ISO 9001:2000 and Competitiveness

Tijuana, Baja California, Mexico
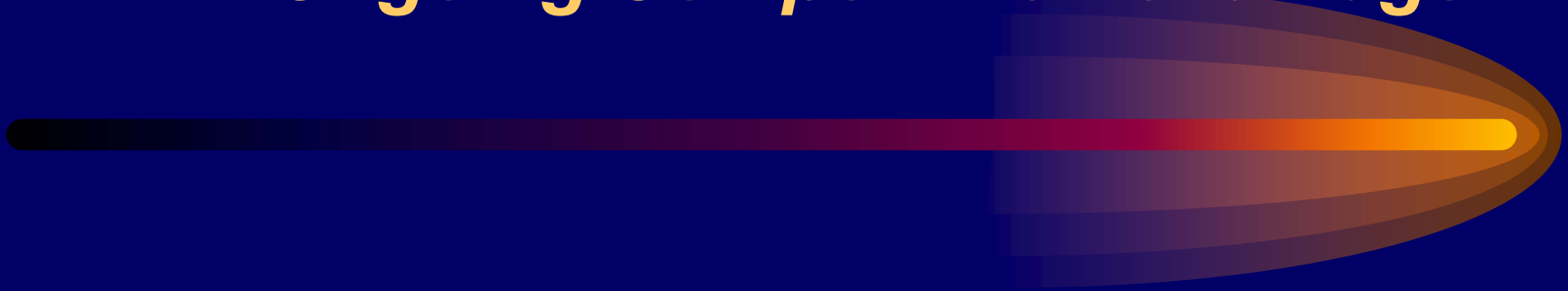
27 October 2006
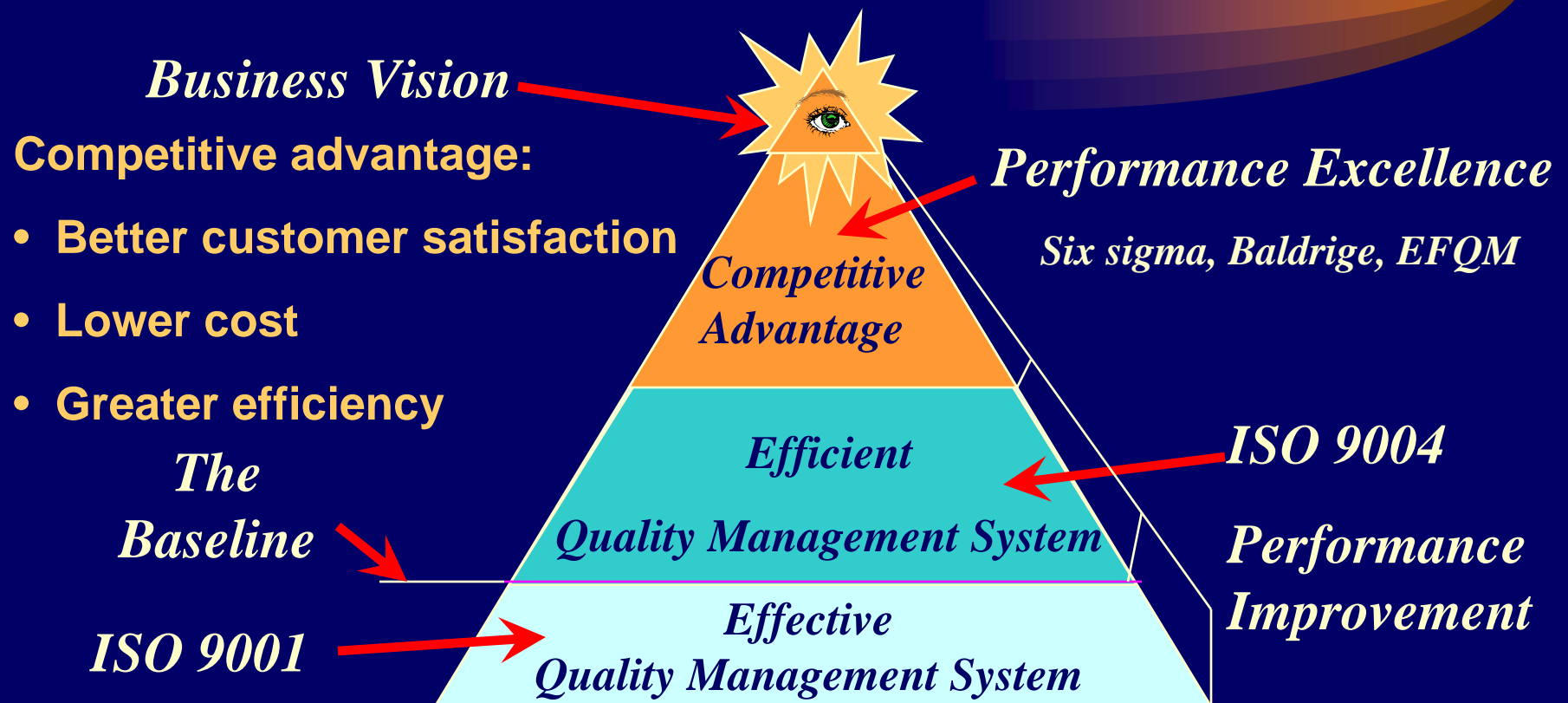
Jack West

Competition Is Not a New Idea

- Organizations have long achieved improvements in competitive position during implementation of ISO 9000 systems

- There are four strategies that have been important

So, What Should We Do to Get Ongoing Competitive Advantage?

Role of *ISO 9004:2000-Performance Improvement*

Business Vision

Competitive advantage:

- **Better customer satisfaction**

- **Lower cost**

- **Greater efficiency**

The Baseline

ISO 9001

Performance Excellence

Six sigma, Baldrige, EFQM

Competitive Advantage

Efficient

Quality Management System

Effective Quality Management System

ISO 9004

Performance Improvement

From material developed by Joe Tsiakals

Use ISO 9004 Not Just 9001

ISO 9001:2000

- Single requirements standard
- Useful for demonstrating system conformance
- Appropriate for certification

ISO 9004:2000

- Guidelines for performance improvement
- Not appropriate for certification
- Use with 9001 to improve the system

Common Structure and Language

Understand and Use The Eight Quality Management Principles

- Customer focus

- Leadership

- Involvement of people

- Process approach

- System approach to management

- Continual improvement

- Factual approach to decision making

- Mutually beneficial supplier relationships

OK, but What Specific Actions Should We Take?

1. **Shift your Focus From Internal Operatios to the Customer**

2. **Use Process Management Techniques**

3. **Fully Embrace the Continual Improvement Process**

4. **Change Your Thinking on Corrective Action and Preventive Action**

5. **Change the Way You Audit**

Action #1

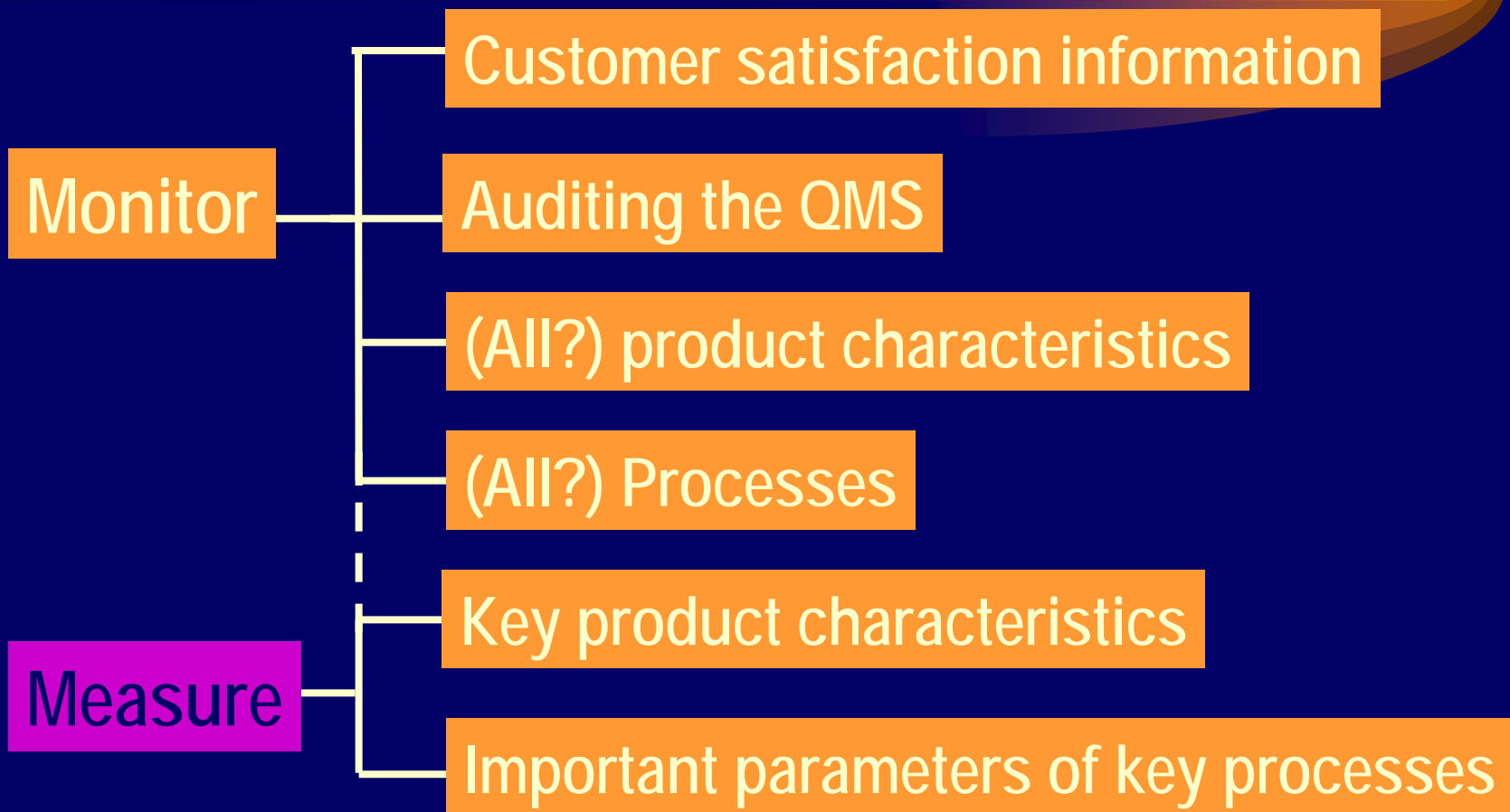## Shift Your Focus from Internal Operations to the Customer

Customer Satisfaction

Include "sales and marketing" in activities of the system that focus on the customer

You may have no greater opportunity to help them improve your market position!

Clause 8.2 Monitoring and measurement

Monitor
- Customer satisfaction information
- Auditing the QMS
- (All?) product characteristics
- (All?) Processes

Measure
- Key product characteristics
- Important parameters of key processes

Clause 8.2.1 Customer satisfaction

Measuring

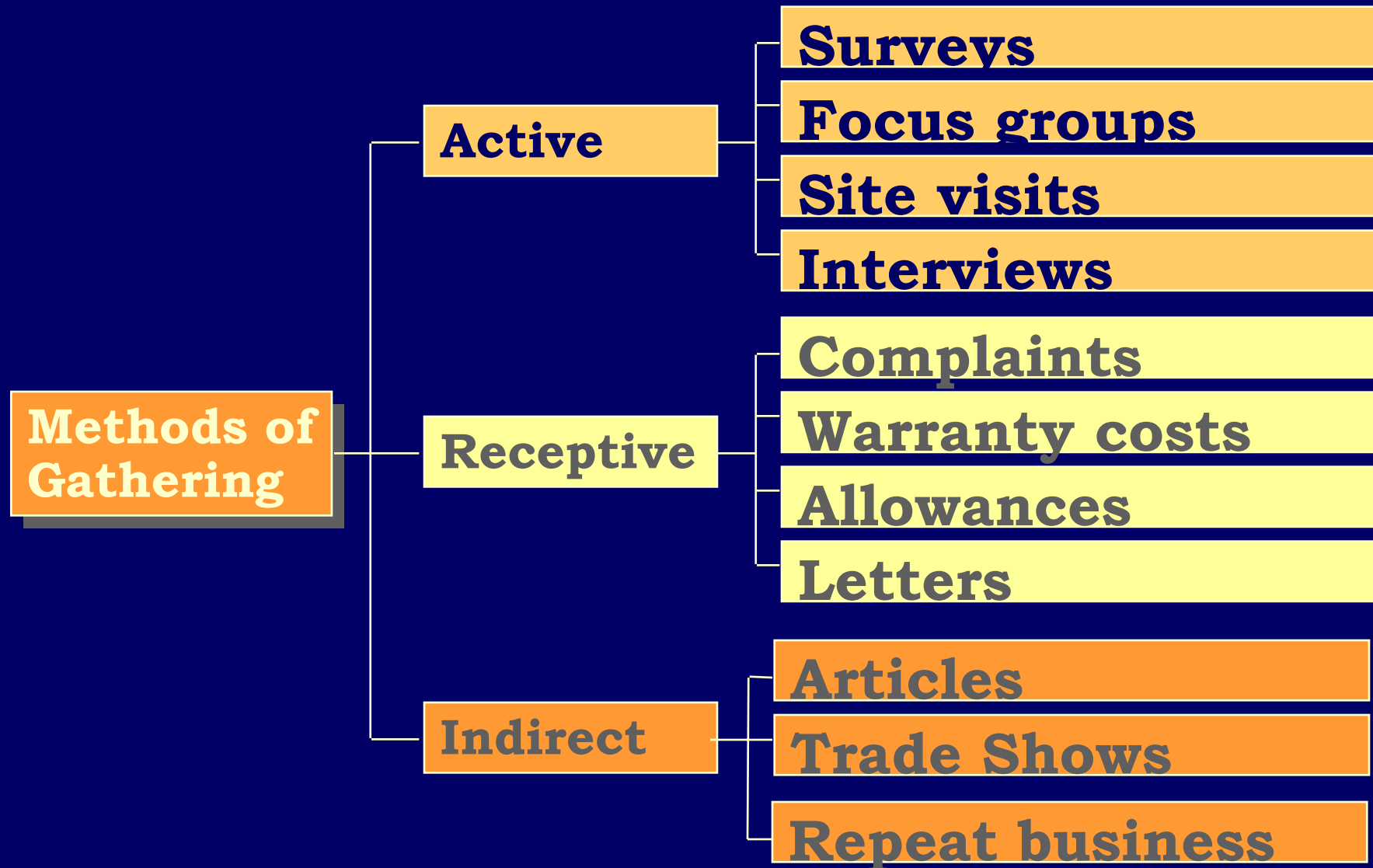Monitoring

Customer satisfaction data

Analyzing

Improving

Define how data are used

9004 Provides Ideas

- **Start by asking questions :**
  - **What customer information do you have?**
  - **What customer information do you want?**
  - **Do you want your own internal customer study capability?**
  - **Do you want to selectively go to the outside for specific research projects?**

