

# The Process-Based Approach: Going Beyond the Element Approach



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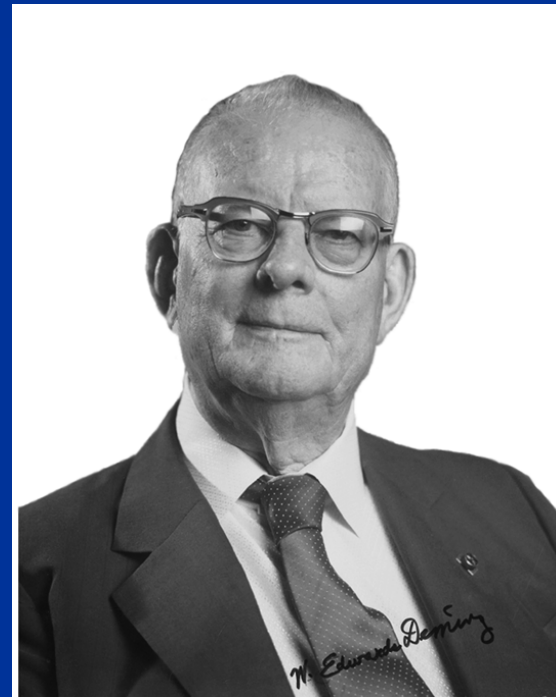
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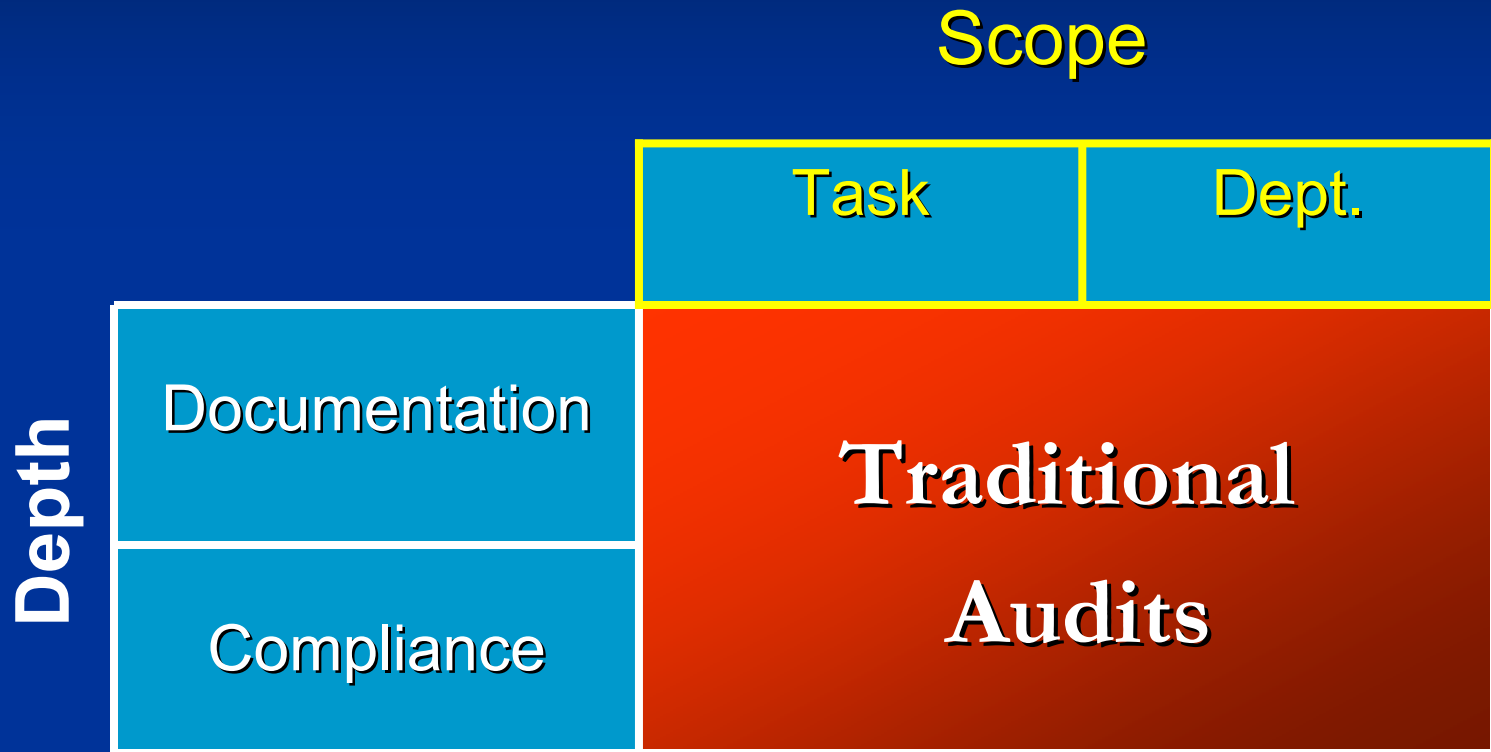
**“There is no one  
recipe for quality.”**



# ISO 9000 Series Quality Elements (1987)

Requirements
1. Management Responsibility
2. Quality System
3. Contract Review
4. Design Control
5. Document and Data Control
6. Purchasing
7. Control of Customer-Supplied Product
8. Product Identification and Traceability
9. Process Control
10. Inspection and Testing
11. Control of Inspection, Measuring, and Test Equipment
12. Inspection and Test Status
13. Control of Nonconforming Product
14. Corrective Action
15. Handling, Storage, Packaging, Preservation, and Delivery
16. Control of Quality Records
17. Internal Quality Audits
18. Training
19. Servicing
20. Statistical Techniques

# Scope and Depth



# The Element Approach

- Not how a business really works
- Not easy for the user to interpret
- No need to include the customer
- No connection to improvement
- No need for process linkages

