

ISO 9001:2008 and ISO 9004:2009

Managing for the sustained success of an organization

Presenter: Branko Dimitrijevic

Deming Profound Knowledge

Knowledge

System

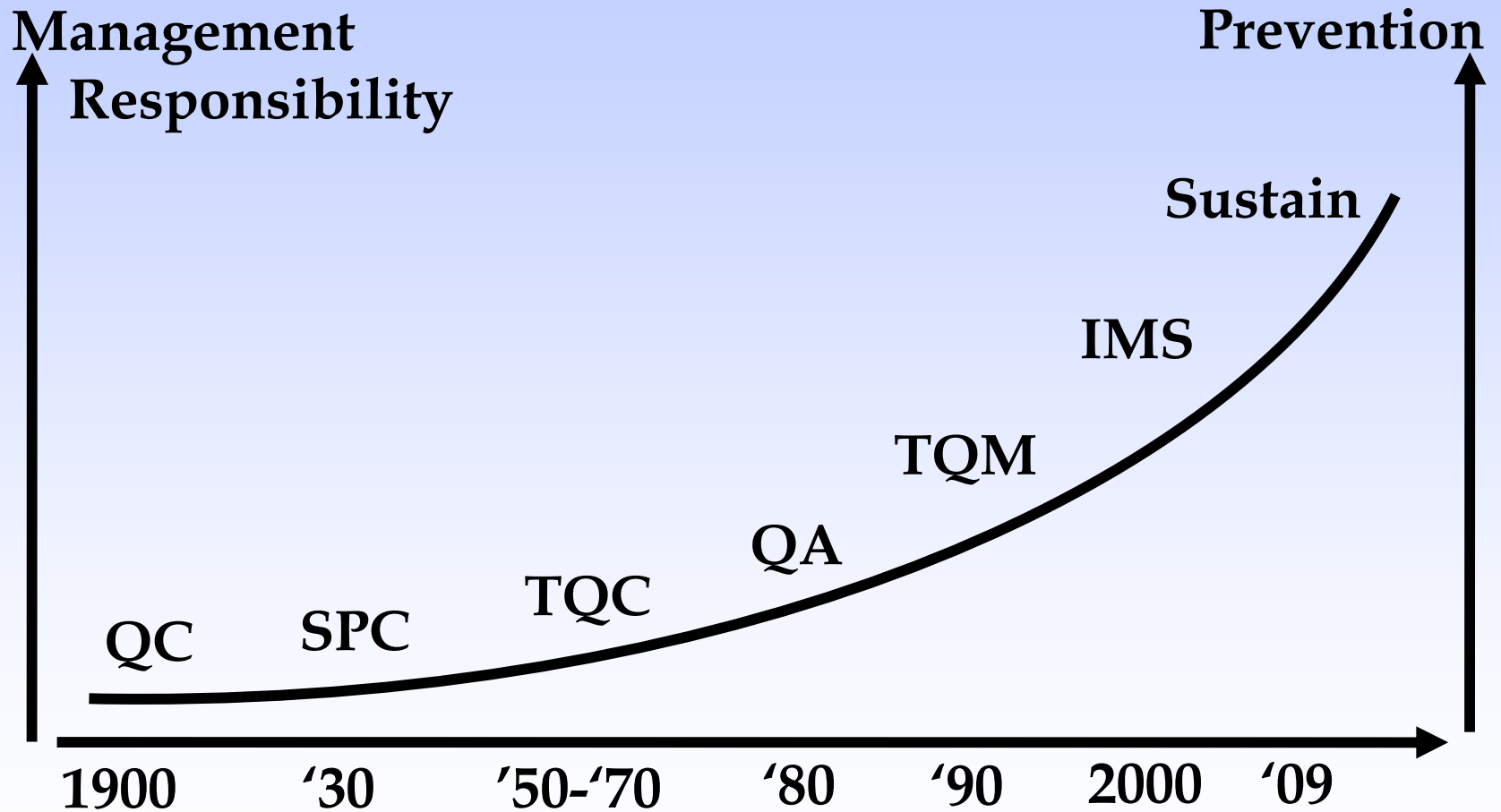
Variation

Psychology

Presentation Objectives

1. Quality Management System Evolution,
2. Process Approach,
3. ISO 9001:2008 Summary of Changes,
4. Integrated Management Systems,
5. Leadership and Management,
6. Define Sustainability
7. ISO 9004:2009 Overview
8. Questions and Discussions

