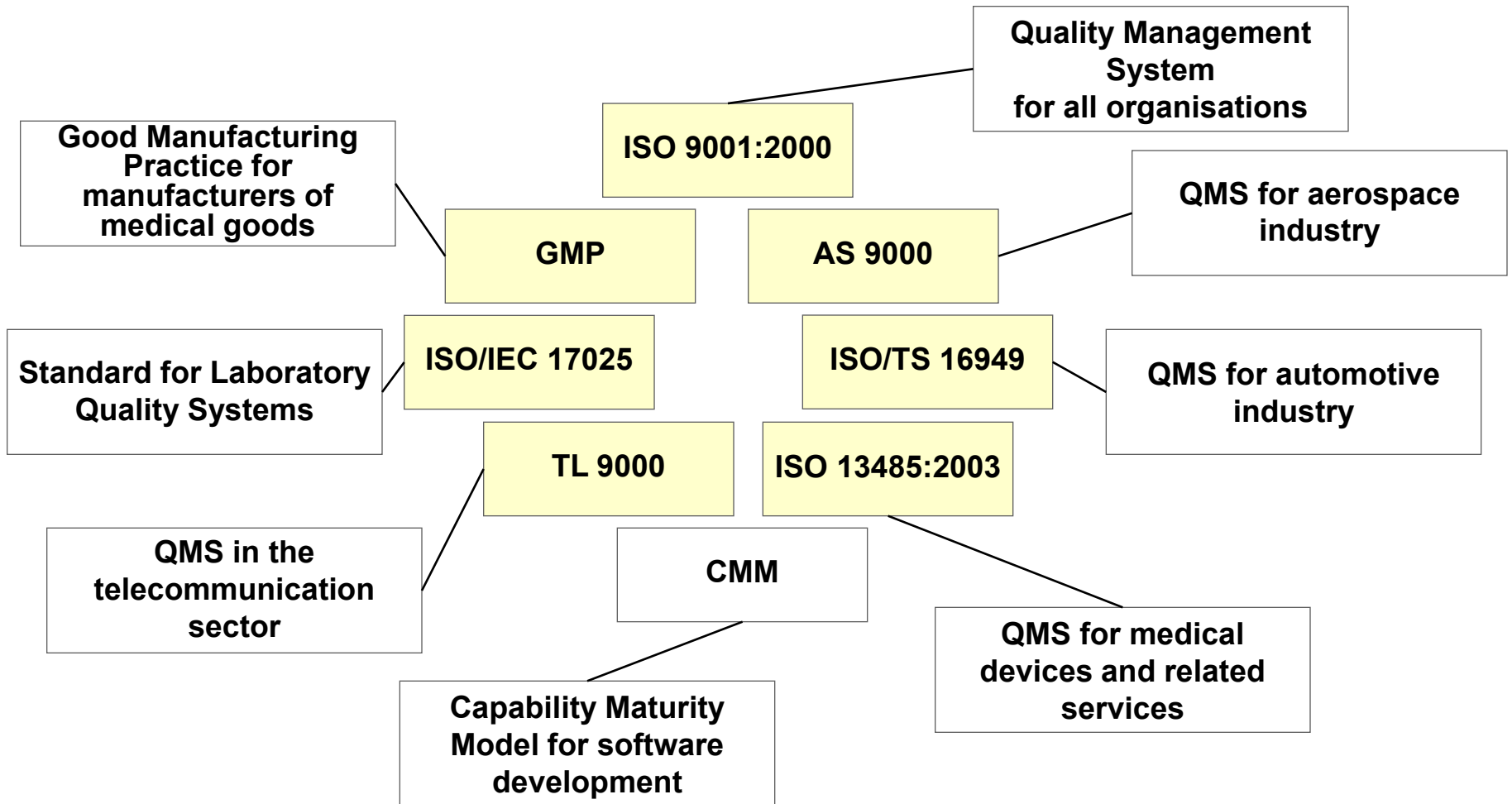

ISO 9000:2000

ISO 9001:2000

ISO 9001: 2008

Quality management system

Different Quality Management Systems



Core principles of QMS

- **Standardised and documented processes**
 - Documents that describe what is done in the organisation to identify and achieve the customers' requirements
- **Conformance**
 - An audit trail, so that it is possible to see the system working as described in the documents
- **Monitoring and measurement**
 - Records to prove that it has been working according to plan
- **Improvement!**

www.iei.liu.se/content/1/c6/09/62/40/QMS_miljo.ppt

Implementation strategy vs. maturity of quality management

		Maturity of quality management	
		Low level	High level
Implementation strategy	Standardising practice	Business as usual	Business as usual
	Practising standard	Radical change	Development

ISO



- some 157 national Standard institutes
- a non-governmental organization
- its members are not delegations of national governments
- voluntary standards on technology
- only standards required by the market
- central secretariat in Geneva, Switzerland
- ISO's national members pay subscriptions that meet the operational cost of ISO's Central Secretariat

www.iso.org

ISO 9000 and quality management

- **Quality** refers to all those features of a product (or service) which are required by the customer.
- **Quality management** means what the organization does to:
 - ensure that its products or services satisfy the customer's **quality requirements** and
 - comply with any **regulations** applicable to those products or services
 - enhance **customer satisfaction**, and
 - achieve **continual improvement** of its performance.

ISO 9000 – generic standards

Generic means that the same standards can be applied:

- to **any organization**, large or small, whatever its product or service,
- in **any sector** of activity, and
- whether it is a business enterprise, a public administration, or a government department.

„Boosting quality to differentiate yourself from the competition“ ????

ISO 9000



- An international set of standards for quality management.
- Applicable to a range of organisations from manufacturing to service industries.
- ISO 9001 applicable to organisations which design, develop and maintain products.
- ISO 9001 is a generic model of the quality process that must be instantiated for each organisation using the standard.

