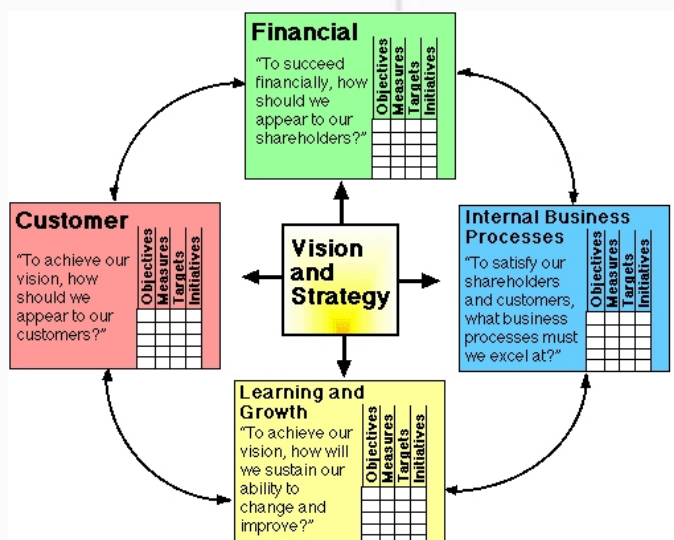


Aligning the quality management system with the achievement of organizational and business success

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 quality management systems
- six sigma
- Deming and Juran models

'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).