Sources of Customer Satisfaction Data

Methods of Gathering

- **Active**
  - Surveys
  - Focus groups
  - Site visits
  - Interviews

- **Receptive**
  - Complaints
  - Warranty costs
  - Allowances
  - Letters

- **Indirect**
  - Articles
  - Trade Shows
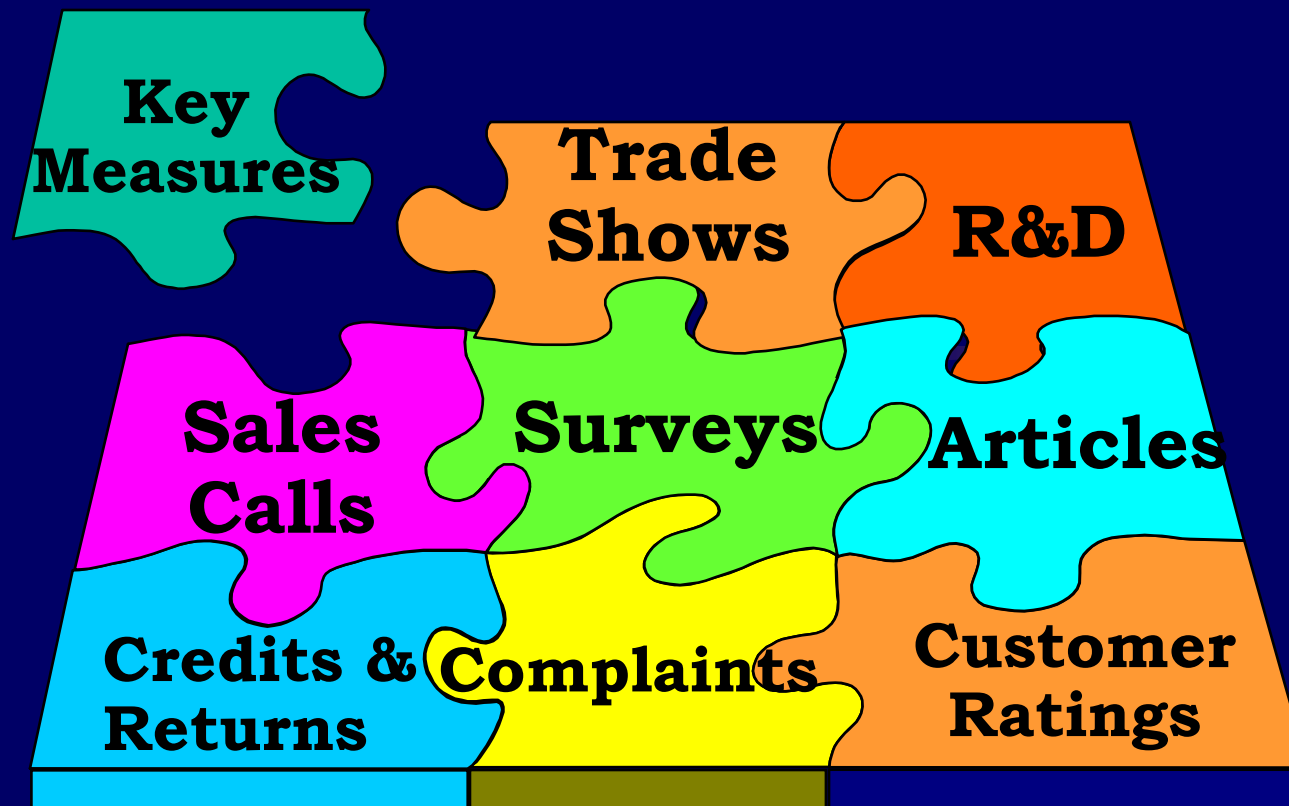 - Repeat business

Key Measures

Trade Shows

R&D

Sales Calls

Surveys

Articles

Credits & Returns

Complaints
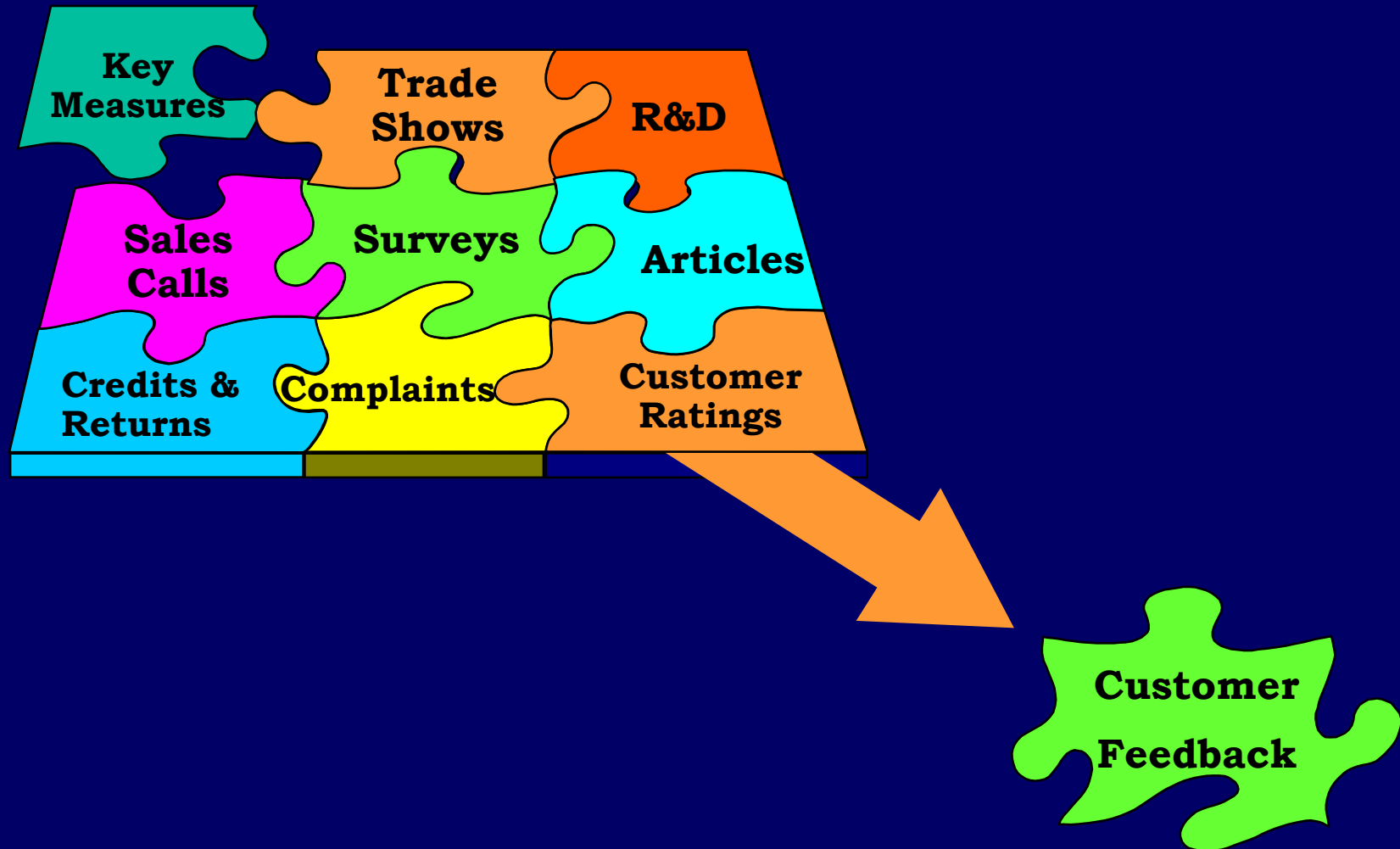
Customer Ratings

Often our customer data is like an incomplete puzzle

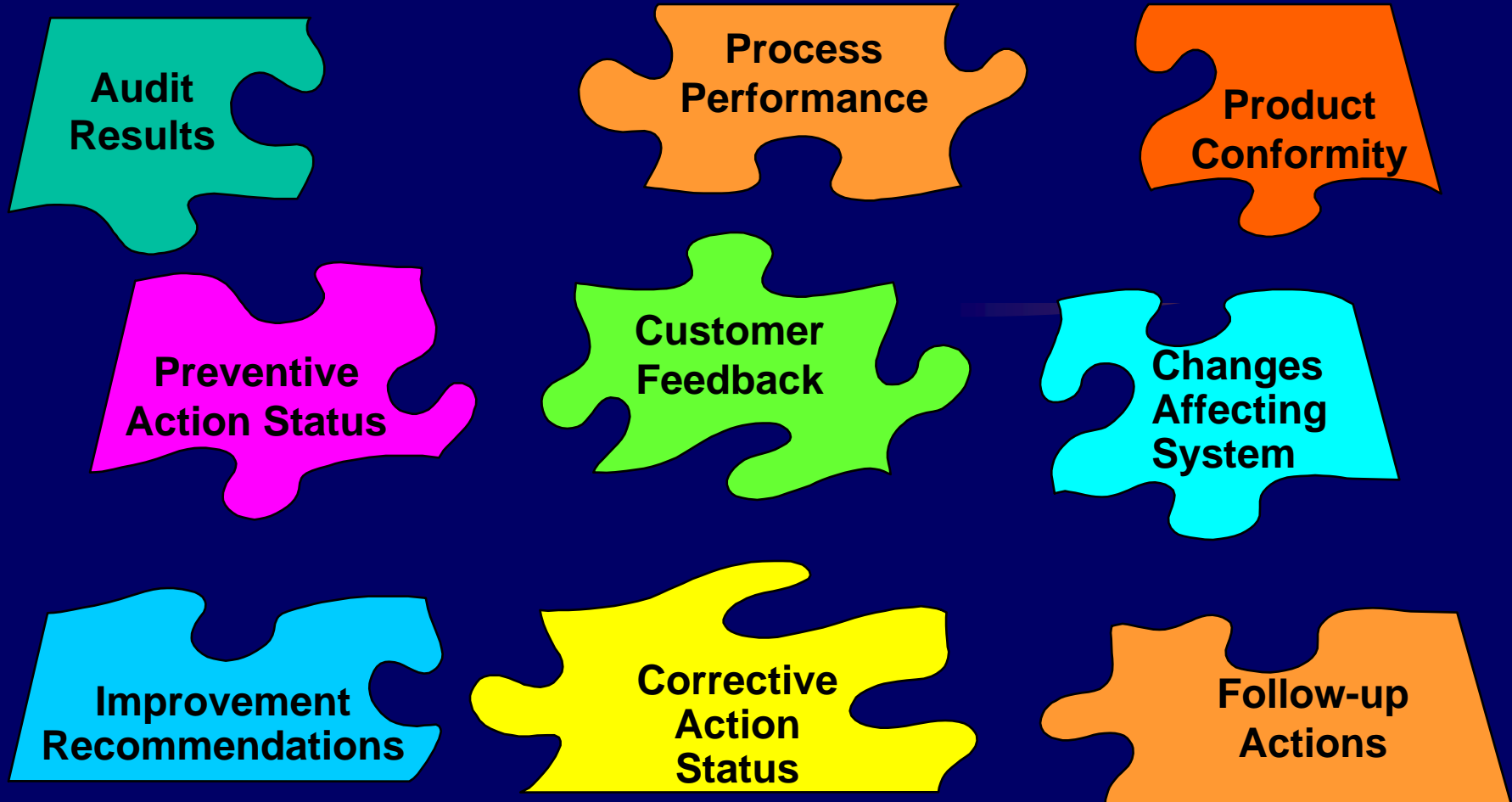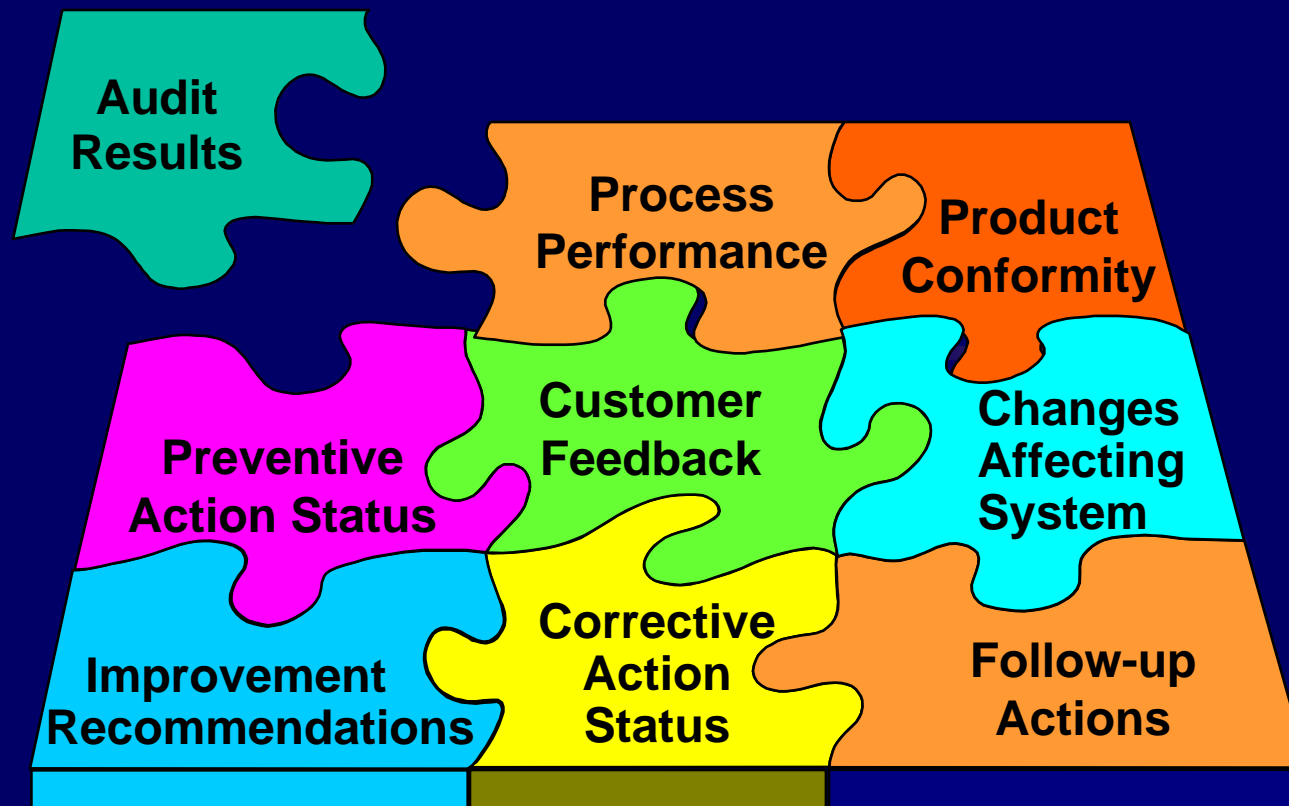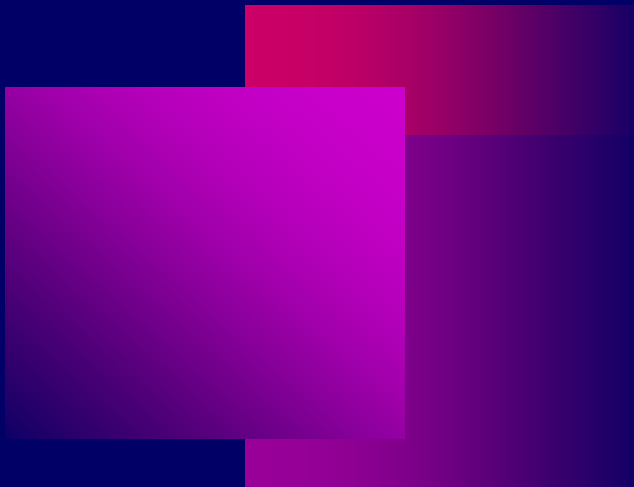Get the pieces to fit together

Aggregate customer and internal data

Audit Results

Process Performance

Product Conformity

Preventive Action Status

Customer Feedback

Changes Affecting System

Improvement Recommendations

Corrective Action Status

Follow-up Actions

Often managers look at the pieces

Audit Results

Process Performance

Product Conformity

Preventive Action Status

Customer Feedback

Changes Affecting System

Improvement Recommendations
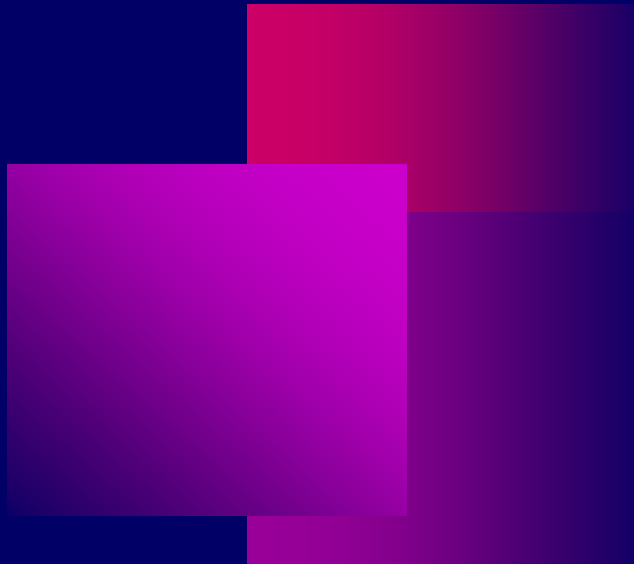
Corrective Action Status
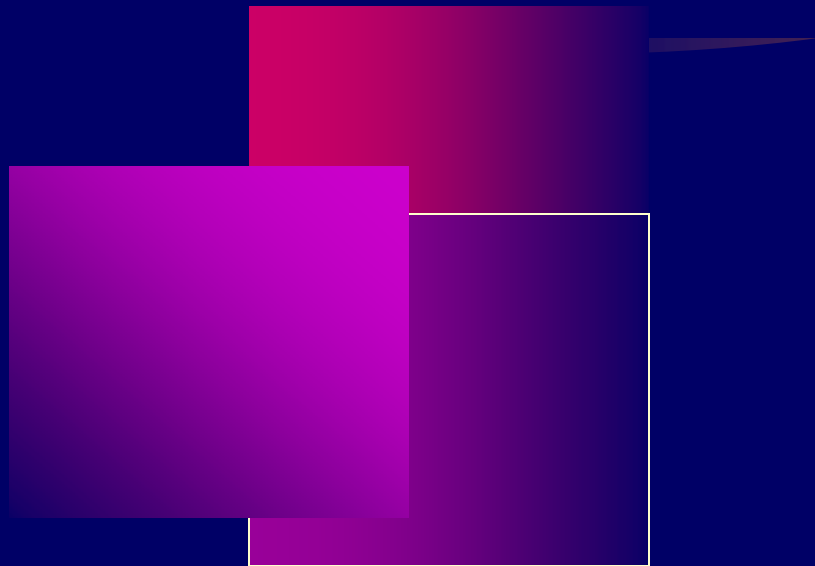
Follow-up Actions

Get the overall picture!