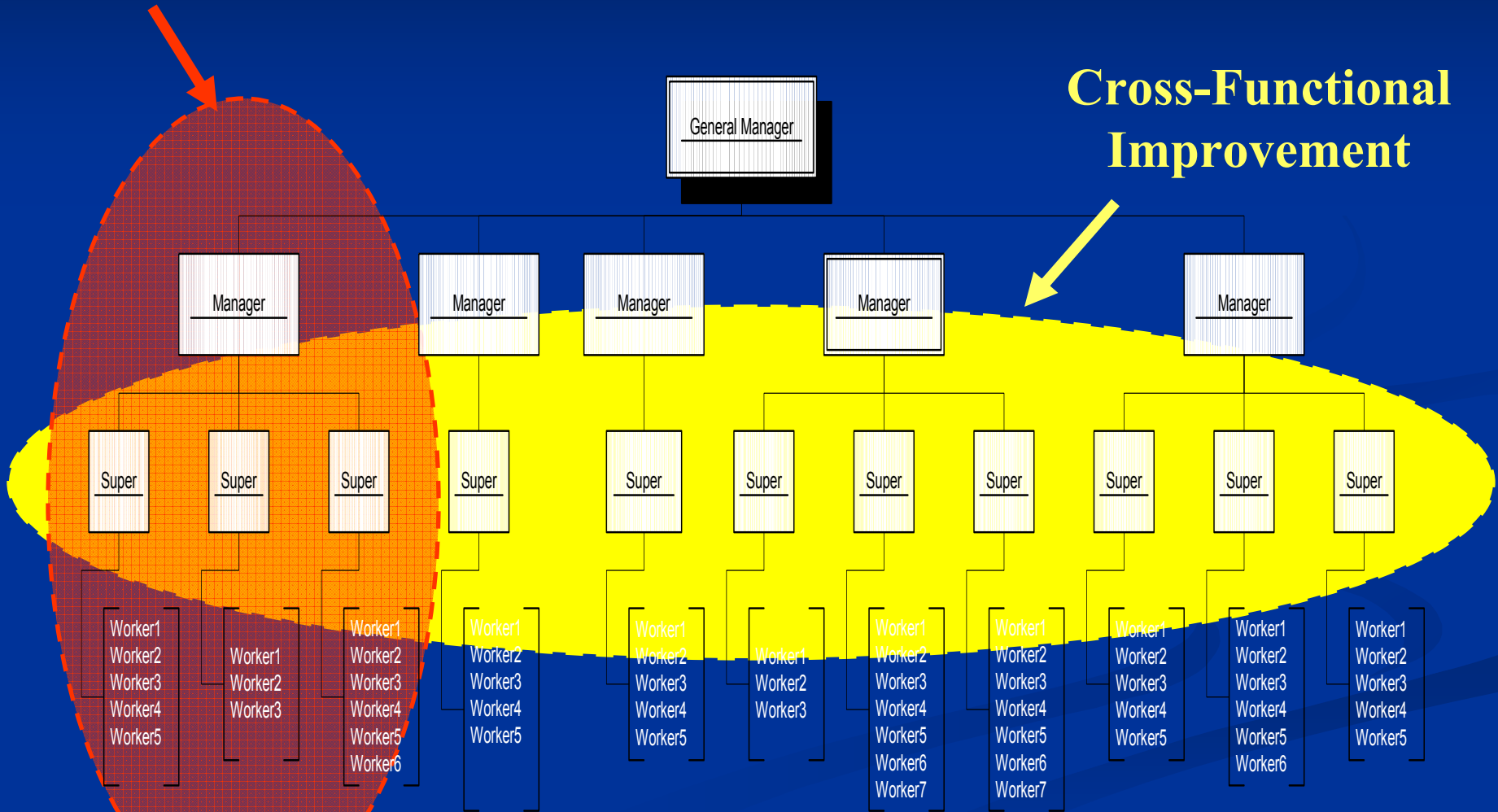


**“Quality is the result  
of the system.”**

# The System

**Functional Control**


**Cross-Functional Improvement**



# Scope and Depth

Scope

Depth

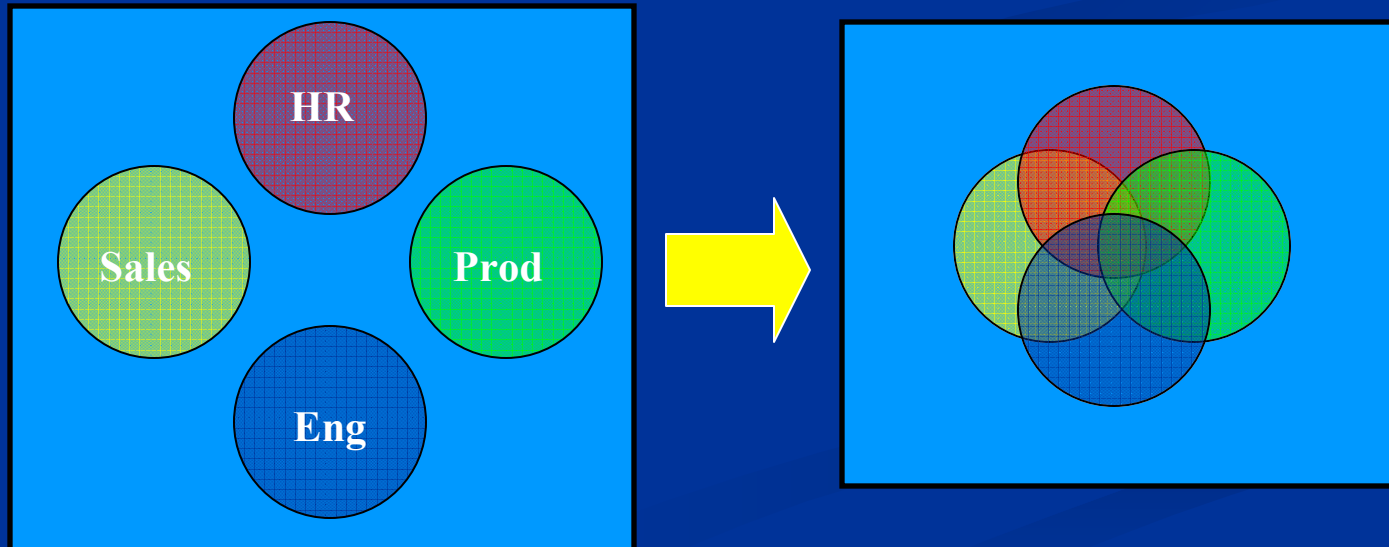
	Task	Dept.	Links	System
Documentation	<b>Traditional Audits</b>  <b>Process-Based Assessments</b>			
Compliance				
Effective				
Improve				

# ISO9001:2000

## 0.2 Process approach

The application of a system of processes within an organization, together with the identification and **interactions** of these processes, and their management, can be referred to as the “process approach”.