Quality Background - History

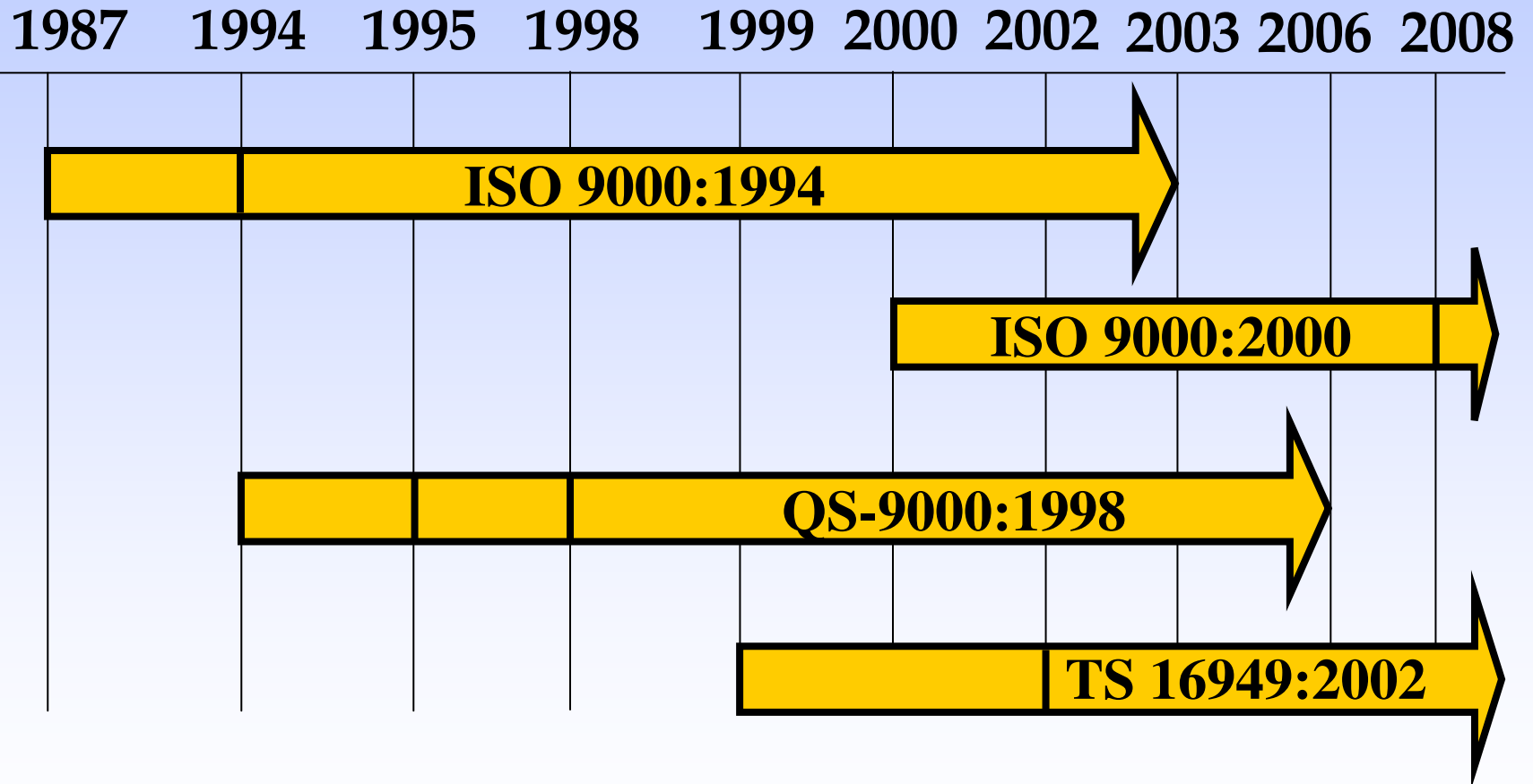


ISO 9000

History and Changes

- **Some of the ISO 9000 predecessor standards:
BS 5750, CAN Z299, ASQC Series, MIL 9858
(USA) and company specific standards**
- **The need for international quality management
standard**
- **ISO Technical Committee 176**
- **ISO 9000 Series published in 1987**

ISO 9000/QS-9000/TS 16949 History and Changes



ISO 9001:1994/QS-9000:1998

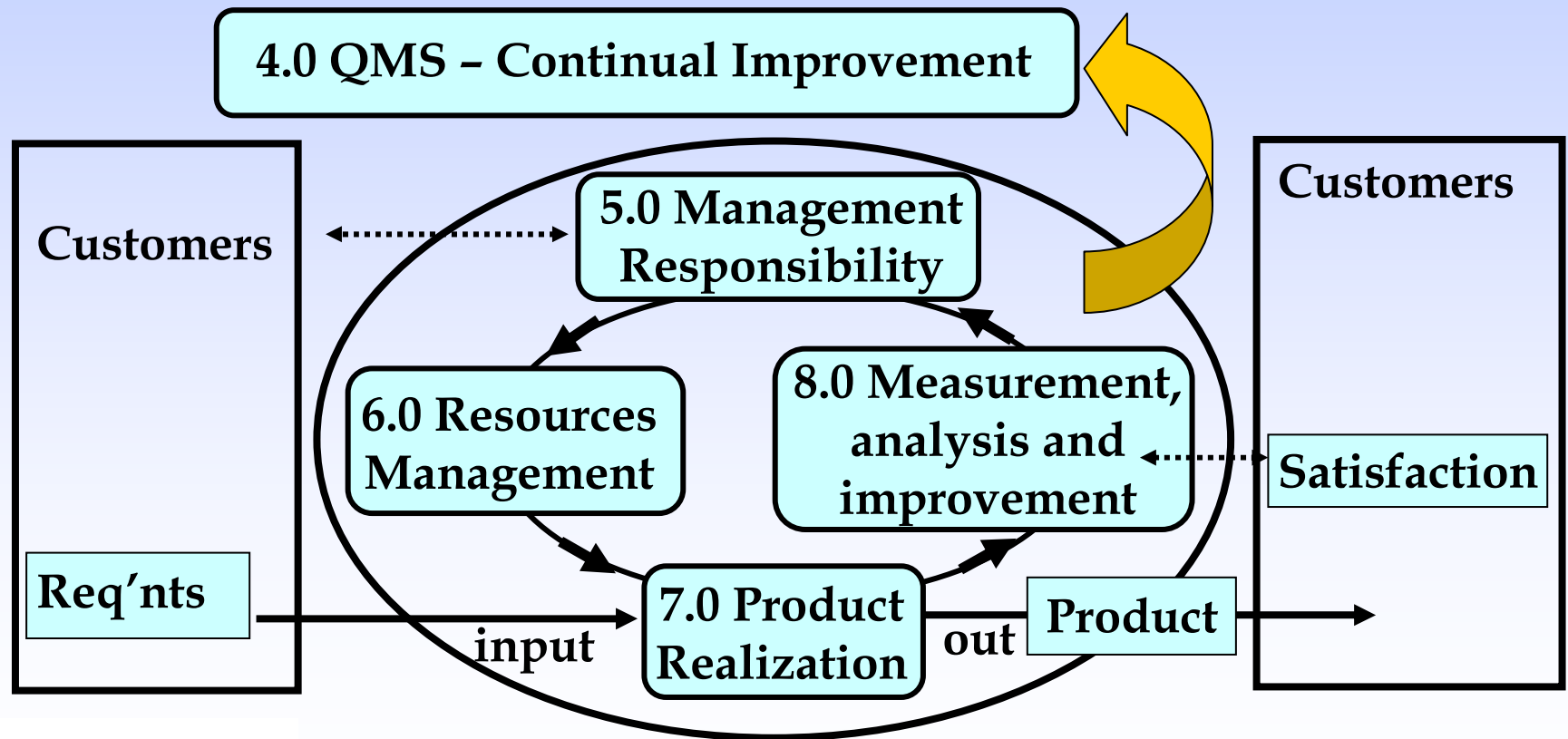
System Element	ISO Clauses		
	9001	9002	9003
<i>Italics = ISO 9001 Requirements</i>			
Management Responsibility	4.1	4.1	4.1
Quality System	4.2	4.2	4.2
Contract Review	4.3	4.3	4.3
Design Control	4.4	N/A	N/A
Document and Data Control	4.5	4.5	4.5
Purchasing	4.6	4.6	N/A
Control of Customer Supplied Product	4.7	4.7	4.7
Product Identification and Traceability	4.8	4.8	4.8
Process Control	4.9	4.9	N/A
Inspection and Testing	4.10	4.10	4.10

