

ISO 9001 Auditing Practices Group

Guidance on: Effectiveness

*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:

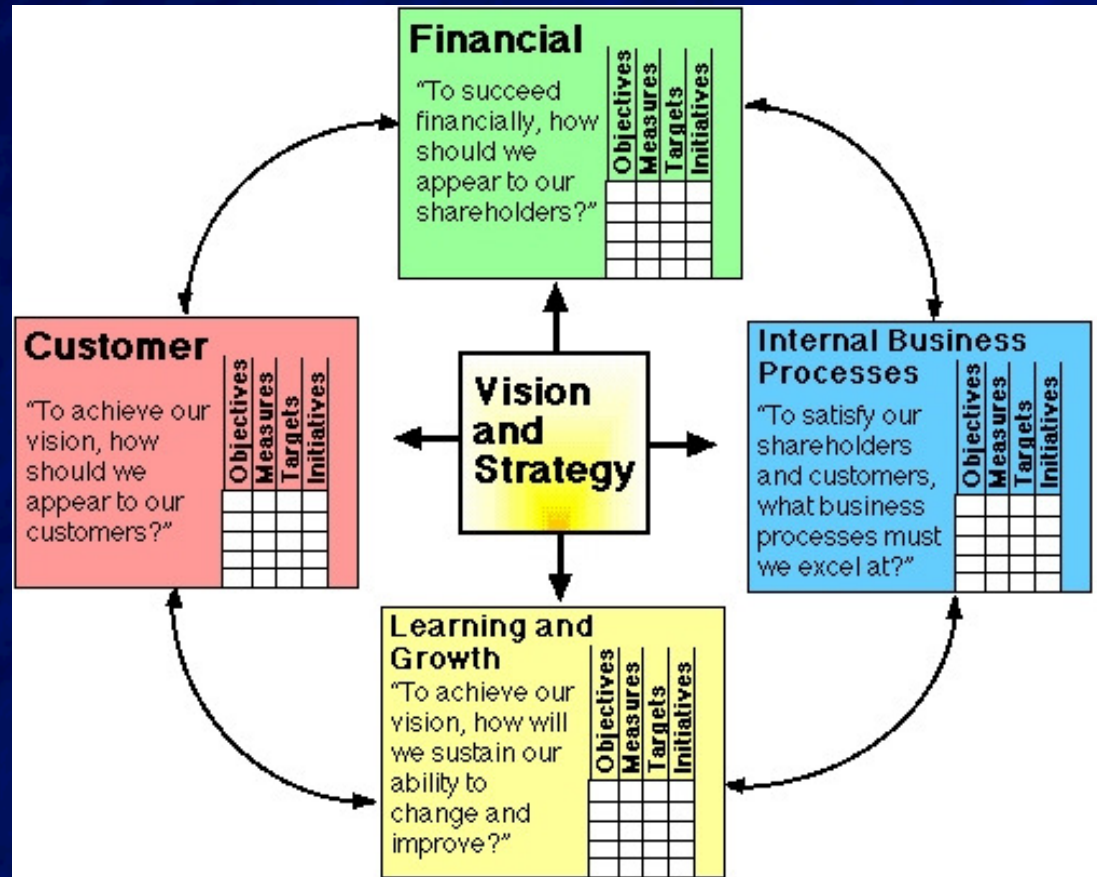
- The Balanced Scorecard, SWOT analysis, etc
- Business Excellence models
- ISO 9001 Quality Management Systems. Requirements
- Quality tools (six sigma, lean, etc.)
- Deming and Juran models