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and **interaction**.



ISO 9001

Nonconformance

Audit

Malcolm Baldrige

Strengths & Weaknesses

Assessment

*An assessment of the effectiveness  
of the Quality Management System (QMS)*

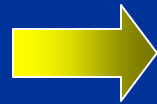
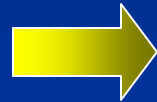
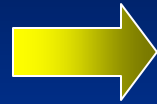
# Traditional Quality

Problem solving

Root Cause Analysis

*What do we need to do less of?*

*Weaknesses*



# Appreciative Inquiry Quality

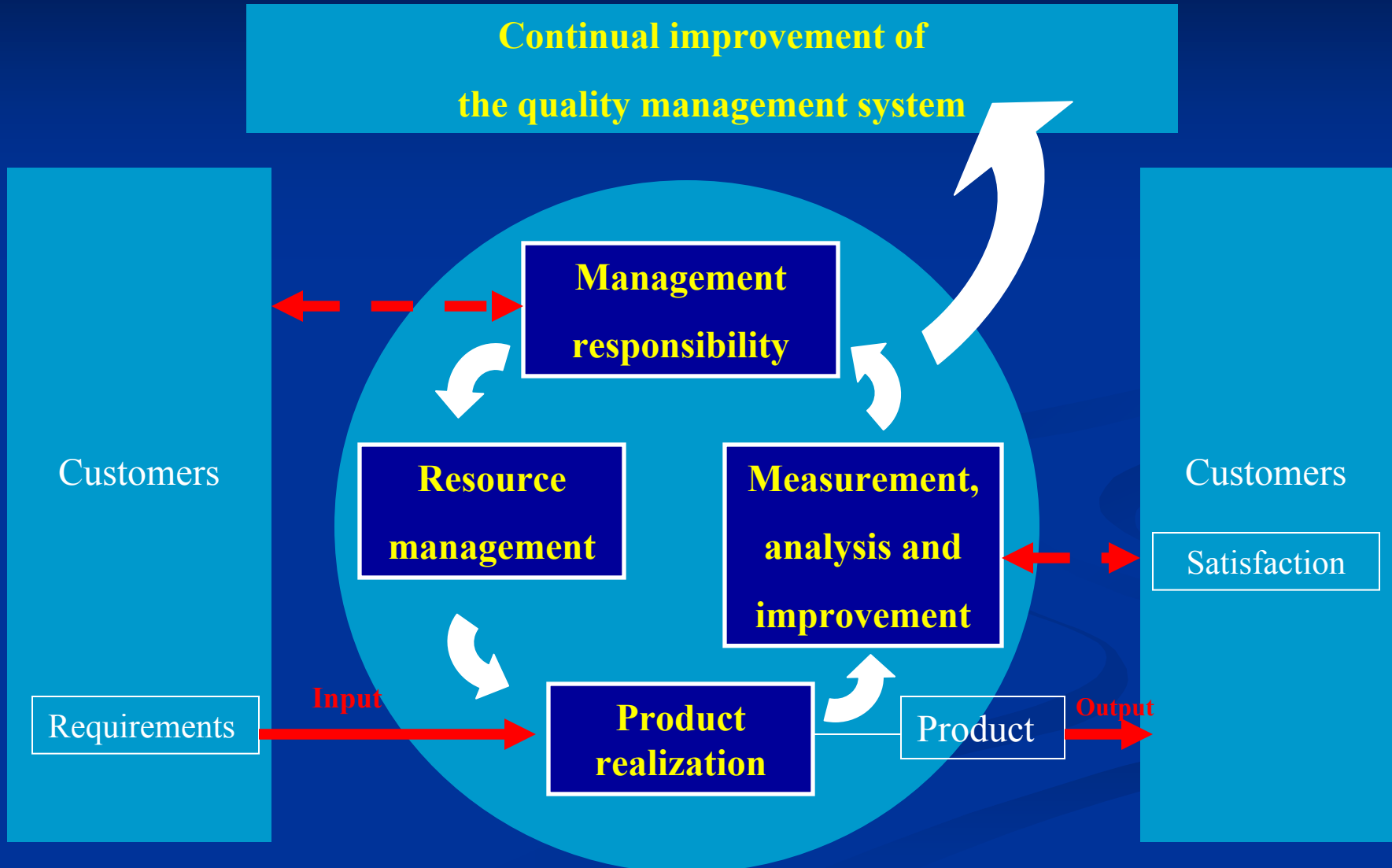
Existing solution searching

What-is-working amplification

*What do we need to do more of?*

*Strengths*

# Model of a Process-Based Quality Management System (QMS)



# Business Processes

## Customer Oriented Processes (COP's)

Market Analysis/Customer Requirements • Bid/Tender • Order/Request • Product and Process Design • Product and Process • Verification/Validation • Product Production/Realization • Delivery • Payment • Warranty/Service • Post Sales/Customer Feedback