ISO 9001:1994/QS-9000:1998

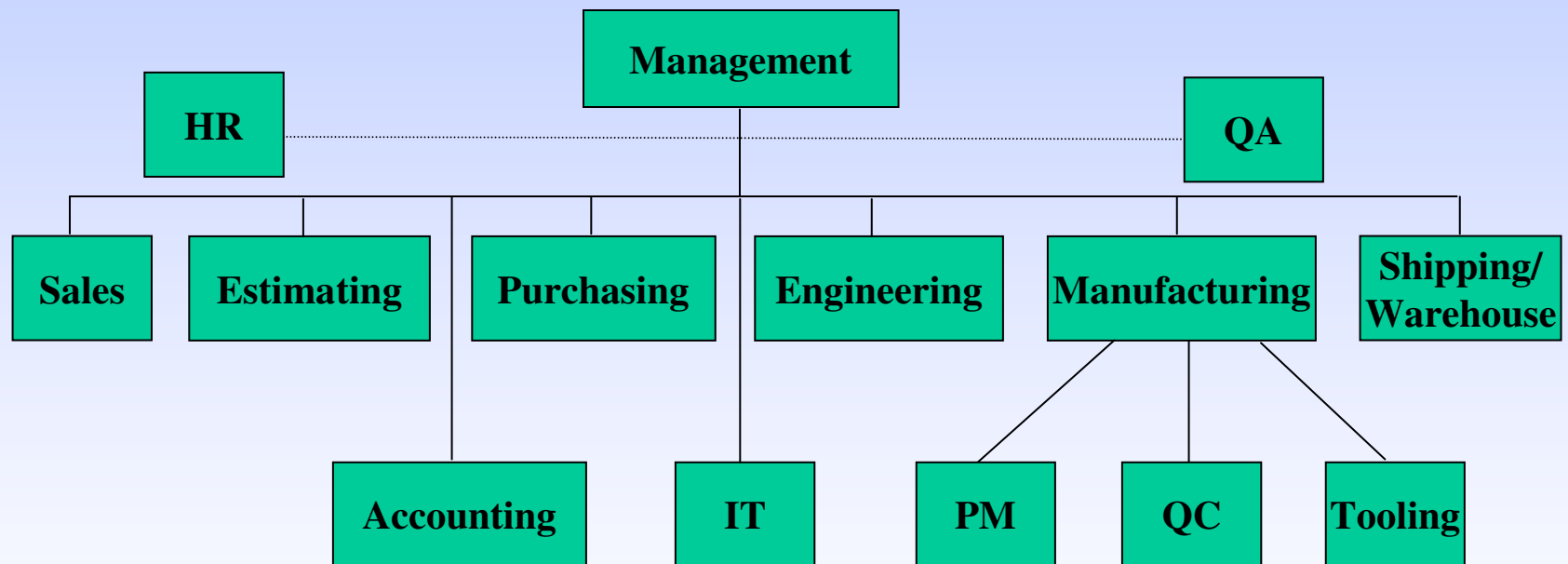
System Element	ISO Clauses		
	9001	9002	9003
<i>Italics = ISO 9001 Requirements</i>			
Control of IMT Equipment	4.11	4.11	4.11
Inspection and Test Status	4.12	4.12	4.12
Control of NC Product	4.13	4.13	4.13
Corrective and Preventive Action	4.14	4.14	4.14
Handl., Stor., Packaging, Preserv., Deliv.	4.15	4.15	4.15
Control of Quality Records	4.16	4.16	4.16
Internal Auditing	4.17	4.17	4.17
Training	4.18	4.18	4.18
Servicing	4.19	4.19	N/A
Statistical Techniques	4.20	4.20	4.20

ISO 9000:2000/TS 16949:2002

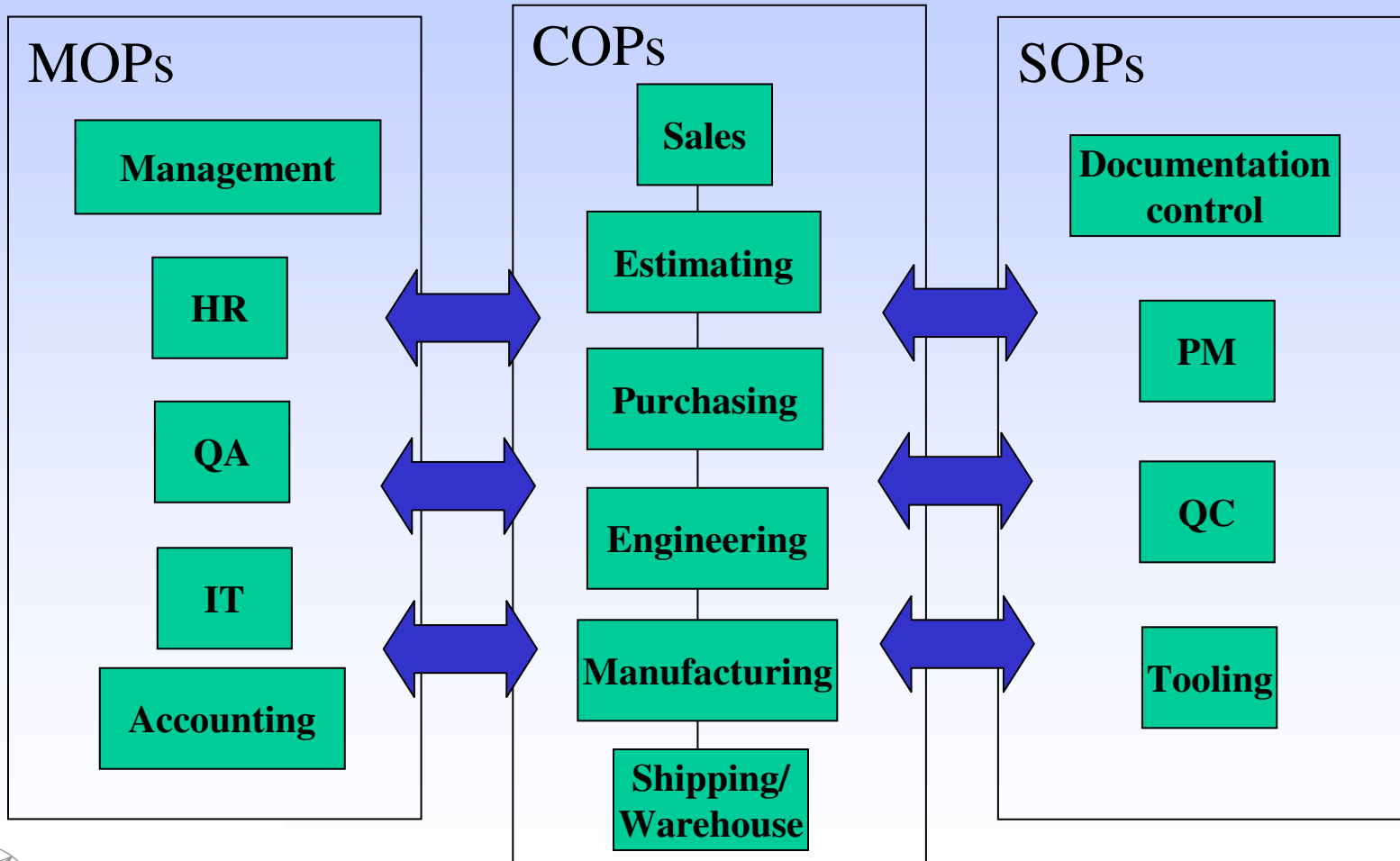
ISO 9000:2000 - Major difference is "Business Process Model"