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

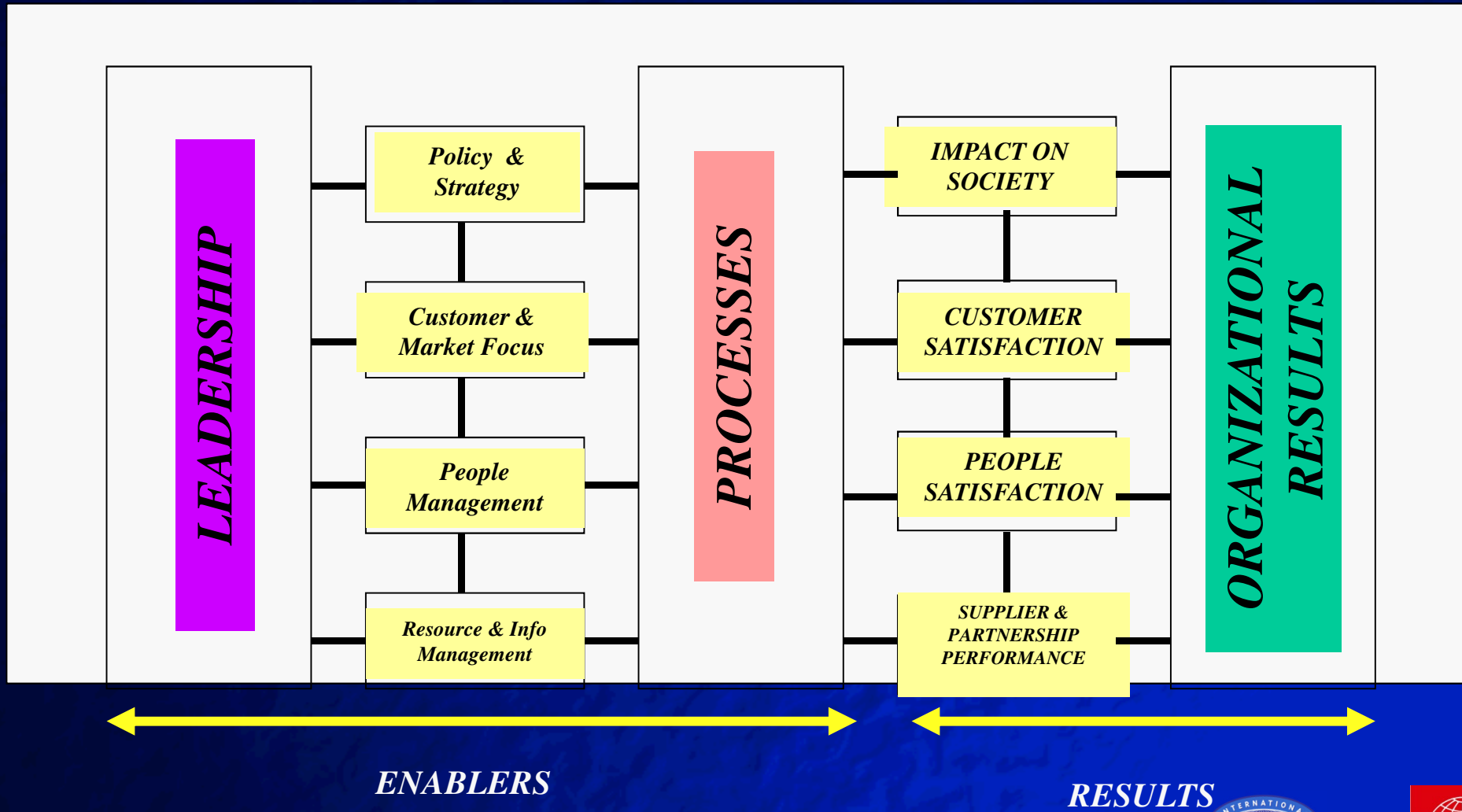


Business Excellence Models

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

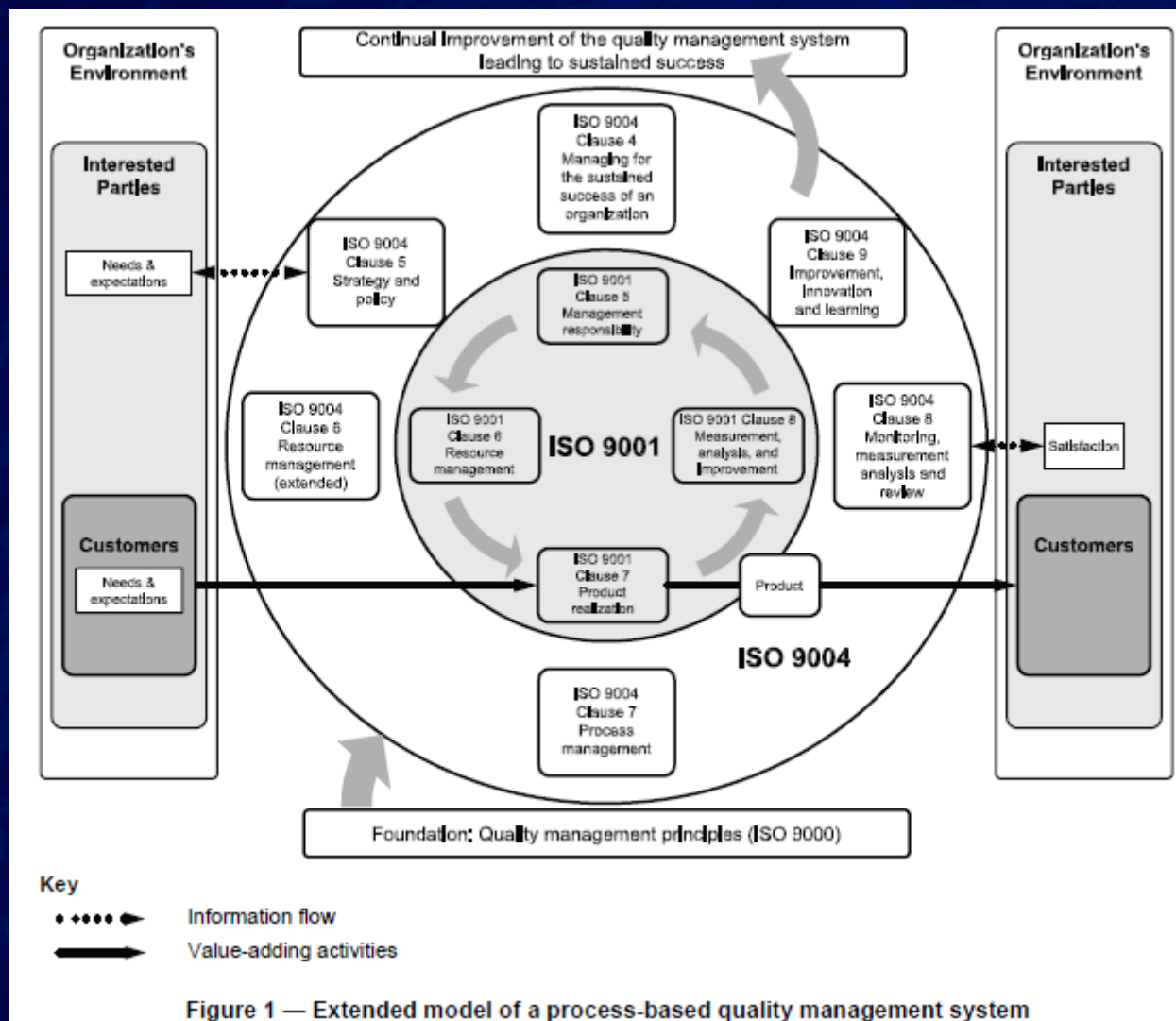


ISO 9001 and ISO 9004

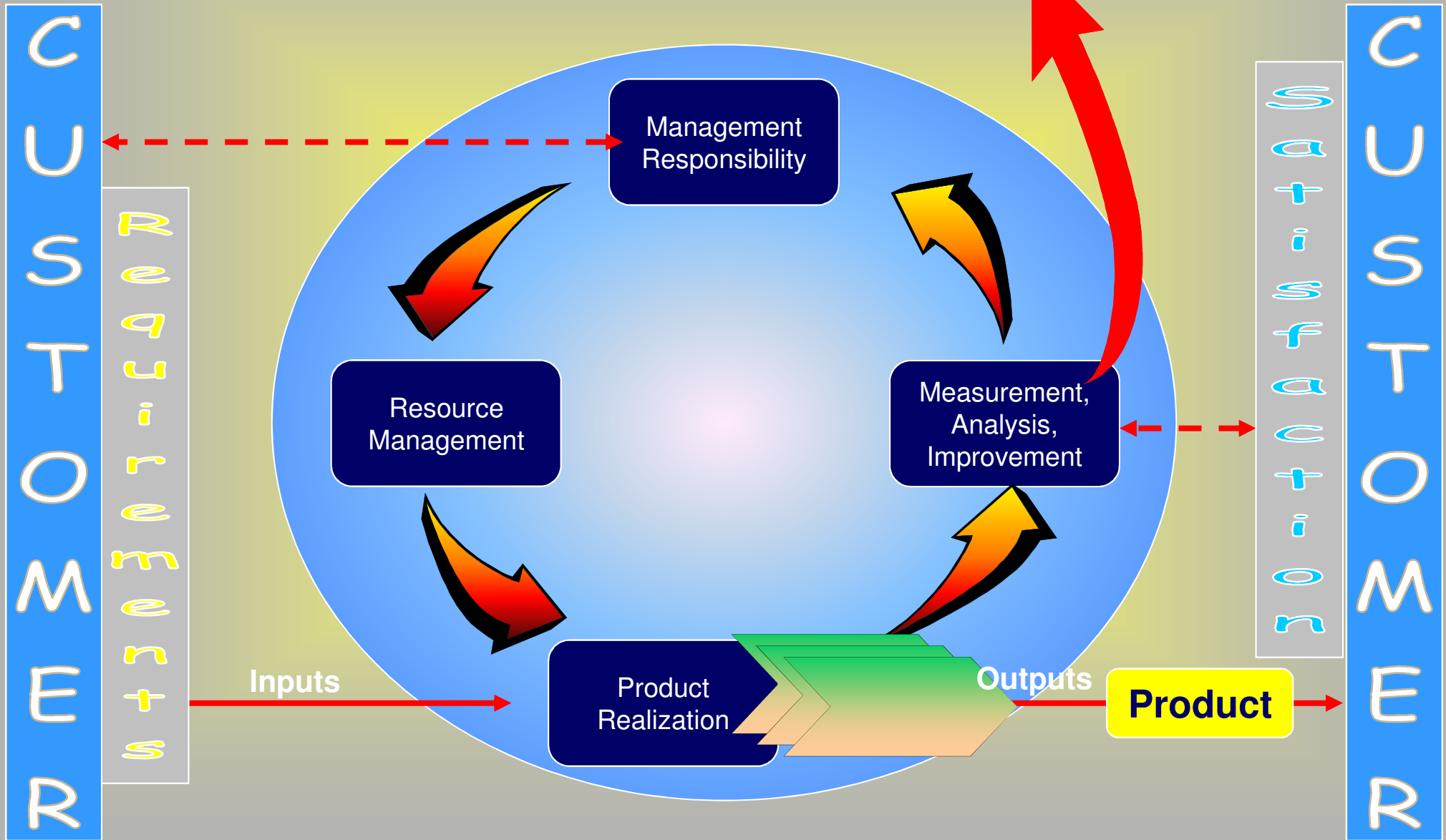
Quality Management Systems - Requirements

Quality Management Systems

– Managing for the sustained success of an organization – A quality management approach



Continual Improvement of the Quality Management System



Comparison

<u>Balanced Scorecard</u>	<u>ISO 9001</u>
Vision and Strategy	Context of the organization Quality Policy Quality objectives
Customer	Customer focus Understanding the needs and expectations of interested parties Requirements for product and services
Internal Business Processes	QMS and its Processes Operations
Organization's Business Results	Performance evaluation

Comparison

<u>Excellence Model</u>	<u>ISO 9001</u>
Policy and Strategy	Policy Planning
Customer & Market Focus Customer Satisfaction	Customer focus Customer communication Customer satisfaction
People Management	People
Business Processes	QMS and its processes Operation
Organization's business results	Performance evaluation

ISO 9001

ISO 9001 specifies requirements for a quality management system when an organization:

- Needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and**
- Aims to enhance customer satisfaction through the effective application of the system, including processes for 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 Practices 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 that require the organization to address the effectiveness of its quality management system.

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

Effectiveness

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

ISO 9000:2015, 3.7.11

ISO 9001 promotes the adoption of a process approach when developing, implementing and improving **the effectiveness of a quality management system**, to enhance customer satisfaction by meeting customer requirements.

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ISO 9001: 2015 0.3.1

Improvement and Effectiveness

The organization shall **continually improve** the suitability, adequacy and **effectiveness** of the quality management system.

ISO 9001: 2015 10.3

The Concept of the Sydney Model

The organization shall analyze and **evaluate** appropriate data and information arising from monitoring and measurement.