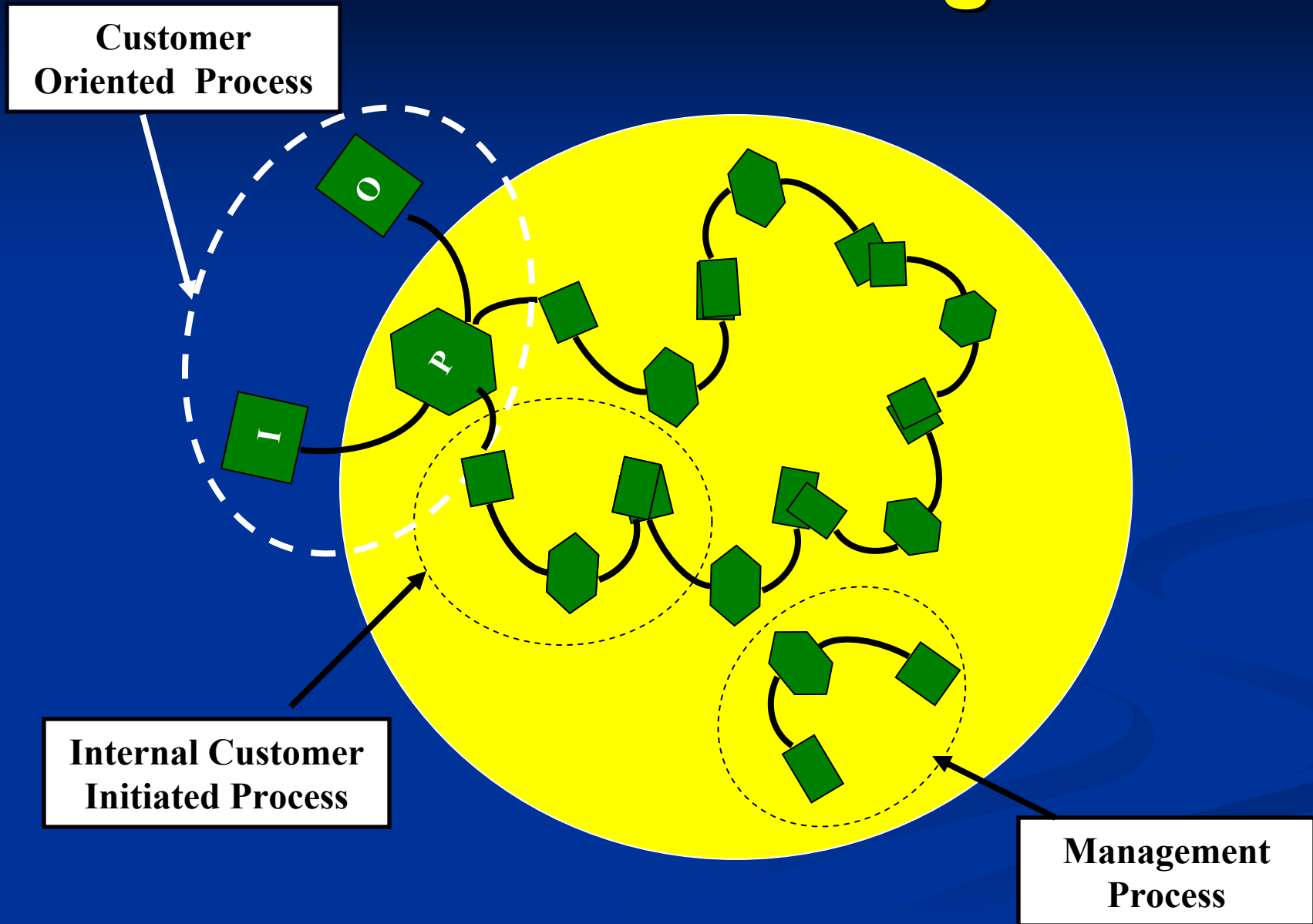
## Internal Customer Initiated (or core processes)

Marketing • Sales • Design • Purchasing • Production • Delivery • Service • Accounting

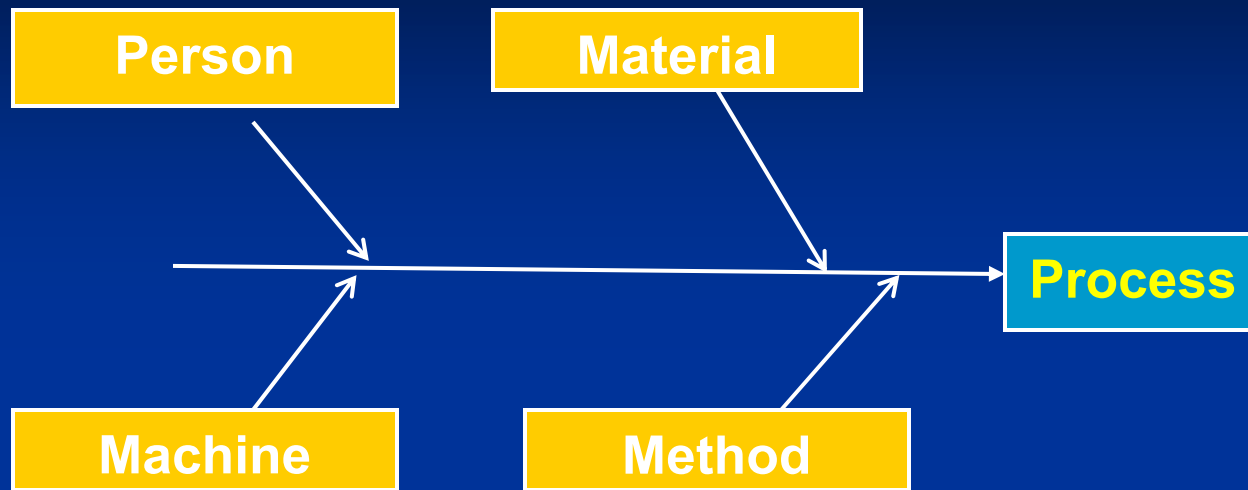
## Management Initiated (or support processes)

Benchmarking • Communication • Contract Review • Customer Property • Data Analysis  
Human Resource • Infrastructure • Inspection • Material Handling • Metrology  
Product Identification • Quality Policy • Resource Management • Training • Management Review • Customer Satisfaction and Measures • Corrective and Preventive Action • Records • Document and Data Control • Internal Audit  
Nonconforming Product Control • Continual Improvement  
Records • Auditing • Management Review • Maintenance