Management systems in general and ISO 9000

- To be really **efficient and effective**, the organization can manage its way of doing things by **systemizing** it.
- Nothing important should be left out.
- **Everyone should be clear about who is responsible** for doing what, when, how, why and where.
- Management system standards provide the organization with an international, **state-of-the-art model to follow**.
- not product standards.

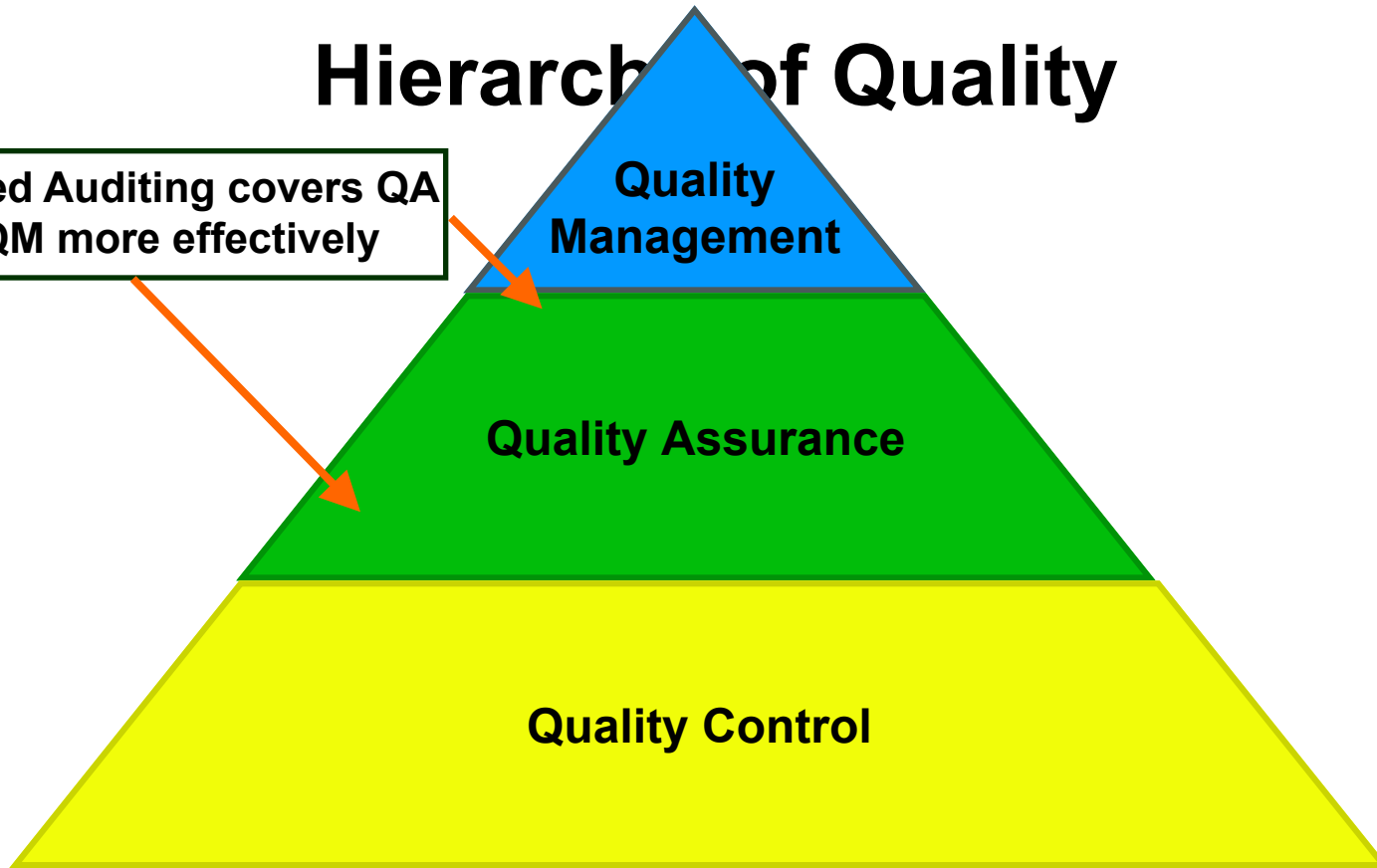
ISO 9000 family standards

They **are not product standards**

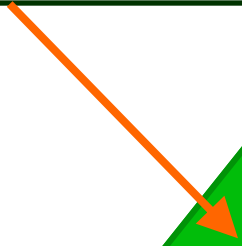
They **are not service standards**.

- They are **process standards**.
- They can be used by **product manufacturers and service providers**.

Hierarchy of Quality



Advanced Auditing covers QA and QM more effectively



Basic "conformance" auditing covers QC level

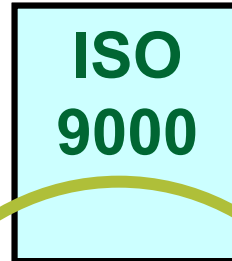


ISO 9000:2000 Family

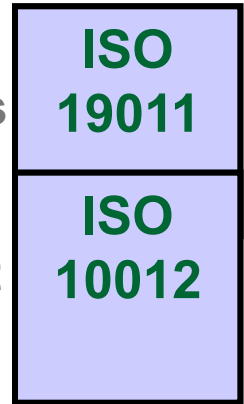
There are **16 other standards** in the family that can help an organization on specific aspects such as performance improvement, auditing, training...

Annexes A & B for information only

Quality management systems -
Fundamentals & vocabulary



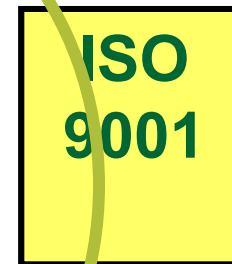
Measurement



Audits

Guidelines

Quality management systems -
Guidelines for performance improvement



Quality management systems -
Requirements



ISO 9001 gives the requirements for what the organization must do to manage **processes affecting quality** of its products and services.

