Unit-5
Quality Management Standards

THE ISO 9000 FAMILY

ISO 9000: 2005

- Identifies the fundamentals and vocabulary for Quality Management Systems (QMS)

ISO 9001:2008

- Specifies requirements for a QMS where capability to provide product that meets customer and regulatory requirements needs to be demonstrated

ISO 9004:2009

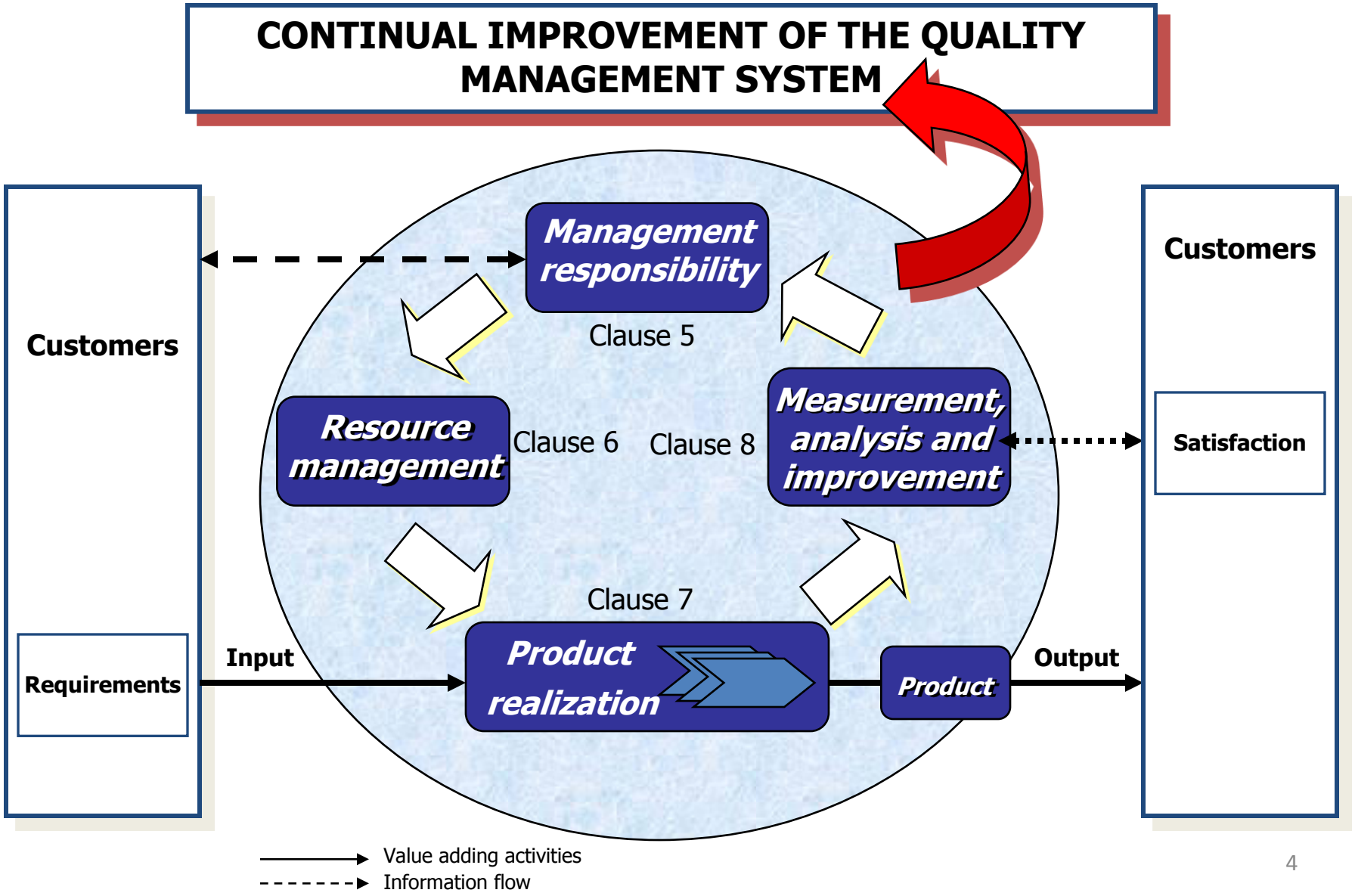
- Provides guidance on QMS that contributes to the satisfaction of customers and other interested parties

