

# ISO 9001 Auditing Practices Group

Guidance on:

*Aligning the QMS with the  
achievement of organizational  
and business success*



# **Business, Quality and Excellence Models and Tools**

There are many links between business, quality and excellence and many models and tools from which an organization can choose. The following are some examples:

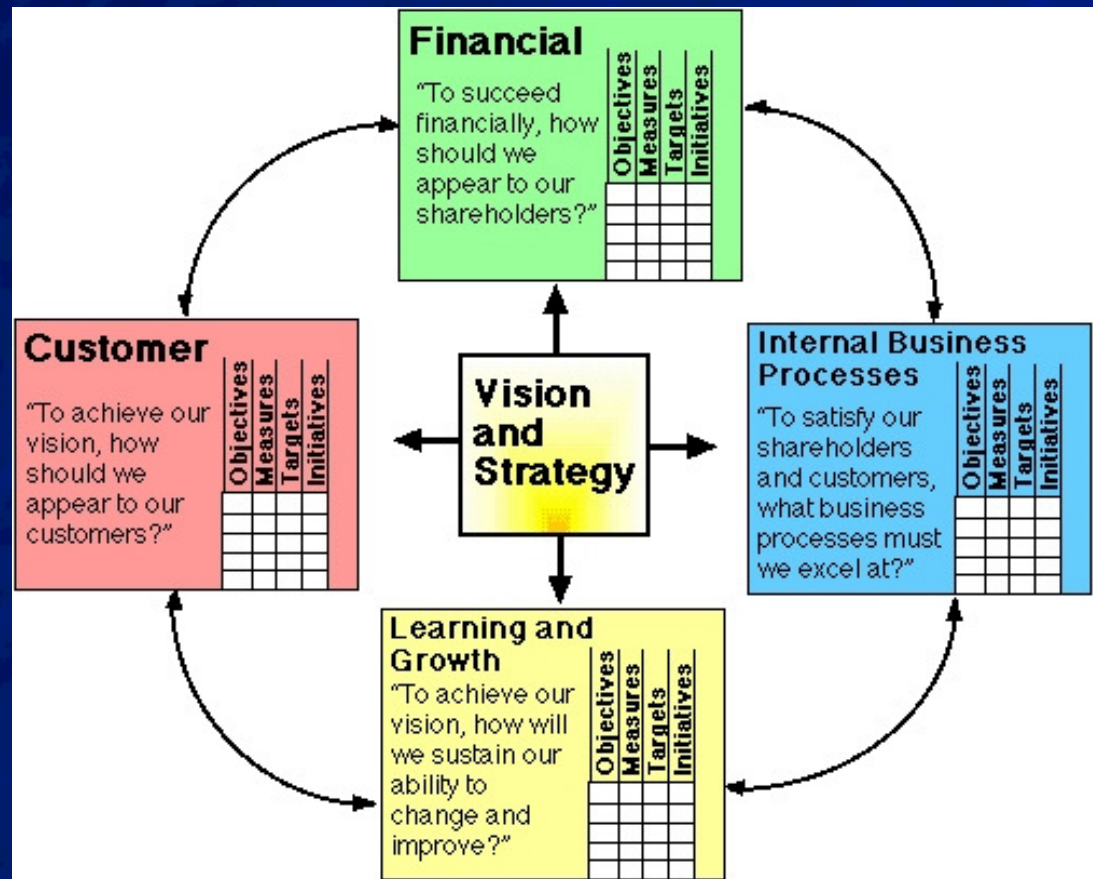
- **The Balanced Scorecard**
- **Business Excellence models**
- **ISO 9001:2008 Quality Management Systems**
- **Six Sigma**
- **Deming and Juran models**

# Balanced Scorecard

*A system that translates an organization's mission and strategy into a comprehensive set of performance measures that provides the framework for a strategic measurement and management system.*

