International Organization for Standardization

www.iso.org
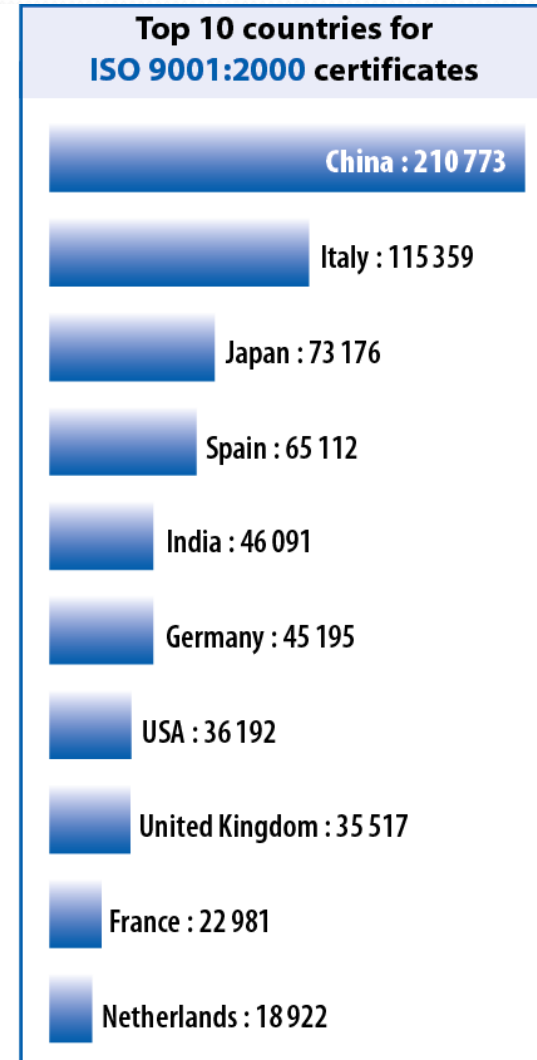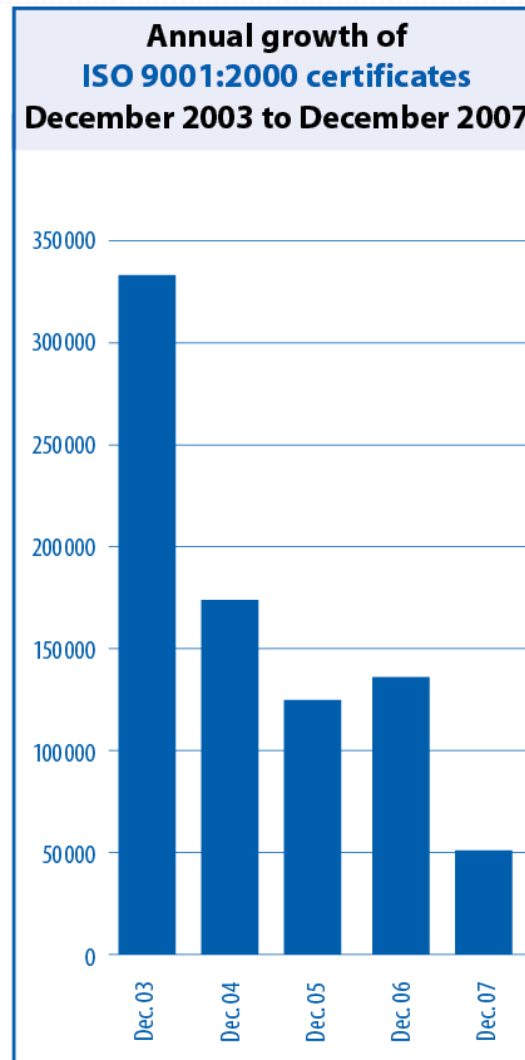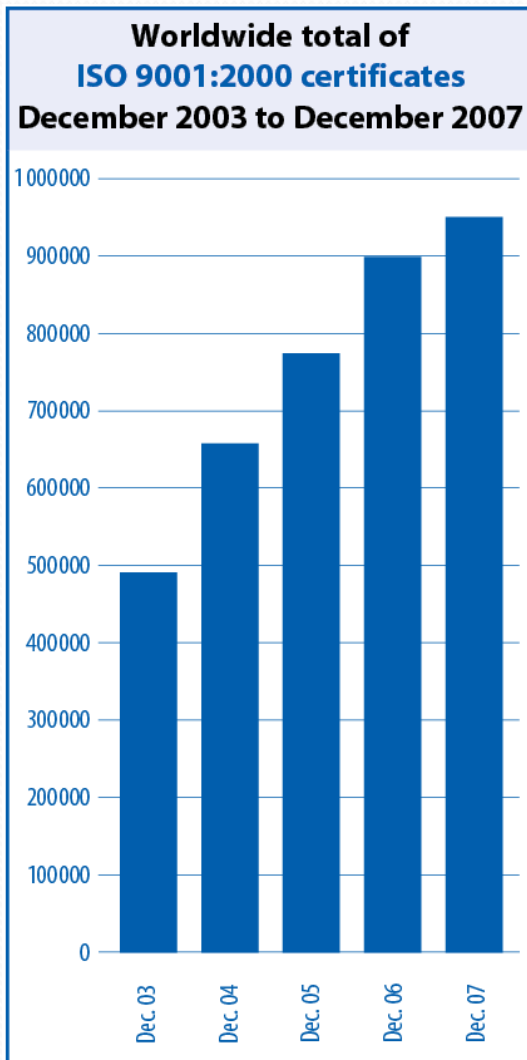
Overview of ISO 9001