ISO 9000 : 2008

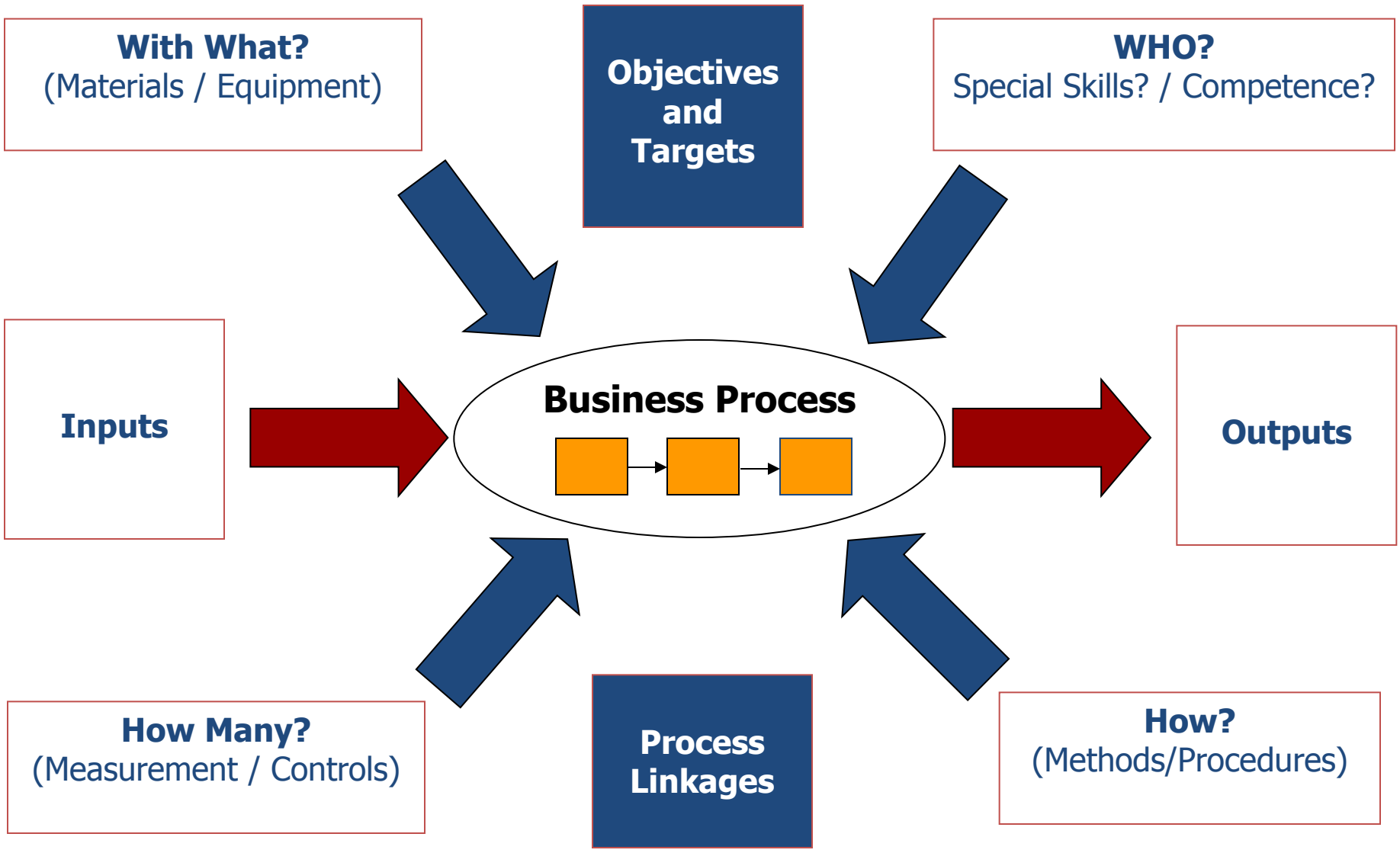
Eight quality management principles

1. Customer focus
2. Leadership
3. Involvement of people
4. Process approach
5. System approach to management
6. Continual improvement
7. Factual approach to decision making
8. Mutually beneficial supplier relationships

ISO 9001:2008



PROCESS REQUIREMENTS



Source: AIAG ISO/TS 16949:2002 Implementation Guide

SCOPE OF STANDARD

1. **Scope**
   - General
   - Application
2. **Normative reference**
3. **Terms and definition**
   e.g., Supplier Organization Customer

QUALITY MANAGEMENT SYSTEM REQUIREMENTS

General requirements

- Document, implement, maintain and continually improve
- Identify and determine sequence and interaction of processes
- Determine criteria and methods needed
- Ensure availability of resources
- Monitor, measure and analyze processes
- Implement actions to achieve planned results

QUALITY MANAGEMENT SYSTEM REQUIREMENTS

Documentation requirements

- Management system documentation
- Quality Manual
- Control of documents
- Control of records

MANAGEMENT RESPONSIBILITY

Management commitment

Customer focus

Quality policy

- Must be documented
- Must be used for setting objectives

Planning

- Document objectives- Must be Measurable
- Quality management system planning

MANAGEMENT RESPONSIBILITY

Responsibility, authority and communication

- Responsibility and authority
- Management representative
- Internal communication