*Kaplan and Norton*

# The Balanced Scorecard Model

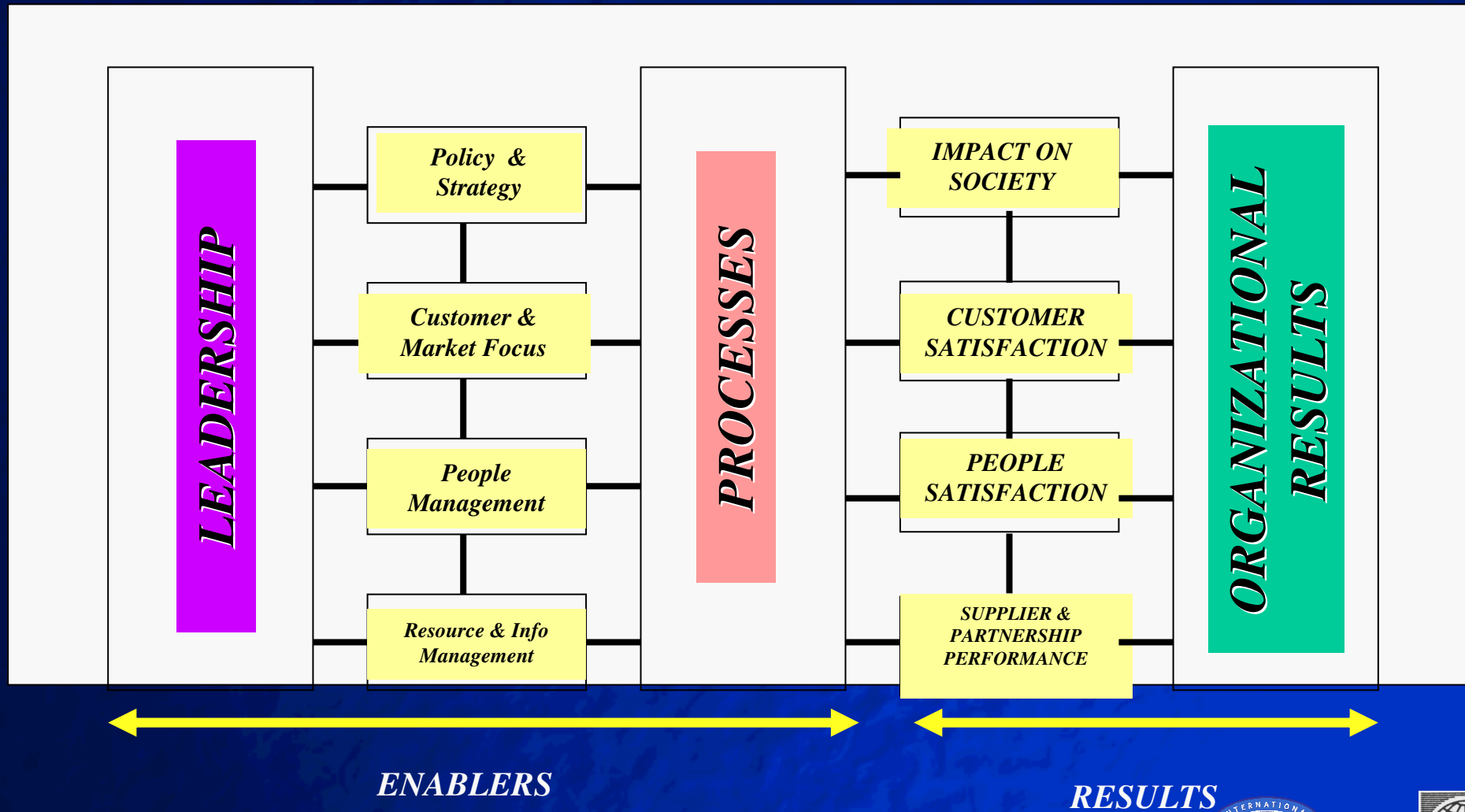


# Business Excellence Models

Many types of business excellence models exist throughout the world:

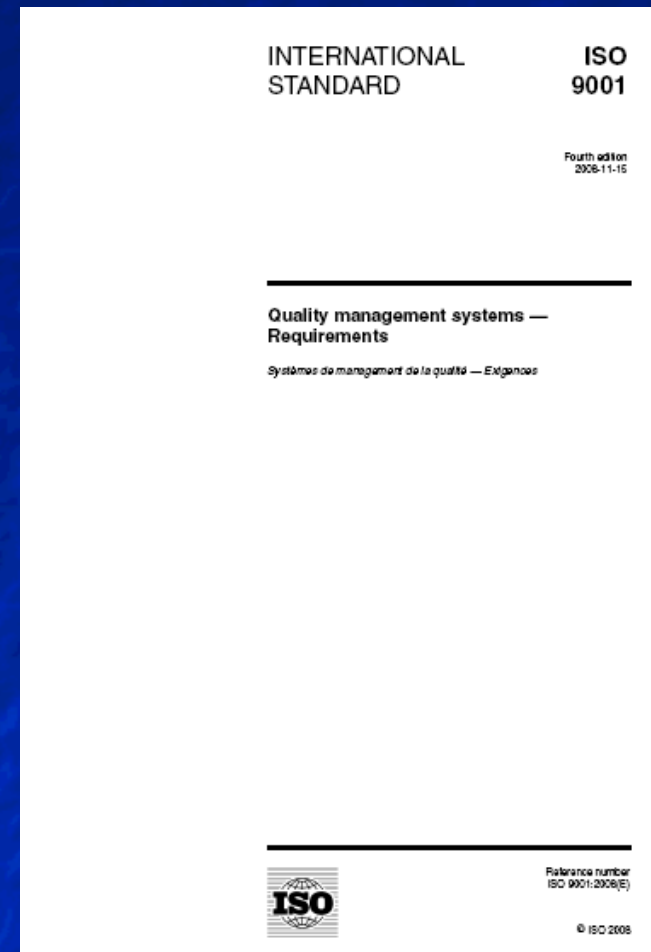
- **Deming Award**
- **Malcolm Baldrige Award**
- **EFQM Model and Award**
- **National Business Excellence Models and Awards**