# Process Linkages



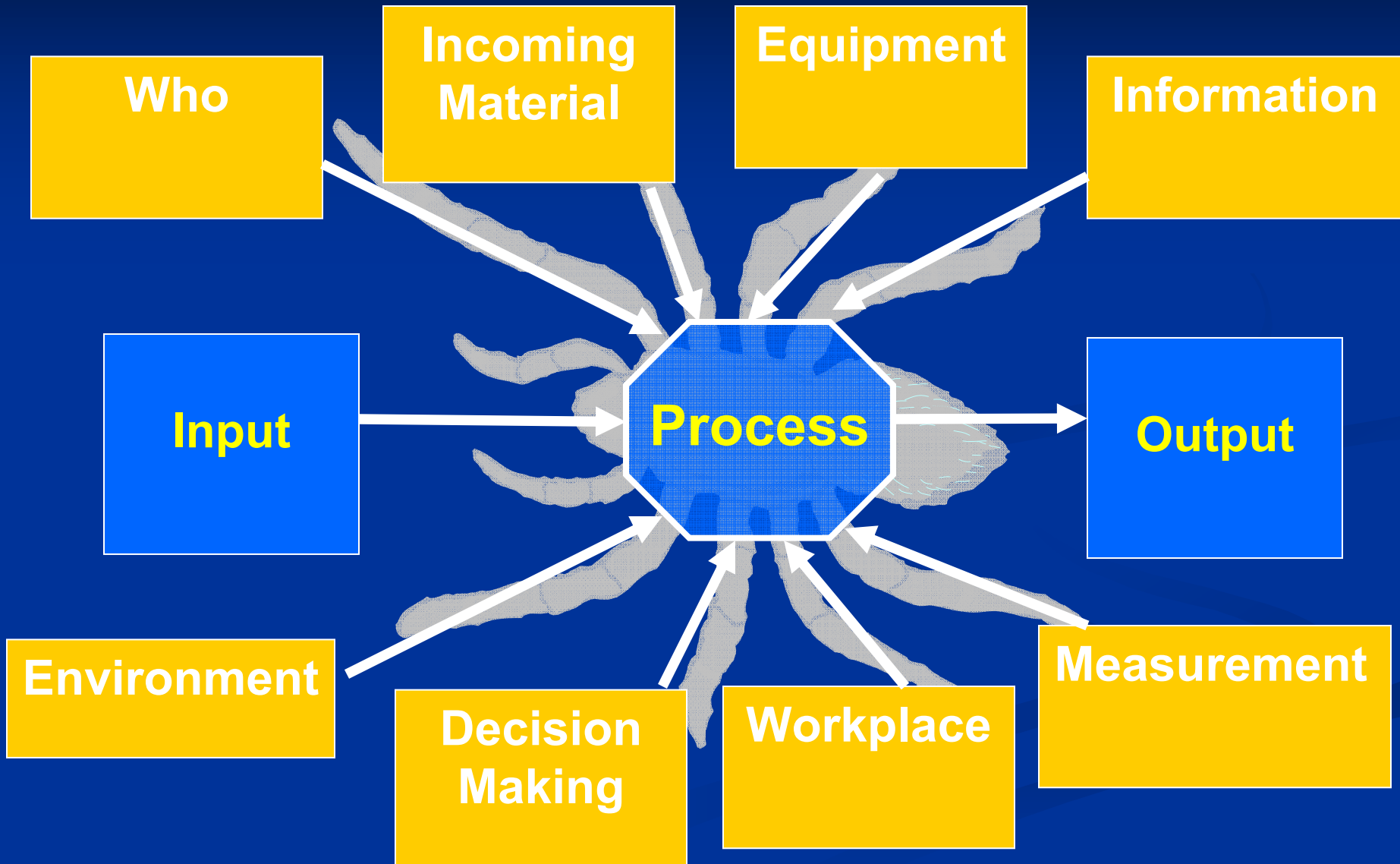
# Fishbone Process Model



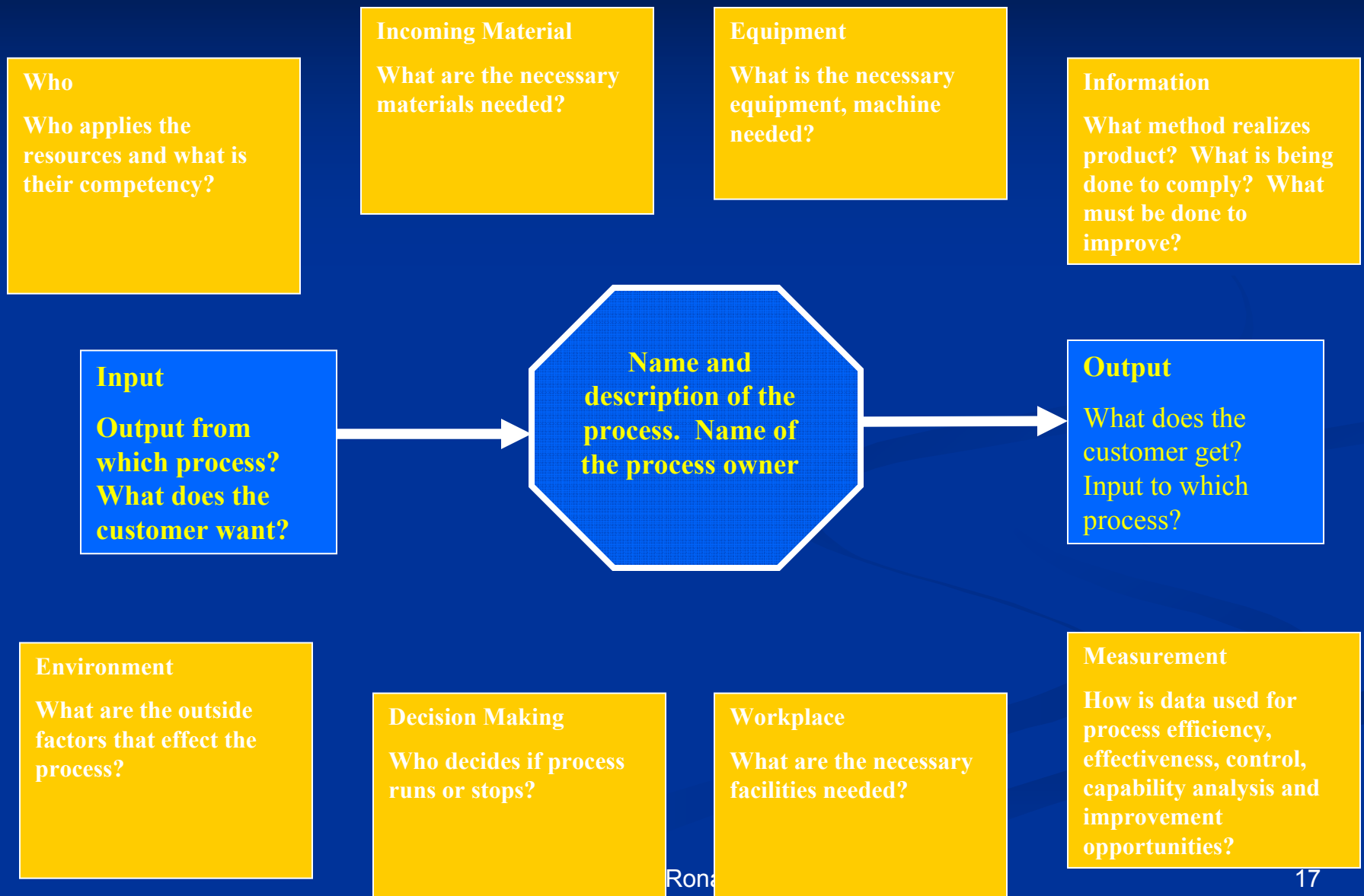
# S.I.P.O.C. Process Model



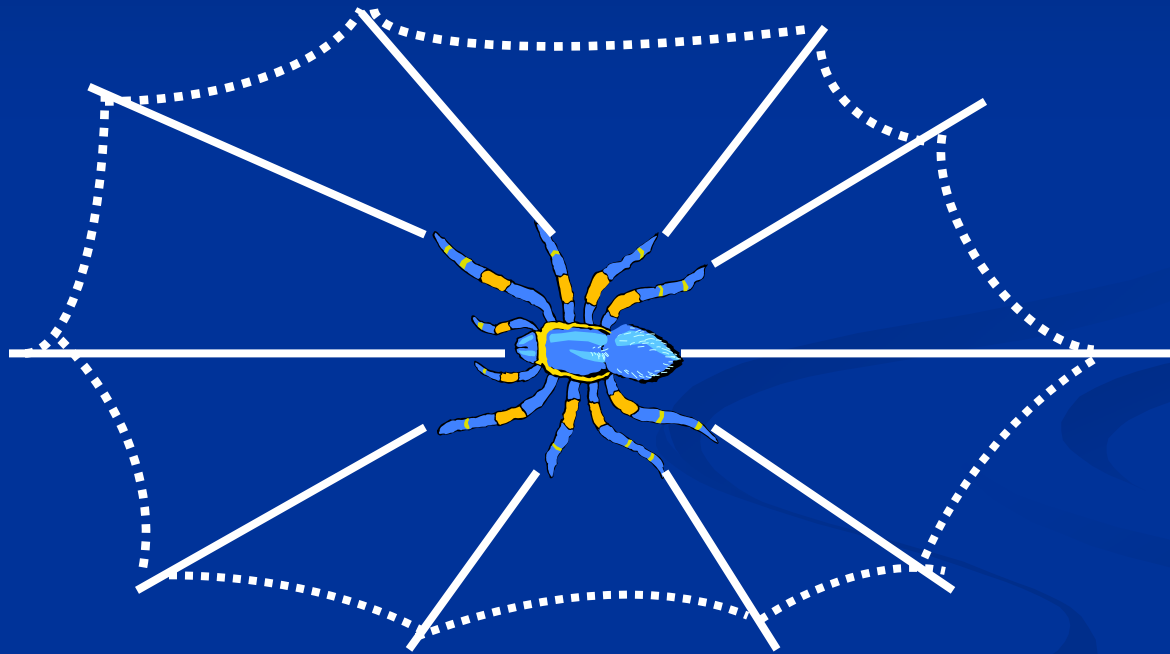
# IPO Spider Process Model™



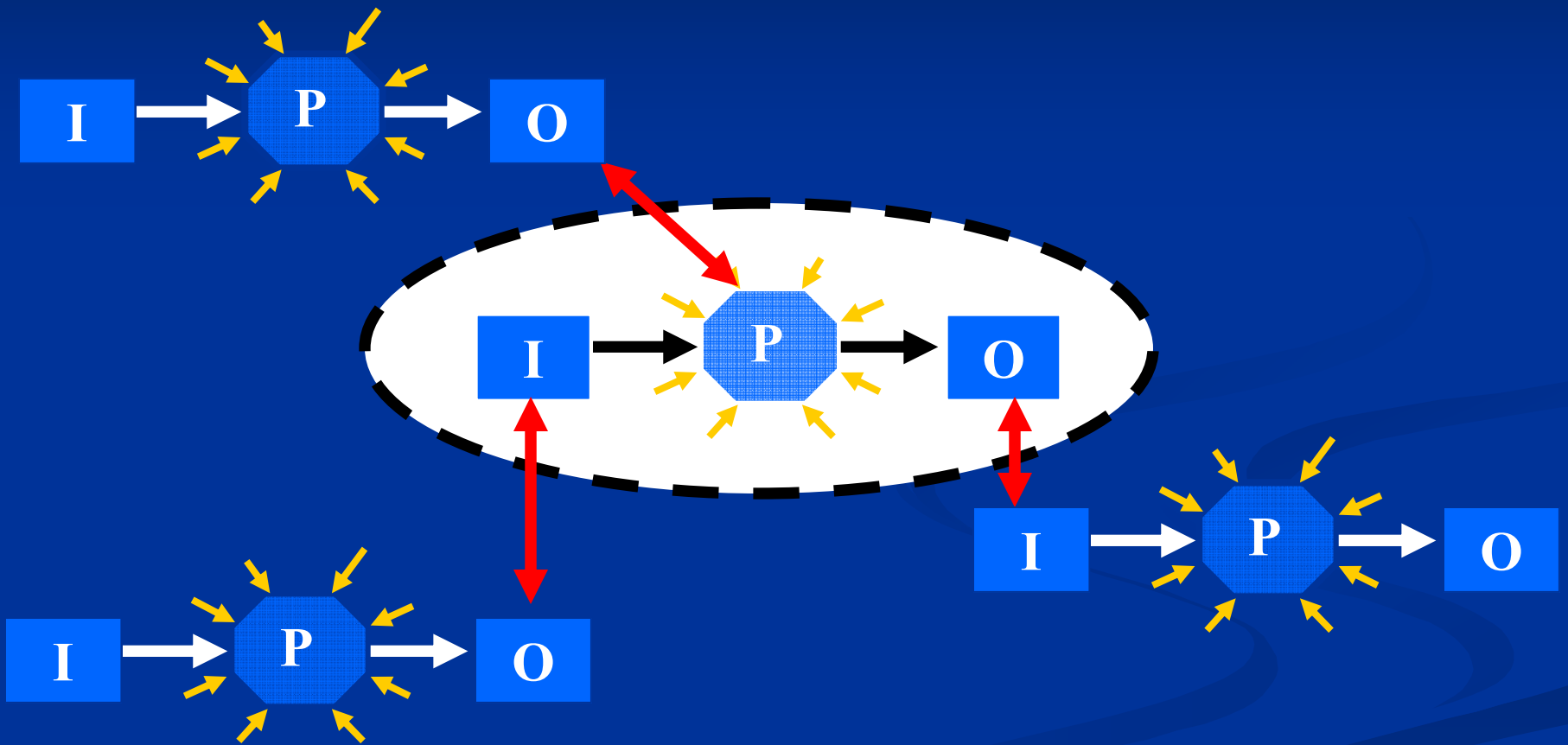
# IPO Spider Process Model™



# IPO Spider Web Model™



# IPO Spider Web Model™












ISO Clause	Processes											
	Material Acquire	Shipping Receiving	Test / QA	Engineering Development	Factory Accountability	Tool / Fod Control	HR	MRB Process	MRB Tags	Oil Analysis	Hydraulic Contamination	Fastener Install
<b>4. Quality Management System</b>												
4.1 General Requirements					3							
4.2 Documentation Requirements	2	3	2	2	2	2						
