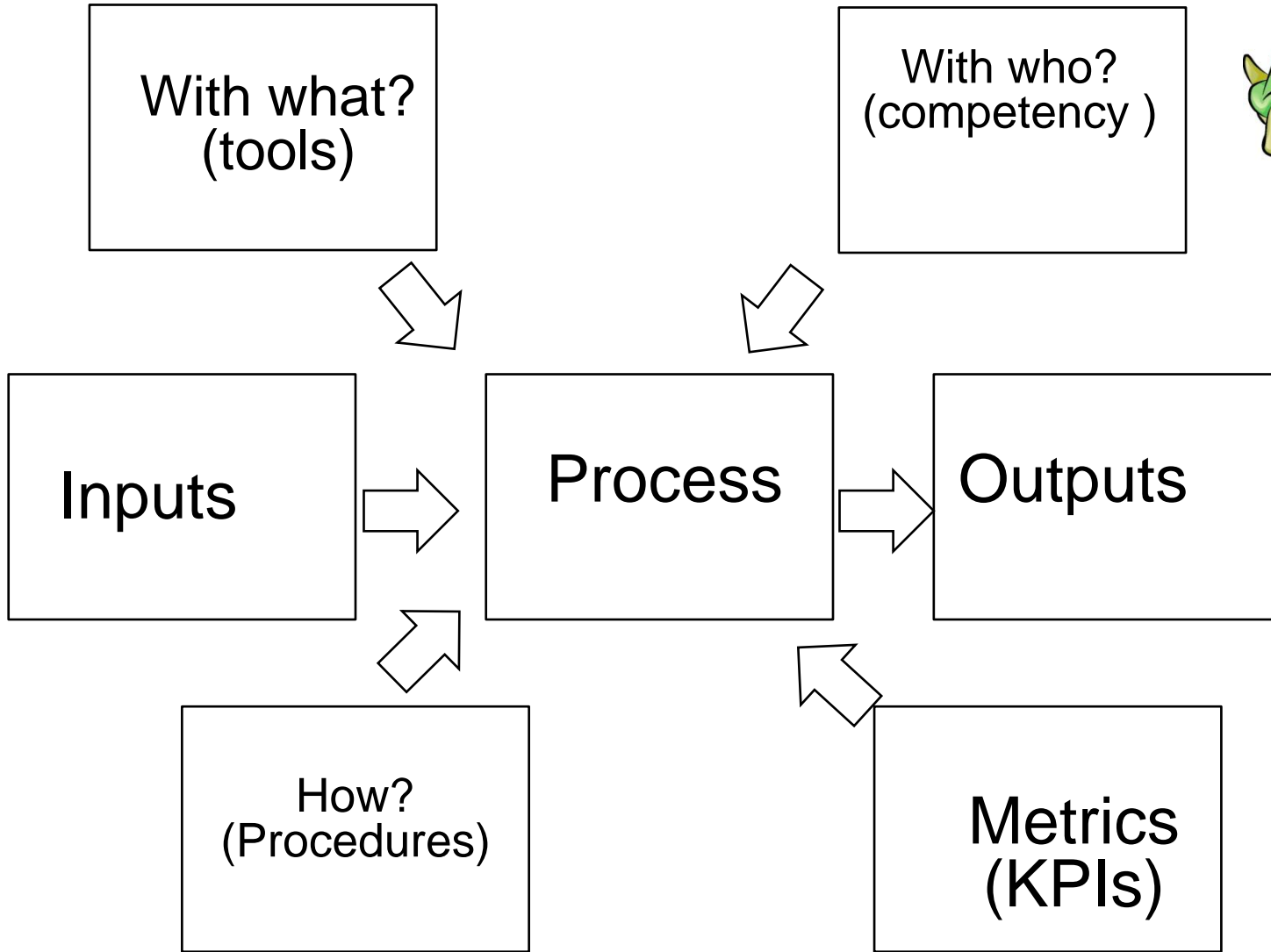
- a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and
- b) is effectively implemented and maintained.