MANAGEMENT RESPONSIBILITY

Management Review

- General
- Review input
- Review output

RESOURCE MANAGEMENT

Provision of resources

Human resources

- General
- Competence, awareness and training

Infrastructure

Work environment

PRODUCT REALIZATION

Planning of product realization

Customer-related processes

- Determination of requirements related to the product
- Review of requirements related to the product
- Customer communication

PRODUCT REALIZATION

Design and development

- Planning, inputs, outputs, systematic reviews, verification and validation, control of changes

Purchasing

- Supplier evaluation and selection
- Relevant purchasing information
- Verification of purchased product - receiving, source

PRODUCT REALIZATION

Production and service provision

- - Controlled conditions including product characteristics, work instructions (as necessary), suitable equipment, monitoring and measuring devices, monitoring and measurement, and release, delivery and post- delivery activities
- - Validation of processes when no other method
- - Identification and traceability of product and it's status
- - Care of customer property
- - Preservation of product
  - Includes constituent parts

PRODUCT REALIZATION

Control of monitoring and measuring devices

- Calibrated or verified where necessary
- Adjusted and re-adjusted as necessary
- Identified to enable calibration status
- Safeguarded from invalid adjustment
- Protected from damage and deterioration

MEASUREMENT, ANALYSIS, AND IMPROVEMENT

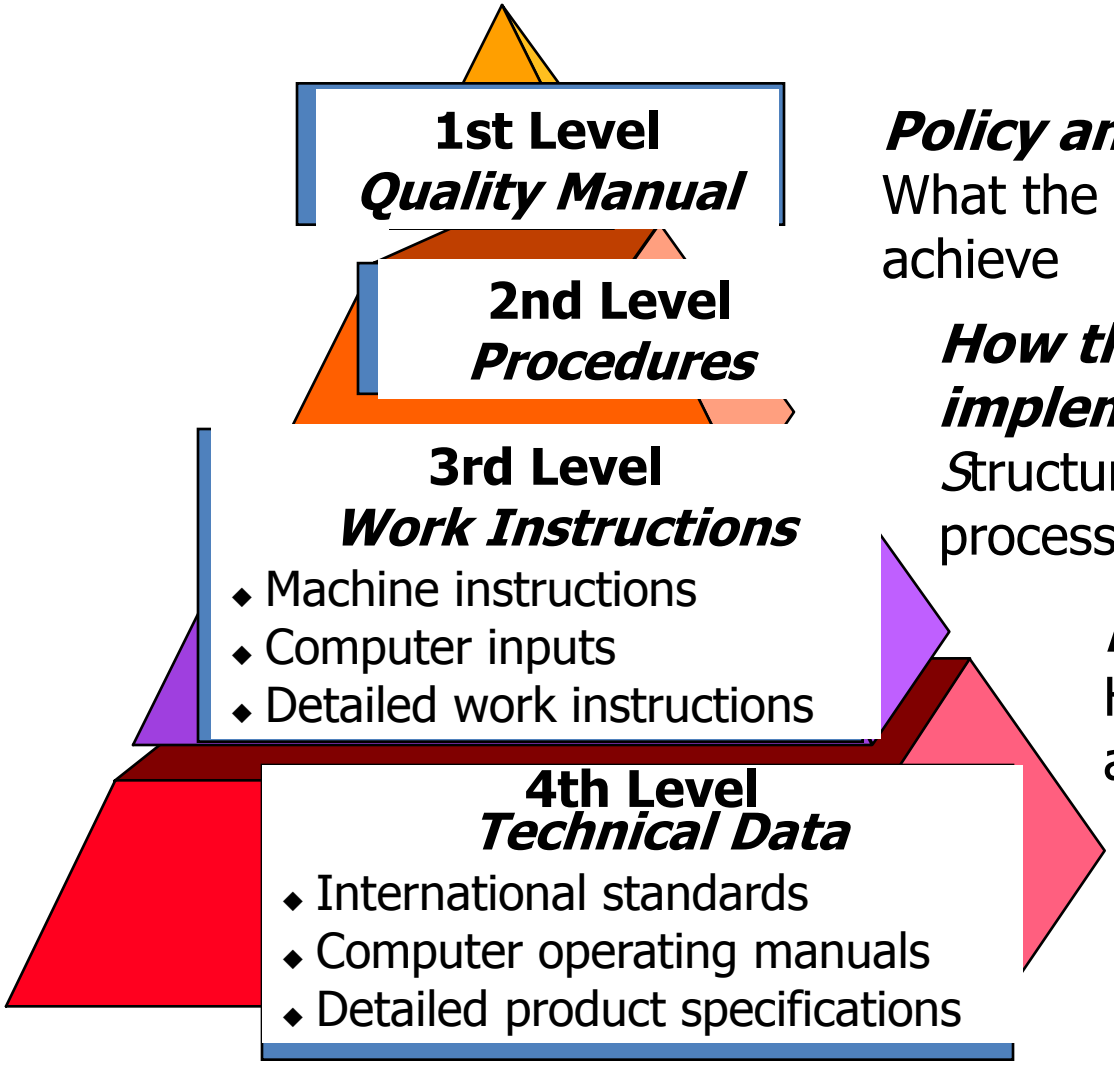
* **General**
* **Monitoring and measurement**
  - Customer satisfaction
  - Internal audit
  - Monitoring and measurement of processes
  - Monitoring and measurement of product