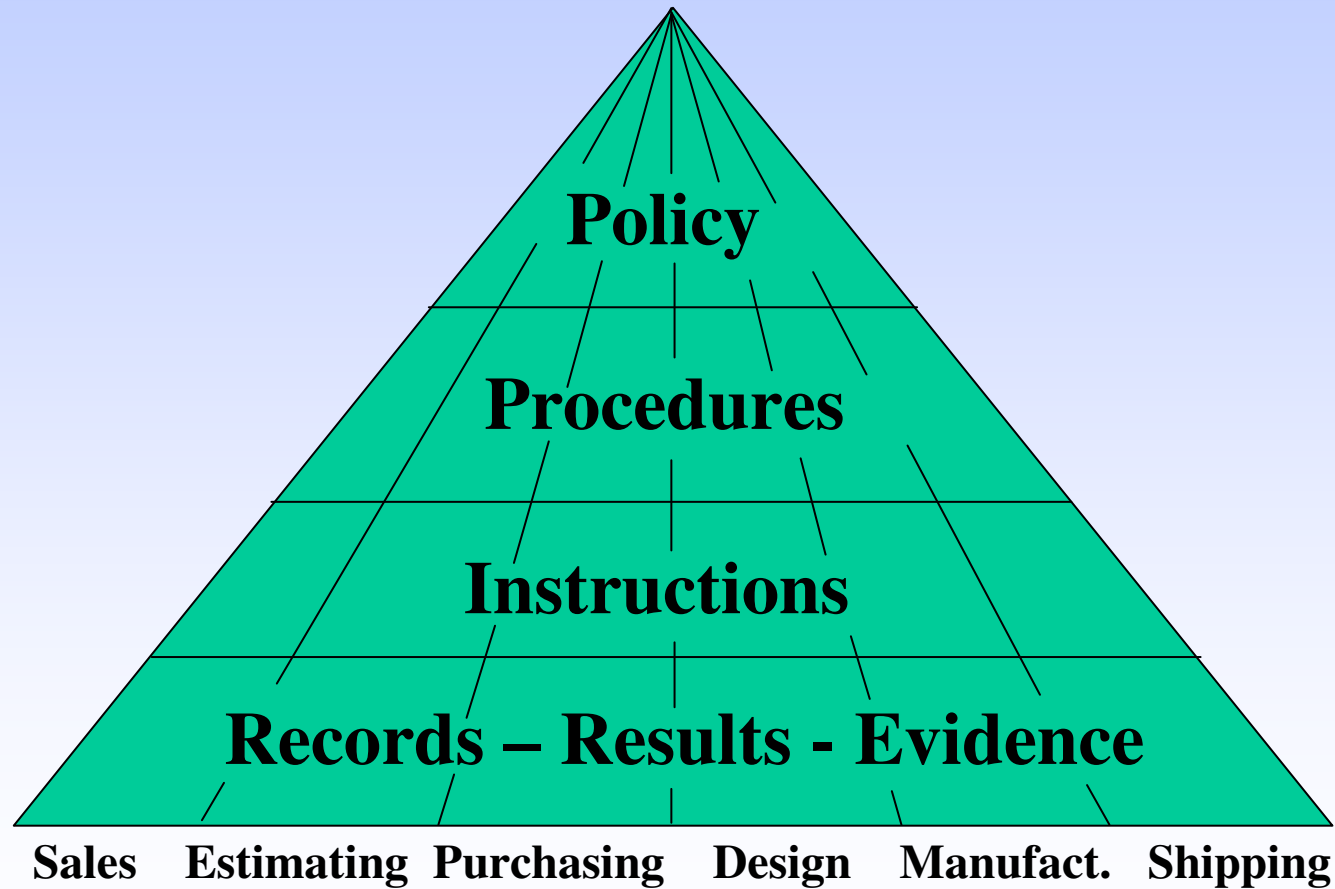
QMS Process Approach



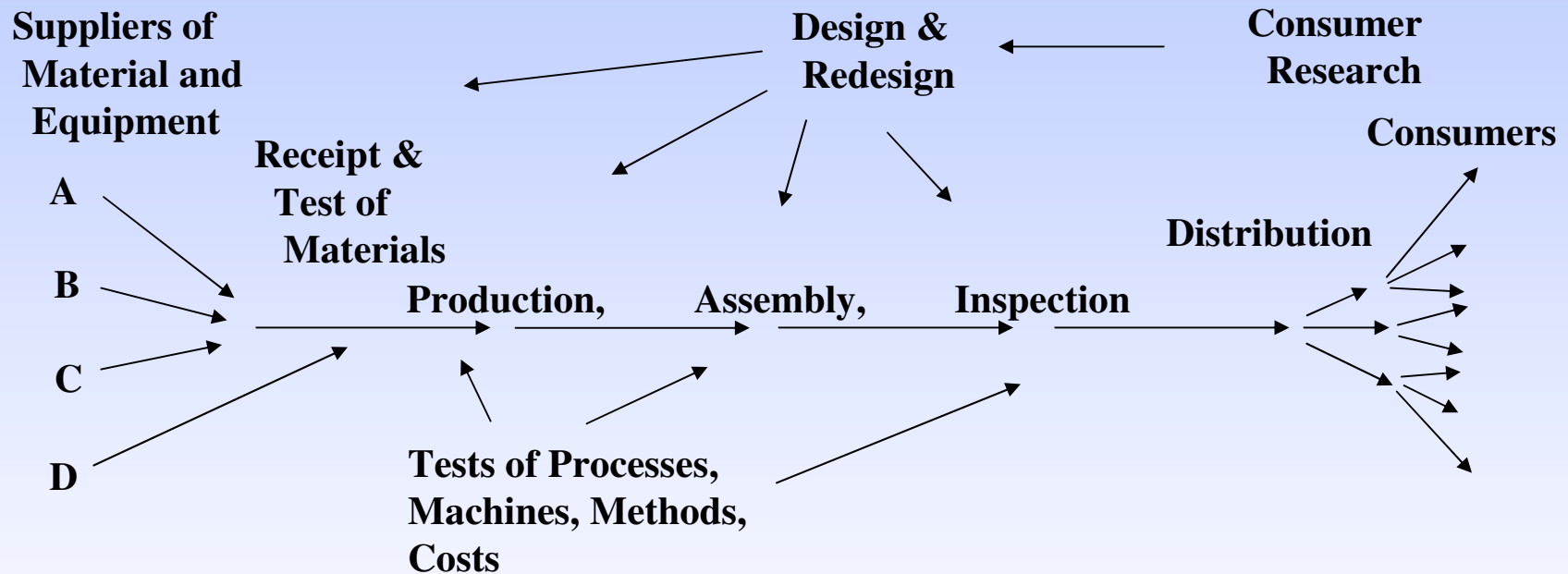
QMS Process Approach



QMS Process Approach



Process Model - 1950



Production viewed as a System. This chart was first used in August 1950 at a conference with Top Management at the Hotel de Yama on Mount Hakone Japan.

Source: ``Out of the Crisis`` - W. Edwards Deming

ISO 9001:2008

What is new?

ISO 9001:2008 Update

- **Impact on Organization:**
 - **No new requirements**
 - **Certification of conformity to ISO 9001:2008 and/or national equivalents shall only be issued after official publication of ISO 9001:2008 (which should take place before the end of 2008) and after a routine surveillance or recertification audit against ISO 9001:2008.**
 - **Validity of certifications to ISO 9001:2000**
 - **One year after publication of ISO 9001:2008 all accredited certifications issued (new certifications or re-certifications) shall be to ISO 9001:2008.**
 - **Twenty four months after publication by ISO of ISO 9001:2008, any existing certification issued to ISO 9001:2000 shall not be valid.**

ISO 9001:2008 Changes

- Changes:
 - Table of content
 - sub closes included (i.e. 4.2.1)
 - Annex A - ISO 9001:2008 vs. ISO 14001:2004
 - Introduction
 - 0.1 General - added organization's environment as a factor for implementing QMS
 - 0.3 Relationship with ISO 9004 - not a consistent pair any more
 - 0.4 Compatibility with other standards - replaced the word aligned with ISO 14001, with the words due consideration

ISO 9001:2008 Changes

- Changes:
 - 1 Scope
 - Note 1: term “product” applies to the product intended for, or required by, the customer or the product realization process
 - Note 2: Statutory and regulatory requirements may be expressed as legal requirements
 - 2 Normative Reference
 - Referencing ISO 9000:2005 QMS - Fundamentals and Vocabulary