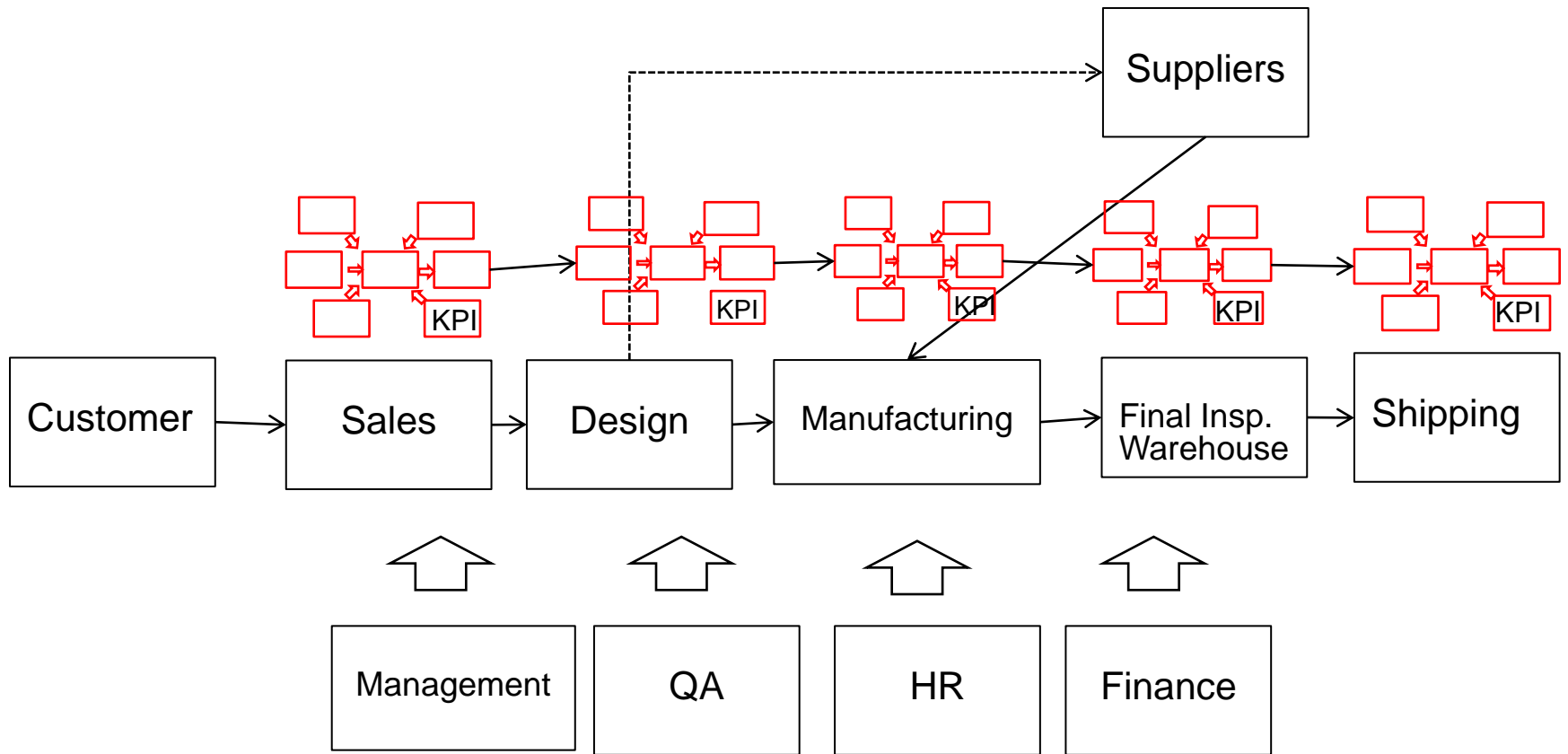
Elemental Checklist/Audit

ISO 9001:2000	What to look for	STATUS		
		AD	NC	NA
7.2 Customer-related processes 7.2.1 Determination of requirements related to the product The organization shall determine <ul style="list-style-type: none"> a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, 	Has the organization determined Requirements specified by the customer, including the requirements for delivery and post-delivery activities			
<ul style="list-style-type: none"> b) requirements not stated by the customer but necessary for specified use or known and intended use, 	Requirements not stated by the customer but necessary for specified use or known and intended use?			
<ul style="list-style-type: none"> c) statutory and regulatory requirements related to the product, and 	Statutory and regulatory requirements related to the product?			
<ul style="list-style-type: none"> d) any additional requirements determined by the organization. 	Any additional requirements determined by the organization?			
7.2.2 Review of requirements related to the product The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that <ul style="list-style-type: none"> a) product requirements are defined, 	Has the organization determined and managed the work environment needed to achieve conformity to product requirements?			
<ul style="list-style-type: none"> b) contract or order requirements differing from those 				