Getting it All Together

Getting it All Together

Getting it All Together

Action #2

## Use Process Management Techniques

Process—Based Quality Management System

CONTINUAL IMPROVEMENT OF THE QUALITY MANAGEMENT SYSTEM

CUSTOMERS

Management responsibility

Resource management

Measurement, analysis and improvement

CUSTOMERS

SATISFACTION

REQURIEMENTS

Input

Product realization

Product

Output

Key

→ Value adding activities

┄┄► Information flow
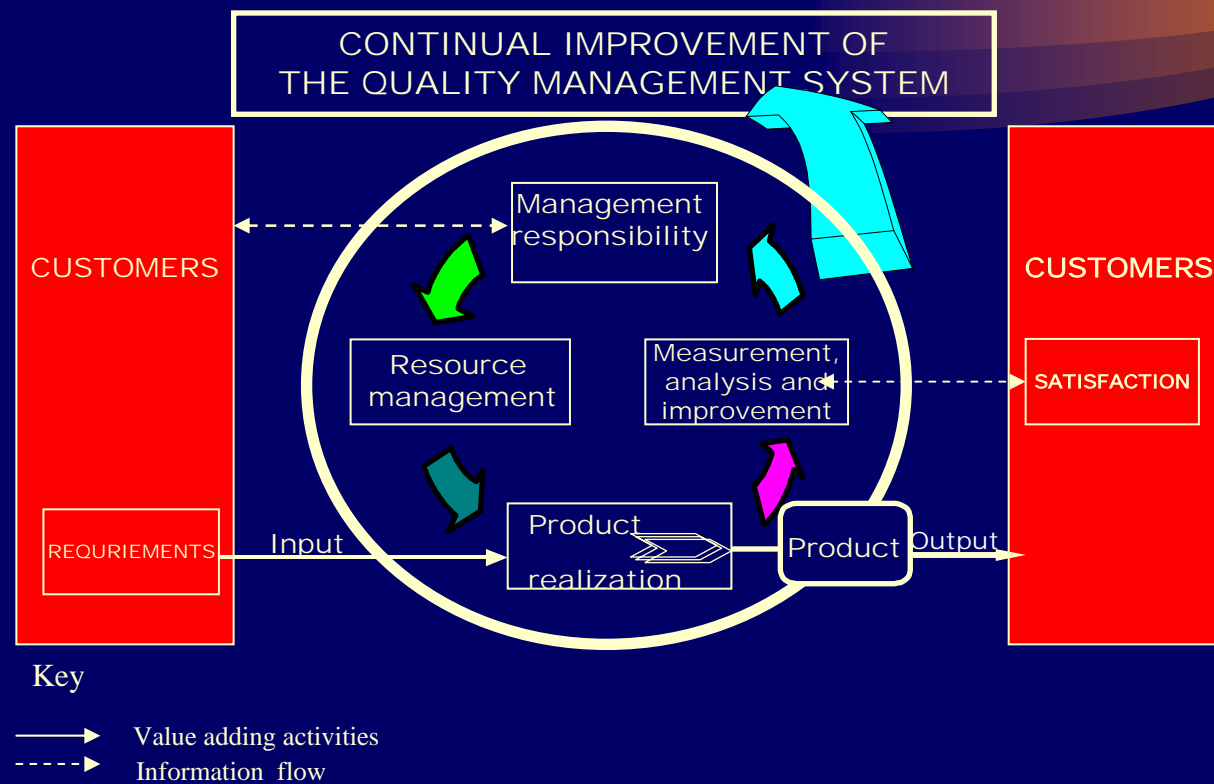
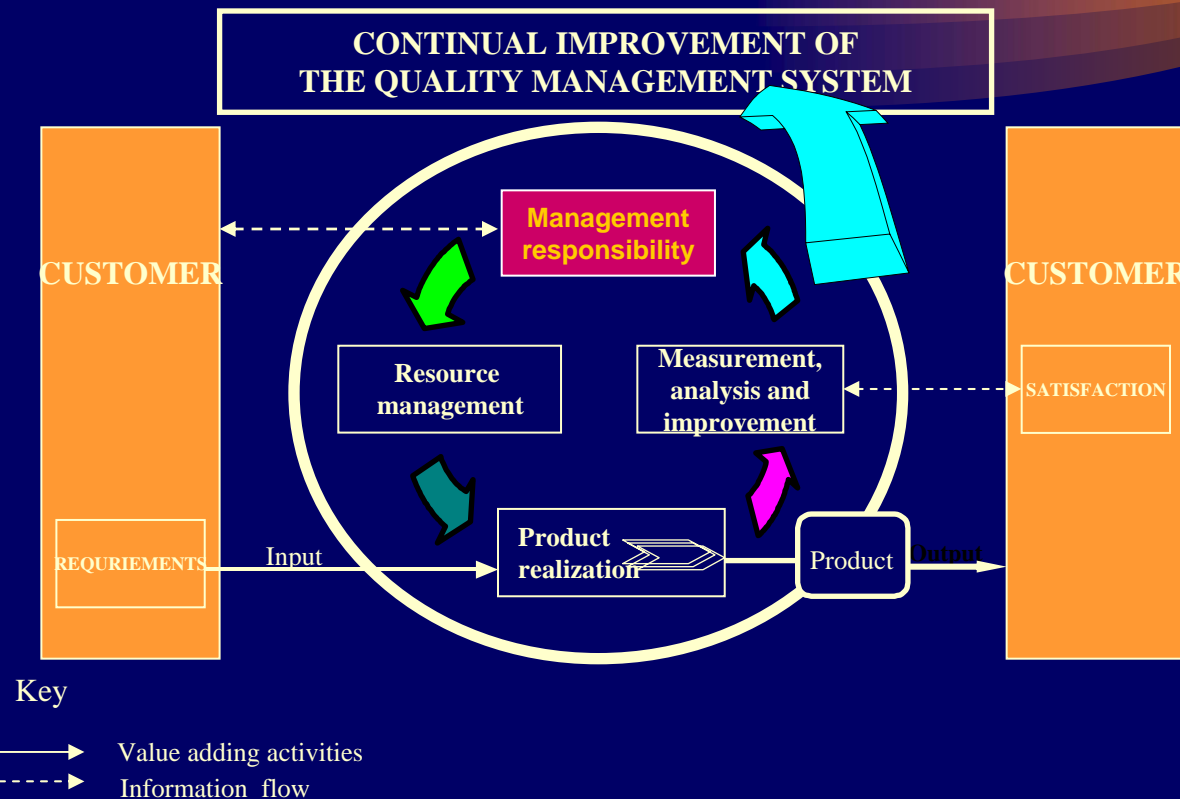**Figure 1 — Model of a process-based quality management system**

Clause 4 *Quality management system*
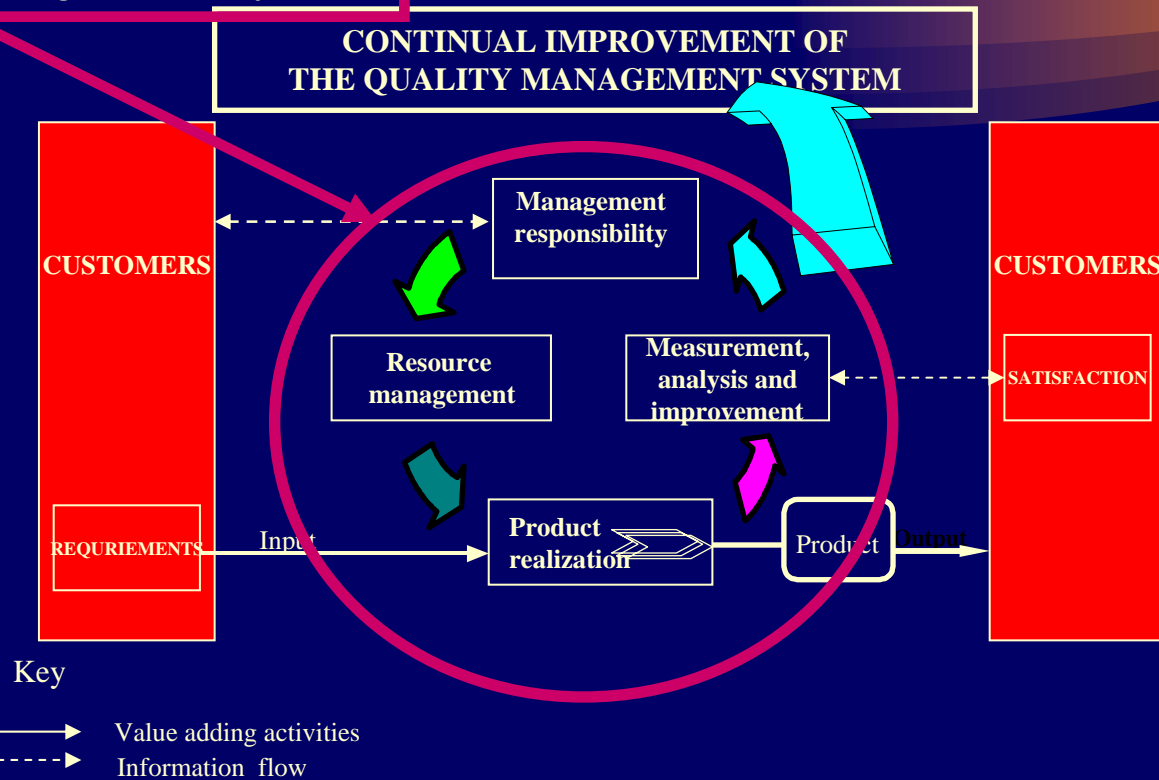
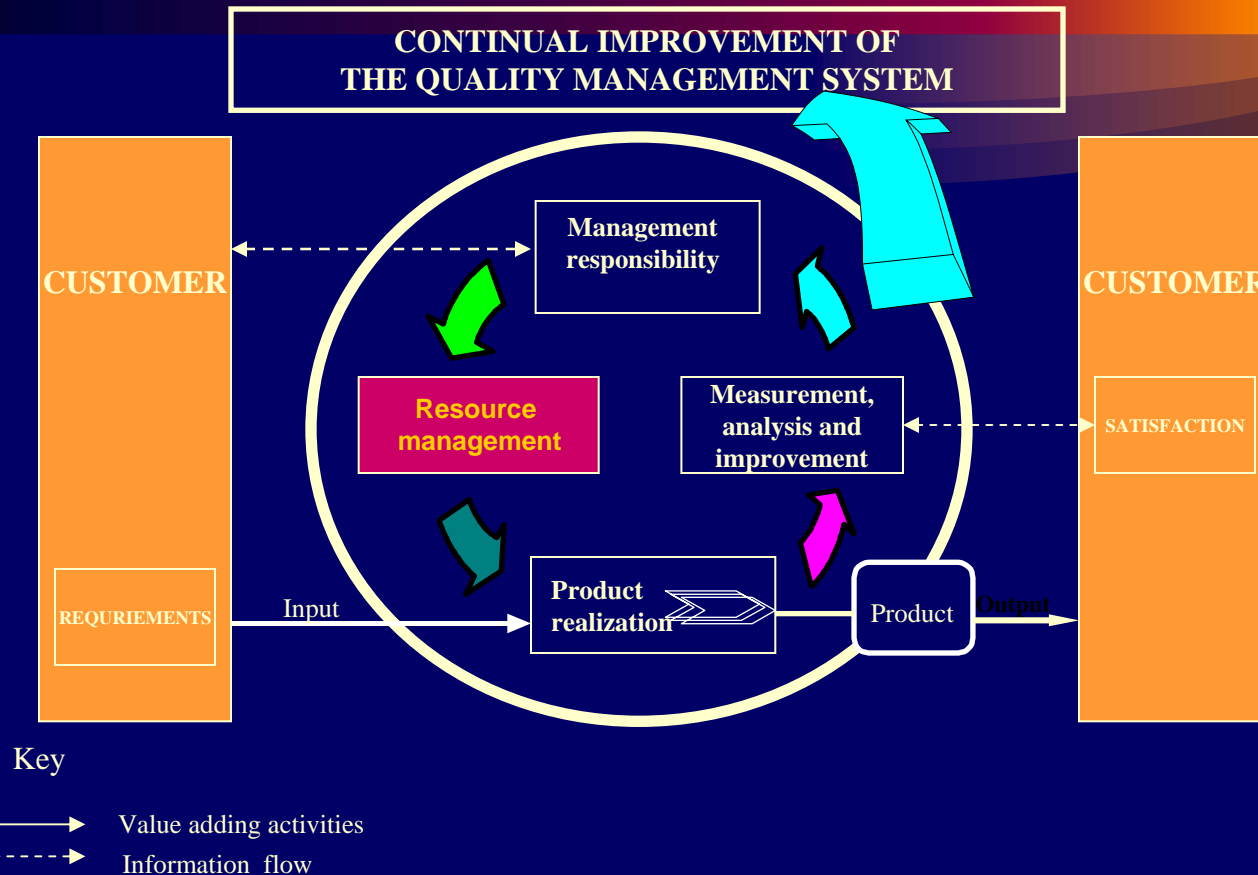

Figure 1 — Model of a process-based quality management system
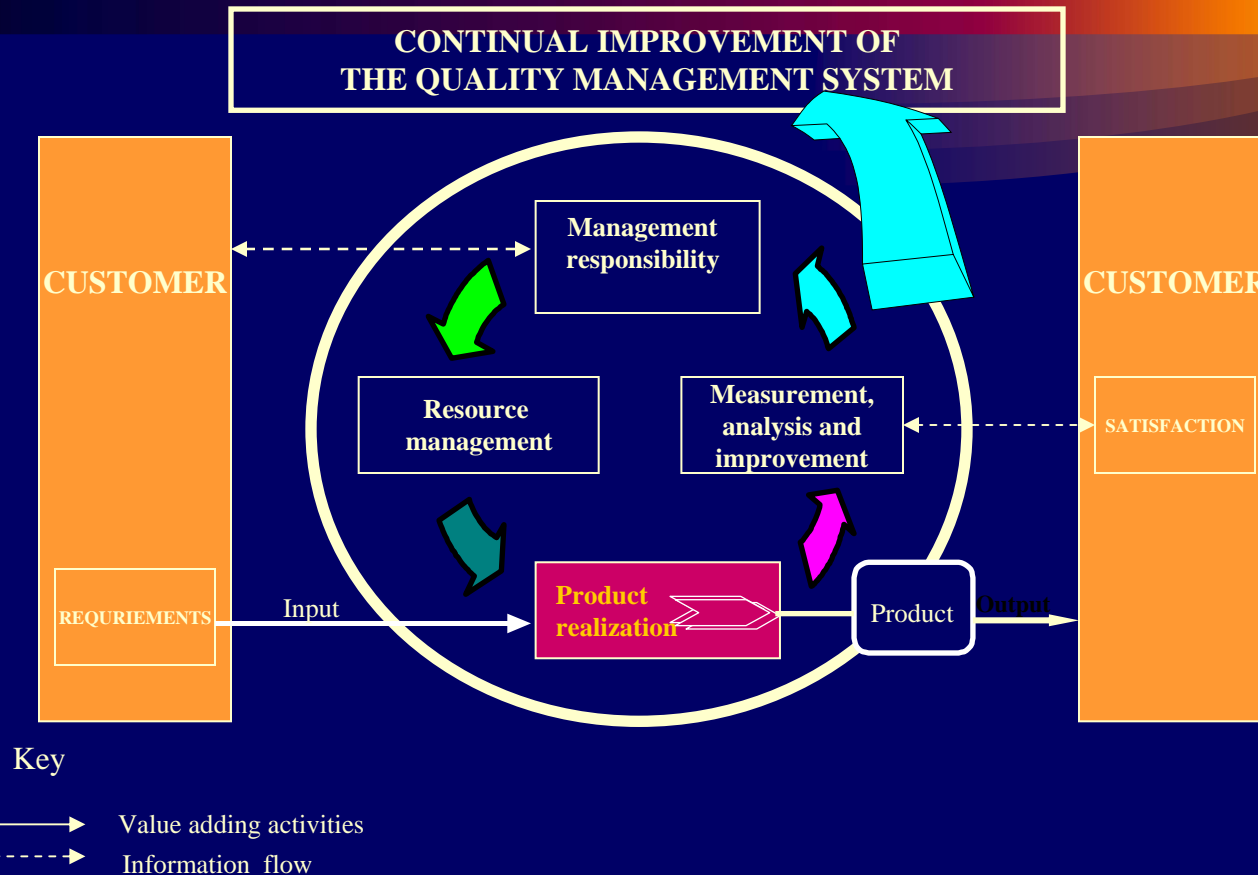
Clause 5 *Management responsibility*