The ISO 9000 Series of Standards



ISO 9000



ISO 9001



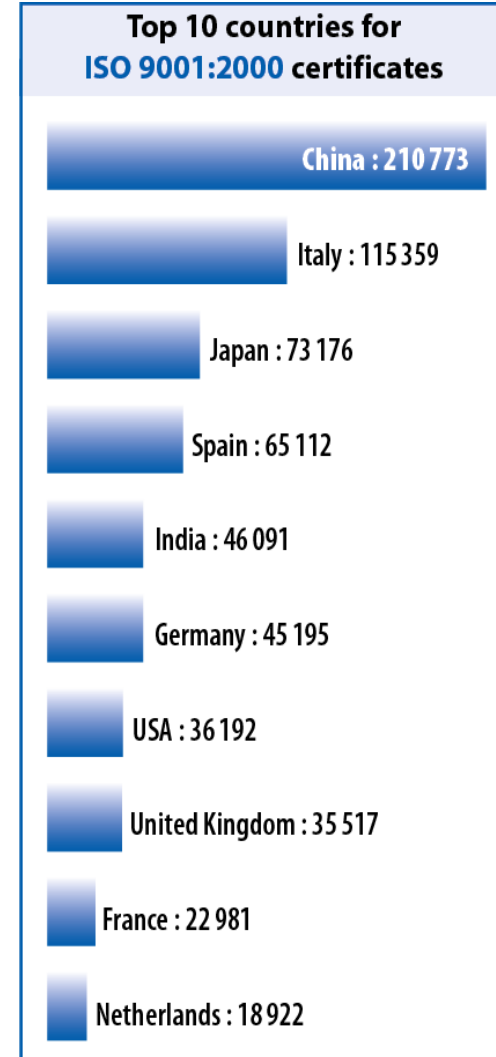
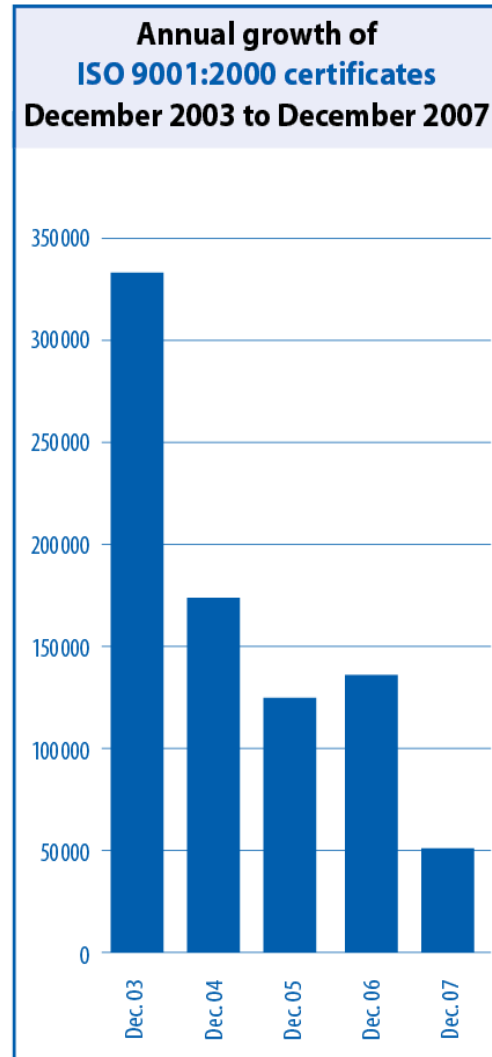
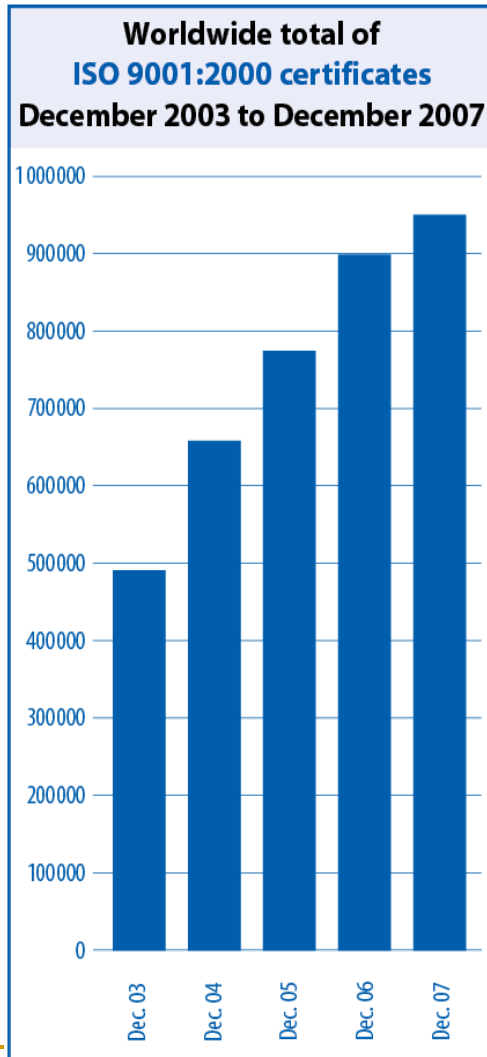
ISO 9004

- Specifies terminology and describes quality management systems
- Was initially released in 2000 along with ISO 9001, but was updated in 2005 per the normal 5 year ISO review period
- Specifies requirements for a quality management system
- Was expected to be updated in 2005, but because of a 3 year transition period from the 1994 version to the 2000 version, revision was delayed until 2008
- The aim is improvement of the performance of the organization and satisfaction of customer and other interested parties.
- This standard is currently under revision and expected to be released with major changes in 2009.