MEASUREMENT, ANALYSIS, AND IMPROVEMENT

* **Control of nonconforming product**
* **Analysis of data**
* **Improvement**
  - Continual improvement
  - Corrective action
  - Preventive action

ISO 9001:2008

QUALITY SYSTEM DOCUMENTATION STRUCTURE



Policy and Objectives
What the company wishes to achieve

How the company implements its policy
*S*tructured to reflect process flow of events

Detailed instructions
How to complete a job or task

Six Sigma

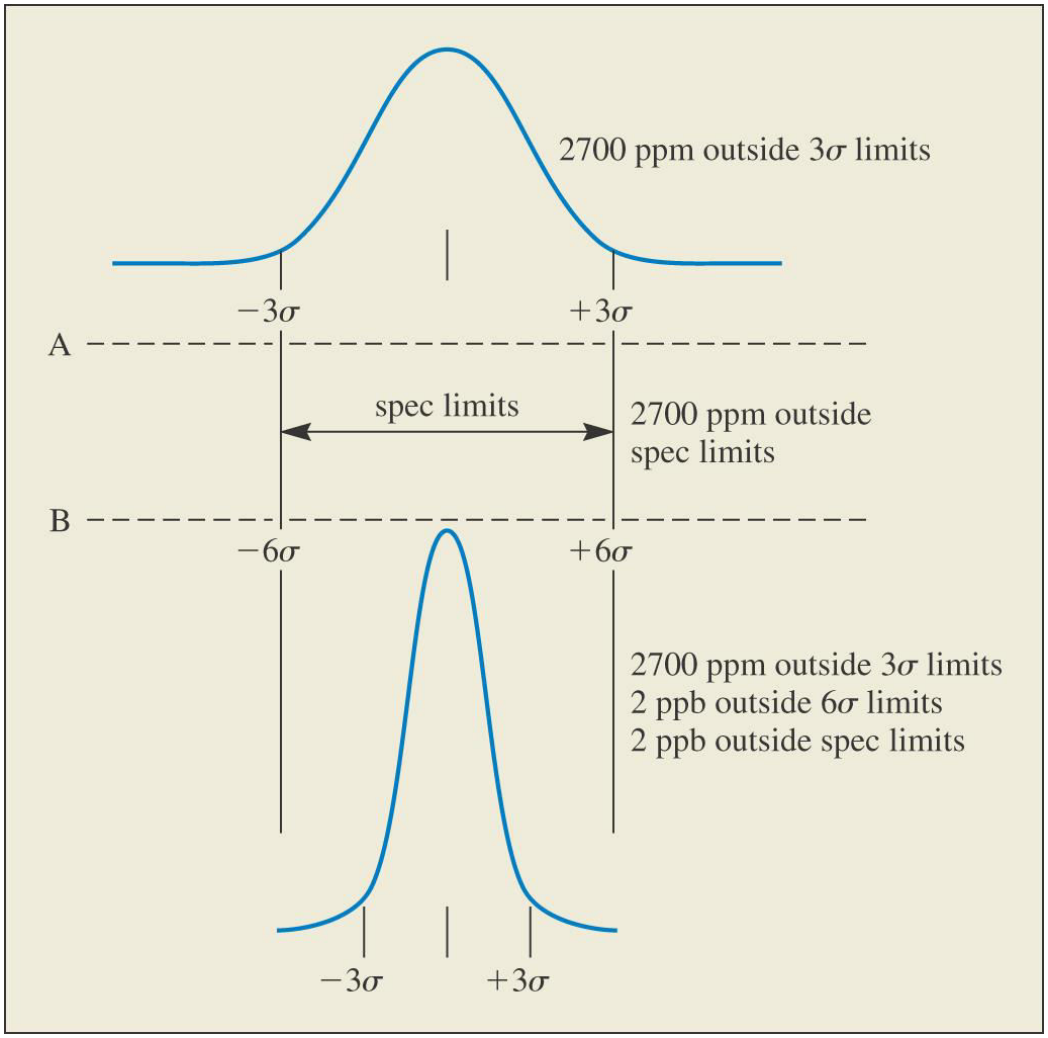
- **Two meanings**
  - Statistical definition of a process that is 99.9997% capable, 3.4 defects per million opportunities (DPMO)
  - A program designed to reduce defects, lower costs, and improve customer satisfaction