Figure 1 — Model of a process-based quality management system

Clause 6 *Resource management*

CONTINUAL IMPROVEMENT OF THE QUALITY MANAGEMENT SYSTEM

CUSTOMER

Management responsibility

Resource management

Measurement, analysis and improvement

CUSTOMER

SATISFACTION

REQURIEMENTS

Input

Product realization

Product

Output

Key

→ Value adding activities

-----→ Information flow

Figure 1 — Model of a process-based quality management system

Clause 7 *Product realization*

**CONTINUAL IMPROVEMENT OF
THE QUALITY MANAGEMENT SYSTEM**

CUSTOMER

CUSTOMER

Management
responsibility

Resource
management

Measurement,
analysis and
improvement

SATISFACTION

REQURIEMENTS

Input

Product
realization

Product

Output
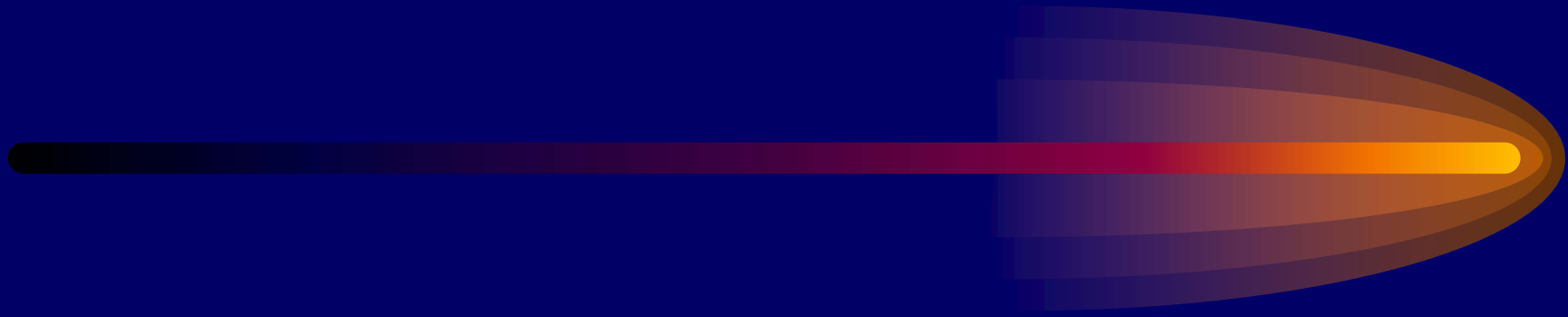
Key

→ Value adding activities

----→ Information flow

Figure 1 — Model of a process-based quality management system
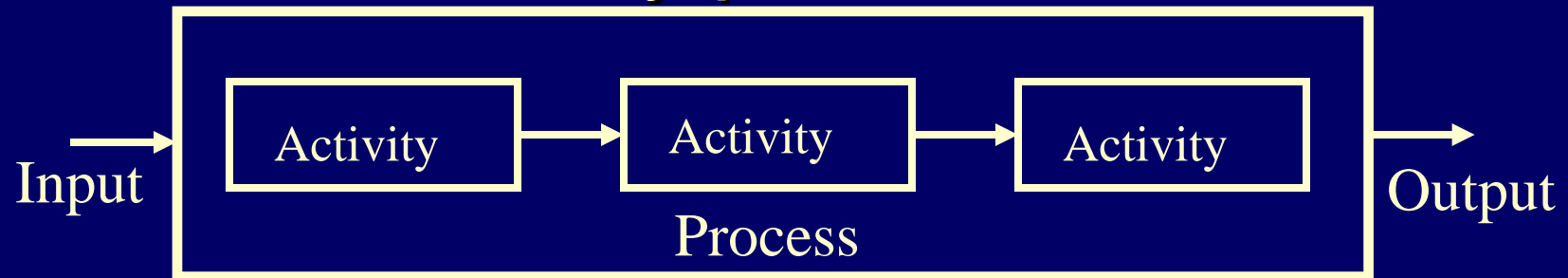
Clause 8 *Measurement, analysis and improvement*
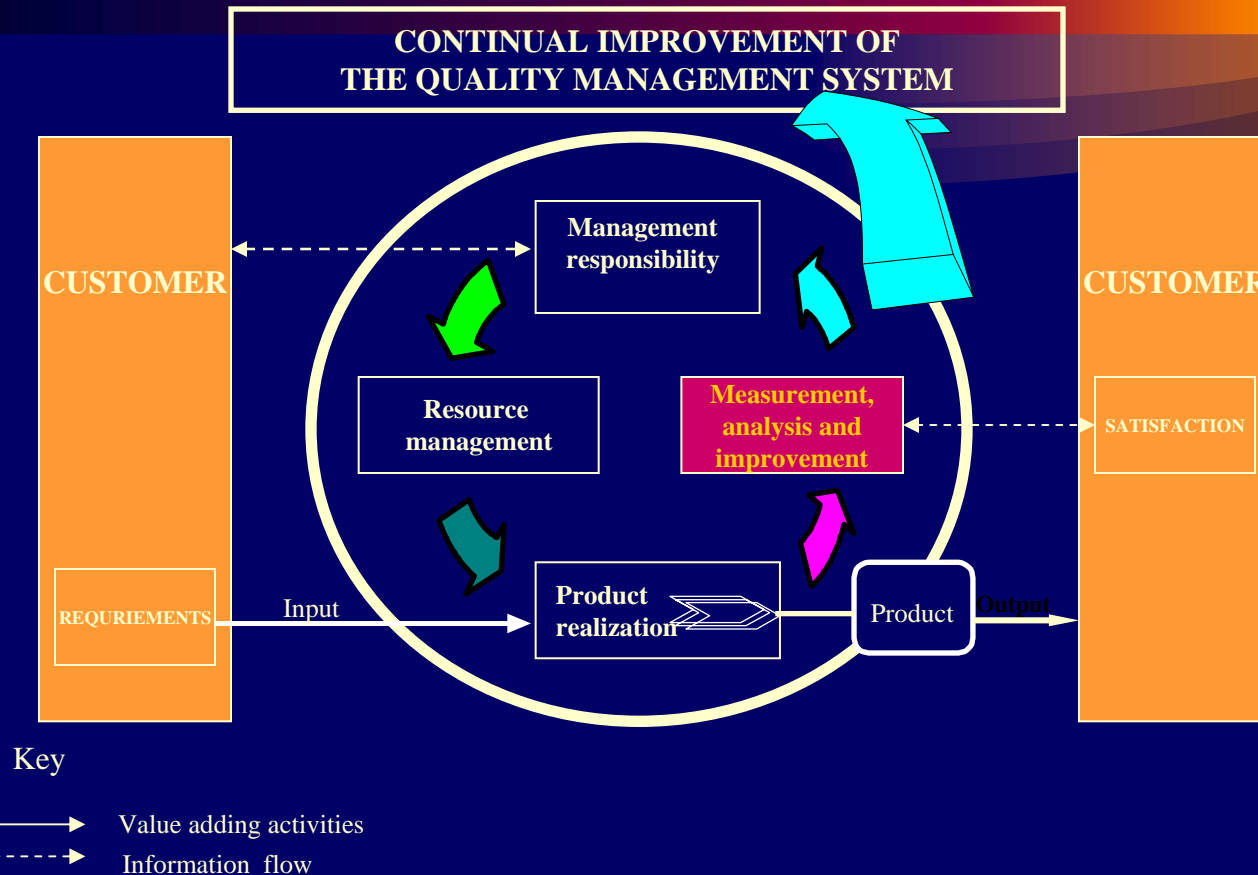
Figure 1 — Model of a process-based quality management system

Determine sequence & interaction

Input → [ ] → [ ] → [ ]

[ ] (cylinder) → [ ] → Output
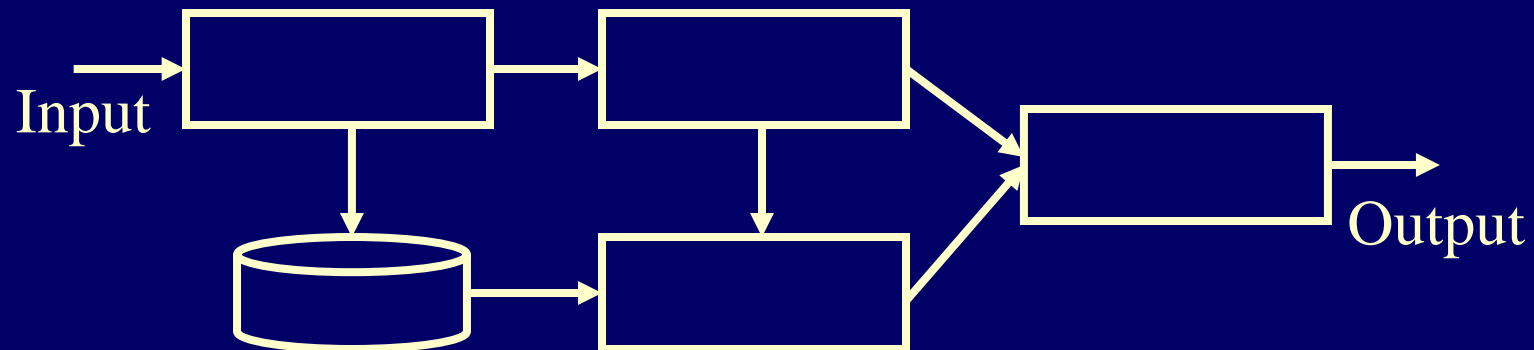
Determine methods to operate & control processes

Input

Output
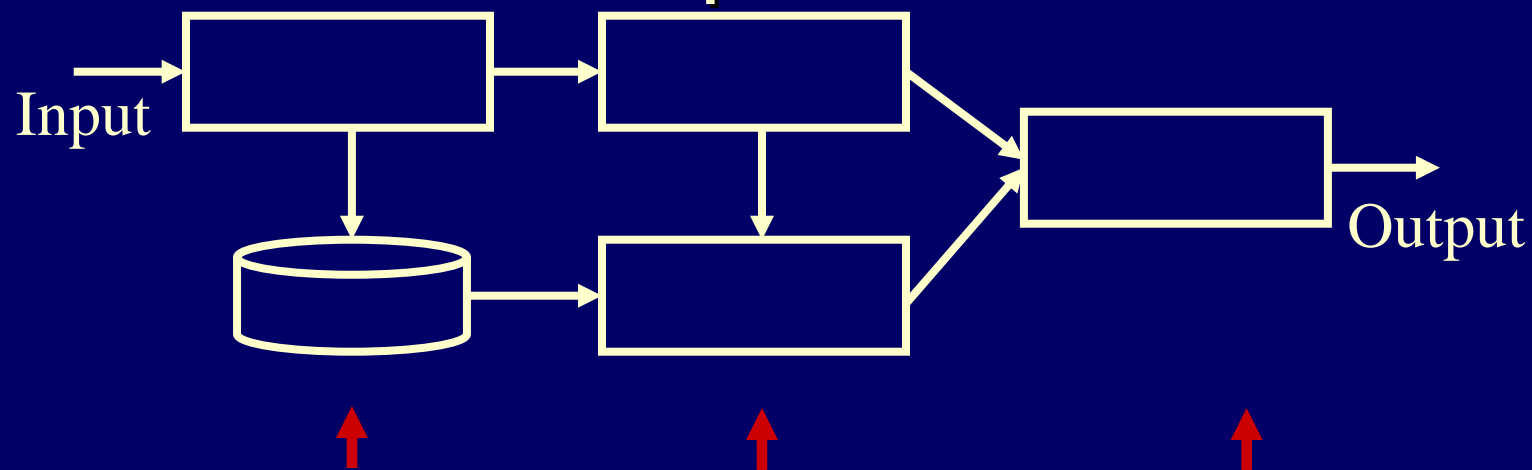
Resources and Information
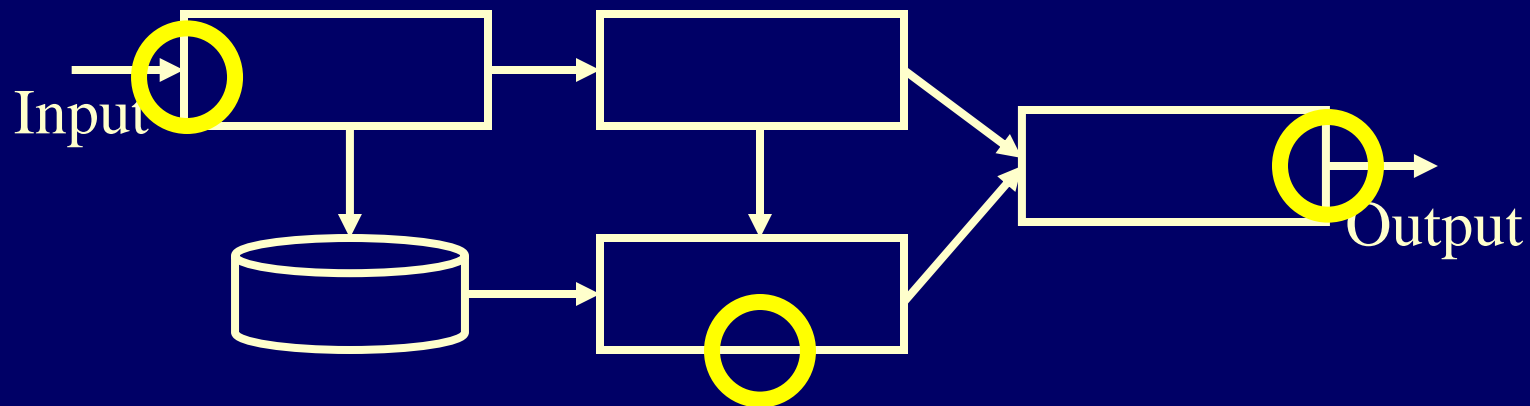
Get Competitive Advantage