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ISO 9001 in brief

- ISO 9001 and ISO 14001 are among **ISO's most well known standards** ever.

- They are implemented by more than a million **organizations** in some **175 countries**.

- **ISO 9001** helps organizations to implement **quality management.**

- **ISO 14001** helps organizations to implement **environmental management**.

The ISO Survey

Worldwide total of ISO 9001:2000 certificates December 2003 to December 2007

Annual growth of ISO 9001:2000 certificates December 2003 to December 2007

Top 10 countries for ISO 9001:2000 certificates

China : 210 773
Italy : 115 359
Japan : 73 176
Spain : 65 112
India : 46 091
Germany : 45 195
USA : 36 192
United Kingdom : 35 517
France : 22 981
Netherlands : 18 922

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Quality management

- ISO 9001 is for **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.

Quality management *(cont.)*

- Quality management also means what the organization does to enhance **customer satisfaction**, and achieve **continual improvement** of its performance.

Generic standards

ISO 9001 is **generic** standard.

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.

Generic standards *(cont.)*

Generic also signifies that

- no matter what the organization's scope of activity
- if it wants to establish a **quality management system**, ISO 9001 gives the essential features

Management systems

- **Management system** means what the organization does to manage its processes, or activities in order that

- its products or services meet **the organization's objectives**, such as

- satisfying the **customer's quality requirements**,

- complying to **regulations**, or

- meeting **environmental objectives**

Management systems

- To be really efficient and effective, the organization can manage its way of doing things by **systemizing** it.

- Nothing important is left out.

- **Everyone is 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.

Management systems *(cont.)*

- Large organizations, or ones with complicated processes, could not function well without management systems.

- Companies in such fields as aerospace, automobiles, defence, or health care devices have been operating management systems for years.

- The **ISO 9001** management system standards now make these successful practices available **for all organizations**.

Processes, not products

- ISO 9001 concern **the way an organization goes about its work**.
- It is not product standard.
- It is not service standard.
- It is **process** standard.
- It can be used by **product manufacturers and service providers**.

Processes, not products *(cont.)*

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

Certification and registration

- **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).
- **ISO does not carry out certification** and does not issue or approve certificates,

Certification not a requirement

- **Certification is not a requirement of ISO 9001**
- The organization can implement and benefit from an ISO 9001 system without having it certified.
- The organization can implement them for the **internal benefits** without spending money on a certification programme.

Certification is a business decision

- Certification is **a decision to be taken for business reasons**:
- if it is a contractual, regulatory, or market requirement,
- If it meets customer preferences
- If it is part of a risk management programme, or
- if it will motivate staff by setting a clear goal.

ISO does not certify

- **ISO does not carry out ISO 9001 certification**.
- ISO does not issue certificates.
- ISO does not accredit, approve or control the certification bodies.
- ISO develops **standards and guides to encourage good practice** in accreditation and certification.

The ISO 9000 family

- **ISO 9001** is the standard that gives the requirements for a **quality management system**.
- **ISO 9001:2008** is the latest, improved version.
- It is the **only standard** in the ISO 9000 family that can be used for **certification**.
- There are **16 other standards** in the family that can help an organization on specific aspects such as performance improvement, auditing, training...