 - 3 Terms and Definition
 - Removed the clarification about word “organization” vs. “supplier”

ISO 9001:2008 Changes

- Changes:
 - 4 QMS
 - 4.1 Note 1: definition of processes includes processes for analysis and improvement
 - 4.1 Note 2 and 3: Clarification of Outsourced Processes
 - 5 Management Responsibility - no changes
 - 6 Resources
 - 6.2.1 Note: Conformity may be affected directly or indirectly by personnel performing any task
 - 6.2.2 c): instead of evaluate actions taken, new wording is ensure that the necessary competence has been achieved
 - 6.4 Note: Clarification of the work environment - conditions under which the work is performed including physical, environmental and other factors

ISO 9001:2008 Changes

- Changes:
 - 7 Product Realization
 - 7.2.1 Note: Clarification of Post Delivery activities
 - 7.3.1 Note: Clarification of design review vs. verification vs. validation
 - 7.3.3 Note: Design output information may include preservation
 - 7.6 Note: Clarification of the confirmation of the software ability
 - 8 Measurement, analysis and improvement
 - 8.2.1 Note: Monitoring customer perception - examples
 - 8.2.2 Note: Reference to ISO 19011 for Guidance
 - 8.2.3 Note: Extent of Monitoring processes to be based on their impact on customer and QMS performance

ISO 9001:2008

**ISO
World Wide Survey
2007**

ISO 9001:2008

Questions about ISO 9001:2008?

ISO 9001:2008

ISO 9001

What is the problem?

1. Is Management all about quality and customers?
2. What is TQM ?
 - Managing Total Quality, or
 - Total Quality of Management

Quality Background of the ISO 9000 Standards - TQM

TQM is:

“the management approach of an organization centered on quality, based on the participation of all its members and aiming at long-term success through customer satisfaction, and benefits to all members of the organization and to society.”