When You Go Beyond Minimum Requirements

- Focus on Actions to Achieve Results
- Avoid Adding Other Activities

Example Quality Management System **Relationship Map**
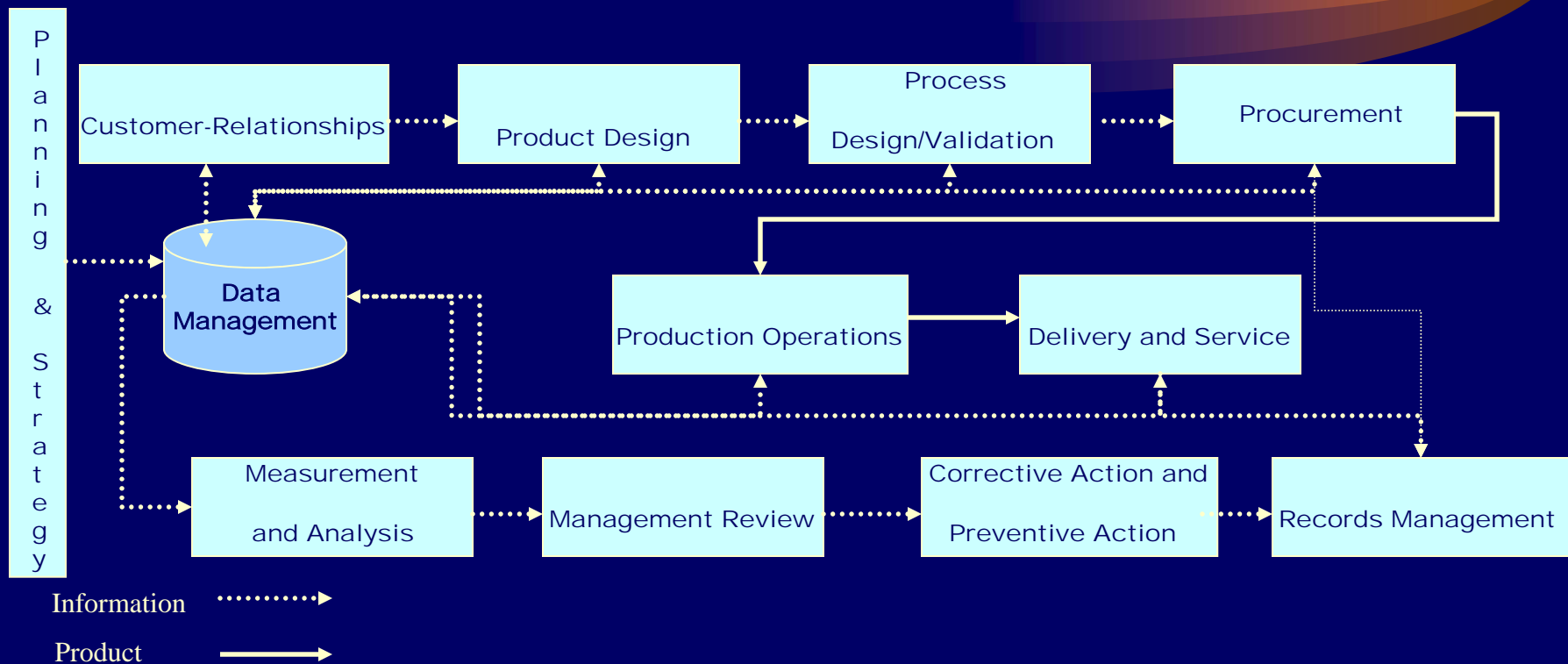
Chart the Basic Processes of the System

Planning & Strategy

| Customer-Relationships | **Product Design** | Process Design/Validation | Procurement |

Data Management

| Production Operations | Delivery and Service |

| Measurement and Analysis | Management Review | Corrective Action and Preventive Action | Records Management |

Information ┈┈┈▶

Product ────▶
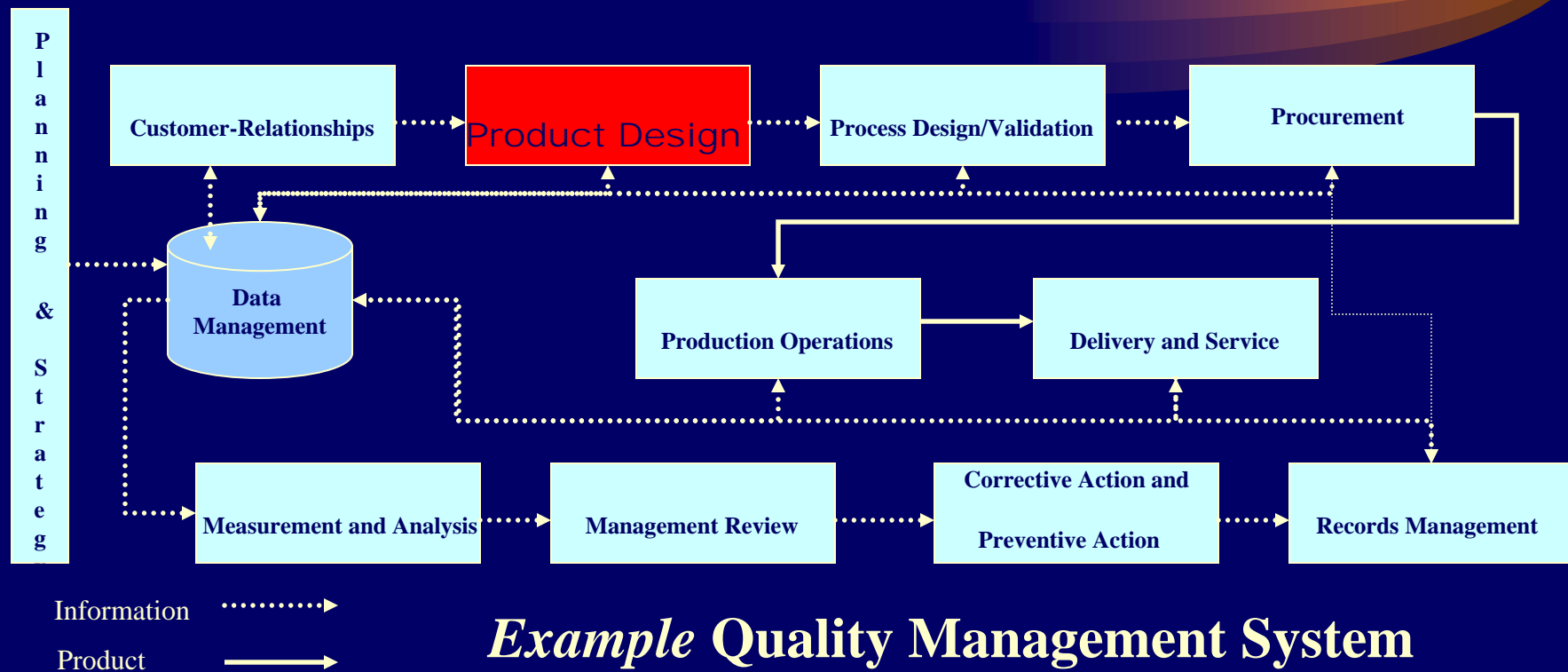
Example **Quality Management System**
Relationship Map

Start With Process Outputs

Process

Inputs

Product Design

Outputs

To Identify outputs ask questions:

- What are the outputs of the process

- Who are the customers of the outputs

- How do those customers use the output

- How should the output be measured

**Involve the people working in the process
Talk to the customers of the process**

Start With Process Outputs

Process

Product design

These are just some examples, your process may have many outputs, Outputs - A simple example customers, targets and results.

Outputs	Customer	Target	Current Results
• Designs that meet user needs	• Ultimate product users	• No complaints	• No complaints
• Specifications for process development	• Process Engineering	• 6-month product cycle	• 12 month design cycle
		• No process budget variance due to design issues	• $100,000 over process budget for last year due to design issues

Align Process Objectives with Overall Quality Objectives

Maintain this Alignment Forever!

- **As Quality Objectives Change, Process objectives are modified**

- **Process must be Improved to Meet the new Objectives!**

Define the Process Inputs

These are just some examples, your process may have many inputs, suppliers, targets and results.

Process

A simple example - Inputs → **Product Design**

| **Inputs** ⬇	**Supplier** ⬇	**Target** ⬇	**Current Results** ⬇
• Requirements of specific customers	• Sales Department	• Zero orders returned to sales for more information	• 50% of orders returned for more data over last 12 months
• Market needs for new products	• Marketing	• New product needs 12 months out	• Last ten products defined 10 to 12 months out
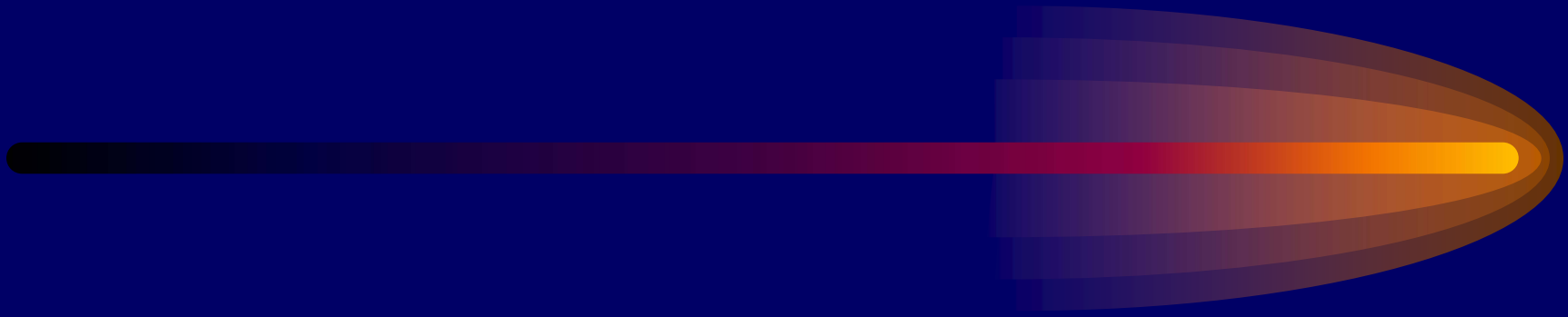
Targets Not Met are
Opportunities for Improvement

Flow Chart The Process

## Inputs

•*Suppliers*

•*Targets*

•*Results*

Product Design Process
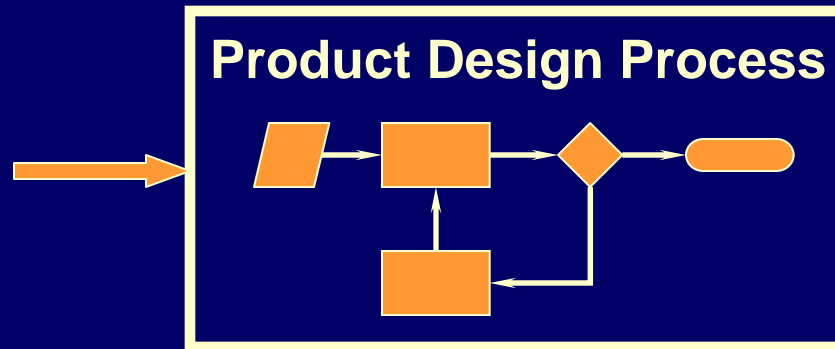
Outputs

•*Customers*

•*Targets*

•*Results*

Map the Process--As IS

- **Use simple flow charts for the process flow**

- **Record data related to the process targets for key process activities**
  - **Defect trends**
  - **Resources**
  - **Process capability**
  - **Etc.**

Process maps are more than just flow charts: *they are supported by data*

- **Chart the process as it actually works NOW, Don't make changes yet**
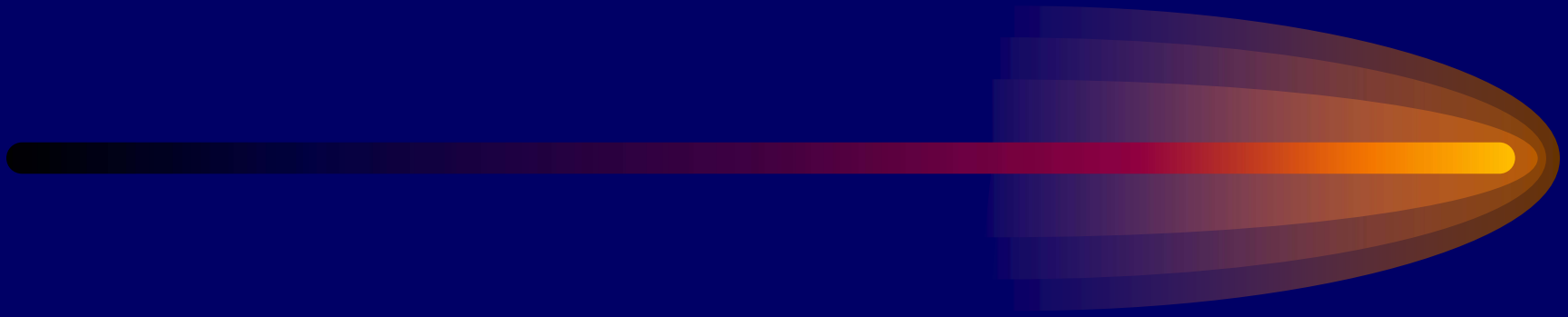
Analyze the Maps to find Improvements

Improve the Process

Three Situations:

- **Obvious process disconnects**

- **Data show process has *some individual activities with problems***

- **Data shows process fails to meet target but *individual activity data are stable with no clear problems***

Improve the Process

First Situation:

- **Obvious process disconnects**
  - **Outputs go to the wrong place**
  - **Obvious missing processing steps**
  - **Obvious redundancies**
- **Correct the obvious problems**
  - **Change routing of misdirected outputs**
  - **Introduce needed new steps**
  - **Eliminate redundant steps and reallocate resource**

Improve the Process

Second Situation:

- **Process has *individual activities with problems***
  - Overall process may or may not meet targets
  - Not effective in meeting quality objectives
  - Not efficient
- **Identify and solve the problems in the process**
  - Identify problems and root causes
  - Develop and implement actions to correct the causes
  - Measure improvements

Improve the Process

Third Situation:

- **Process fails to meet target but results *are stable with no clear problems***
  - Most activities seem OK but results are bad
  - Process has never meet expectations
  - Process is stable
- **Consider re-engineering the process**
  - Clean sheet approach with out-of-the-box thinking
  - Apply new technology

Preventive Action—the "What If" of Process Management

- **Clause 8.5.3 requires determination of action to eliminate the causes of potential nonconformities**

- **This analysis phase is an ideal time to find opportunities for "preventive action"**

Preventive Action—Ask *Two "Whats" and Three "Hows"*

Ask:

- **What can go wrong?**
- **What would the failure look like?**

Preventive Action -- Ask Two "Whats" and Three "Hows"

Ask:

- **How probable is each potential failure?**

- **How likely is it for these potential failures to reach a customer?**

- **How serious would these failures be if they did occur?**
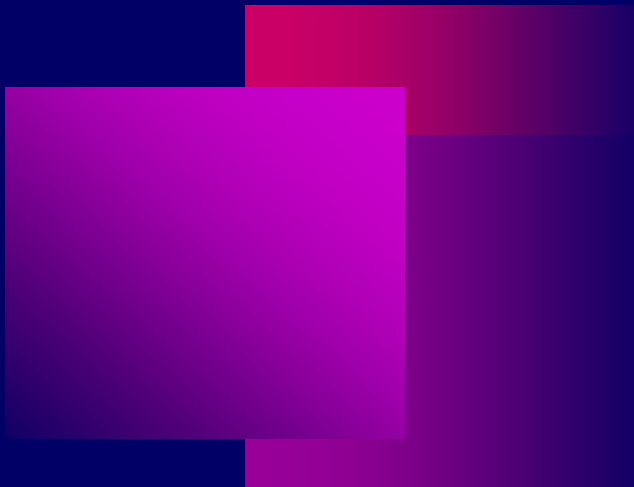
Preventive Action—Act

Act:

- **Prioritize the overall risk for each potential failure**

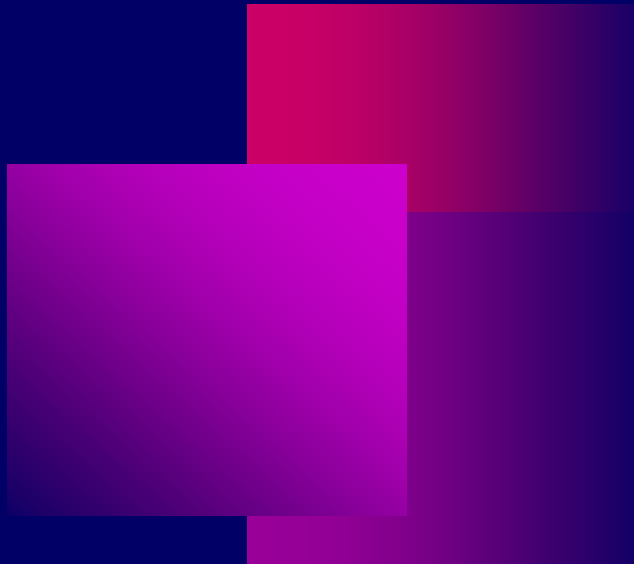- **Define preventive actions**

- **Implement preventive actions**

Revise The Process Maps to Reflect the Improvements

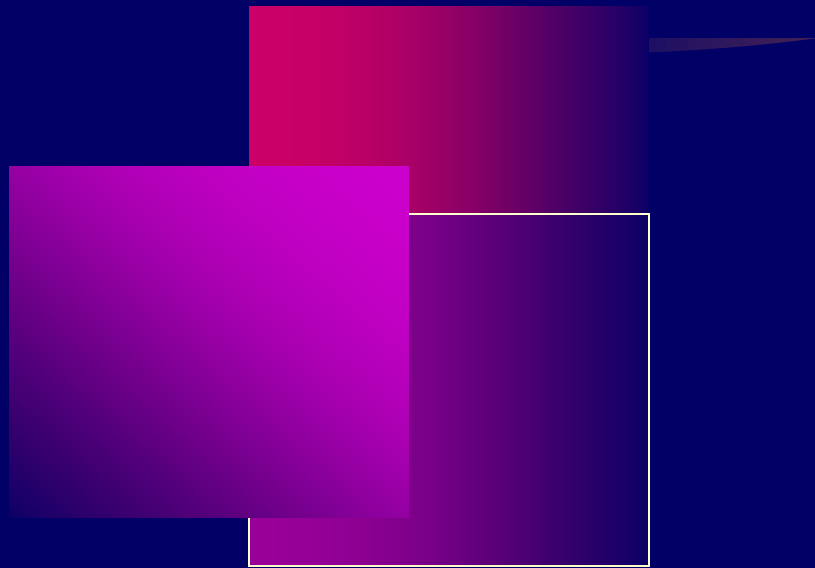## And Do It All Over Again As Objectives Change*!!*