Six Sigma Quality

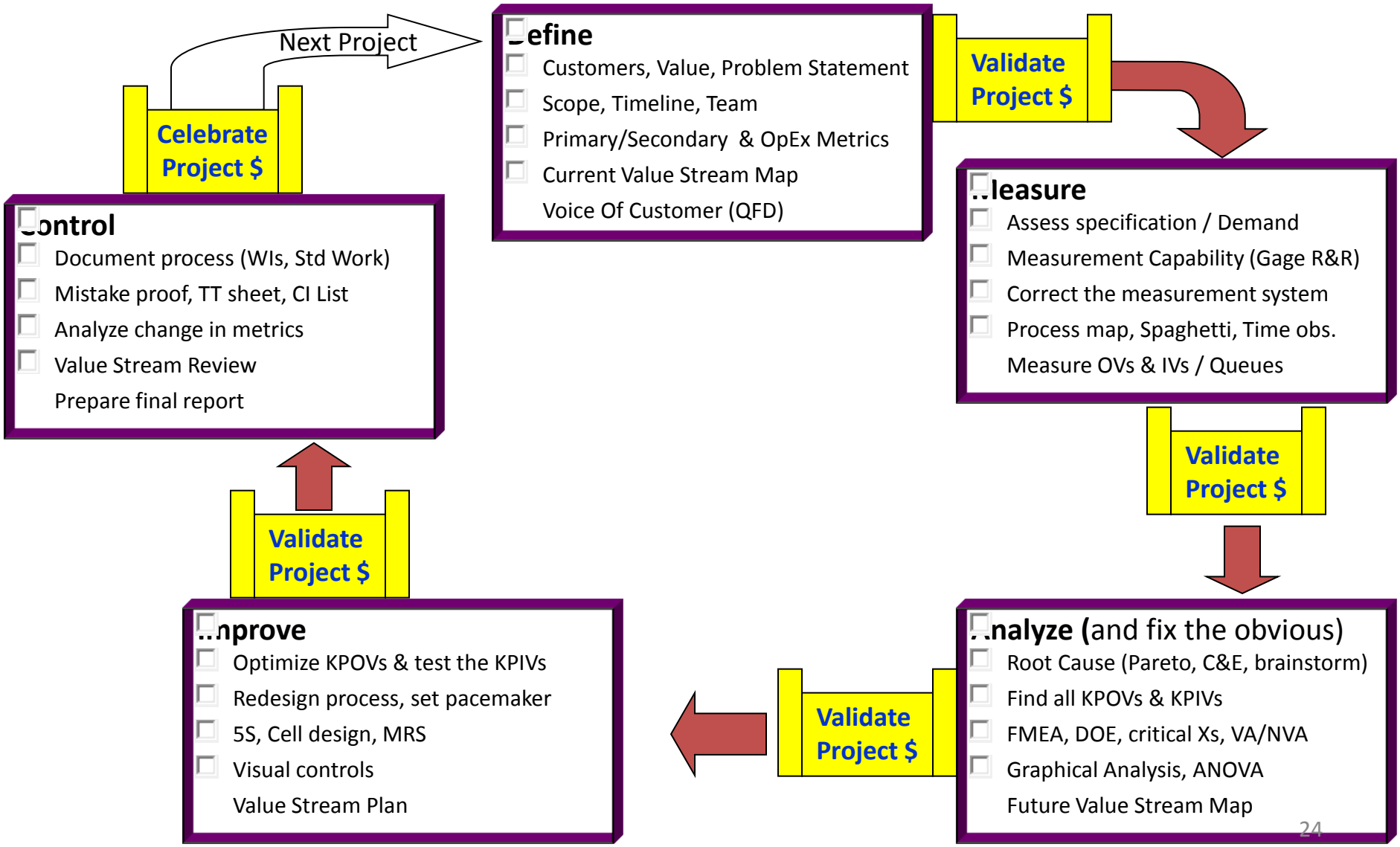
$\pm 6\sigma$

- A philosophy and set of methods companies use to eliminate defects in their products and processes
- Seeks to reduce variation in the processes that lead to product defects
- The name “six sigma” refers to the variation that exists within plus or minus six standard deviations of the process outputs