Benefits of ISO 9001

- Model for satisfying customers and other stakeholders.
- Build quality into products and services from design onwards.
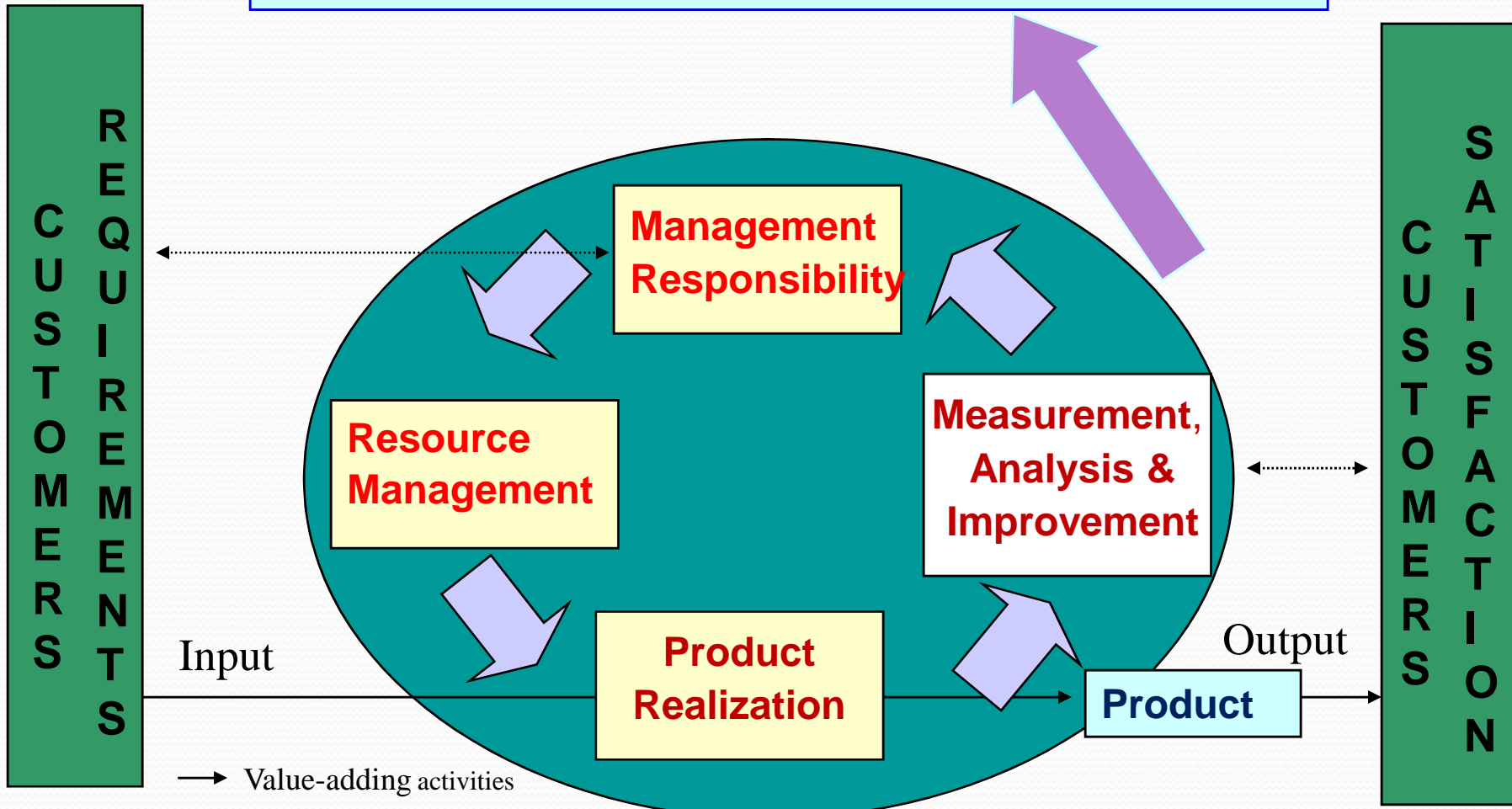- Integrate with global economy.

ISO 9001:2008 (Rangkuman)

❑ **ISO 9001:2008 adalah suatu standar internasional untuk sistem manajemen Mutu yang** menetapkan persyaratan - persyaratan dan rekomendasi untuk desain dan penilaian dari suatu sistem manajemen mutu.