# Typical National Excellence Model

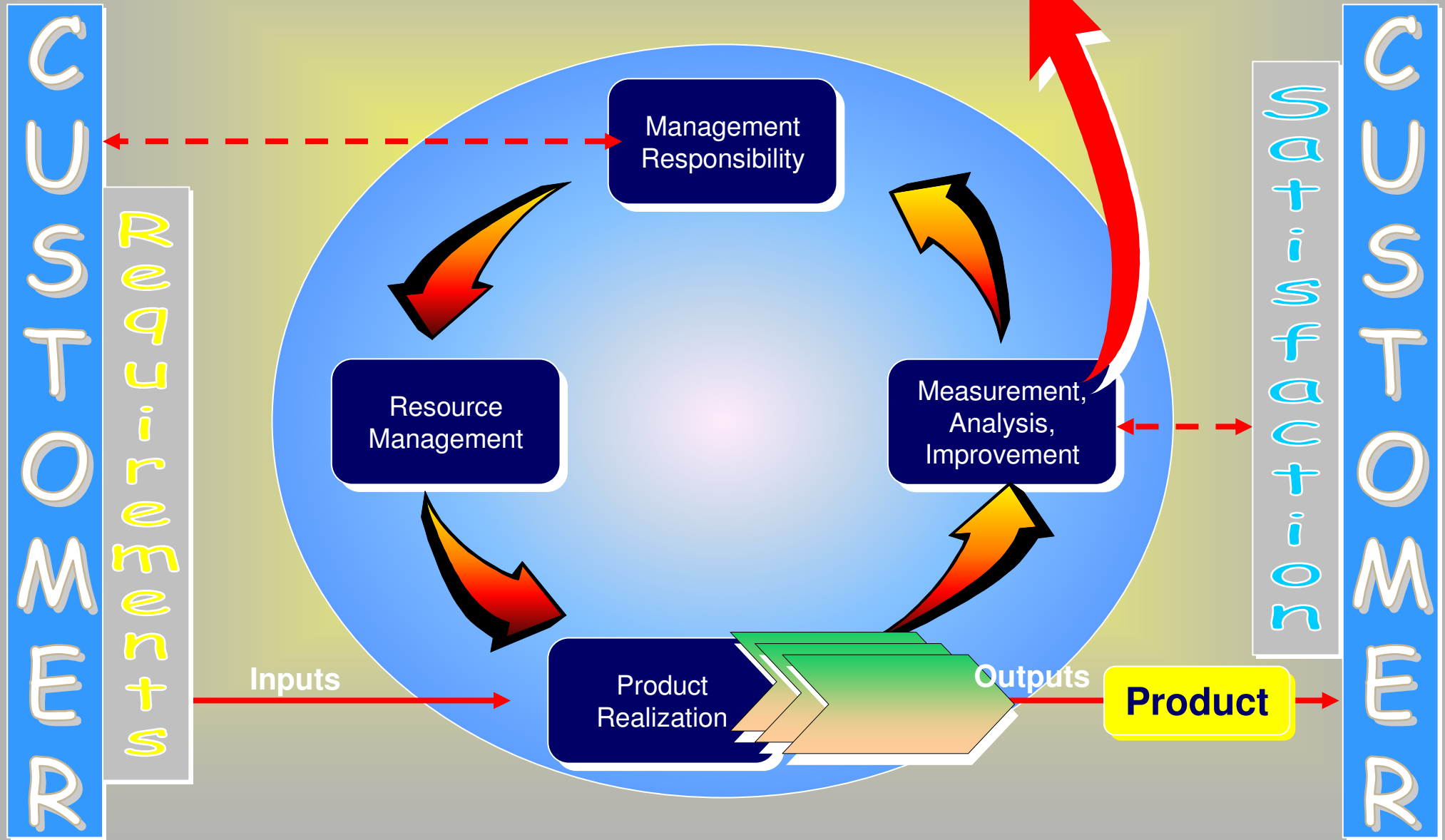


# ISO 9001:2008

## Quality Management Systems



# Continual Improvement of the Quality Management System



# Comparison

<b><u>Balanced Scorecard</u></b>	<b><u>ISO 9001:2008</u></b>
<b>Vision and Strategy</b>	<b>Quality Policy Quality objectives</b>
<b>Customer</b>	<b>Customer focus Customer related processes Customer satisfaction</b>
<b>Internal Business Processes</b>	<b>QMS General requirements Product Realization</b>
<b>Organization's Business Results</b>	<b>Not specifically addressed in the standard.</b>

# Comparison

<b><u>Excellence Model</u></b>	<b><u>ISO 9001:2008</u></b>
<b>Policy and Strategy</b>	<b>Quality Policy Quality objectives</b>
<b>Customer &amp; Market Focus Customer Satisfaction</b>	<b>Customer focus Customer related processes Customer satisfaction</b>
<b>People Management</b>	<b>Human Resources</b>
<b>Business Processes</b>	<b>QMS General requirements Product Realization</b>
<b>Organization's business results</b>	<b>Not specifically addressed in the standard.</b>

# ISO 9001:2008

**ISO 9001:2008 specifies requirements for a quality management system where an organization:**

- **Needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and**
- **Aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.**

# The Sydney Model

The concept of this model was developed by the ISO/TC176/IAF ISO 9001 Auditing Practice Group during their meeting in Sydney, Australia during 2003.

The model illustrates that **effectiveness** and **improvement** can be represented as a cyclical process that uses the components of the QMS to analyze data and then direct changes and initiatives that ensure continual improvement. The overall result is an enhanced pro-active approach to meet QMS objectives and more importantly their related corporate organizational, business and/or financial objectives.

# Improvement and Effectiveness

**There are many examples and requirements in ISO 9001:2008 that require the organization to address the effectiveness of its quality management system.**

**Further requirements specify the need for continual improvements to the quality management system – not just sporadic quality campaigns.**

# Effectiveness

Extent to which planned activities are realized and planned results achieved.

ISO 9000:2005 3.2.14

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. **It focuses on the effectiveness of the quality management system in meeting customer requirements.**

ISO 9001: 2008 0.3

# Improvement and Effectiveness

Top Management shall ensure that the quality policy includes a commitment to comply with requirements and **continually improve the effectiveness** of the quality management system.

ISO 9001: 2008 5.3

The organization shall **continually improve the effectiveness** of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

ISO 9001: 2008 8.5.1

# The Concept of the Sydney Model

The organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to **evaluate** where continual improvement of the effectiveness of the quality management system can be made.

ISO 9001: 2008 8.4

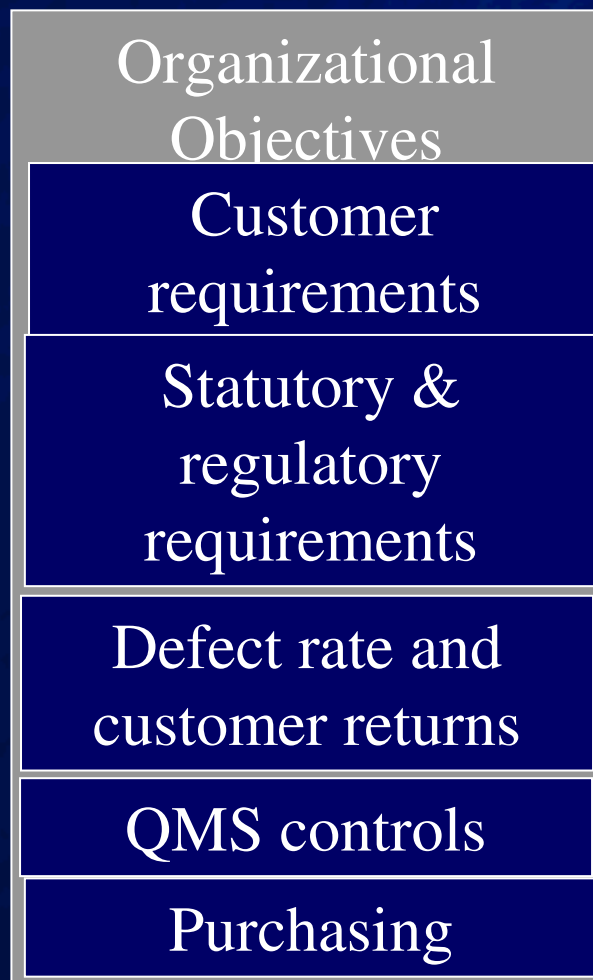
And to ensure that the organization's quality and/or business objectives have been met!

# The Sydney Model

In the following example, an organization has identified several quality objectives and has collected data on the results of these objectives. Using a gap analysis technique, the results are compared to the objectives and the degree of effectiveness of the QMS is established for a given time period.