Getting it All Together
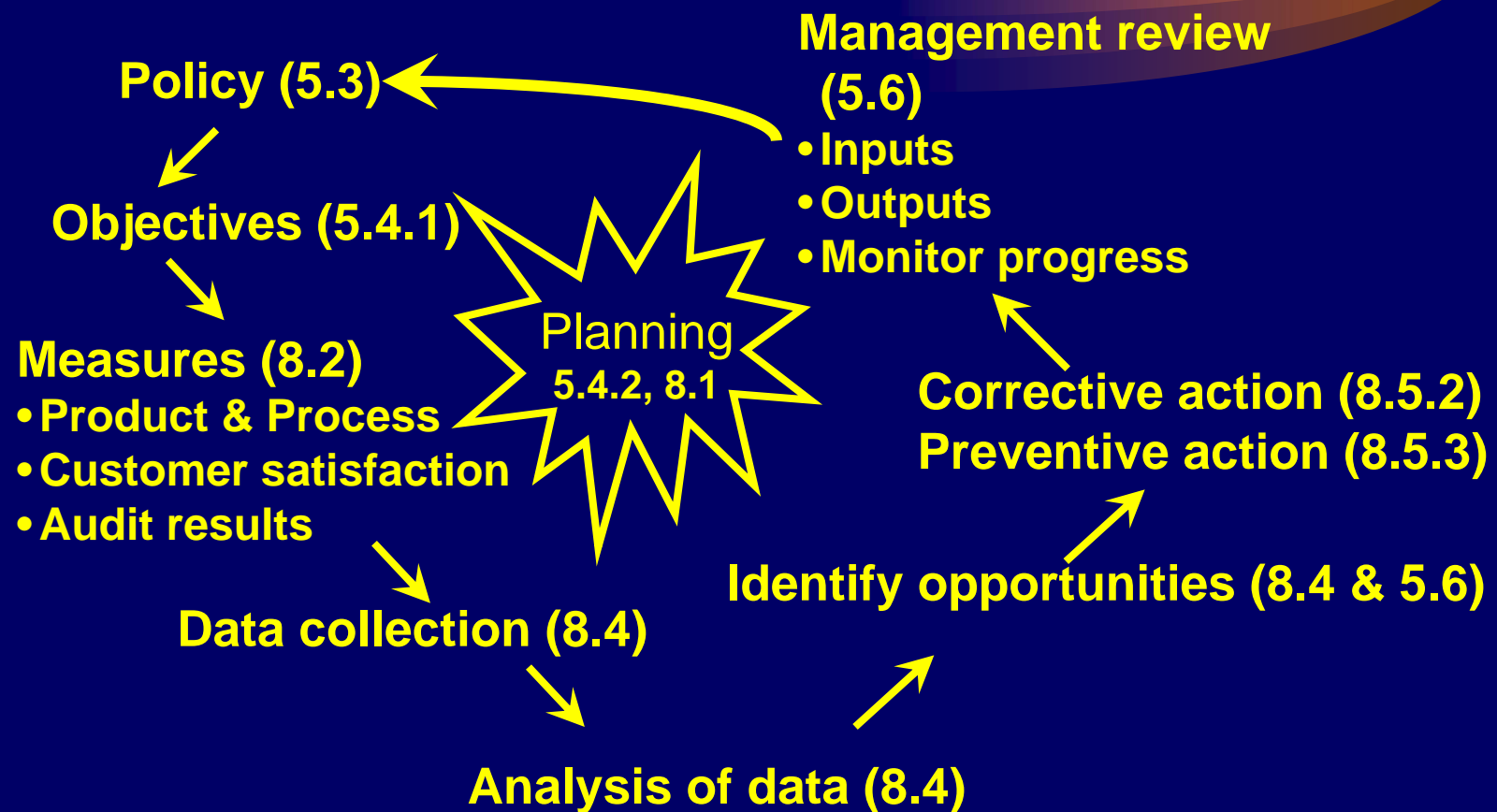
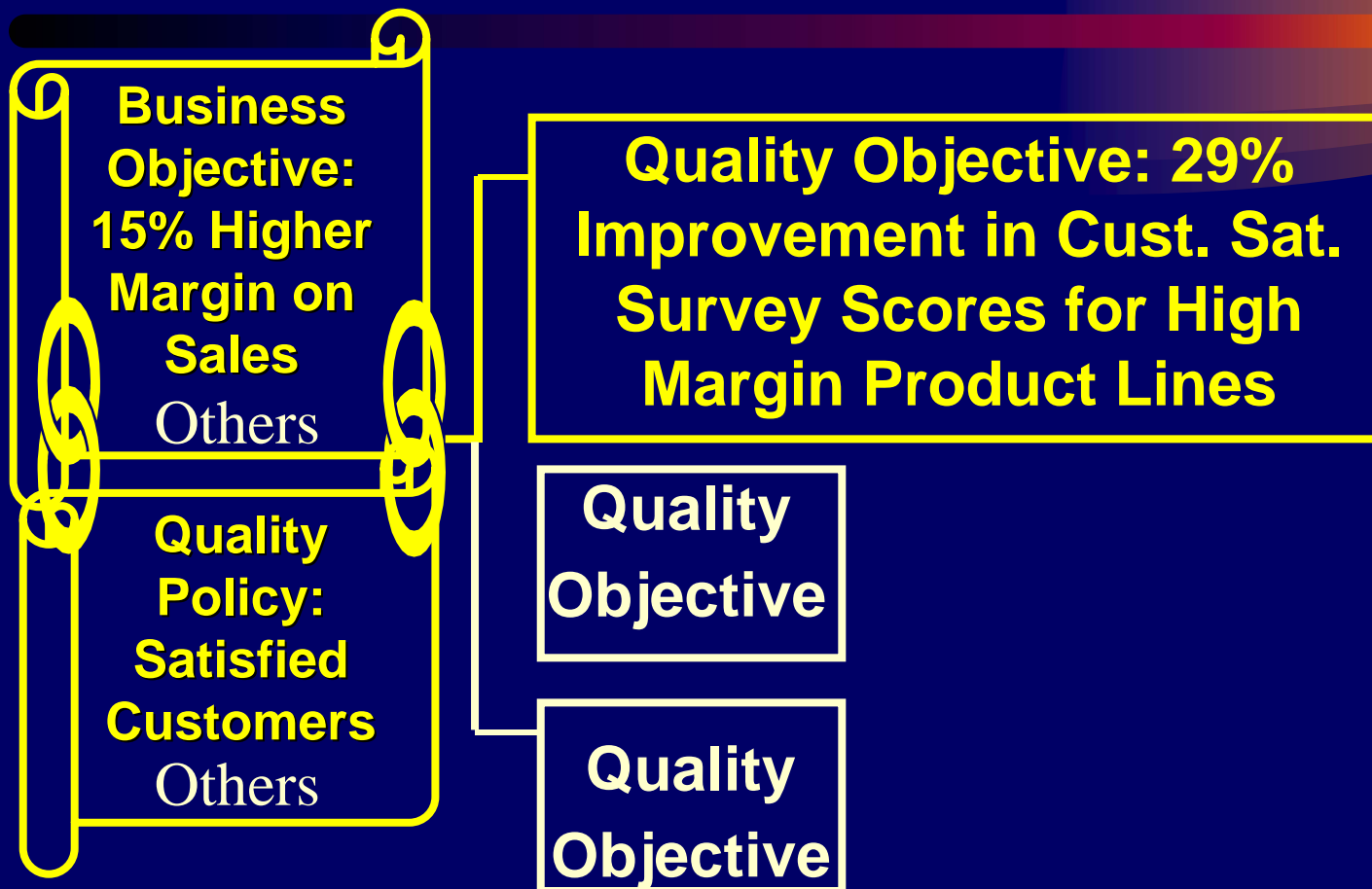# *Getting it All Together*

Getting it All Together

Action #3

Fully Embrace the Continual Improvement Concept

Requirements related to *Continual Improvement*

Policy (5.3)

Objectives (5.4.1)

Measures (8.2)
- Product & Process
- Customer satisfaction
- Audit results

Planning 5.4.2, 8.1

Management review (5.6)
- Inputs
- Outputs
- Monitor progress

Corrective action (8.5.2)
Preventive action (8.5.3)

Identify opportunities (8.4 & 5.6)

Data collection (8.4)

Analysis of data (8.4)

Example: Policy and Objectives Related to Customers

Business Objective: 15% Higher Margin on Sales
Others

Quality Policy: Satisfied Customers
Others

Quality Objective: 29% Improvement in Cust. Sat. Survey Scores for High Margin Product Lines

Quality Objective

Quality Objective

Example: Policy and Objectives Related to Customers

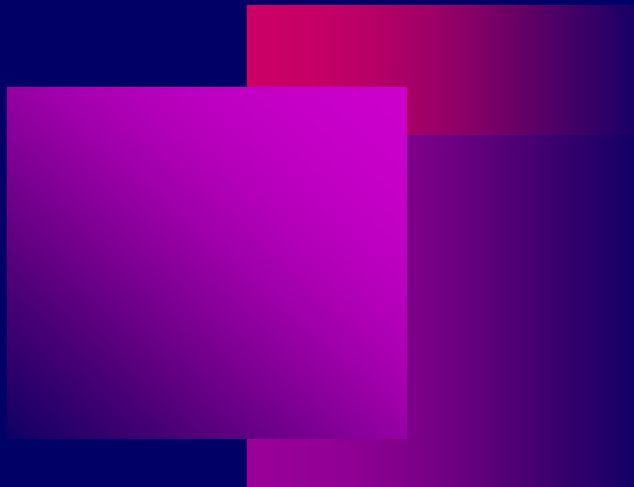**Quality Objective: 29% Improvement in Cust. Sat. Survey Scores for High Margin Product Lines**

Measure

Analyze

Improve

Monitor

Customer Satisfaction Data

Use Simple Analytical Tools

Continual improvement trend—WOW

UP
Is
good

Oops, spoke to soon!

TIME

UP
Is
bad
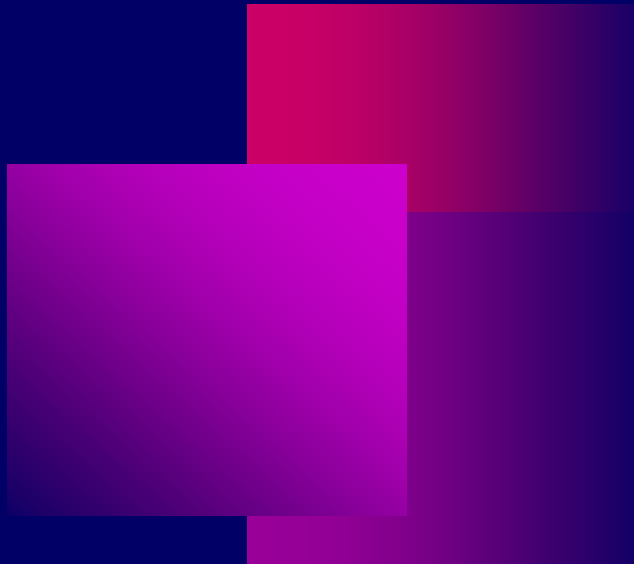
What would
you work on?

Drivers of current
performance

Run Chart and Pareto
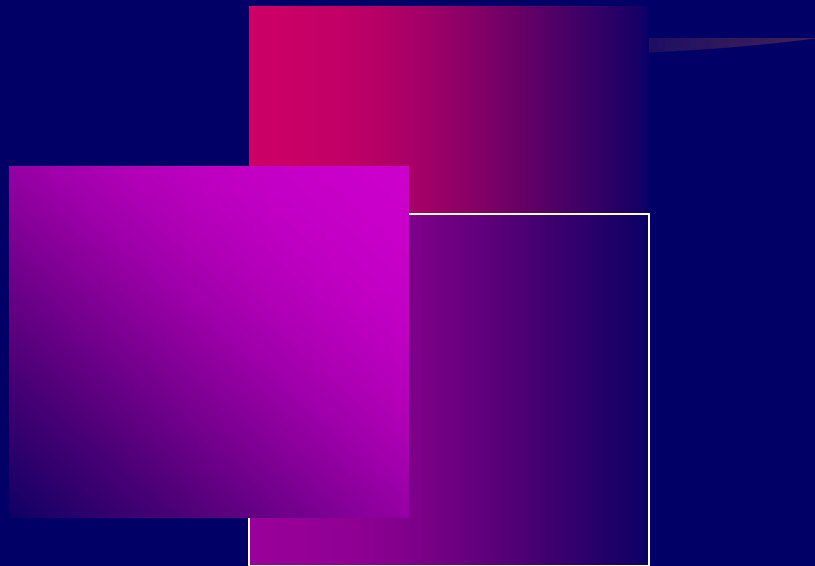
Getting it All Together
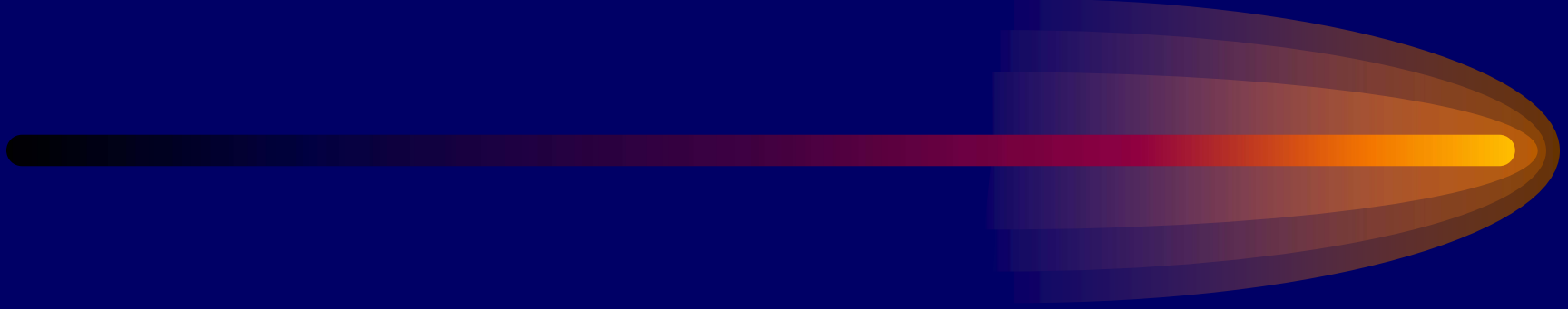
Getting it All Together

Getting it All Together

Action #4

Change Your Thinking on Corrective Action and Preventive Action

Corrective and Preventive Action

Two very different concepts and their use for performance improvement requires different tools and tactics for each

Effective Corrective Actions

Clearly understand what Corrective Action really is and is not:

- **It is correcting *causes***

- **It involves nonconformities that have happened**

- **It is *not* correction of nonconforming items**

Effective Corrective Actions

When you think of corrective action:

- **Think of *PROBLEM SOLVING***
- **Think of problem solving tools**

Effective Corrective Actions

- **Integrate corrective action, team problem solving and other tactics**

Effective Preventive Actions

Clearly understand what Preventive Action really is and is not:

- **It is action to prevent future nonconformities and problems**
- **It addresses things that have not happened**
- It is *not* correcting the cause of existing problems