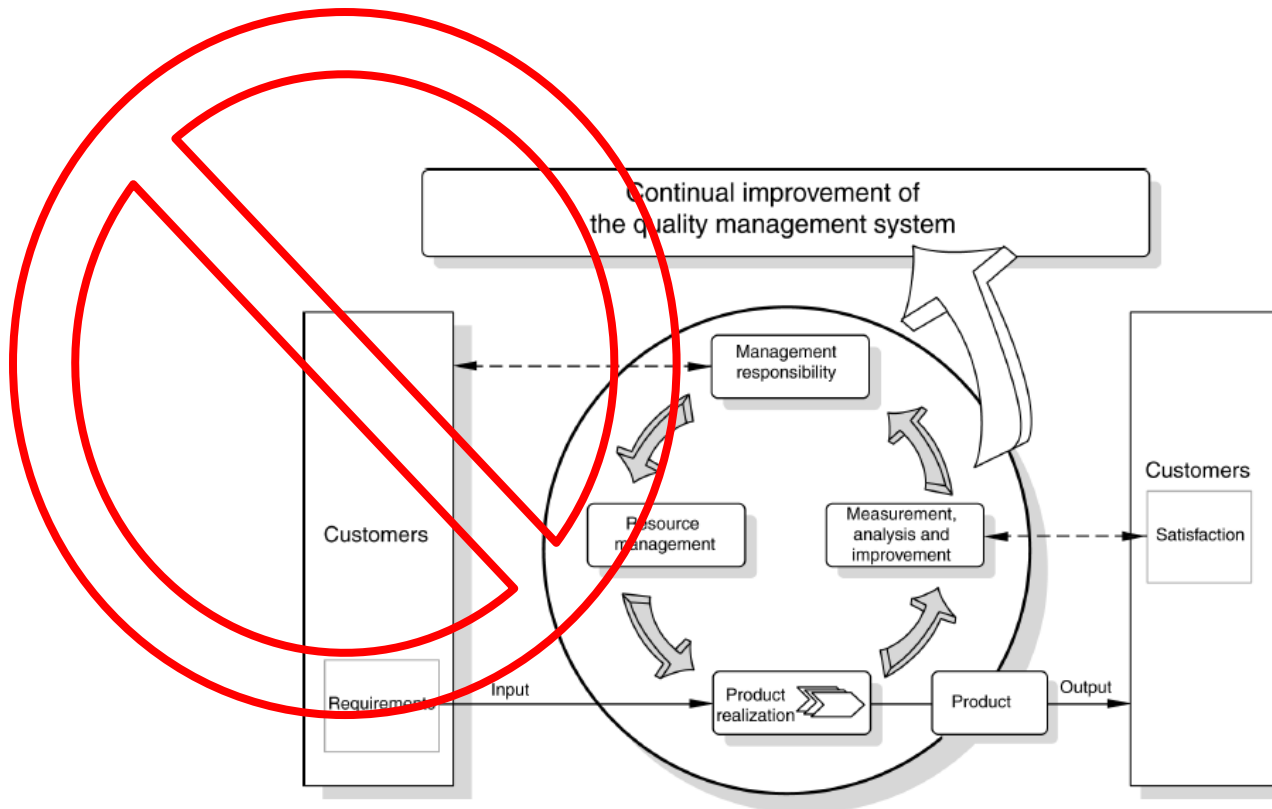
What is a process

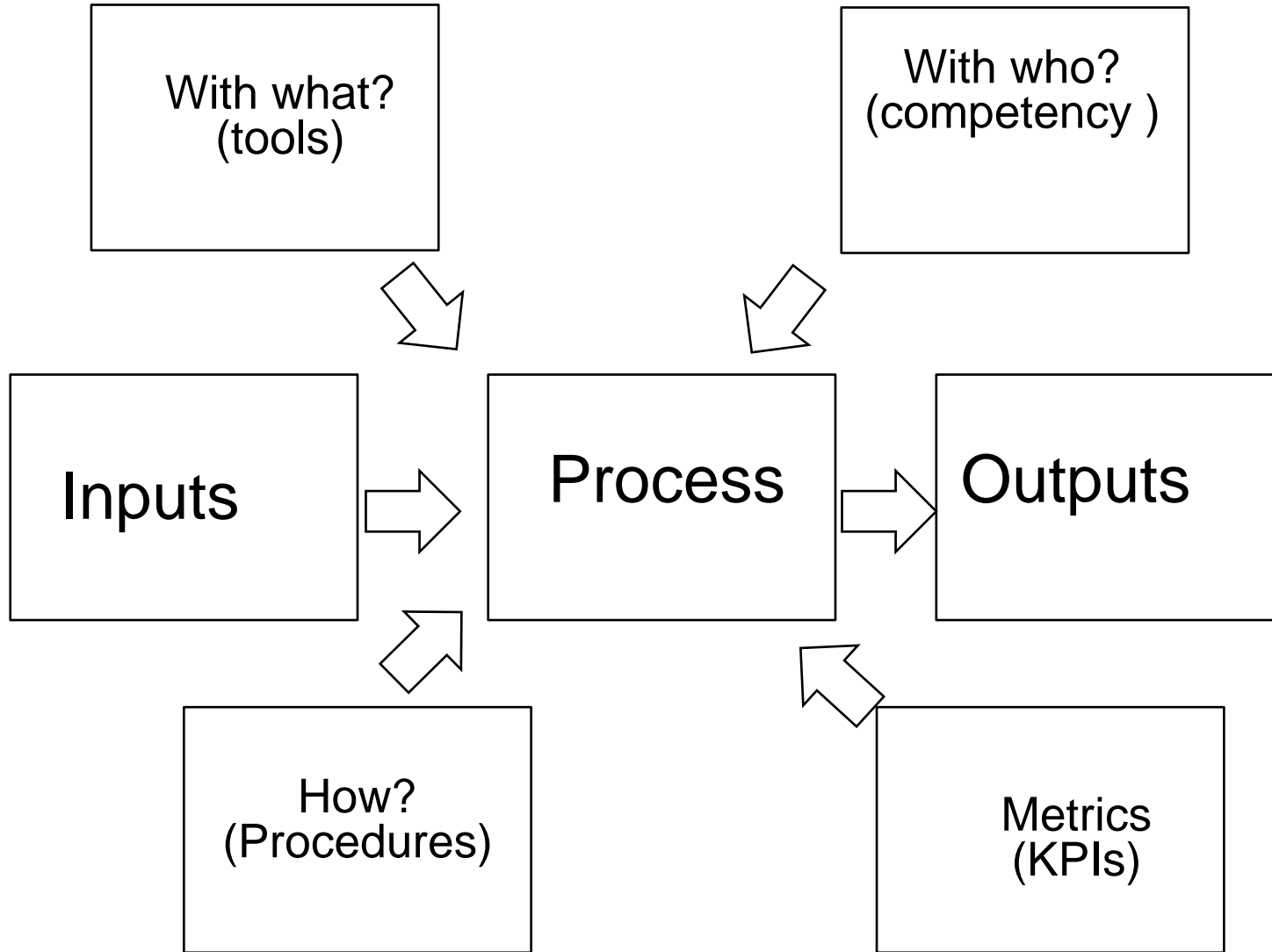