<b>5. Management Responsibility</b>												
5.1 Management commitment	4	4	4			3						
5.2 Customer Focus		4			4							
5.3 Quality Policy	2	3	2	3		2						
5.4 Planning					3							
5.5 Responsibility, Authority & Communication	4	4										
5.6 Management Review		3				3						
<b>6. Resource Management</b>												
6.1 Provision of Resources						3						
6.2 Human Resources		2	2	2	2	2						
6.3 Infrastructure		2				3						
6.4 Work Environment	4	4	4	4	2							
<b>7. Product Realization</b>												
7.1 Planning of Product Realization					2							
7.2 Customer - Realization												
7.3 Design & Development				3								
7.4 Purchasing	4											
7.5 Production & Service Provision		4	3	3								
7.6 Control of Monitoring & Measuring Device		2			2	2						
<b>8 Measurement, Analysis &amp; Improvement</b>												
8.1 General	4											
8.2 Monitoring & Measurement	4											
8.3 Control of Nonconforming Product		4										
8.4 Analysis of Data		4		4	4	3						
8.5.1 Continual Improvement												
8.5.2 Corrective Action	3			3								
8.5.3 Preventive Action												
<b>Health Process</b>	3.44	3.31	2.83	3.00	2.67	2.56						

**Heath Index**

1	Significantly below standards- (Major nonconformance's )
2	Needs improvement- (Minor Nonconformance's)
3	Meets Expectations - (Meets standard, but has some needs improvement observations)
4	Exceeds Expectations (No nonconformance's)
5	Far Exceeds Expectations (No nonconformances and positive observations)
Blank	(Not assessed)