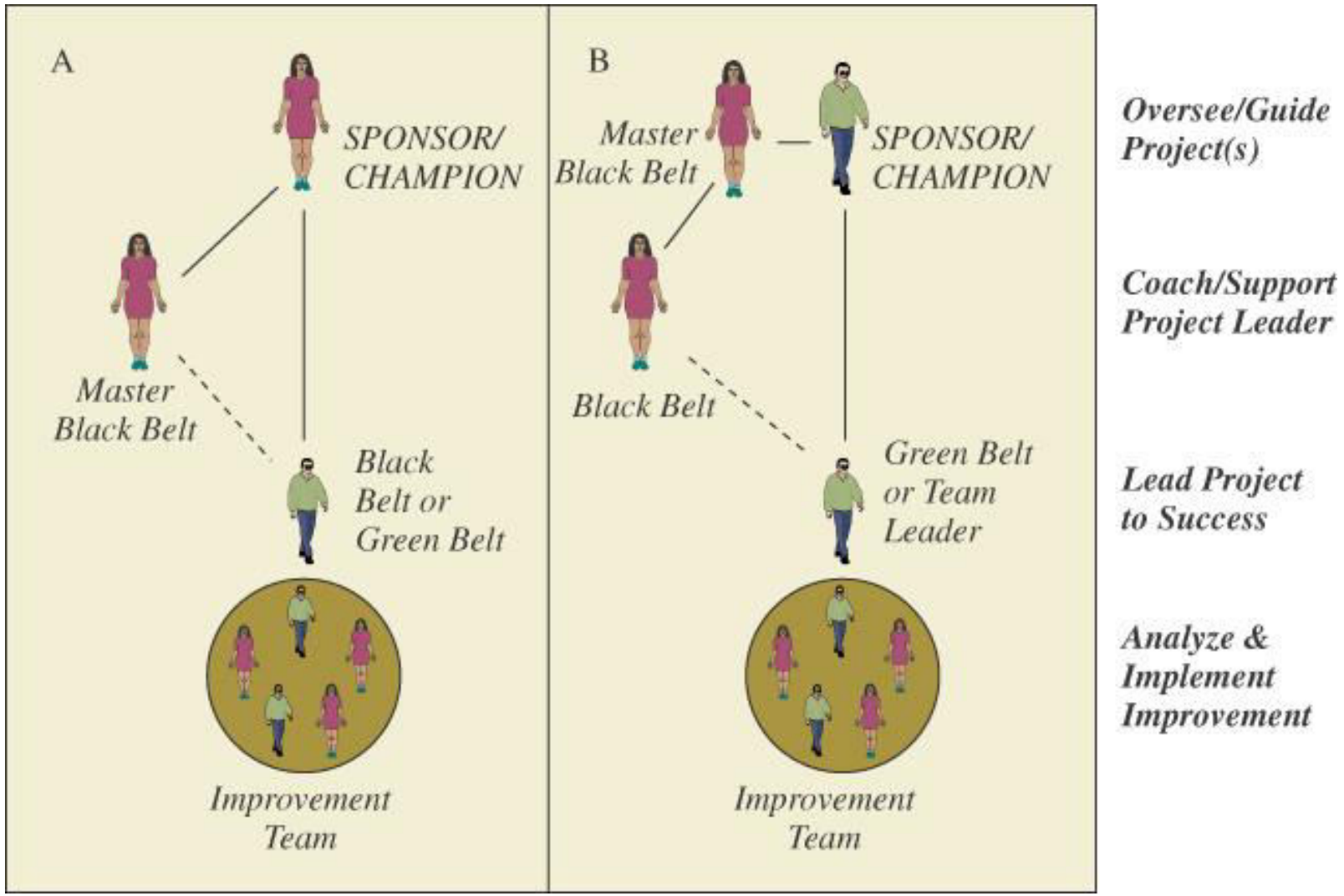
Six Sigma Quality



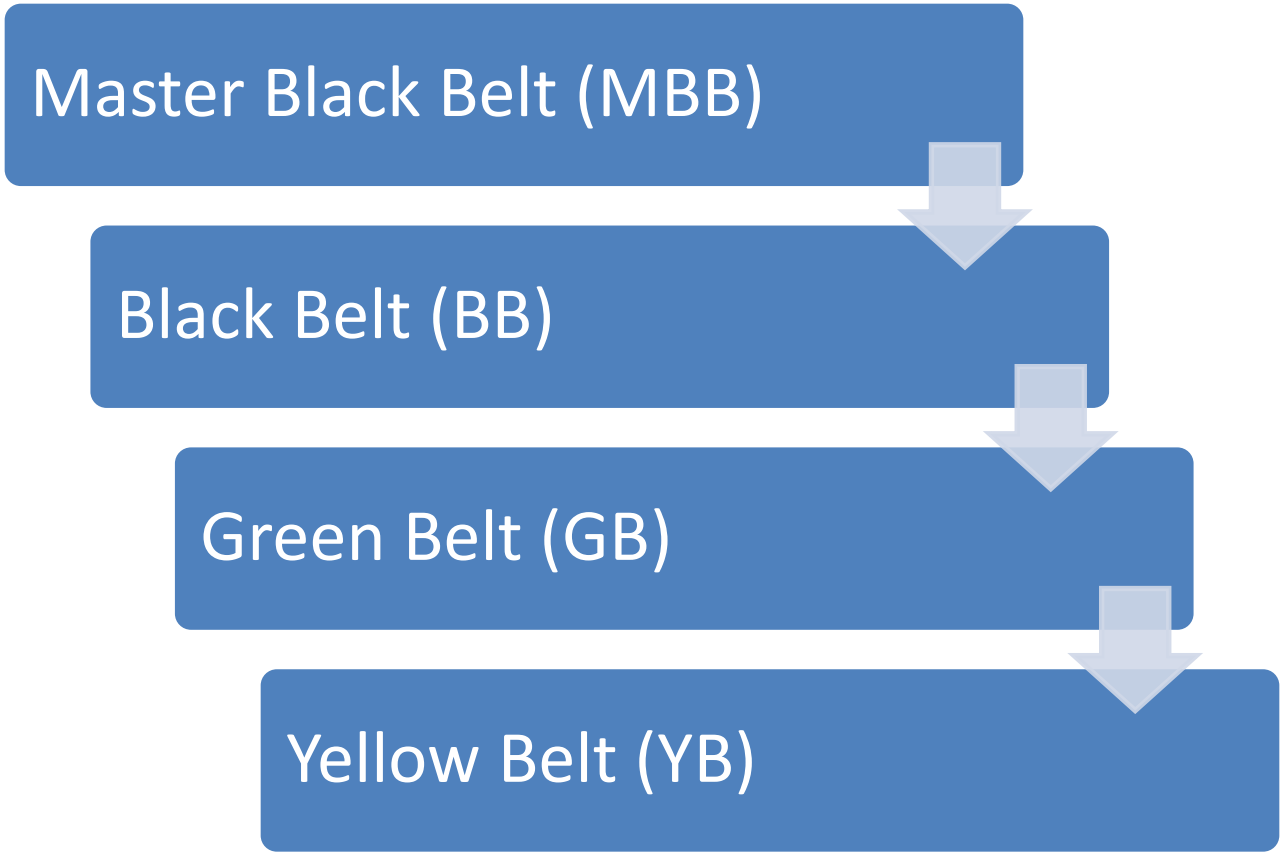
Six Sigma Roadmap (DMAIC)



Six Sigma Organization



Six Sigma Belts



Taguchi Methods

- Genichi Taguchi has been identified with the advent of what has come to be termed quality engineering.

- The goal of quality engineering is to move quality improvement efforts upstream from the production phase to the product/process design stage (off-line).

- As his loss function demonstrates, his main concern is deviation of a characteristic from its nominal value. Uncontrollable factors (noise) are often responsible for this deviation and, therefore, Taguchi's approach to experimental design has as its goal the design of products/process that are robust to these noise factors.