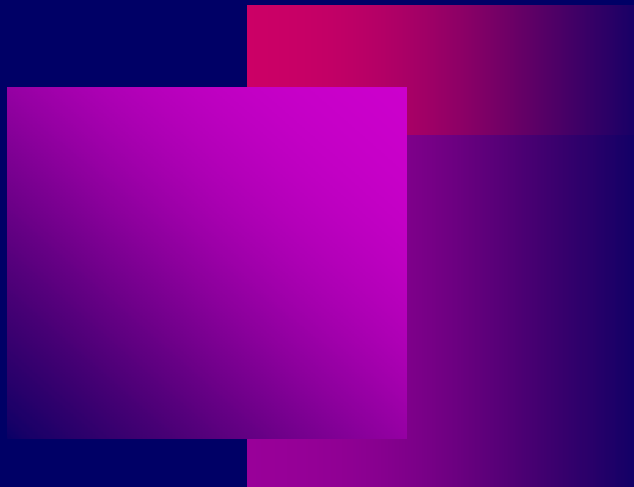# *Effective Preventive Actions*

When you think of preventive action:

- Think *RISK MANAGEMENT*
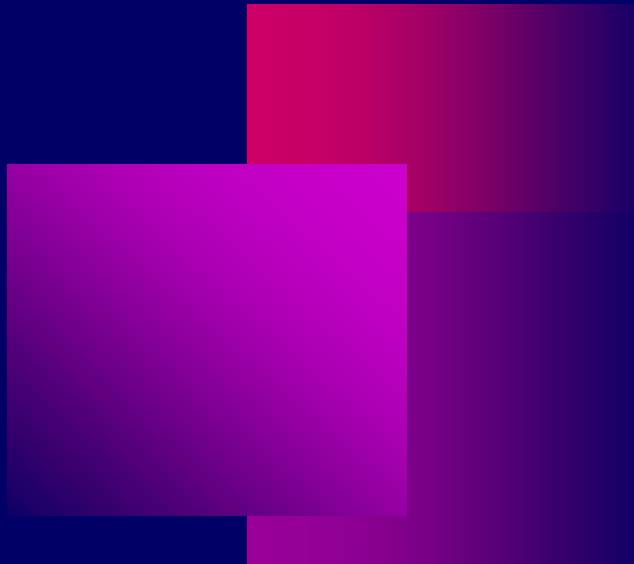- Use FMEA and other risk management tools

Effective Preventive Actions

- **Use preventive action during up-front activities:**
  - **New products**
  - **New processes**
  - **New equipment**
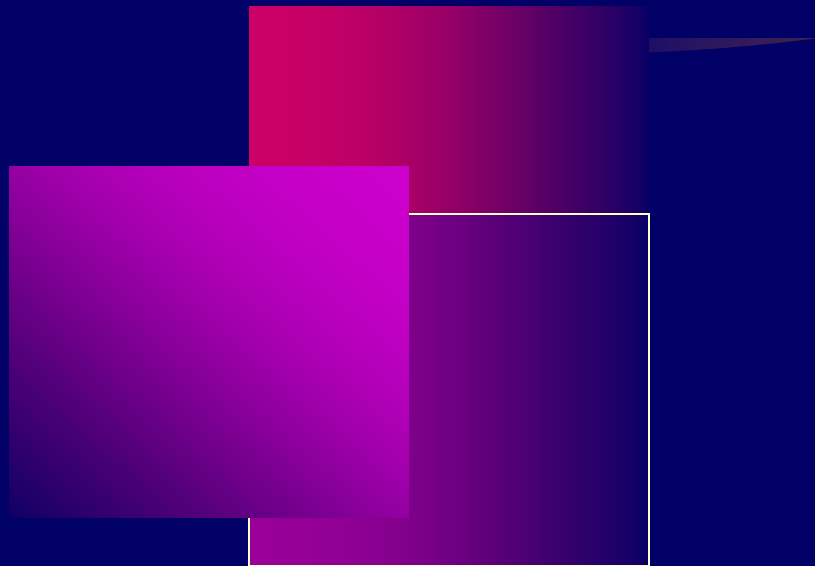- **Keep it separate from corrective action**

Getting it All Together

Getting it All Together

Getting it All Together
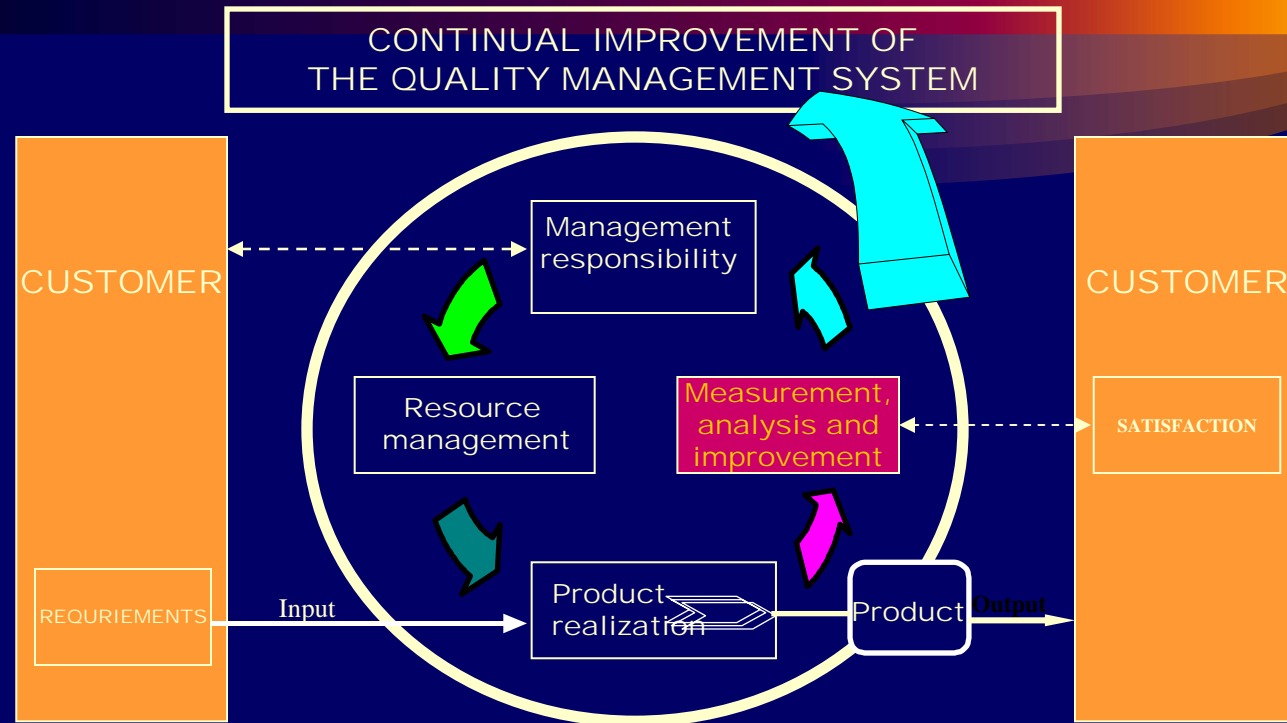
Action #5

Change the Way You Audit

Auditing to ISO 9001:2000

CONTINUAL IMPROVEMENT OF
THE QUALITY MANAGEMENT SYSTEM

CUSTOMER

CUSTOMER

Management responsibility

Resource management

Measurement, analysis and improvement

SATISFACTION

REQURIEMENTS

Input

Product realization

Product

Output

- **Part of Clause 8.2 on Measurement**

- **Key input to the improvement process**

- **Audits are covered in clause 8.2.2 which is part of *measurement***

- **Emphasizes determining *effective implementation* of quality management system**
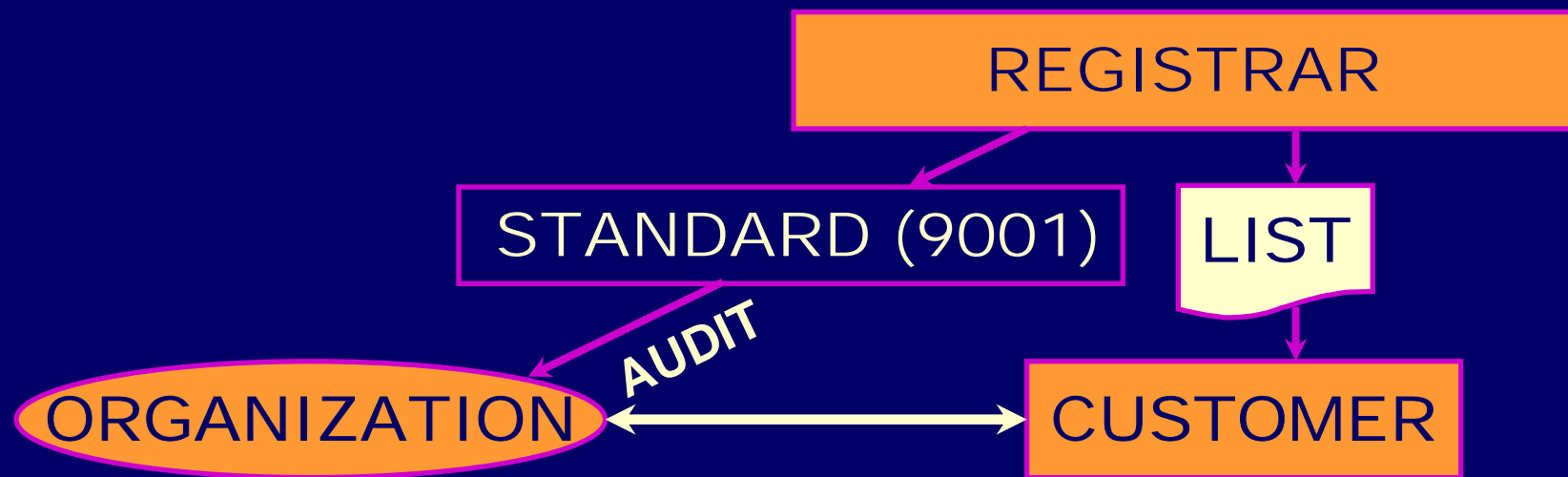
Three categories of audits

- **Internal audits -- 1st party**
- **Customer audits of suppliers -- 2nd party**
- **External independent audits -- 3rd party**

Three categories of audits

External independent audits -- 3rd party

- **Conformity to a specific standard**

```
                              ┌────────────────────┐
                              │    REGISTRAR        │
                              └────────────────────┘
                             ↙                    ↓
        ┌──────────────────────┐          ┌──────────┐
        │  STANDARD (9001)      │          │  LIST    │
        └──────────────────────┘          └──────────┘
                   ↓ AUDIT                       ↓
   ┌────────────────────────┐          ┌──────────────────┐
   │   ORGANIZATION          │ ◄──────► │   CUSTOMER        │
   └────────────────────────┘          └──────────────────┘
```

Three categories of audits

Customer audits of suppliers -- 2nd party

- Conformance to customer requirements
- Customer's special interest items

STANDARD (9001)
OTHER REQUIREMENTS

AUDIT

ORGANIZATION ⟷ CUSTOMER

Three Categories of Audits

Internal audits -- 1st party

- **Conformance to the standard**
- **Conformance to the Organization's System**
- **Performance to the Organization's Objectives**
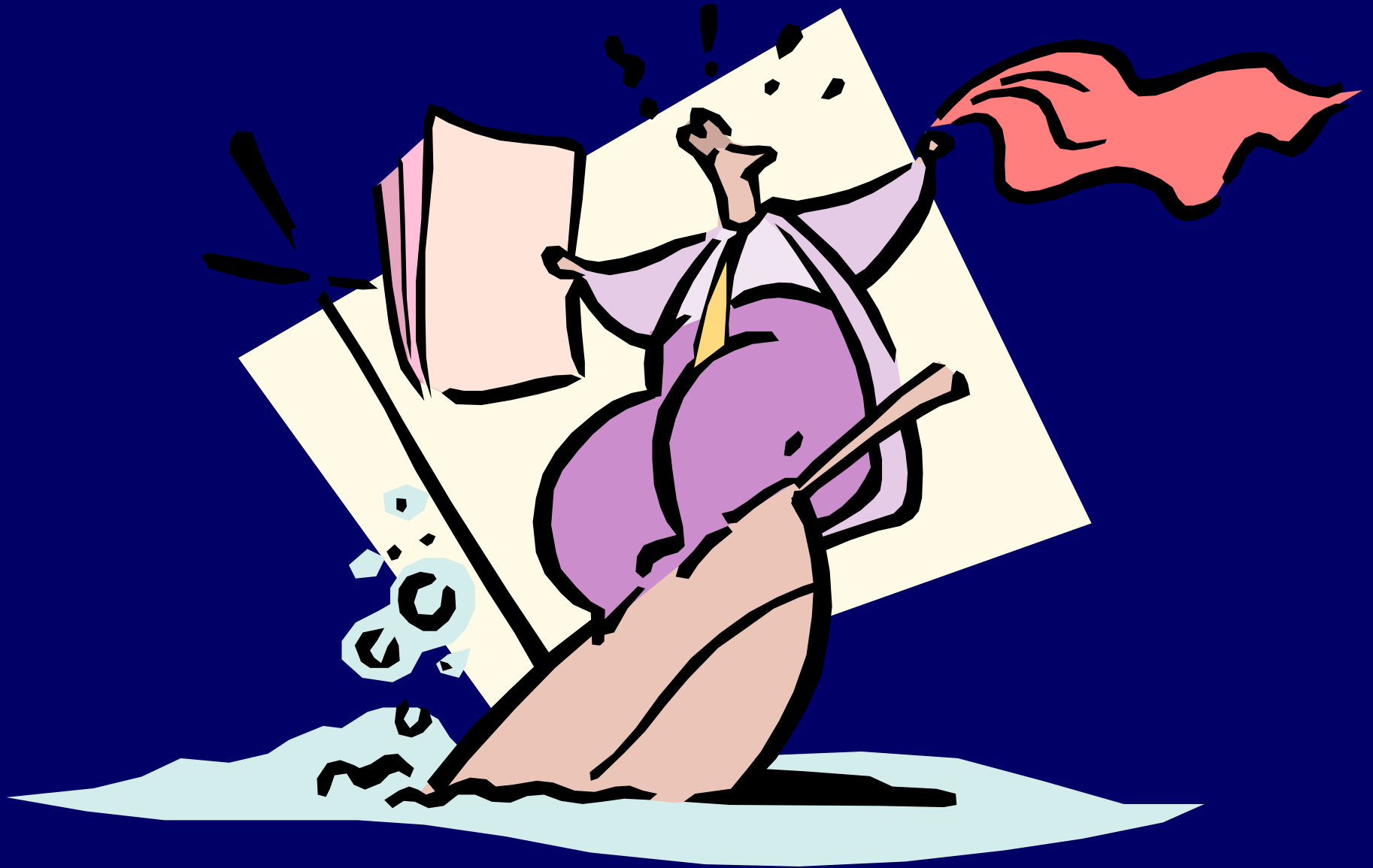- **Problem identification!**
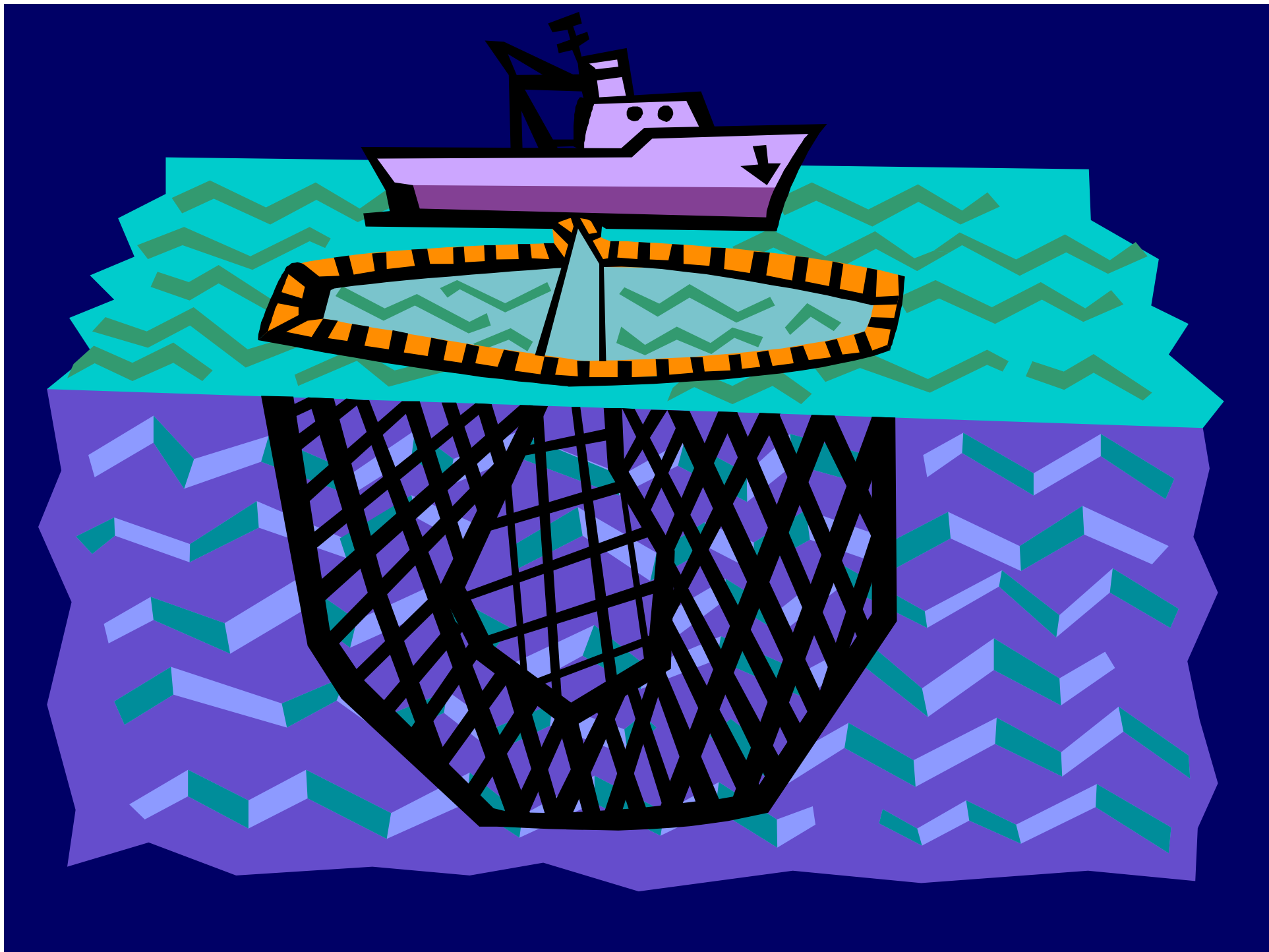- **Opportunity finding!**

- **Processes flow through the functions of the organization**

- **Auditing cross—functional process enables us to find problems between functions**

- **Auditing *all* the processes that flow through an area or department**

Change the Way You Think About Nonconformities

UP

Is

good

TIME

Oops, spoke to soon!