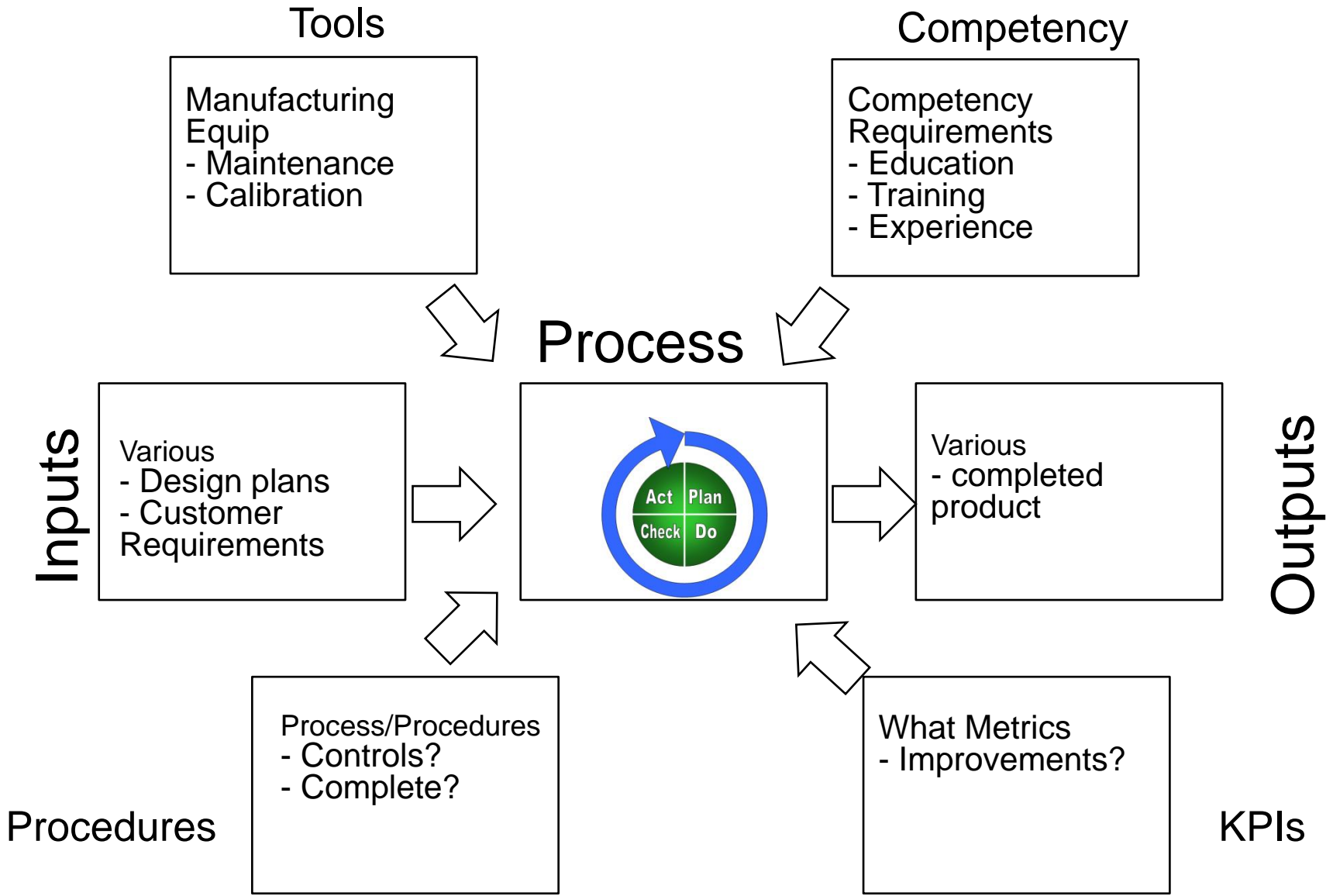




Is this the real process for an organization?