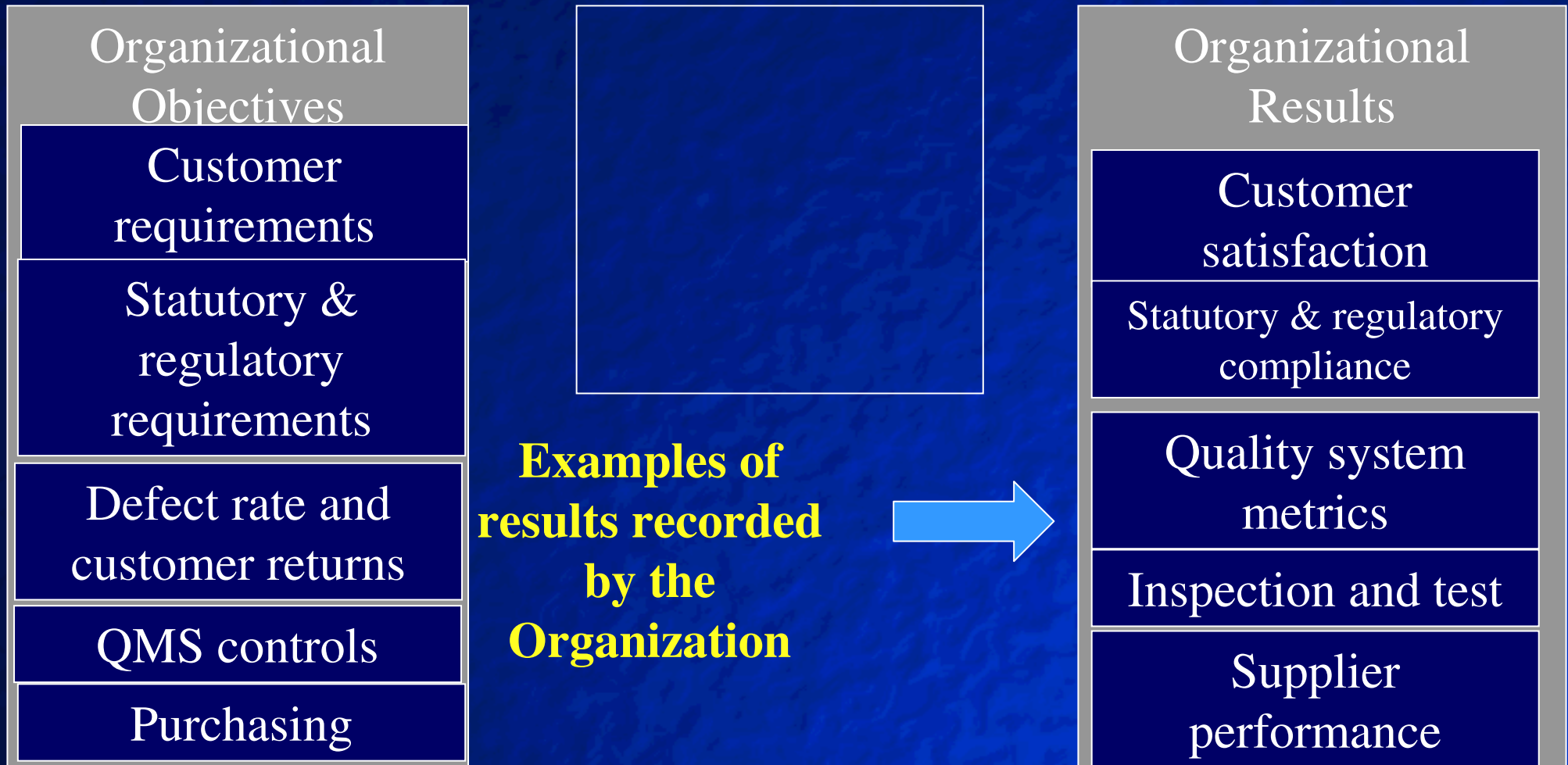
The same data also allows the organization to measure improvement and to take any necessary action based on the information and results.