Business Stakeholders

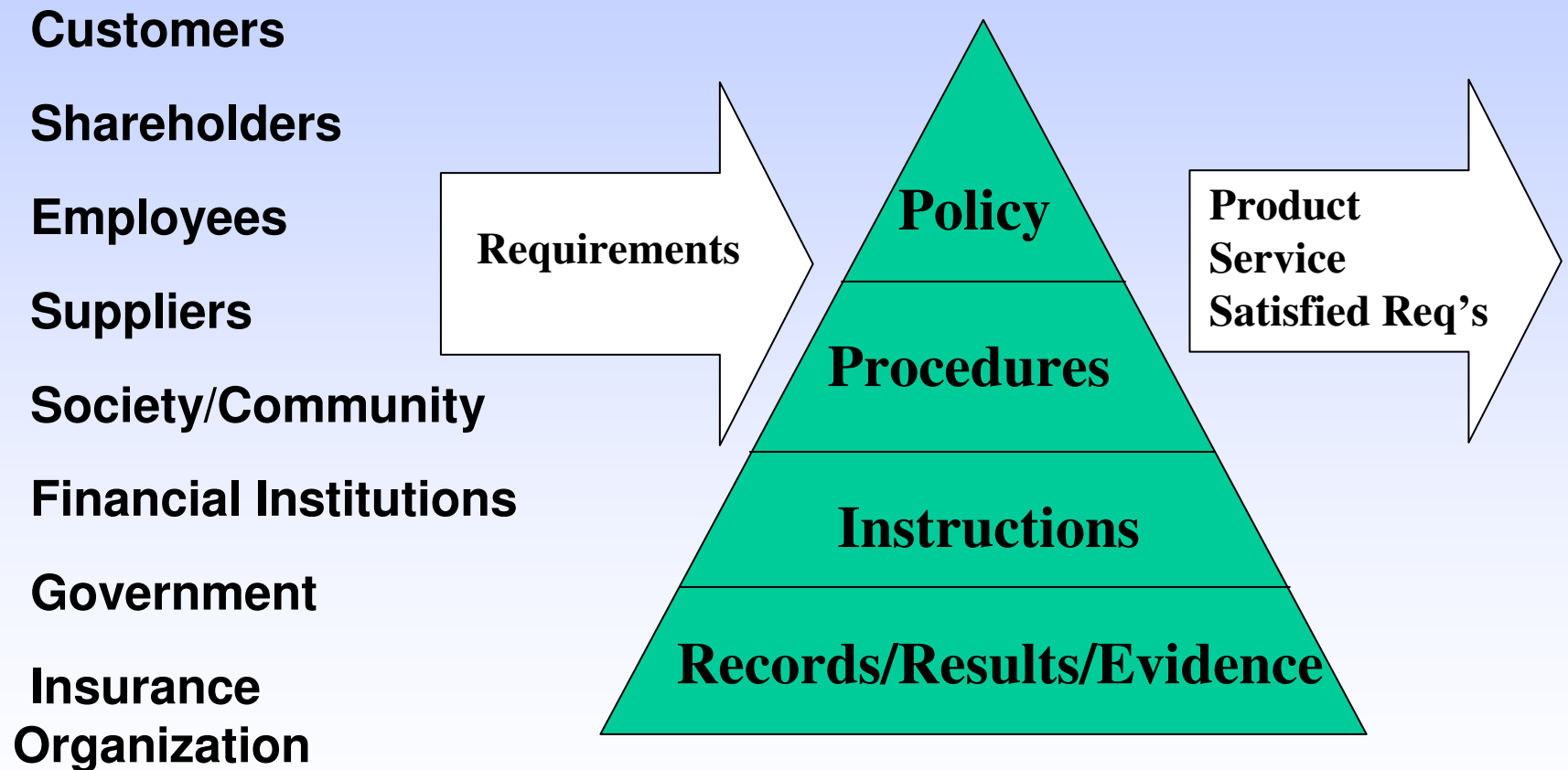
**Who has an interest in your
business?**

**Who are the stakeholders of any
business?**

Business Stakeholders

- Customers/Clients
 - Shareholders
 - Management
 - Employees
 - Suppliers
- Public/Surrounding Community
- Government/Regulatory Bodies
 - Insurers
- Financial Institutions/Lenders

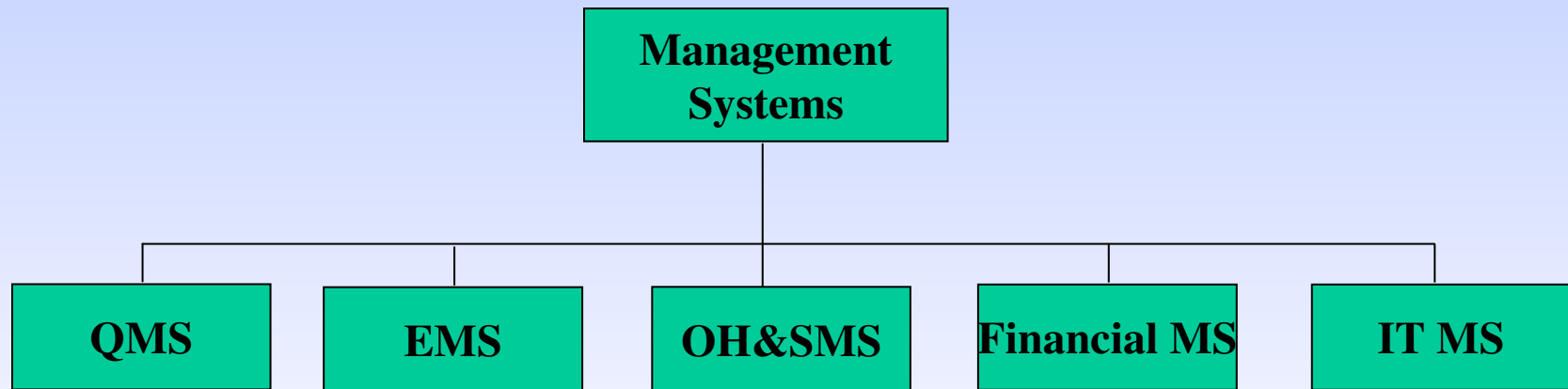
Management System Integration



Management Systems

1. **Quality Management System (ISO 9001:2000, ISO/TS 16949)**
2. **Environmental Management System (ISO 14001)**
3. **Health & Safety Management System (OHSAS 18001)**
4. **Financial Management System**
5. **Information Management System**