ISO 9001: 2015 9.1.3

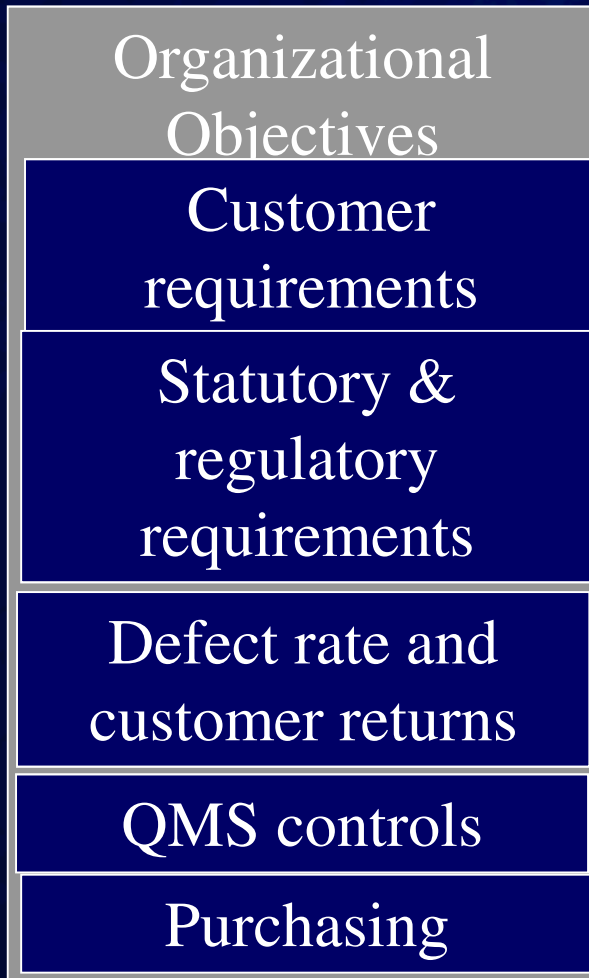
And to ensure that the organization's quality and/or business objectives have been met!

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.

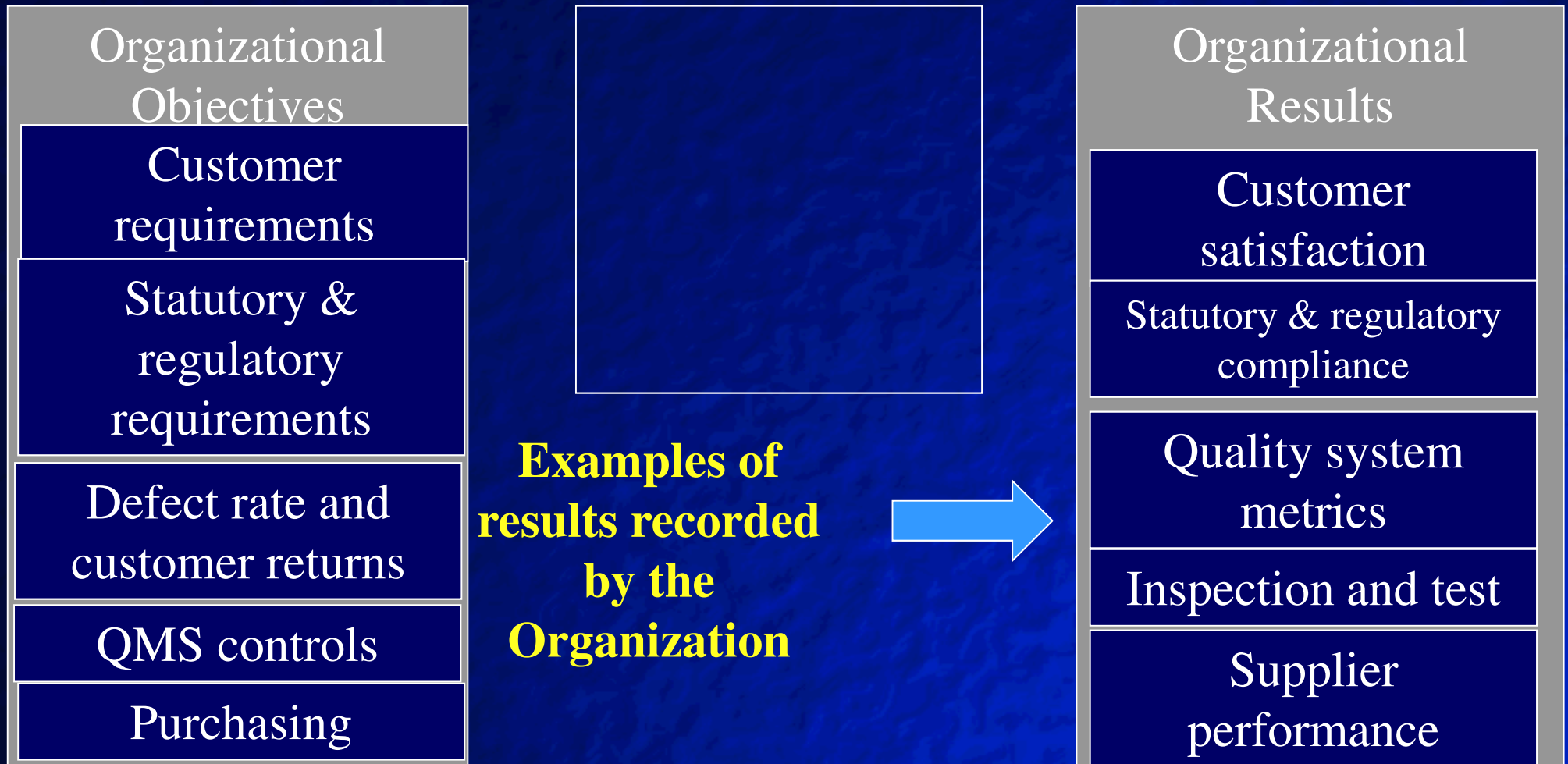
The same data also allows the organization to measure improvement and to take any necessary action based on the information and results.