# Analysis of Data

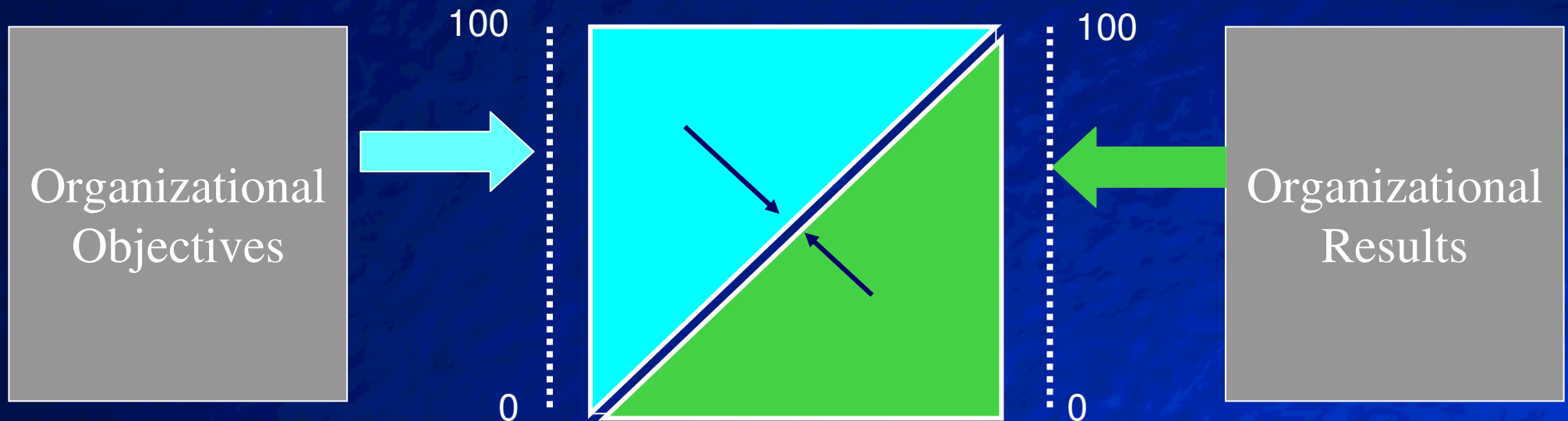


**Examples of  
objectives set by  
the Organization**

# Analysis of Data



# Effectiveness of the QMS

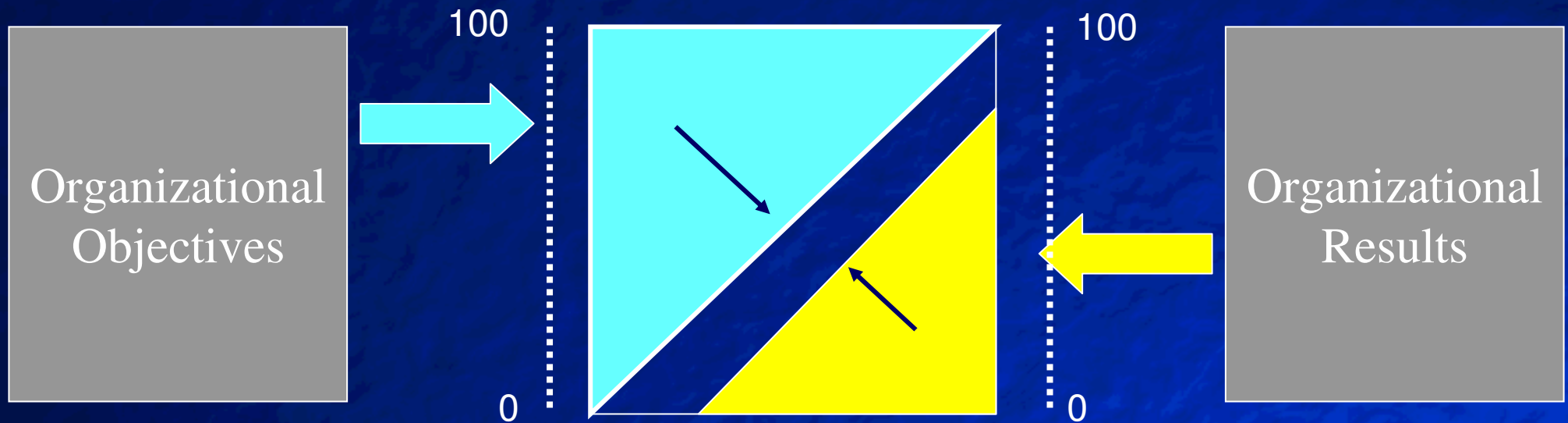


**Things are looking good!**

**The gap measures the lack of effectiveness of the quality management system.**

**The narrower the gap, the more effective the QMS.**

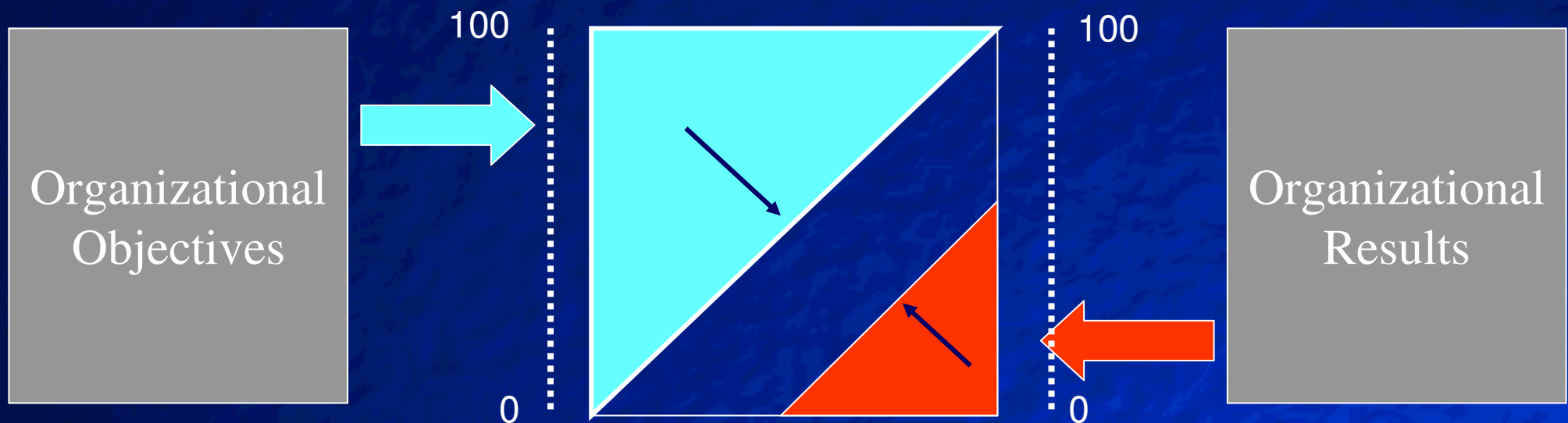