The ISO 9000 “Family”

- **ISO 9000:2005** Quality management - Fundamentals and vocabulary
 - **ISO 9001:2000** Quality management systems - Requirements
 - **ISO 9004:2000** Quality management systems - Guidelines for performance improvements
 - **ISO 10006:2003** Quality management - Guidelines for quality management in projects
 - **ISO 10007:2003** Quality management systems - Guidelines for configuration management
 - **ISO 10012:2003** Measurement management systems - Requirements for measurement processes and measuring equipment
-
- **ISO 19011:2002** Guidelines for quality and/or environmental management systems auditing

The ISO Survey



The ISO Survey (*cont.*)

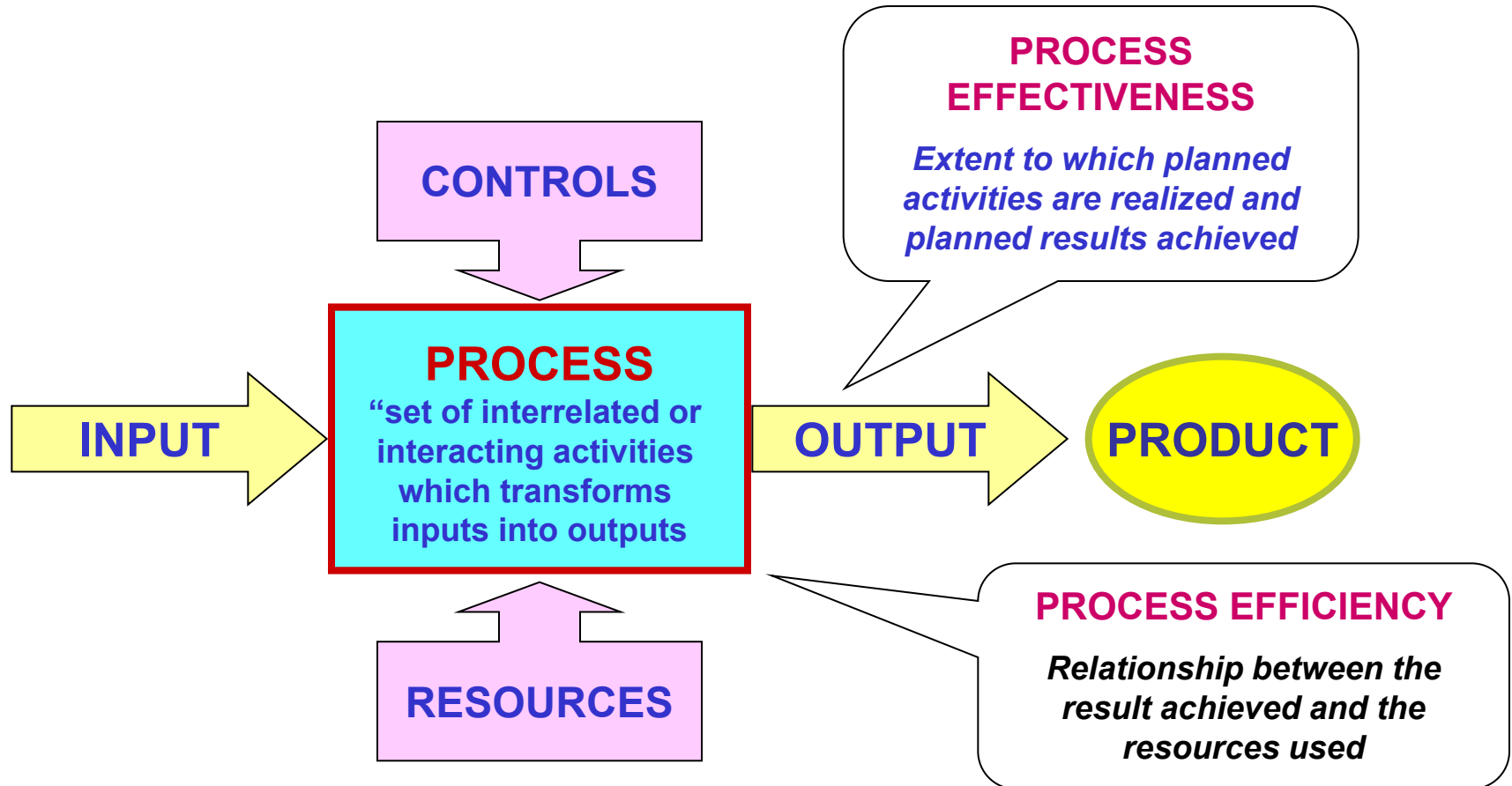
- The **worldwide total of certificates to ISO 9001:2001** at the end of **2007** was **951 486**.
- This was **increase of 6 %** over 2006 when the total was **896 929** certificates.
- Certificates had been issued in **175 countries** compared to 170 the previous year.