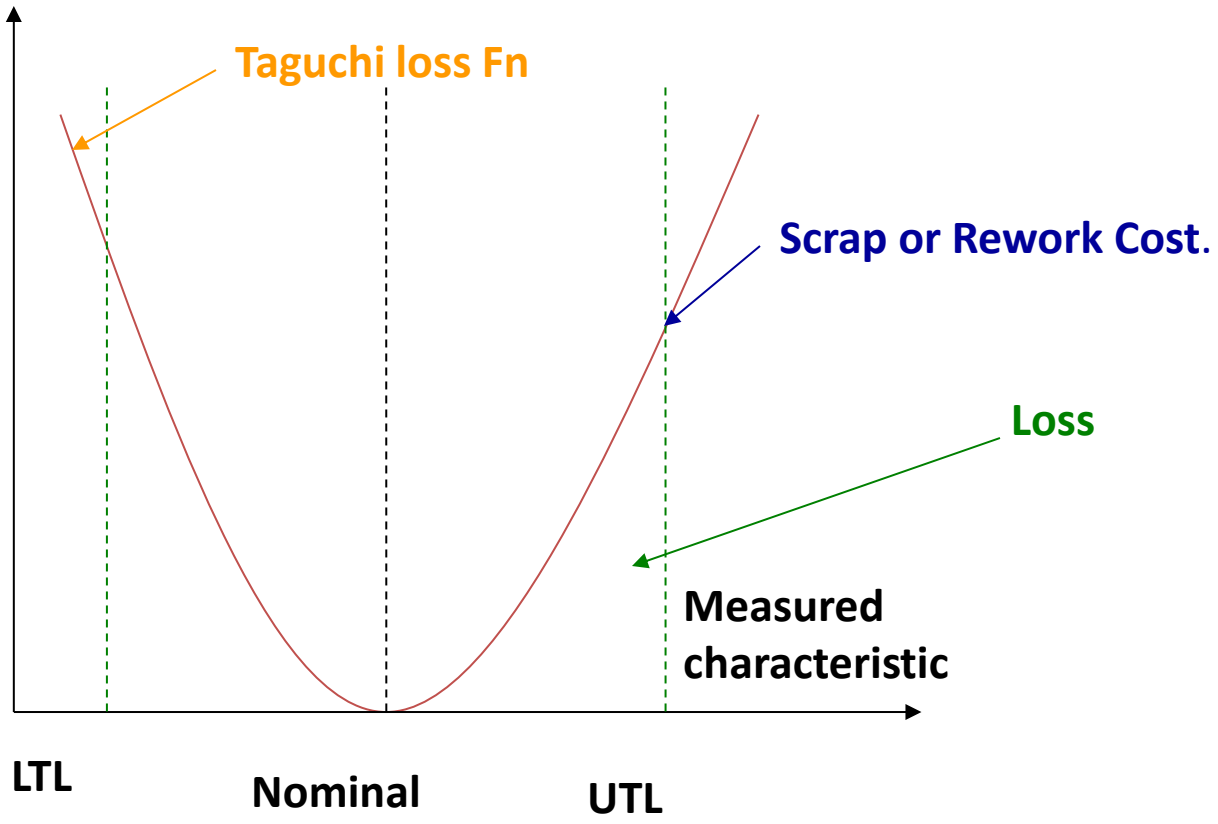
Taguchi's three stage design process

- System Design - create prototype product and process to produce it.
- Parameter Design - find settings of process and product parameters which minimize variability.
- Tolerance Design - tradeoff between loss to consumer and manufacturing costs

Taguchi's Quadratic Quality Loss Function

- Quality Loss Occurs when a product's deviates from target or nominal value.
- Deviation Grows, then Loss increases.
- Taguchi's U-shaped loss Function Curve.

Taguchi's U-shaped loss Function Curve



Just-in-Time

- JIT philosophy means getting the right quantity of goods at the right place and the right time
- JIT exceeds the concept of inventory reduction
- JIT is an all-encompassing philosophy found on eliminating waste
- Waste is anything that does not add value
- A broad JIT view is one that encompasses the entire organization

Philosophy of Just-in-Time

- JIT originated in Japan, post WWII
- Driven by a need survive after the devastation caused by the war
- JIT gained worldwide prominence in the 1970s
- Toyota Motor Co. developed JIT

The Philosophy of JIT - continued

- Often termed “Lean Systems”
- All waste must be eliminated- non value items
- Broad view that entire organization must focus on the same goal - serving customers
- JIT is built on simplicity- the simpler the better
- Focuses on improving every operation- Continuous improvement - Kaizen
- Visibility – all problems must be visible to be identified and solved
- Flexibility to produce different models/features

Three Elements of JIT

Three Elements of JIT - continued

- JIT manufacturing focuses on production system to achieve value-added manufacturing
- TQM is an integrated effort designed to improve quality performance at every level
- Respect for people rests on the philosophy that human resources are an essential part of JIT philosophy

Supplier Relationships and JIT

- Use single-source suppliers when possible
- Build long-term relationships
- Work together to certify processes
- Co-locate facilities to reduce transport if possible
- Stabilize delivery schedules
- Share cost & other information
- Early involvement during new product designs

Benefits of JIT

- Reduction in inventories
- Improved quality
- Shorter lead times
- Lower production costs
- Increased productivity
- Increased machine utilization
- Greater flexibility

Implementing JIT

- Starts with a company shared vision of where it is and where it wants to go
- Management needs to create the right atmosphere
- Implementation needs a designated “Champion”
- Implement the sequence of following steps
  - Make quality improvements
  - Reorganize workplace
  - Reduce setup times

Implementing JIT - continued

- Reduce lot sizes & lead times
- Implement layout changes
  - Cellular manufacturing & close proximity
- Switch to pull production
- Develop relationship with suppliers

JIT in Services

- Most of the JIT concepts apply equally to Service companies
  - Improved quality such as timeliness, service consistency, and courtesy
  - Uniform facility loading to provide better service responsiveness
  - Use of multifunction workers
  - Reduction in cycle time
  - Minimizing setup times and parallel processing
  - Workplace organization

JIT across the organization

- JIT eliminates organizational barriers and improves communications
  - Accounting changes or relies on activity-based costing
  - Marketing by interfacing with the customers
  - Finance approves and evaluates financial investments
  - Information systems create the network of information necessary for JIT to function

Thank you