Analysis of Data

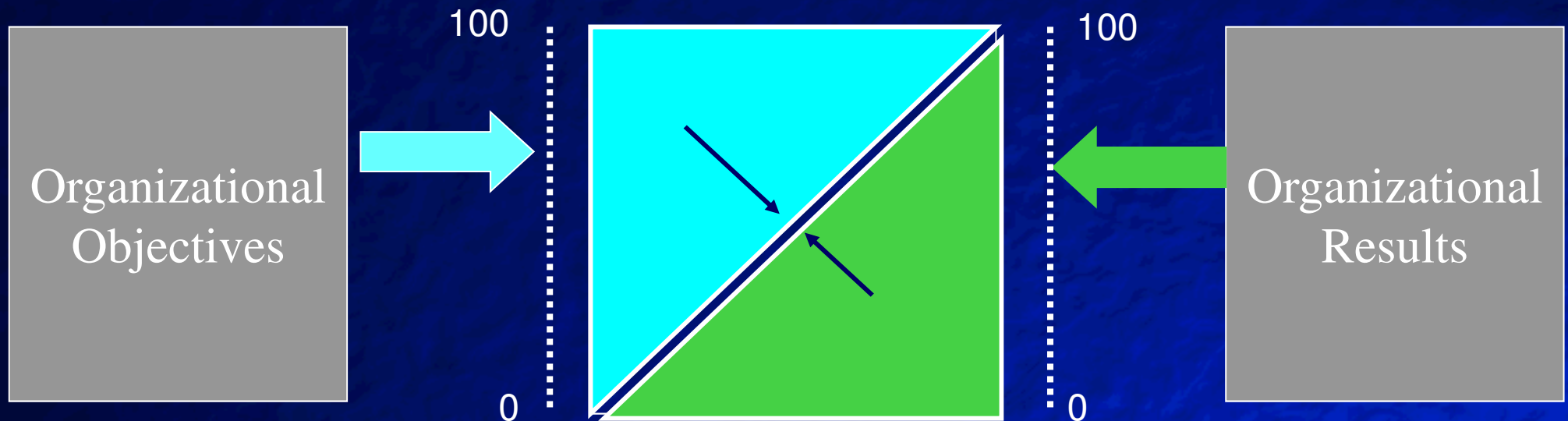


Examples of objectives set by the Organization

Analysis of Data



Effectiveness of the QMS

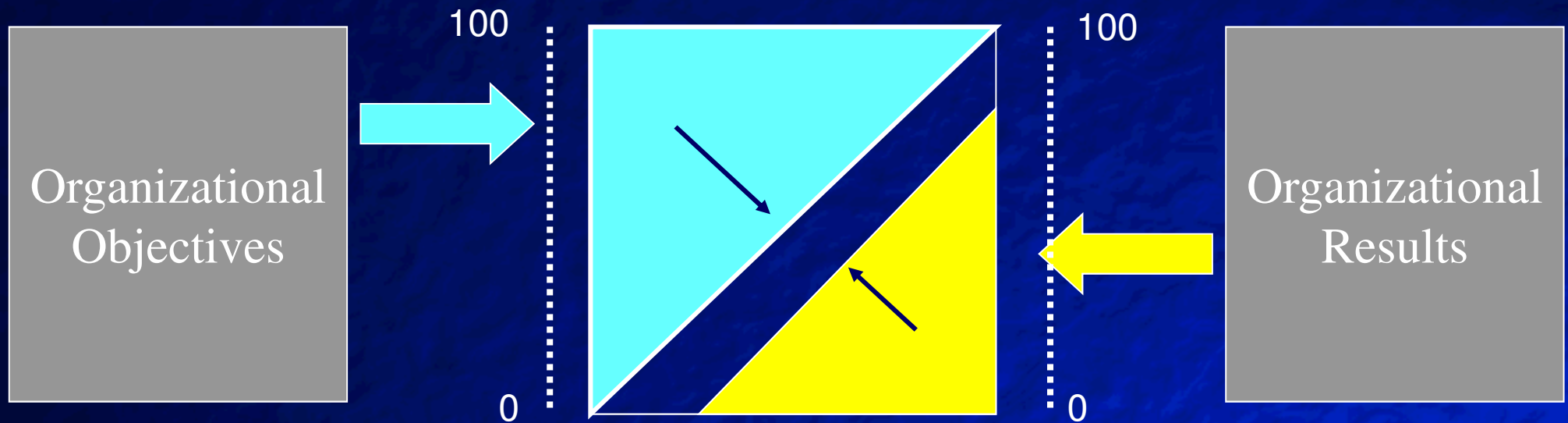


Things are looking good!

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

The narrower the gap, the more effective the QMS.