www.iso.org

Benefits of ISO 9001 and ISO 9004

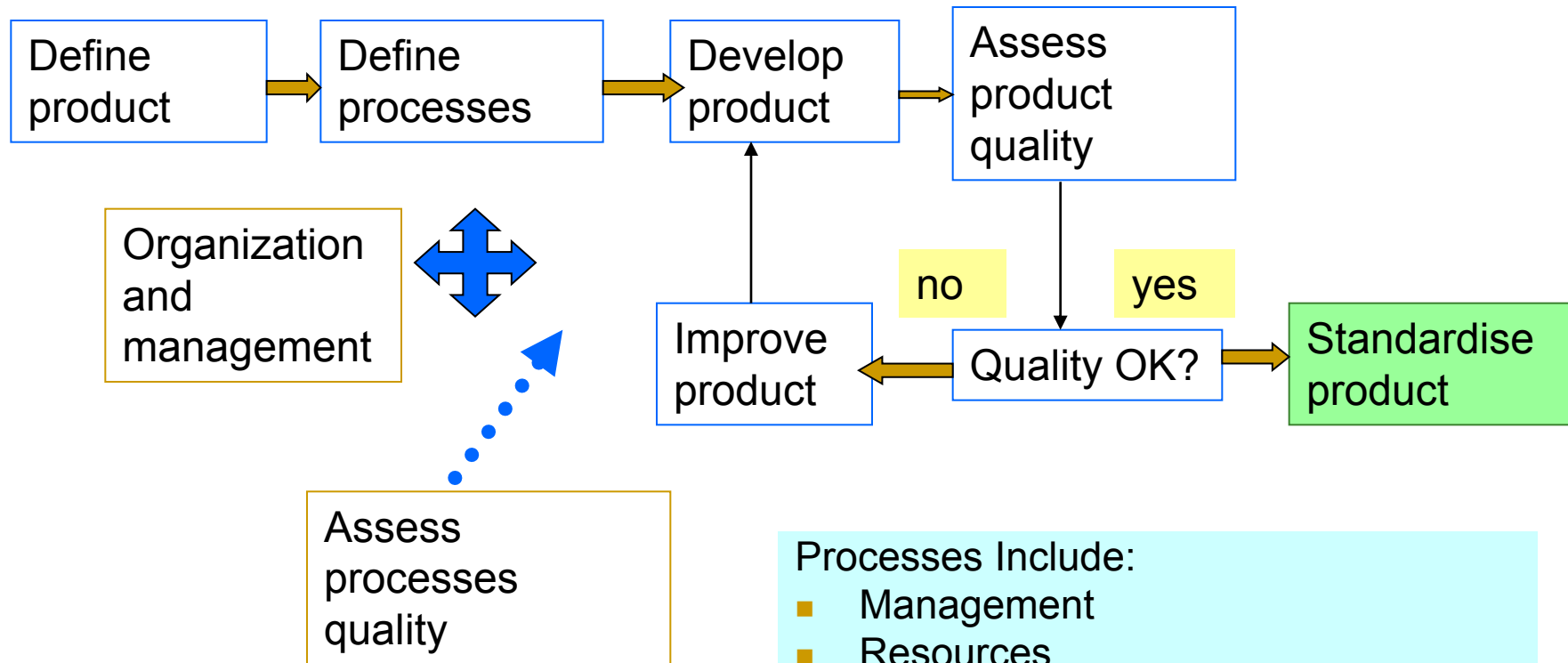
- International, expert consensus on state-of-the-art practices for quality and total quality (ISO 9004) management.
- Common language for dealing with customers and suppliers worldwide in B2B.
- Increase efficiency and effectiveness.
- Model for continual improvement.
- Model for satisfying customers and other stakeholders.
- Build quality into products and services from design onwards.
- Integrate with global economy.
- Sustainable business
- Unifying base for industry sectors
- Qualify suppliers for global supply chains
- Technical support for regulations
- Transfer of good practice to developing countries
- Tools for new economic players
- Regional integration
- Facilitate rise of services

ISO 9001:2000 Process Approach



A desired result is achieved more efficiently when activities and related resources are **managed as a process**

Process-based quality



Process Analysis:

Should be driving force for defining amount of documentation, taking into account the requirements of ISO 9001:2000

Processes Include:

- Management
- Resources
- Product realization
- Measurement

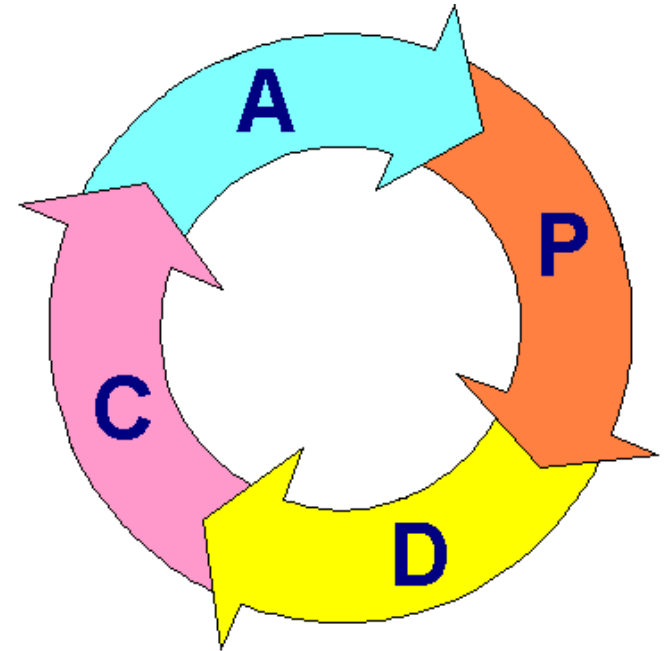
Base of process approach

► ISO ISO 9001:2000, 9001:2008, ISO 9004:2000 and

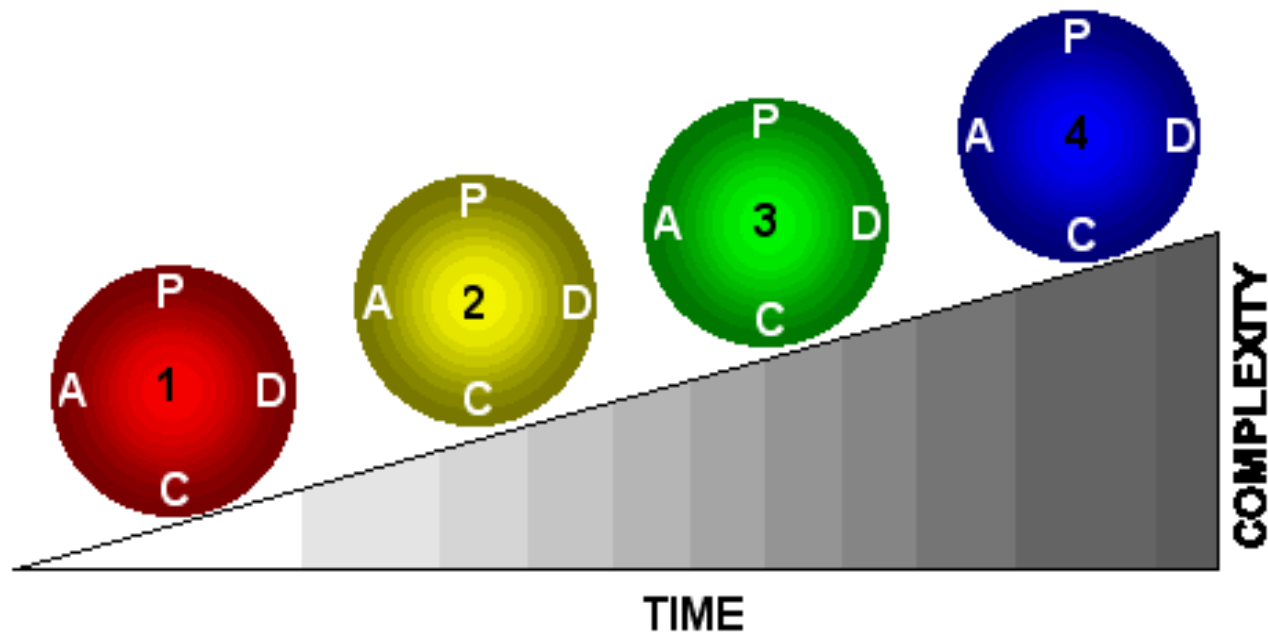
► ISO 14001:2004 & OHSAS 18001:2007 standards

are based on PDCA (Deming „**plan do check act** circle“) concept, therefore having similar structure

Policy
Planning
Implementation and operation
Performance assessment
Improvement
Management review



As the Management Systems mature, effective use of the Deming Cycle will ensure continual improvement



Revisioning standards and ISO 9000

- all standards are subjects to **periodic review** = to determine whether it is still relevant, whether it needs to be updated or whether it should be discarded
- the review period is around **5-6 years**
- for ISO 9001 it is designed such that whenever there are significant changes to be done (major revision) the next revision will be less significant (minor)
- since the revisions issued in 2000 (implemented in individual countries until 2003) were major, the next one will be minor = **changes are more based on the clarification of the existing requirements rather than including new ones**

ISO 9001:2000 and 2008 revision - changes

- Reinforcement of Control over **outsourced processes** that affect product conformity to requirements
- Management representative has to be a **member of the organization management** and not an external individual
- **Competence** of all personnel affecting conformity to product requirement must be controlled by the organization
- Additional guidance to explain the different methods on measuring and monitoring customer satisfaction
- For internal audits, the management of the audited unit must ensure that necessary corrections and corrective actions are taken
- Clarification that information systems are included as part of the company infrastructure, and therefore the management system
- New requirement to review the **effectiveness** of corrective and preventive actions

Example of changes

New in ISO 9001:2008

Text slightly changed in ISO
9001:2008

- ISO 9001: 2000
 - ...The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization...
- ISO 9001: 2008
 - ...The design and implementation of an organization's quality management system is influenced by: its business environment, changes in that environment, or risks associated with that environment; its varying needs; its particular objectives; the products it provides; the processes it employs; its size and organizational structure...
 - This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, statutory and regulatory requirements applicable to the product, and the organization's own requirements.
- **For the 1st time the word risk appears in ISO 9001**

Outsourcing is one area where significant clarification has been added, with three additional notes to help the user with interpretation.

In several places the term "**product quality**" has been replaced with

"conformity to product requirements", putting the emphasis on conformity.

www.us.bureauveritas.com/.../ISO+9001+2008+new+version.ppt

www.iso.org/iso/ims-alerts_9001_14001_overview.ppt

ISO 9001:2008

When will ISO 9001:2008 certifications be valid?

- ❑ 1 year (Nov 15, 2009) after publication of ISO 9001:2008 all accredited certifications issued shall be to ISO 9001:2008.
- ❑ 24 months (Nov 15, 2010) after the publication of ISO 9001:2008, any existing certification issued to ISO 9001:2000 will not be valid

ISO 9001:2000 Quality Management Systems – Requirements

■ Structural Content of the Standard

Foreword

Introduction

1. Scope
2. Normative reference
3. Terms and Definitions
4. Quality Management System
5. Management Responsibility
6. Resource Management
7. Product Realization
8. Measurement, Analysis and Improvement



Quality assurance and standards

- Standards are the key to effective quality management.
 - They may be international, national, organizational or project standards.
 - **Product standards** define characteristics that all components should exhibit e.g. a common programming style.
 - **Process standards** define how the software process should be enacted.
-

ISO 9001:2000 Quality Management Systems – Requirements



- Introduction
 - 0.1 General
 - 0.2 Process approach
 - 0.3 Relationship with ISO 9004- “consistent pair”
 - 0.4 Compatibility with other Management Systems
- 1 Scope
 - 1.1 General
 - 1.2 Application
- 2 Normative Reference
 - ISO 9000:2000 Quality Management Systems -Fundamentals and Vocabulary
- 3 Terms and Definitions
 - As provided in ISO 9000:2000 Quality Management Systems - Fundamentals and Vocabulary
 - Wherever the term “product” is used, it can also mean “service”
 - SUPPLIER → ORGANIZATION → CUSTOMER