Is this a Nonconformity?

Five Actions You Can Take

1. Shift your Focus From Internal Operatios to the Customer

2. Use Process Management Techniques

3. Fully Embrace the Continual Improvement Process

4. Change Your Thinking on Corrective Action and Preventive Action

5. Change the Way You Audit

Remember

- **Success always requires two things**
  - **doing the right things and**
  - **doing them right**
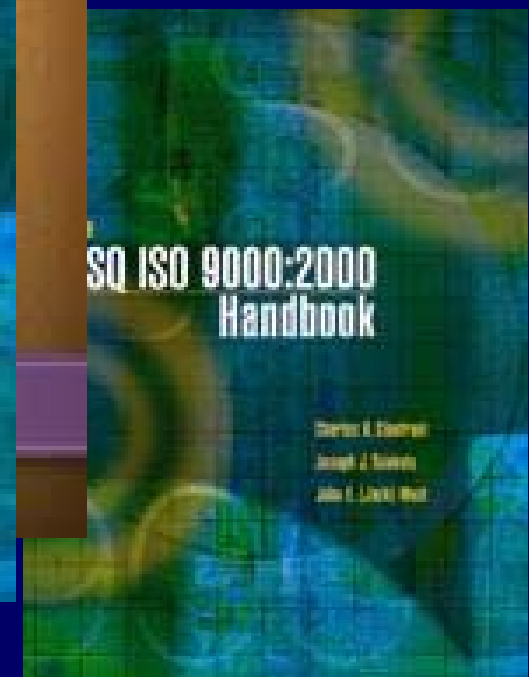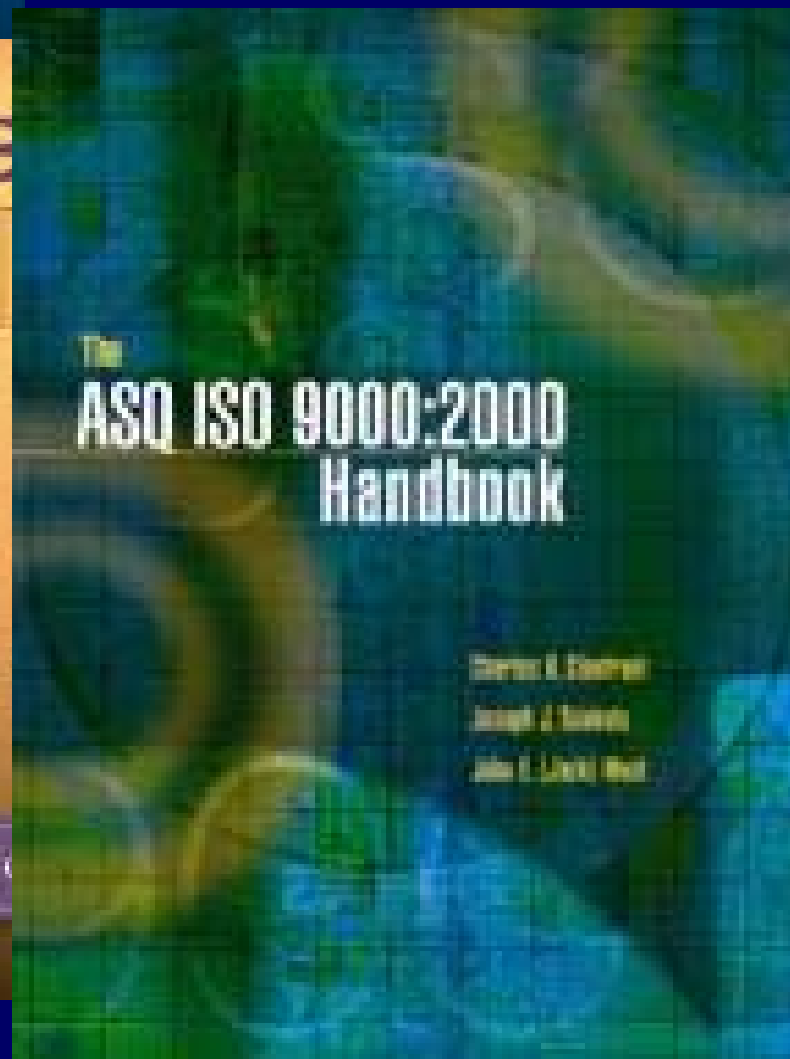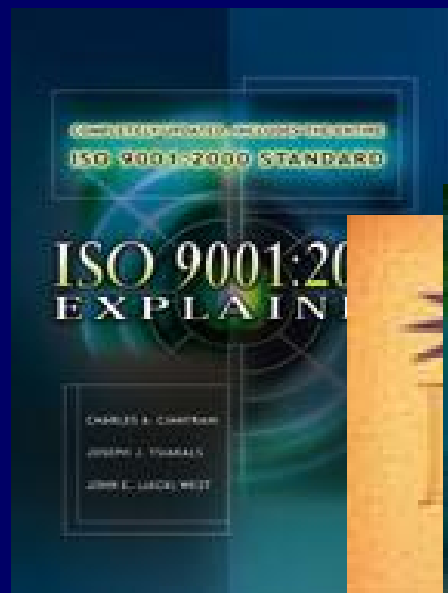- **The new 9001 requires a lot of the right things**

Remember

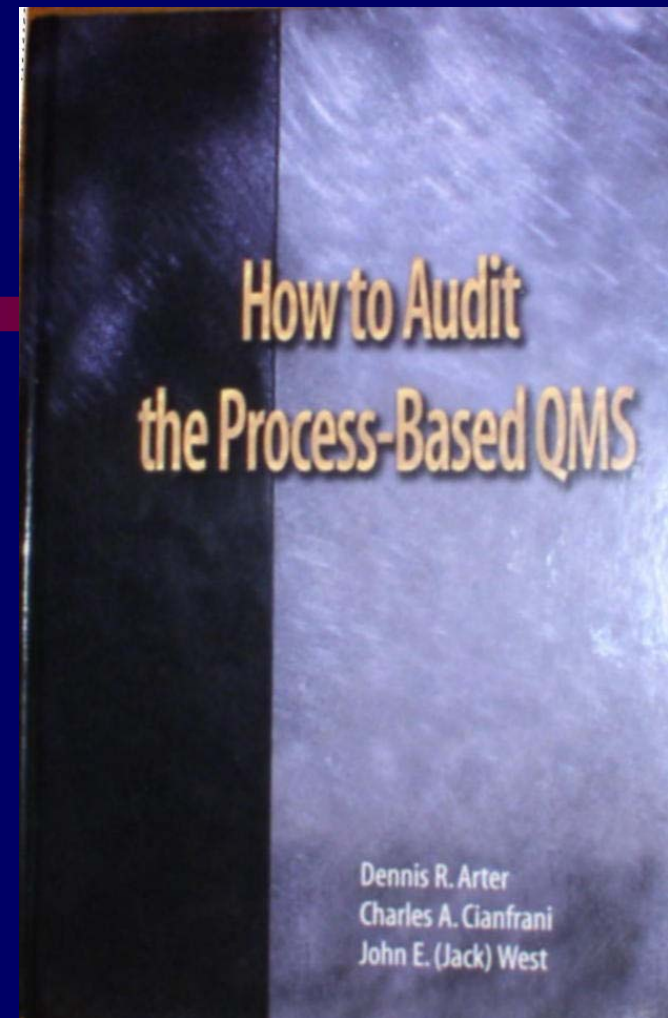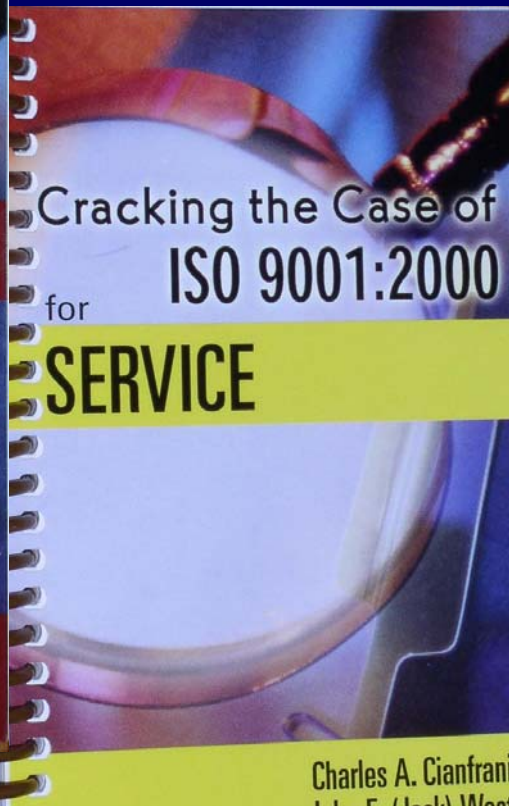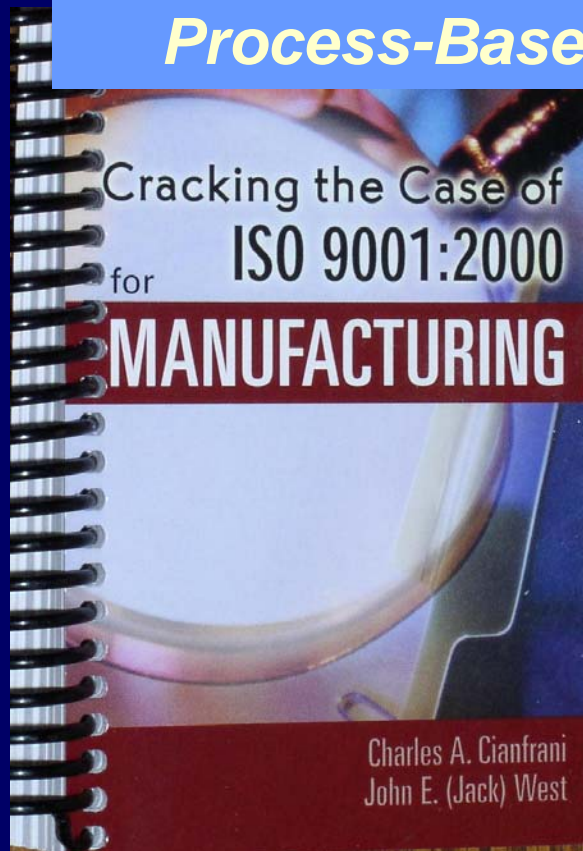- **It is up to you to do those things right**

THINK

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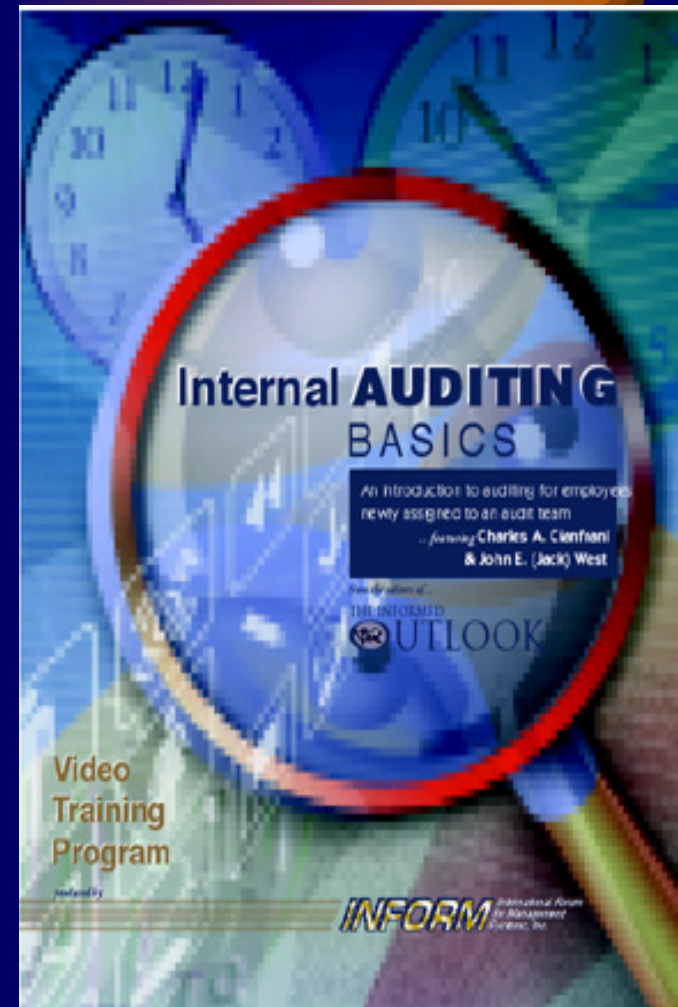- ➤ **Order from:**

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Thanks for your Attention

Questions

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About Jack West
www.SilverFox.org

Jack is a quality professional who helps organizations improve productivity and quality. He has nearly thirty years of experience in industry with Tenneco, Inc. in a wide variety of industries including shipbuilding, packaging, automotive parts manufacturing, chemicals, and manufacturing of farm machinery and construction equipment. In his consulting work, Jack has led implementation of TQM and Cost of Quality processes.

His extensive international experience includes working with organizations around the world to implement effective ISO 9000 quality systems focused on lower costs and higher customer satisfaction. In 1993 and 1994, Jack served as Tenneco's Director of Quality for European operations based in Brussels.

He is a fellow of ASQ. He served for four years (1990-1993) on the Board of Examiners for the Malcolm Baldrige National Quality Award and has implemented internal Total Quality Management Assessment processes based on the Baldrige Award criteria. Jack is now the Chair of the US TAG to ISO TC 176 and lead delegate for the United States to the International Standards Organization committee responsible for the ISO 9000 family of quality management standards. He is also a member of the board of directors of the Registrar Accreditation Board (RAB).

Jack has authored many papers and articles. He is co-editor of the *ASQ ISO 9000:2000 Handbook*, and co-author of *ISO 9001:2000 Explained, ISO 9001:2000, An Audio Workshop and Master Slide Presentation, Cracking the Case of ISO 9001:2000 for Manufacturing, Cracking the Case of ISO 9001:2000 for Service, How to Audit the Process-Based QMS* , all published by the American Society for Quality, and Unlocking the Power of Your QMS. He also has produced the video programs on *Internal Auditing Basics, Dealing with External Auditors,* and *Quality Basics* published by INFORM and also available from ASQ. He was the 2003 recipient of the ASQ's Freund Marquardt Award for his work related to standards.