Integrating Management Systems



Management System Integration

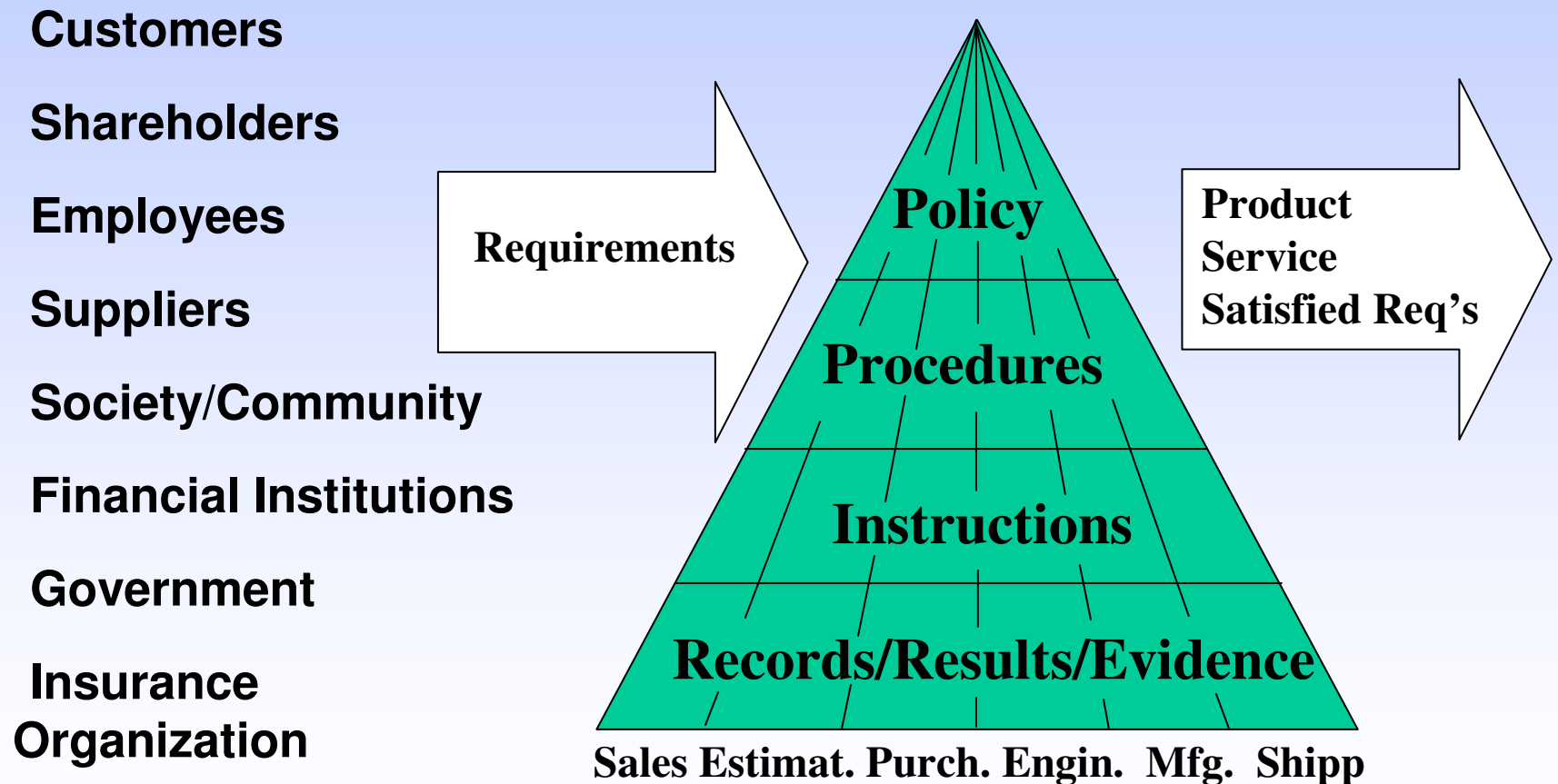
ISO 9001:2008

0.4 Compatibility with other management systems

This International Standard (ISO 9000:2008) has been developed with due consideration to ISO 14001:2004 in order to enhance the compatibility of the two standards for the benefit of the user community.

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, this International Standard enables an organization to align or integrate its own QMS with related management system requirements.

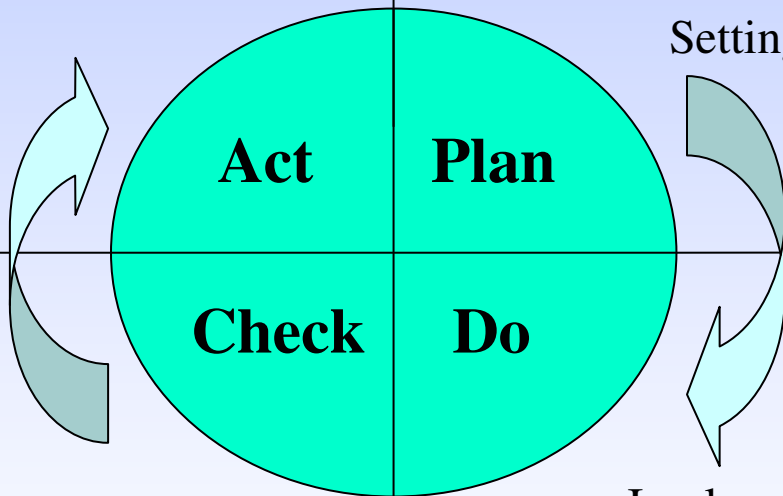
How to Integrate Management Systems - Process Approach



How to Integrate Management Systems - PDCA Approach

Management Review
Corrective Action
Preventive Action

Develop Policies and Structures
Risk Assessment (Legal & Other)
Business Planning
Setting Objectives & Targets



Monitoring & Measuring
- Product
- Process
Nonconformances, Incidents
Auditing

Implementation & Operations
Responsibility & Training
Communication
Document & Record Control
Process Controls

Integrated Management Systems

IMS

What is the problem?

- Is Management all about Systems?
- How do we stay successful over a long term?

Focus of QMS

- Customers/Clients
 - Shareholders
 - Management
 - Employees
 - Suppliers
- Public/Surrounding Community
- Government/Regulatory Bodies
 - Insurers
- Financial Institutions/Lenders

Focus of Management Systems

Knowledge

System

Variation

Psychology

Focus of Management Systems

How do we address the
Knowledge and Psychology?

Leadership

Leadership and Management

Deming - 14 Points

1. **Create constancy of purpose**
2. **Adopt the new philosophy. Management must awaken and take on leadership for change**
3. **Cease dependence on inspection**
4. **End the practice of awarding business based on price tag**
5. **Improve constantly and forever the system of production and service**
6. **Institute training on the job**
7. **Institute Leadership**

Deming - 14 Points

8. Drive out fear, so that everyone may work effectively for the company
9. Break down barriers between departments
10. Eliminate slogans, exhortations, and targets for the work force asking for zero defects
11. Eliminate a) work standards (quotas) on the factory floor, and b) management by objectives
12. Eliminate barriers for the pride of workmanship
13. Institute a vigorous program of education and self-improvement
14. The transformation is everybody's job

ISO/TS 16949

8 QMS Principles

- Customer focus
- Leadership
- Involvement of people
- Process approach
- System approach to management
- Continual improvement
- Factual approach to decision making
- Mutually beneficial supplier relationships

Leadership

Warren Bennis

“Management is getting people to do what needs to be done. Leadership is getting people want to do what needs to be done.