ISO 9001:2000 Quality Management Systems Requirements

- 4 Quality management system

- 4.1 General requirements
- 4.2 Documentation Requirements

- 4.1 General requirements

- The organization shall establish, documents, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

a) identify the *processes* needed for the quality management system and their application throughout the organization (refer clause 1.2 Application)

b) determine the sequence and interaction of these *processes*

c) determine criteria and methods needed to ensure that both the operation and control of these *processes* are effective

ISO 9001:2000 Quality Management Systems Requirements

- 4.1 General requirements

- d) ensure the availability of resources and information necessary to support the operation and monitoring of these *processes*
- e) monitor, measure and analyze these *processes*, and
- f) implement actions necessary to achieve planned results and continual improvement of these *processes*

These *processes* shall be managed by the organization in accordance with the requirements of this International Standard.

ISO 9001:2000 Quality Management Systems Requirements

■ 4.2 Documentation requirements

- 4.2.1 General
- 4.2.2 Quality Manual
- 4.2.3 Control of documents
- 4.2.4 Control of records

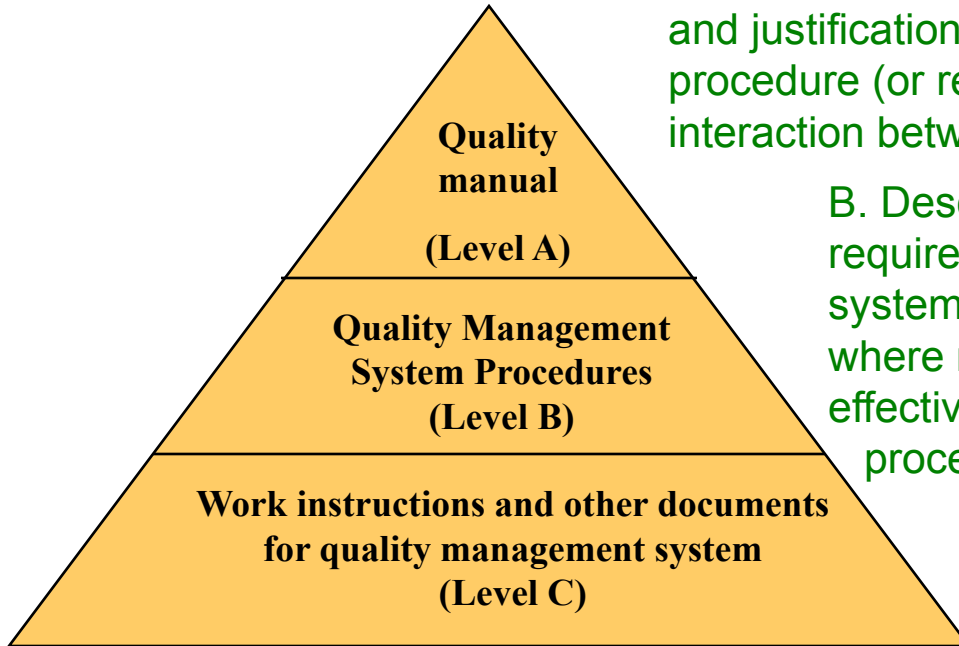
■ 4.2.1 General

The quality management system documentation shall include:

- a) a quality policy and quality objectives, (documented statements)
- b) a quality manual
- c) documented procedures required by this International Standard, i.e. the following:
 - 4.2.3 Control of documents
 - 4.2.4 Control of records
 - 8.2.2 Internal Audit
 - 8.3 Control of nonconforming product
 - 8.5.2 Corrective Action
 - 8.5.3 Preventive Action
- d) documentation as required by the organization to ensure the effective planning, operation and control of its processes, and
- e) records required by this International Standard
(ref. 4.2.4)

Typical Quality Management System Documentation Hierarchy

Document Contents



A. Includes the scope of the QMS, including details of and justification for any exclusions, documented procedure (or reference to them), description of the interaction between the processes of the QMS.

B. Describes the interrelated processes and activities required to implement the quality management system. Required where specified by the standard & where needed by the organization to ensure the effective planning, operation and control of its processes

C. Consists of detailed work documents.

Note 1 The number of levels may be adjusted to meet the organization's needs.

Note 2 Forms may be applicable at all levels of hierarchy

Ref. ISO/TR 10013 - Guidelines for quality management system documentation

Quality Manual



Minimum content specified in Clause 4.2.2

- **Scope** of the Quality Management System, including details of and justification for any exclusions
- Documented **procedures** established for the QMS, or references to them
- Description of the **interaction between processes** of the QMS

Structure of the manual is a decision for the organization based on:

- Organization's size
- Organization's complexity
- Organization's culture

Controlled in accordance with the requirements of Clause 4.2.3

Additional Documentation

- Process maps, process flow charts, and/or process descriptions
- Organization charts
- Specifications
- Work and/or test instructions
- Production schedules
- Approved suppliers lists
- Test and inspection plans
- Quality plans



Records



- Requirements for control of records are different from those for other documents
- All records have to be controlled in accordance with the requirements of Clause 4.2.4
- Organizations are free to develop records that may be needed to demonstrate conformity of their processes, products, and QMS

Required Records (1 Of 2)

- Management reviews (5.6.1)
- Education, training, skills and experience (6.2.2e)
- Evidence that the realization processes and resulting product fulfill requirements (7.1d)
- Design and development inputs (7.3.2)
- Results of design and development reviews (7.3.4)
- Results of design and development verification
- Results of design and development validation
- Results of review of design and development changes (7.3.7)

Required Records (2 of 2)