# Effectiveness of the QMS



**The gap measures the lack of effectiveness of the quality management system.**

**Management should get a wake up warning!**

# Effectiveness of the QMS

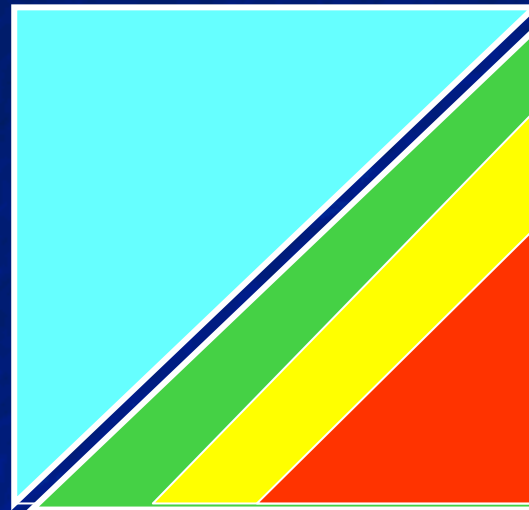


**The gap measures the lack of effectiveness of the quality management system.**

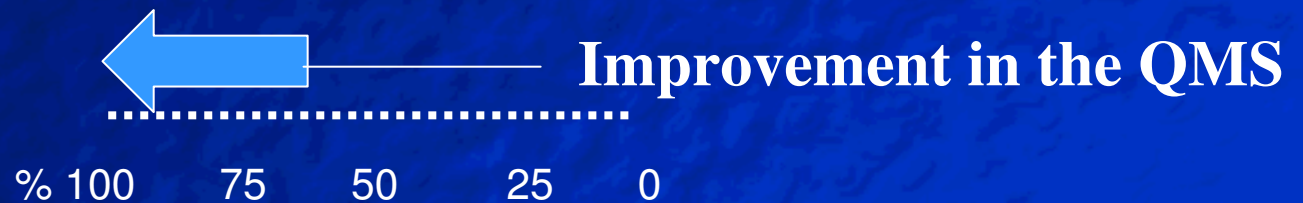
**The Organization is in trouble!**

# Improvement in the QMS

Organizational  
Objectives

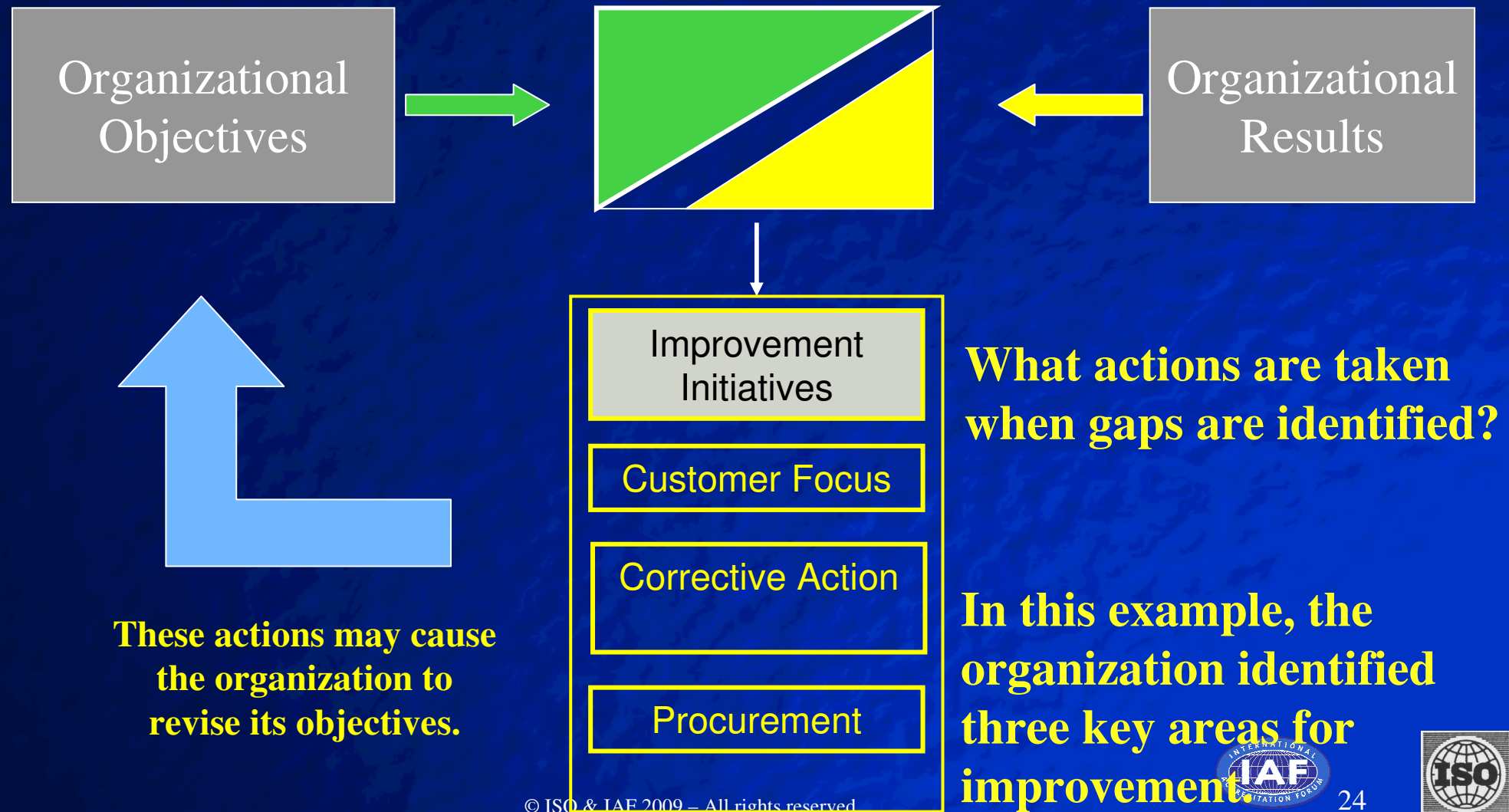


Organizational  
Results

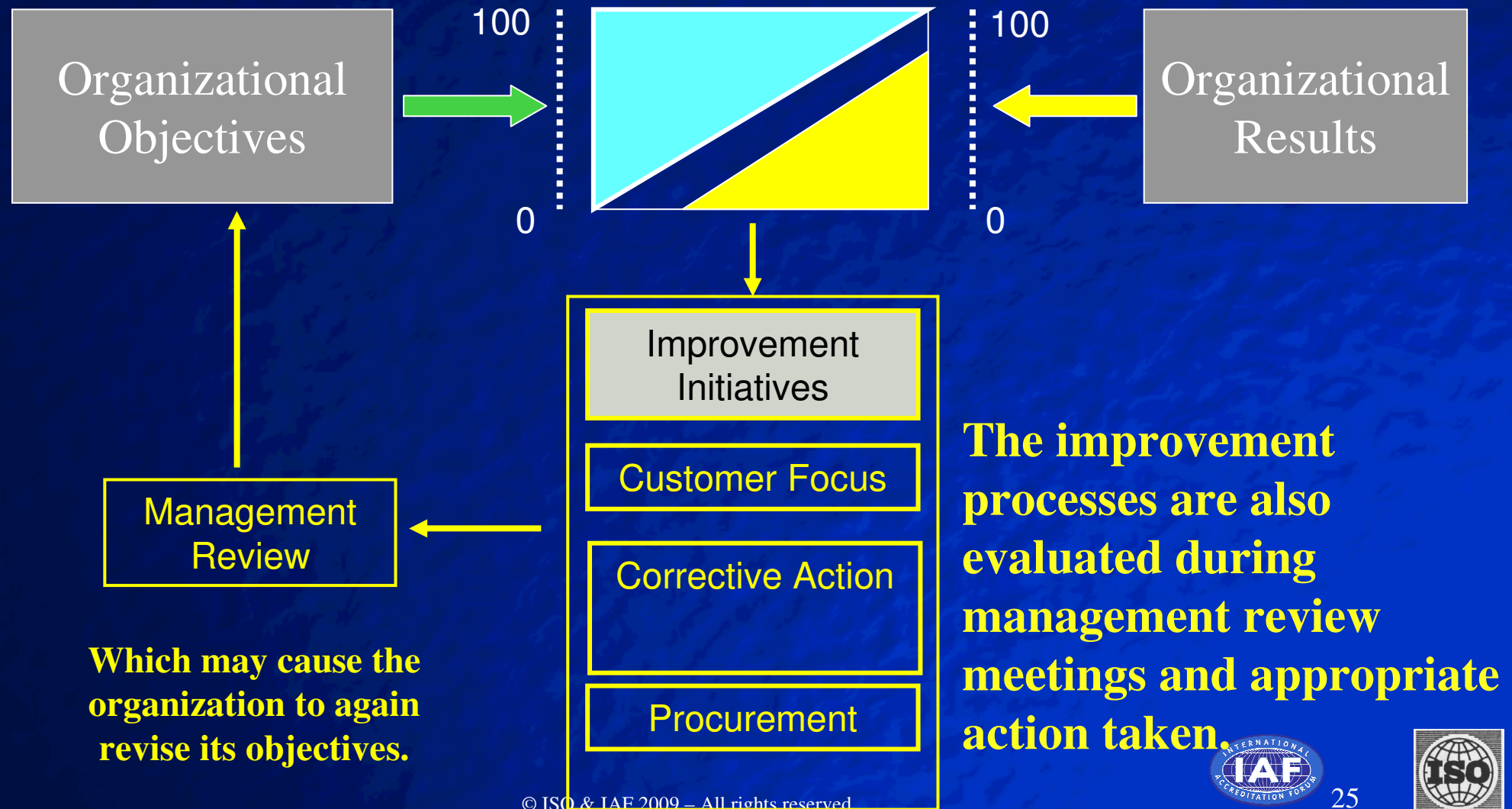