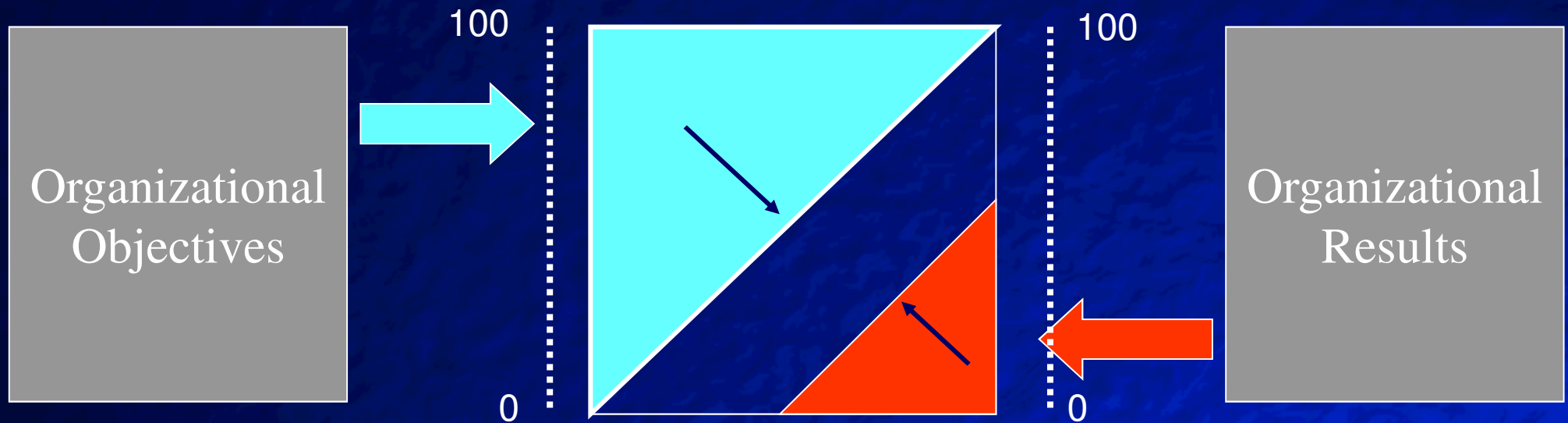
Effectiveness of the QMS



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

Management should get a wake up warning!

Effectiveness of the QMS

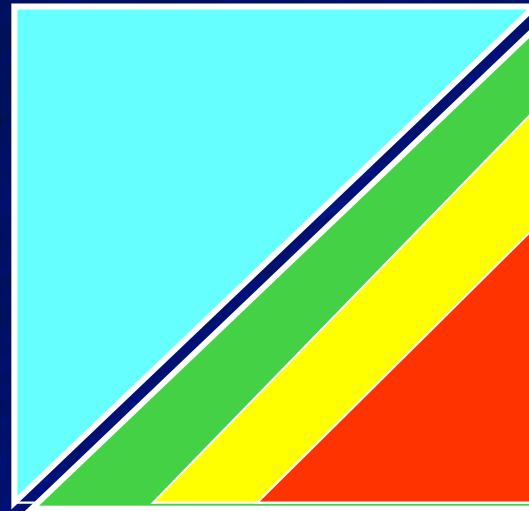


The gap measures the lack of effectiveness of the quality management system.

The Organization is in trouble!

Improvement in the QMS

Organizational
Objectives

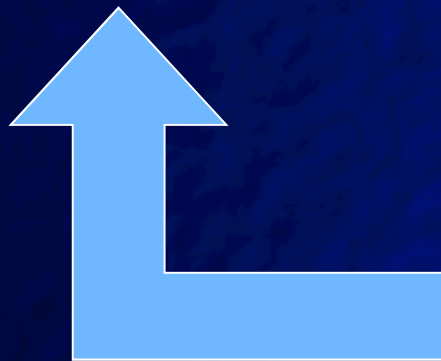
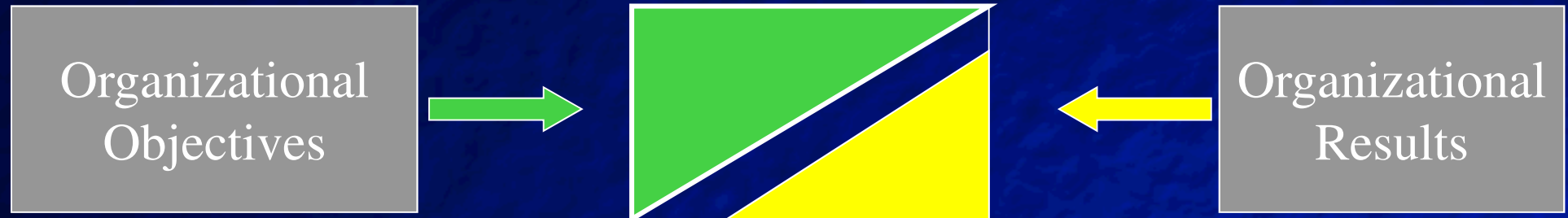


Organizational
Results



**Improvement can also be
measured**

Improvement in the QMS



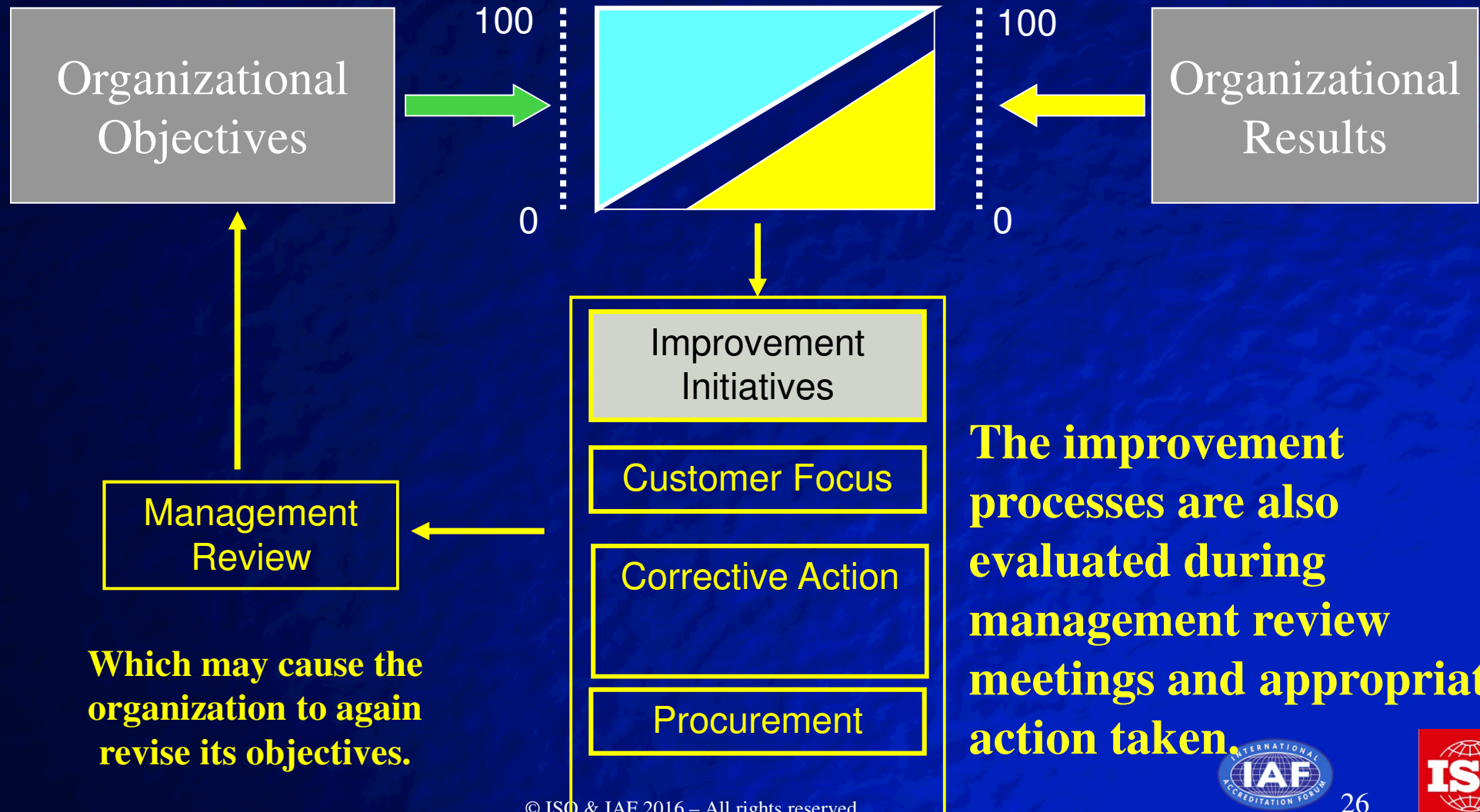
These actions may cause the organization to revise its objectives.