- Results of supplier evaluations (7.4.1)
- To demonstrate process validity where output cannot be measured (7.5.2d)
- The unique identification of a product (7.5.3)
- Customer property (7.5.4)
- Basis for calibration of measuring equipment (7.6a)
- Results of calibration (7.6)
- Internal audits (8.2.2)
- Release of product (8.2.2)
- Nonconforming product (8.3)
- Results of corrective action (8.5.2)
- Results of preventive action (8.5.3)

ISO 9001:2000 Quality Management Systems Requirements

■ 5 Management responsibility

- 5.1 Management Commitment
- 5.2 Customer Focus
- 5.3 Quality Policy
- 5.4 Planning
 - 5.4.1 Quality objectives
 - 5.4.2 Quality management system planning
- 5.5 Responsibility, Authority and Communication
 - 5.5.1 Responsibility and authority
 - 5.5.2 Management representative
 - 5.5.3 Internal Communication
- 5.6 Management review
 - 5.6.1 General
 - 5.6.2 Review input
 - 5.6.2 Review output



- 6 Resource management
 - 6.1 Provision of resources
 - 6.2 Human Resources
 - 6.2.1 General
 - 6.2.2 Competence, awareness and training
 - 6.3 Infrastructure
 - 6.4 Work environment

ISO 9001:2000 Quality Management Systems Requirements

■ 7 Product realization

- 7.1 Planning of product realization
- 7.2 Customer-related processes
 - 7.2.1 Determination of requirements related to the product
 - 7.2.2 Review of requirements related to the product
 - 7.2.3 Customer communication
- 7.3 Design and development
 - 7.3.1 Design and development planning
 - 7.3.2 Design and development inputs
 - 7.3.3 Design and development outputs
 - 7.3.4 Design and development review
 - 7.3.5 Design and development verification
 - 7.3.6 Design and development validation
 - 7.3.7 Control of design and development changes

ISO 9001:2000 Quality Management Systems Requirements

- 7 Product realization (cont'd)
 - 7.4 Purchasing
 - 7.4.1 Purchasing process
 - 7.4.2 Purchasing information
 - 7.4.3 Verification of purchased product
 - 7.5 Production and service provision
 - 7.5.1 Control of production and service provision
 - 7.5.2 Validation of processes for production and service provision
 - 7.5.3 Identification and traceability
 - 7.5.4 Customer property
 - 7.5.5 Preservation of product
 - 7.6 Control of monitoring and measuring devices

ISO 9001:2000 Quality Management Systems Requirements

- 8 Measurement, analysis and improvement
 - 8.1 General
 - 8.2 Monitoring and measurement
 - 8.2.1 Customer satisfaction
 - 8.2.2 Internal audit
 - 8.2.3 Monitoring and measurement of processes
 - 8.2.4 Monitoring and measurement of product
 - 7.5.5 Preservation of product
 - 8.3 Control of nonconforming product
 - 8.4 Analysis of data
 - 8.5 Improvement
 - 8.5.1 Continual Improvement
 - 8.5.2 Corrective action
 - 8.5.3 Preventive action



Processes must be monitored and measured -



Measurement categories that need to be considered are:

- **Quality:** Does the process consistently produce desired outputs?
- **Delivery:** Does the process consistently deliver the outputs on time?
- **Efficiency:** Does the process produce and deliver the outputs using the least amount of resources necessary
- **Others** such as Cost, Safety, Regulatory Compliance, etc.

Too often only one of these categories is applied and that **misleads management** into thinking that everything is alright.

Importance of standards



- Encapsulation of best practice- avoids repetition of past mistakes.
- They are a framework for quality assurance processes - they involve checking compliance to standards.
- They provide continuity - new staff can understand the organisation by understanding the standards that are used.

Quality planning



- A quality plan sets out the desired product qualities and how these are assessed and defines the most significant quality attributes.
- The quality plan should define the quality assessment process.
- It should set out which organisational standards should be applied and, where necessary, define new standards to be used.

Review functions



- Quality function - they are part of the general quality management process.
- Project management function - they provide information for project managers.
- Training and communication function - product knowledge is passed between development team members.

Quality reviews



- The objective is the discovery of system defects and inconsistencies.
 - Any documents produced in the process may be reviewed.
 - Review teams should be relatively small and reviews should be fairly short.
 - Records should always be maintained of quality reviews.
-

Review results



- Comments made during the review should be classified
 - No action. No change to the software or documentation is required;
 - Refer for repair. Designer or programmer should correct an identified fault;
 - Reconsider overall design. The problem identified in the review impacts other parts of the design. Some overall judgement must be made about the most cost-effective way of solving the problem;
- Requirements and specification errors may have to be referred to the client.

ISO 9001 (or 9004) certification and registration; accreditation



- **Certification** is known in some countries as **registration**.
- It means that an **independent, external body** has audited an organization's management system and verified that it conforms to the requirements specified in the standard (ISO 9001 or ISO 9004).
- **Accreditation** is like certification of the certification body.
- It means the formal approval by a specialized body - an accreditation body - that a certification body is competent to carry out ISO 9001:2008 or ISO 14001:2004 certification in specified business sectors.
- Certificates issued by accredited certification bodies - and known as **accredited certificates** - may be perceived on the market as having increased credibility.
- **ISO does not carry out certification or accreditation** and does not issue or approve certificates.

Certification of ISO 9000 (or other standards at all)

- **Certification is not a requirement of ISO 9001 or ISO 9004.**
- The organization can implement and benefit from an ISO 9001 or ISO 9004 system without having it certified.
- The organization can implement them for the **internal benefits** without spending money on a certification programme.
- **Certification is a decision to be taken for business reasons:**
 - if it is a contractual, regulatory, or market requirement,
 - If it meets customer preferences
 - it is part of a risk management programme, or
 - if it will motivate staff by setting a clear goal.