**Improvement can also be  
measured**

# Improvement in the QMS



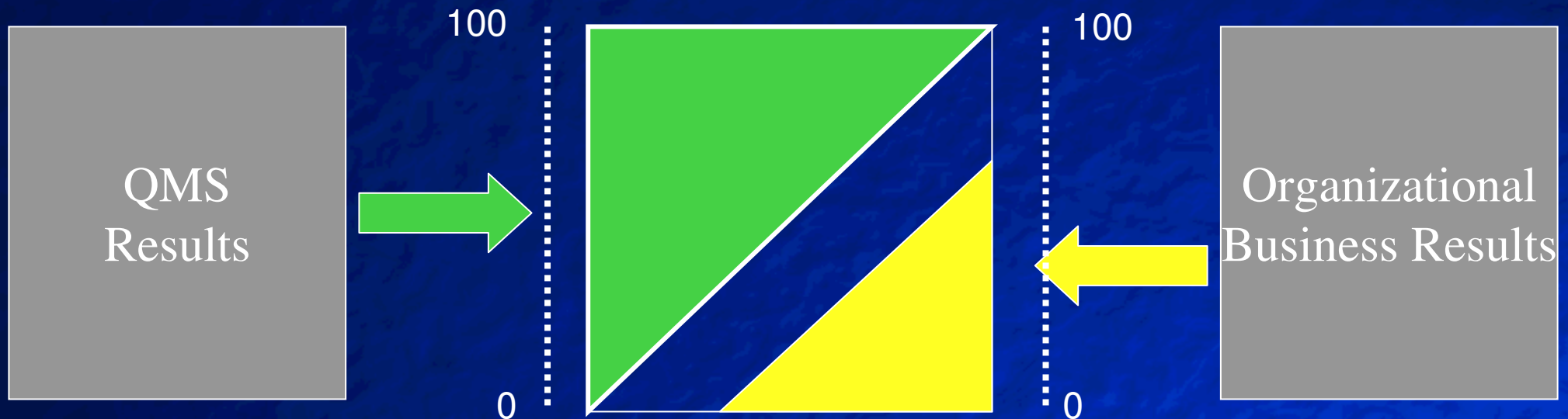
# Management Review



# The Effectiveness of the Organization

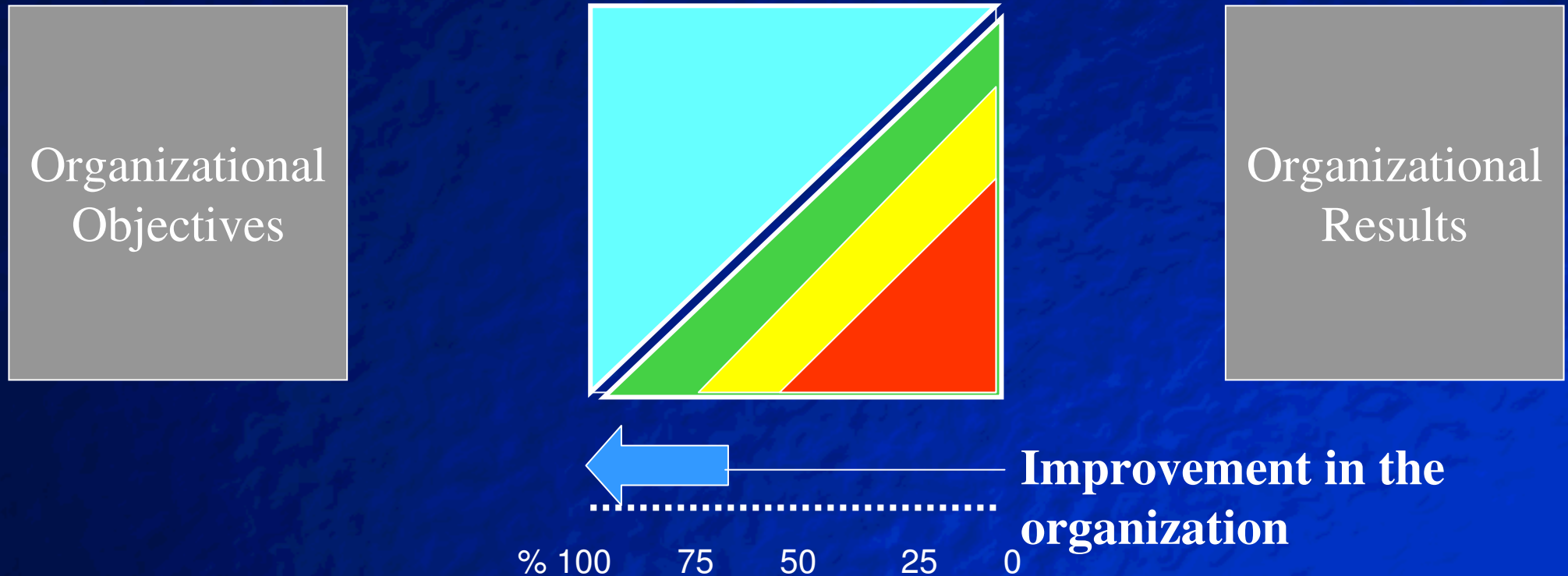
After analyzing the data and reaching a conclusion on the effectiveness of the **QMS**, the same process is then used to determine if the quality management system has had an effect on the Organization's **business and/or financial results**.