What actions are taken when gaps are identified?

In this example, the organization identified three key areas for improvement.

Management Review



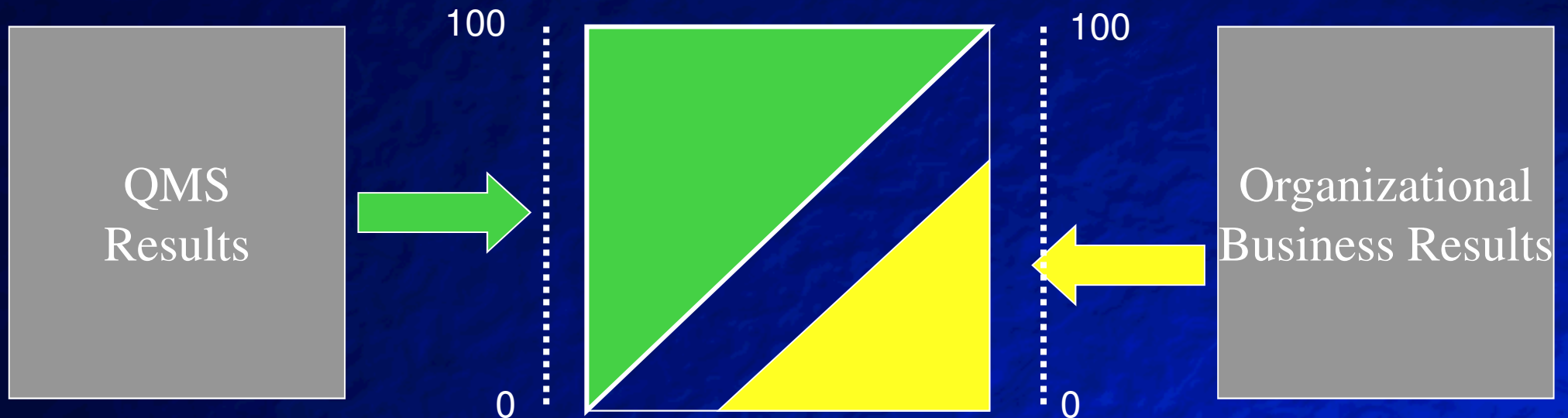
Which may cause the organization to again revise its objectives.

The improvement processes are also evaluated during management review meetings and appropriate action taken.