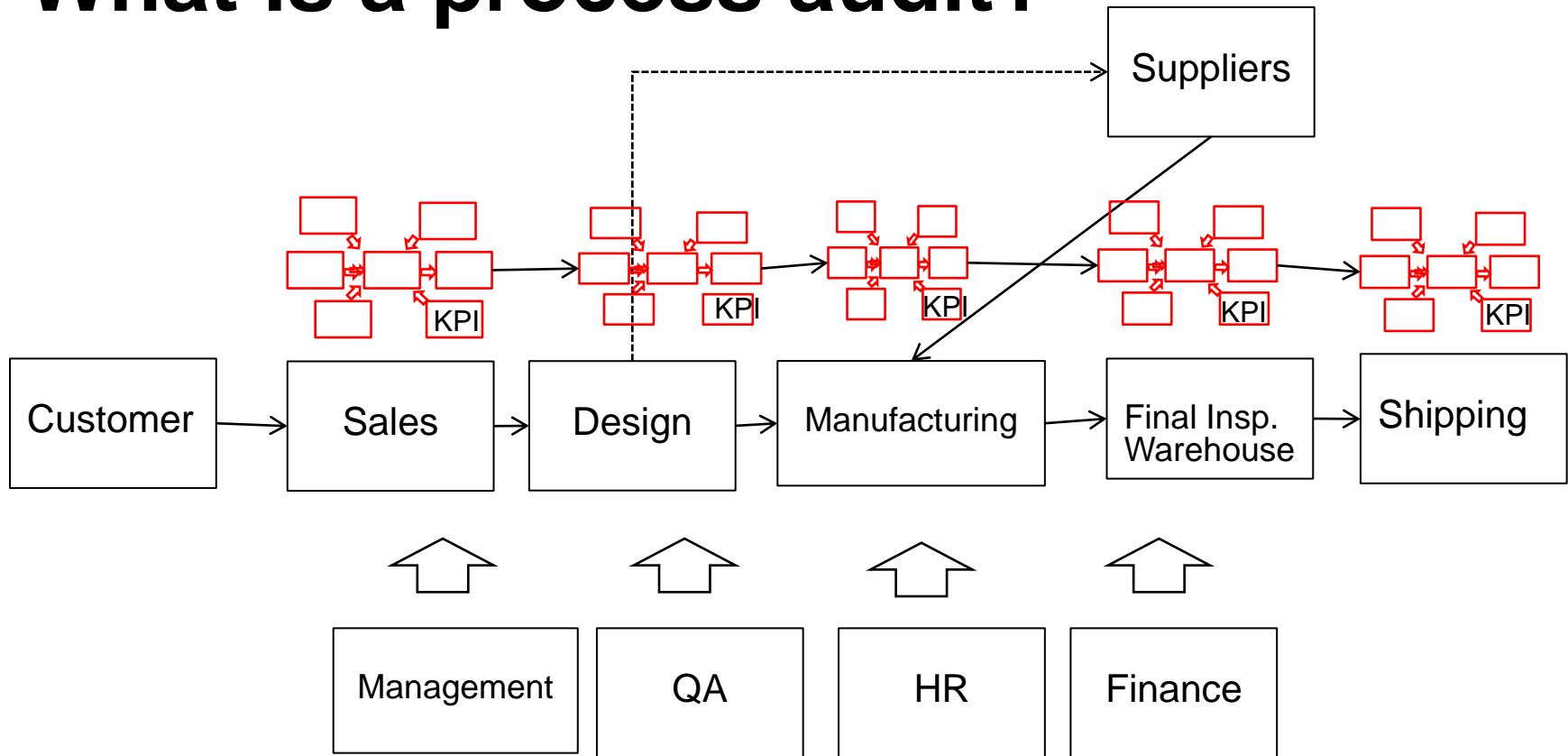
Competence

6.2.2 Competence, training and awareness

The organization shall

- a) determine the necessary competence for personnel performing work affecting conformity to product requirements,
- b) where applicable, provide training or take other actions to achieve the necessary competence,

What is a process audit?



Someone has to manage the audit program

	J	F	M	A	M	J	J	A	S	O	N	D
Process 1	X											
Process 2			X									
Process 3		X										