# Effectiveness of the Organization



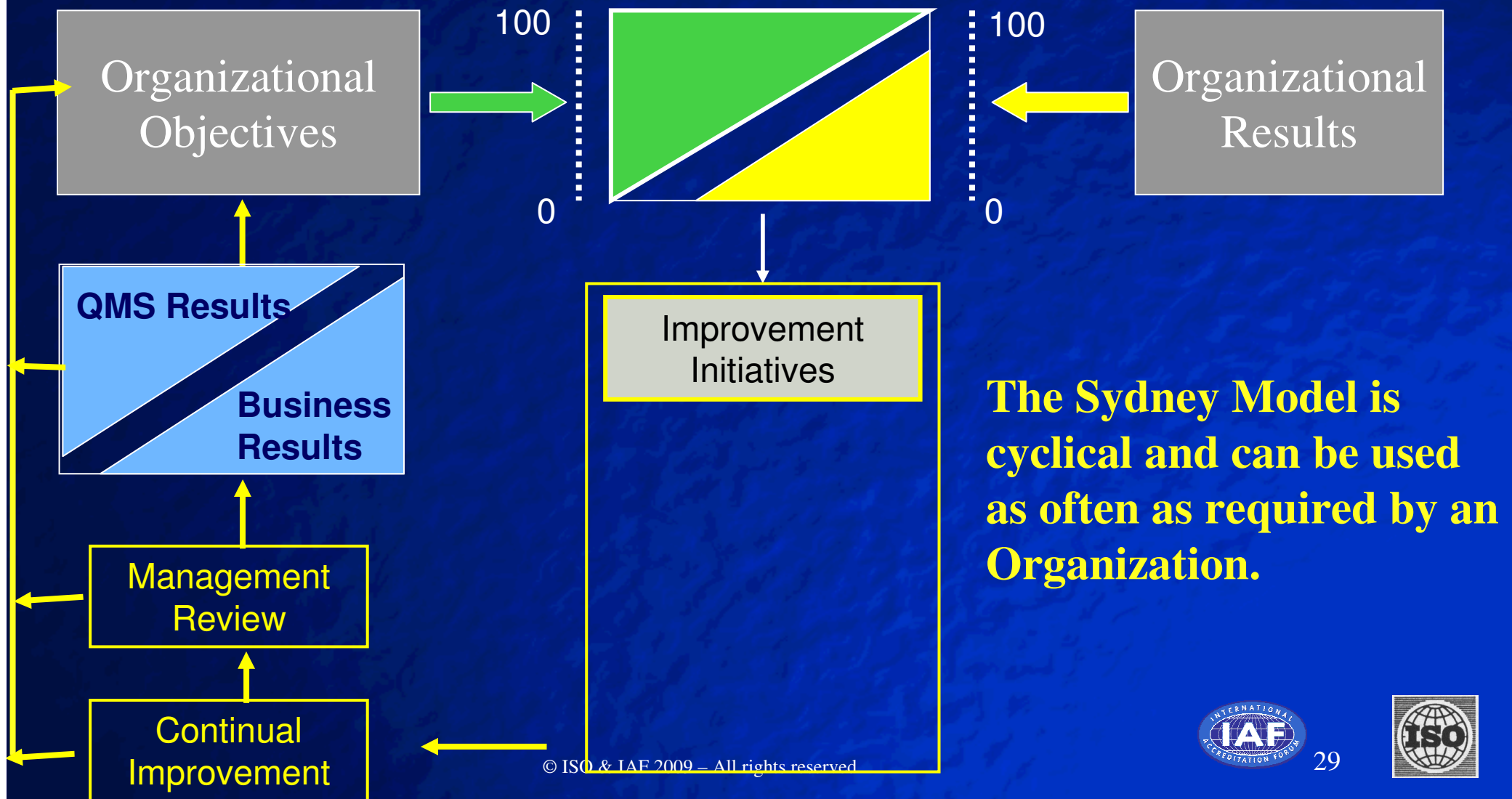
**The gap now measures the lack of business effectiveness of the organization. The narrower the gap, the more effective the organization.**

# Business Improvement in the Organization



**And again, the improvements in the organization can be measured and managed.**

# Analysis of Data



# Conclusion

The overall result of using the Sydney model is an enhanced pro-active approach to meet QMS objectives **and more importantly their related corporate business and/or financial objectives.**

The **effectiveness** of the quality management system in meeting both quality and/or business objectives is likely to be the key attribute that ensures the on-going support and resource allocation to maintain the ISO 9001:2008 quality management system within the corporate environment.

For further information on the ISO 9001 Auditing Practices Group, please refer to the paper:  
*Introduction to the ISO 9001 Auditing Practices Group*

Feedback from users will be used by the *ISO 9001 Auditing Practices Group* to determine whether additional guidance documents should be developed, or if these current ones should be revised. Comments on the papers or presentations can be sent to the following email address:  
[charles.corrie@bsigroup.com](mailto:charles.corrie@bsigroup.com) .

The other ISO 9001 Auditing Practices Group papers and presentations may be downloaded from the web sites:

[www.iaf.nu](http://www.iaf.nu)

[www.iso.org/tc176/ISO9001AuditingPracticesGroup](http://www.iso.org/tc176/ISO9001AuditingPracticesGroup)

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