❑ ISO 9001:2008 hanya merupakan standar sistem manajemen kualitas. Namun, bagaimanapun juga diharapkan bahwa produk yang dihasilkan dari suatu sistem manajemen kualitas internasional, akan berkualitas baik (standar).

❑ Manfaat Penerapan ISO 9001:2008 adalah :

• Meningkatkan Kepercayaan Pelanggan

• Jaminan Kualitas Produk dan Proses

• Meningkatkan Produktivitas perusahaan & "market gain"

• Meningkatkan motivasi, moral & kinerja karyawan

• Meningkatkan cost efficiency & keamanan produk

• Meningkatkan komunikasi internal

• Meningkatkan image positif perusahaan

• Sistem terdokumentasi

Model of a Process based Quality Management System


Continual Improvement of the quality management system

CUSTOMERS
REQUIREMENTS

Management Responsibility

Resource Management

Product Realization

Measurement, Analysis & Improvement

Input

Product

Output

CUSTOMERS
SATISFACTION

→ Value-adding activities

┄┄► Information flow

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organization
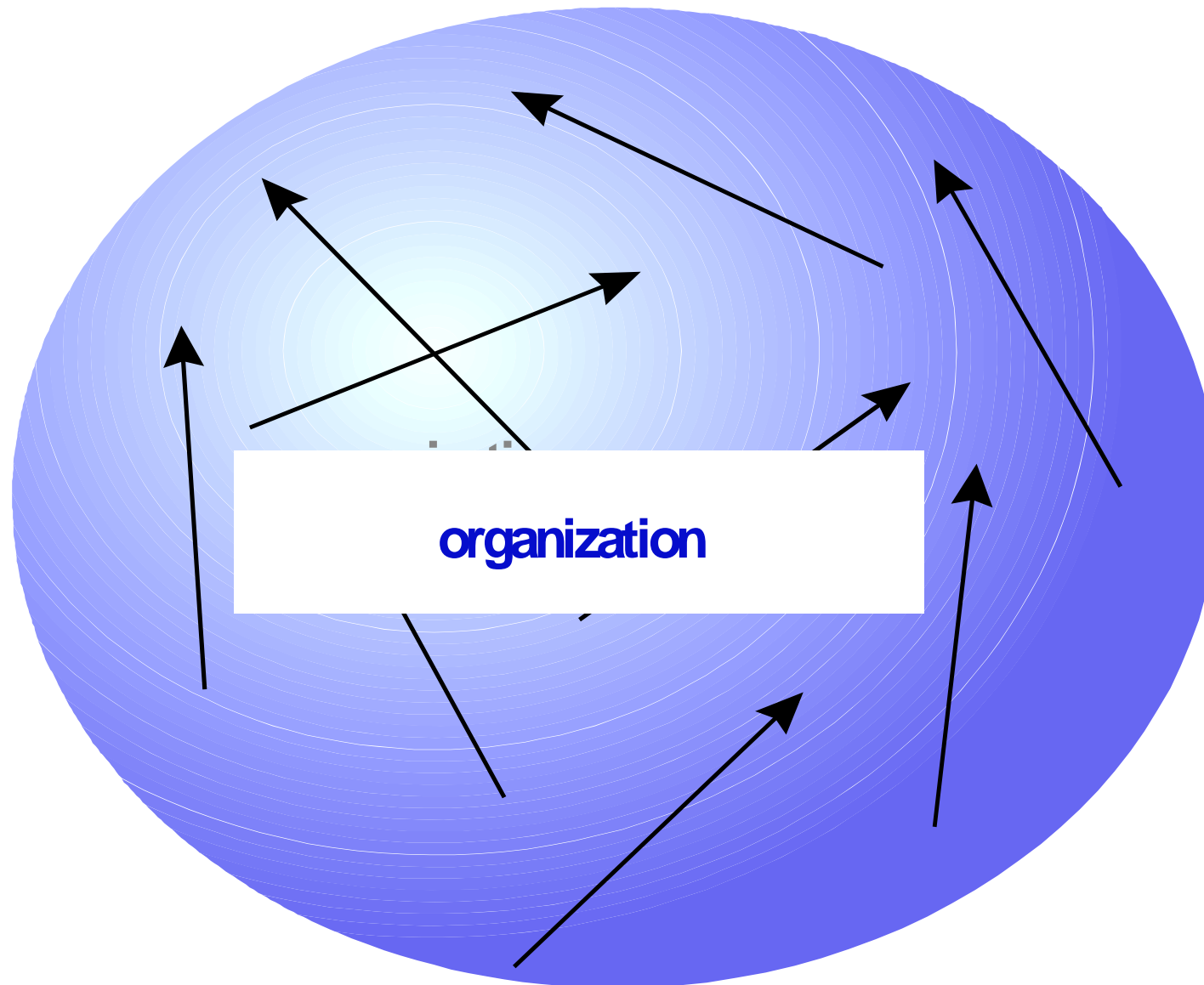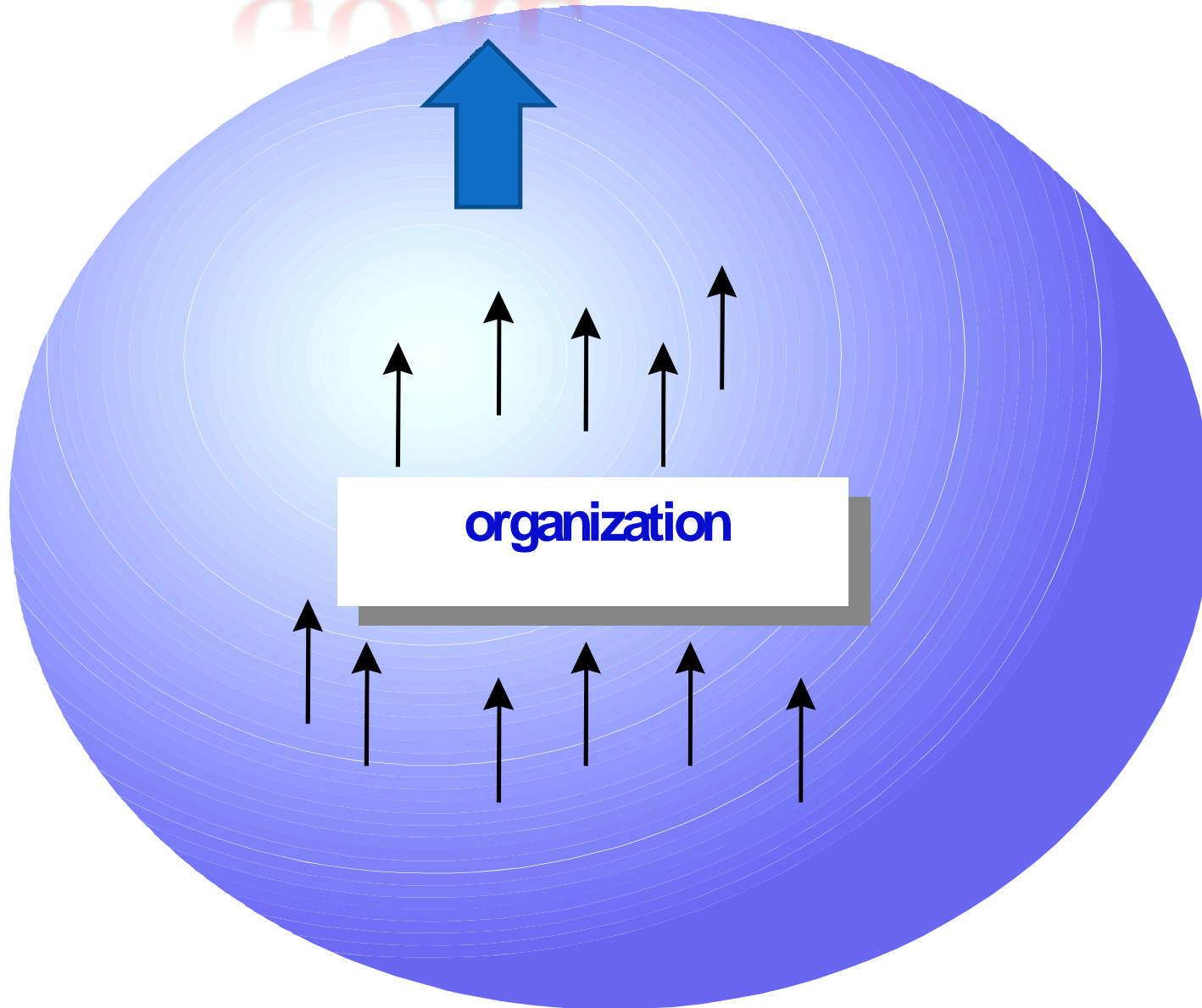
Semoga dengan ISO 9001
Bisa mencapai puncak