Process 4					X							
Process 5				X								
.....						X	X	X		X	X	X
Process N									X			

Element Vs Process

- Element – focuses on are all elements identified
 - Are the requirements met
 - Ensures elements audited
- Process – Focus on effectiveness
 - Are the metrics indicating improvements! If not, what actions are being taken.
 - Risk missing elements

Audit evidence is gathered three ways



Interviews

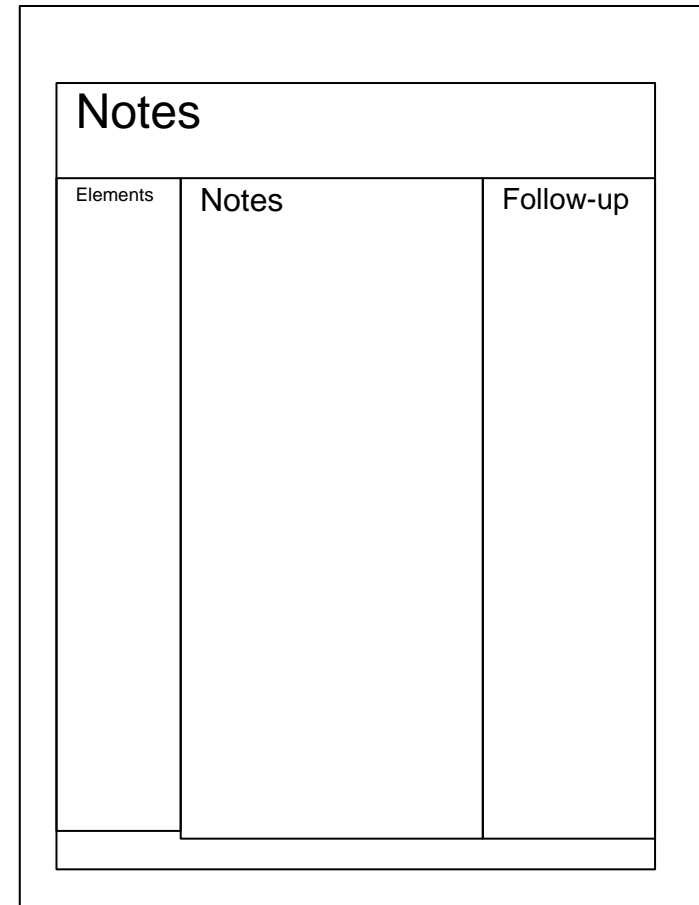
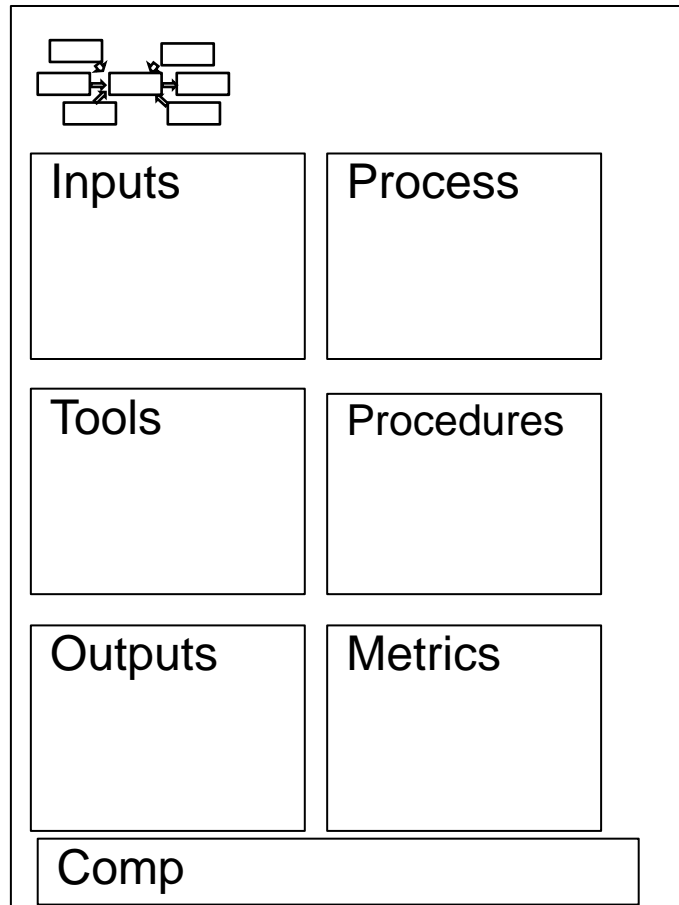