The Effectiveness of the Organization

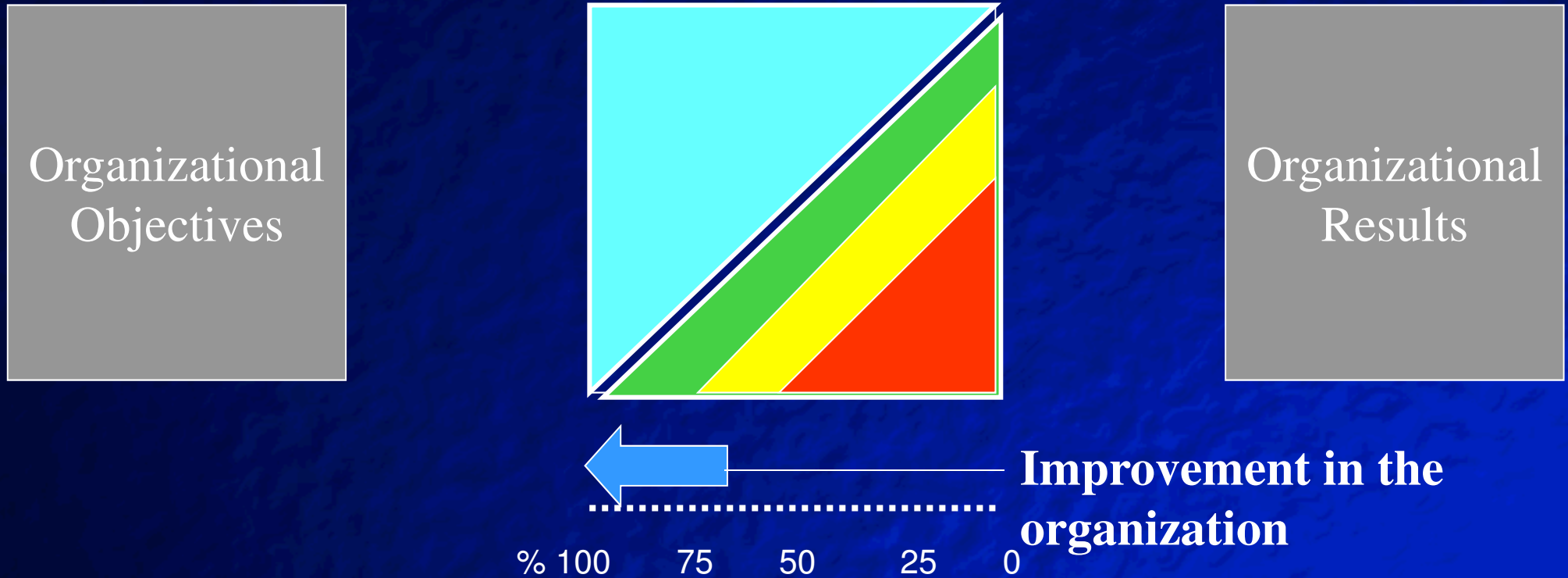
After analyzing the data and reaching a conclusion on the effectiveness of the **QMS**, the same process is then used to determine if the quality management system has had an effect on the Organization's **business and/or financial results**.

Effectiveness of the Organization



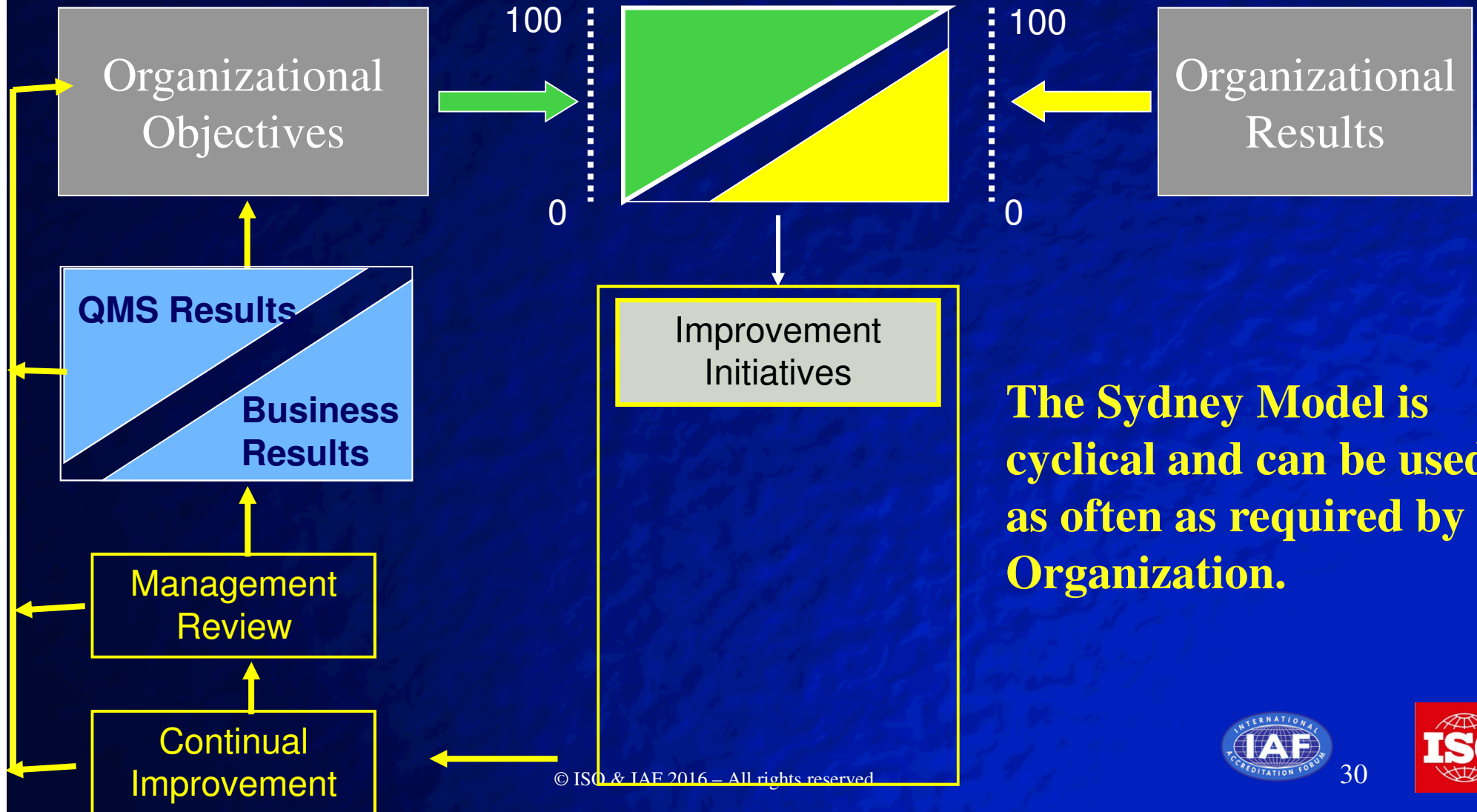
The gap now measures the lack of business effectiveness of the organization. The narrower the gap, the more effective the organization.

Business Improvement in the Organization



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

Analysis of Data



The Sydney Model is cyclical and can be used as often as required by an Organization.

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 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 .

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

www.iaf.nu

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