Managers push. Leaders pull.

Managers command. Leaders communicate.”

Leadership

James Kouzes:

“A major difference between management and leadership can be found in the root meaning of the two words, the difference between what it means to handle things and what it means to go places.”

Leadership

Tom Peters:

“Developing a vision and, more important, living it vigorously are essential elements of leadership...”

Vision occupies an equally important place of honor in the supervisor’s or middle manager’s world.”

Leadership Theories

Great-Man Theories

Situational Theories

Trait Theories

Psychoanalysis Theories

Charismatic Leadership

Managerial and Strategic Leadership

Results Based Leadership

Leader as a Teacher

Servant Leadership

Leadership / Management

People

Spontaneity

Empowerment

Effectiveness

Investment

Doing the right things

Direction

Purpose

Principles

On the system

Things

Structure

Control

Efficiency

Expense

Doing things right

Speed

Methods

Practices

In the system

Leadership Systems

How to align:

Mission,

Structure,

Knowledge,

Skills,

People

ISO 9004:2009

**Managing for the sustained
success of an organization**

Sustainability - Defined

“Build to Last”, Jim Collins and Jerry I. Porras

Try to identify fundamental principles of the so called “Visionary Companies” or companies who survived for at least 50 years through various product life cycles, technological evolutions and revolutions, various management theories and generations of active leaders.

Sustainability - Defined

1812 Citicorp

1837 Procter & Gamble

1847 Philip Morris

1850 American Express

1886 Johnson & Johnson

1891 Merck

1892 General Electric

1901 Nordstrom

1902 3M

1903 Ford

1911 IBM

1915 Boeing

1923 Walt Disney

1927 Marriott

1928 Motorola

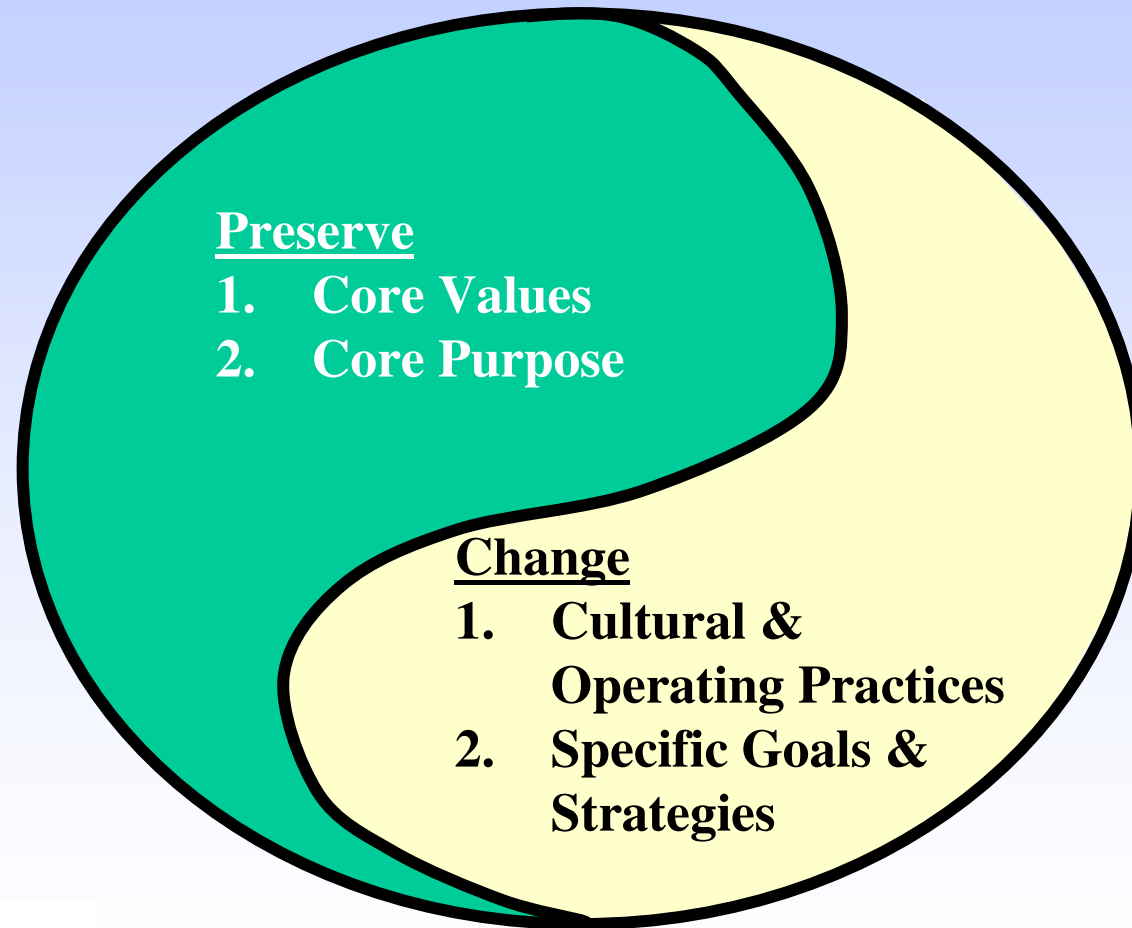
1938 Hewlett-Packard

1945 Sony

1945 Wal-Mart

Sustainability

Balance between Continuity and Change



Sustainability

Balance between Continuity and Change

If the main principle of great organizations is to achieve a constant balance between Continuity and Change, then those two are exactly the main *two roles of leadership*:

- To ensure that Core Values and Core Purpose is defined and preserved over time, and
- To ensure that Changes of Operational and Cultural Practices are taking place as well as constant evaluation and establishment of Goals and Strategies

Sustainability - Defined

- **Definition**
 - **sustained success: result of the ability of the organization to achieve and maintain its objectives in the long term**
- **ISO 9004:2009:**
 - **The sustained success of an organization is demonstrated by its ability to satisfy needs and expectations of its customers and other interested parties over the *long term* and in a *balanced way*.**

Sustainability - Defined

- **Definition**
 - organization's environment is a combination of external and internal factors and conditions that can affect the achievement of an organization's objectives, and its behaviour towards interested parties.
- **ISO 9004:2009:**
 - provides wider focus on quality management than ISO 9001; it addresses the needs and expectations of all interested parties and their satisfaction.

ISO 9004:2009

- Overview of the Standard

Managing for Sustainability

Questions?

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