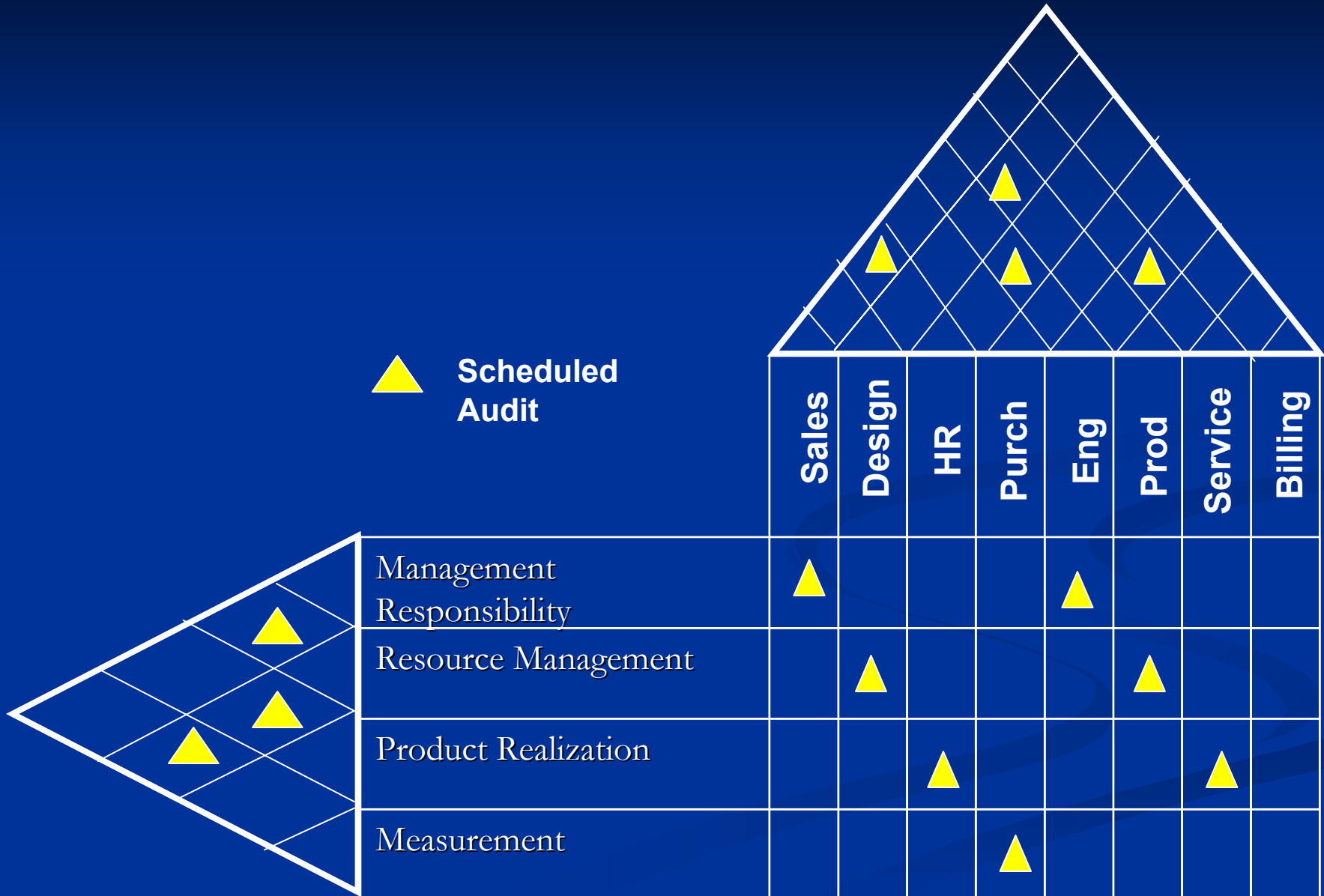
# Process-Based Audit Schedule

 **Scheduled Audit**

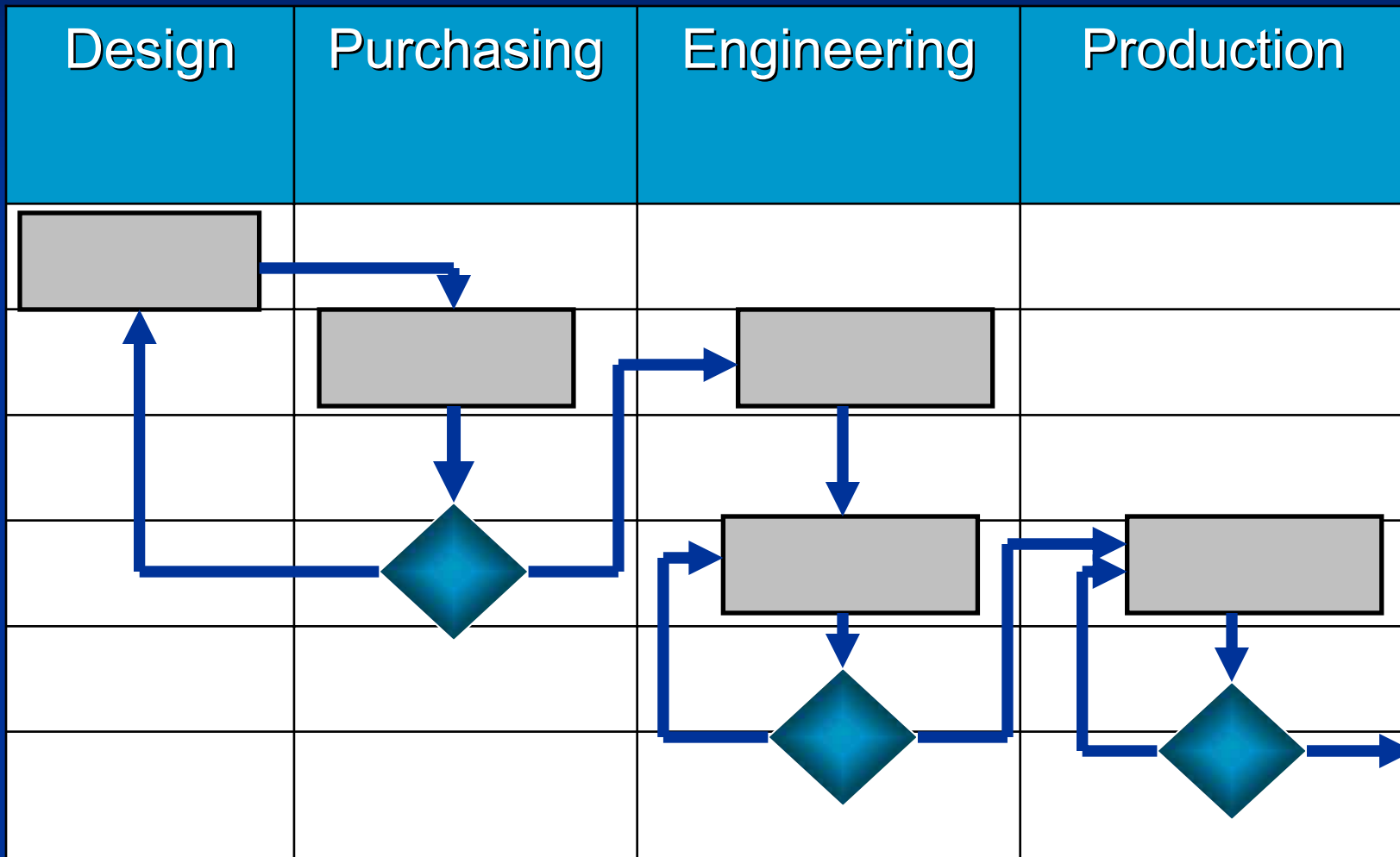
	Sales	Design	Purch	Eng	HR	Prod	QA	Ship
Management Responsibility								
Resource Management								
Product Realization								
Measurement								

# Process-Based Audit Schedule

▲ Scheduled Audit



# Auditing Systems



## ***Audit the arrows***

***A hand-off from one operation to another?***

***A communication link from one department or company to another?***

***Transporting product from one location to another?***

***An input to the process?***

***Indicating off-line processes?***

# ***Audit the diamonds***

***Was the decision based on facts?***

***Who made the decision?***

***How timely?***

***How many yes's vs. no's?***

***Where are they located?***

# Audit Report Content

## SECTION I: Audit Identification

- Auditee's name, location, date, product identification
- Key personnel contacted (*Cross-Functional*)
- Audit team members
- Auditors' qualifications
- Identification of checklist

## SECTION II: Results of Audit

- Strengths***
- Weaknesses***
- Major Discrepancies**
- Minor Discrepancies**
- Recommendations***
- Exit interview attendees (*Cross-Functional*)**

## SECTION III: References

- Audit team's appreciation
- Distribution list
- List of attachments

# Business Assessments

Quality Audits

## *In conclusion...*

1. Audit the arrows
2. Audit the diamonds
3. Report the good

***Bottom Line: Start Doing Business Assessments***

# Thanks for Listening!