Reviewing documents

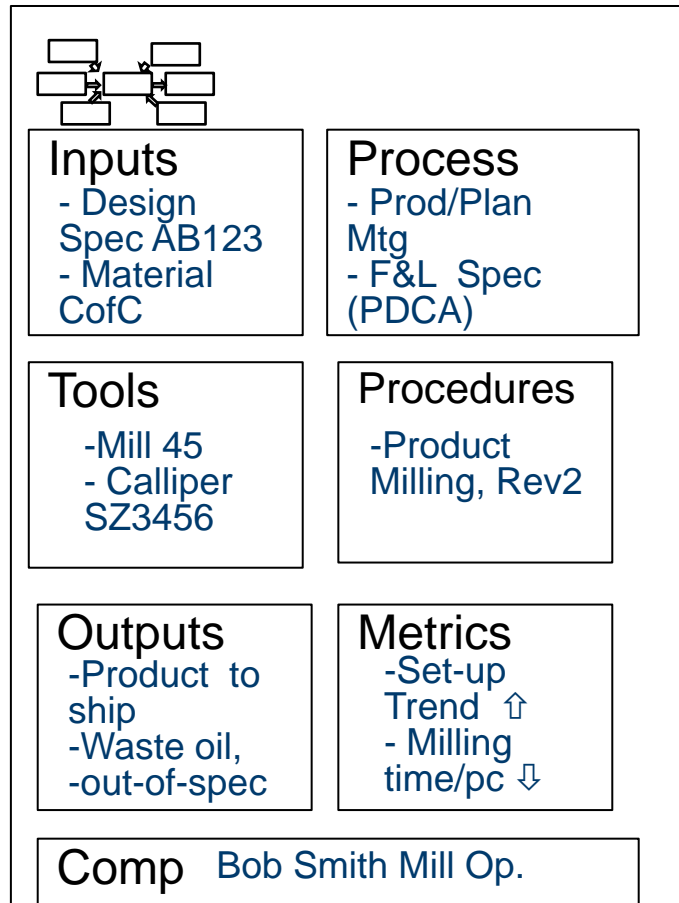


Watching Activities

How to collect Process Data



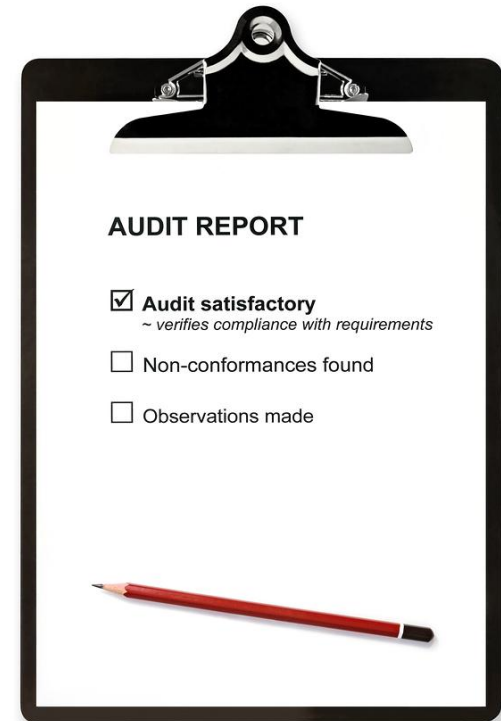
How to collect Process Data

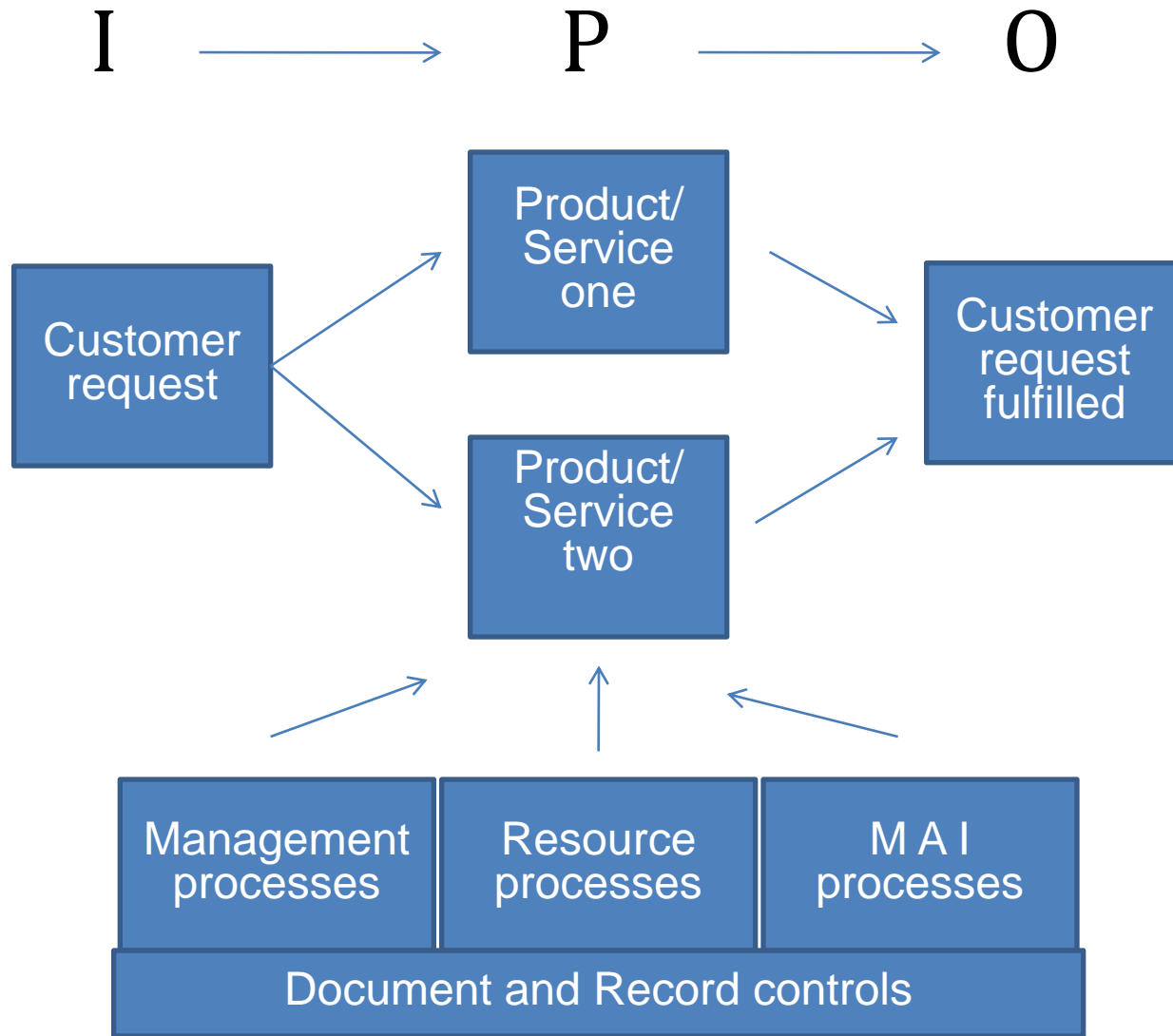


Notes Milling		
Elements	Notes	Follow-up
	Sample 1 – ACME order 45	
4.2.3	Procedure, Product Milling, Rev 2	
6.2	Bob Smith Mill Op.	HR Rec
7.6	Calliper SZ3456	Cal Rcd
8.5.2	Trend ↓ - Milling time/pc	CAR Rcd
8.2/5.6	Out-of Spec Material	???

Is the audit complete?

- Links between processes
- Are all the elements audited?
- Cross Reference with the standard

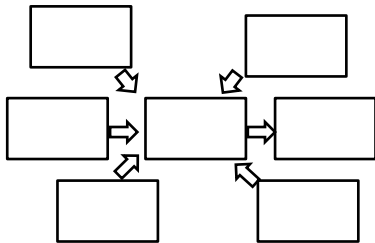






Summary

- How to conduct an effective internal audit:





Questions?

To the Panel