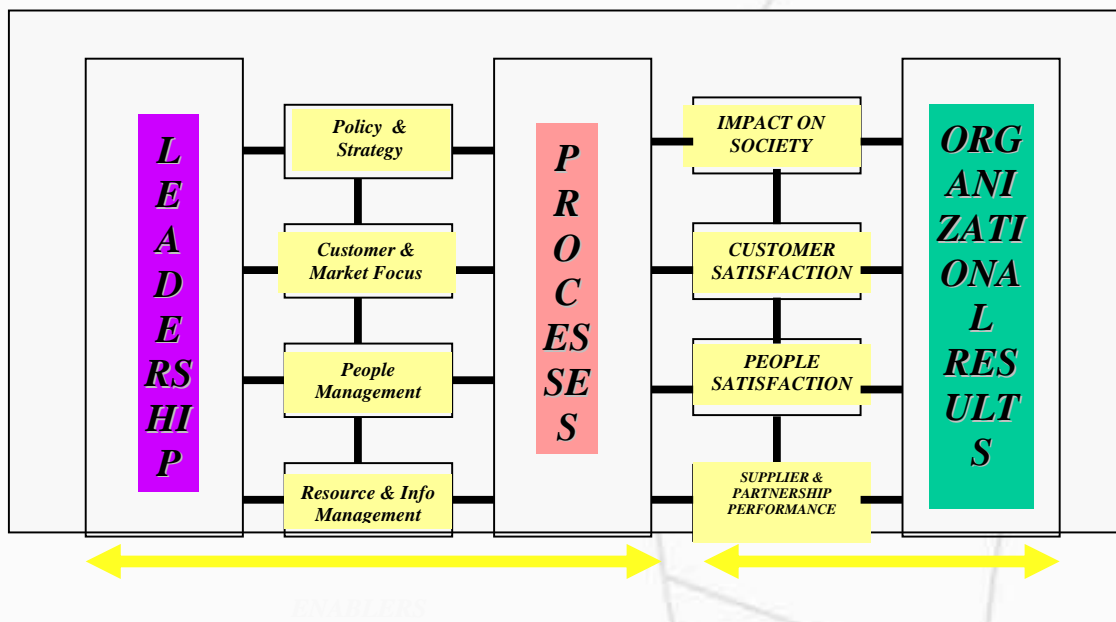


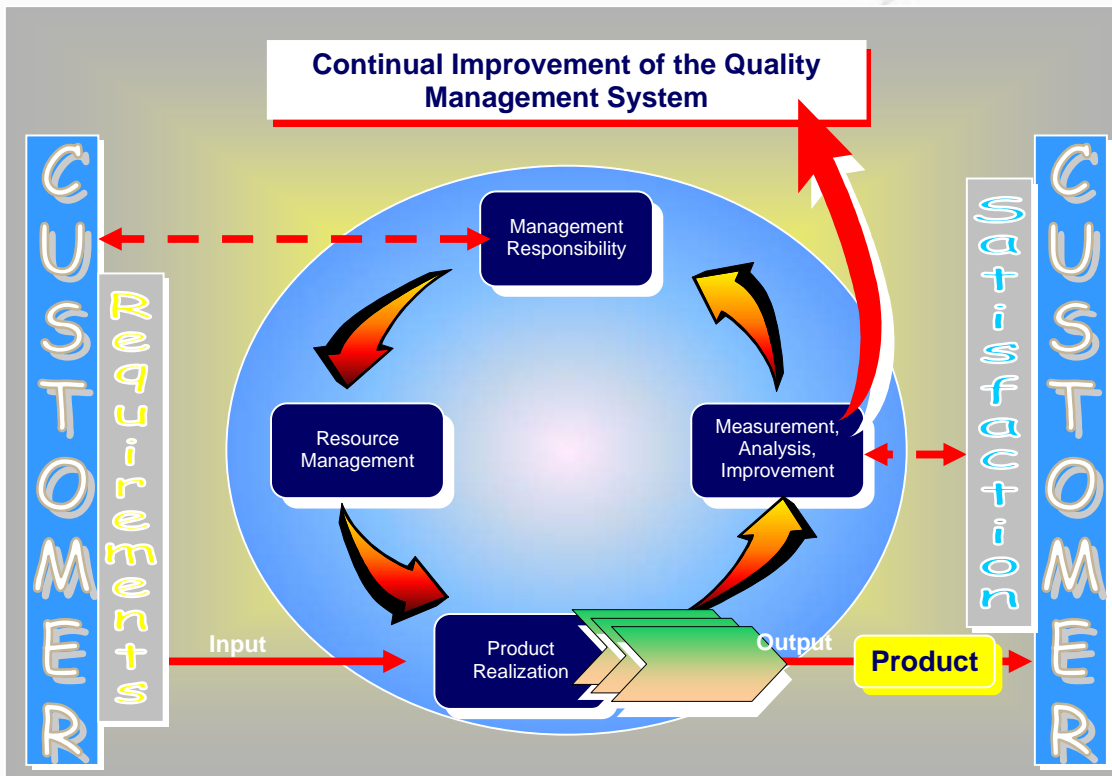
Many types of business excellence models exist throughout the world:

- Deming Award
- Malcolm Baldrige Award

- EFQM Model and Award
- national business excellence models and awards

Typical national excellence model





Balanced Scorecard

Vision and strategy

Customer

Internal business processes

Organization's business results

ISO 9001:2000

Quality policy
Quality objectives

Customer focus
Customer related processes
Customer satisfaction

Quality management system (QMS) general requirements
Product realization

Not specifically addressed in the standard

Excellence Model

ISO 9001:2000

Policy and strategy	Quality policy Quality objectives
Customer and market focus	Customer focus
Customer satisfaction	Customer related processes Customer satisfaction
People management	Human resources
Business processes	QMS general requirements Product realization
Organization's business results	Not specifically addressed in the standard

ISO 9001

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

- needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements
- 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 regulatory requirements

The Sydney model

The concept of this model was developed by the ISO/TC176/IAF ISO 9001 Auditing Practice Group during its 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

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 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 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 clause 0.3).

Improvement and effectiveness

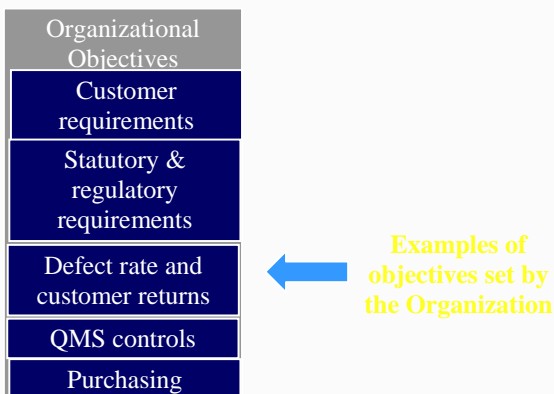
Top management shall ensure that the quality policy includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system (ISO 9001 clause 5.3).

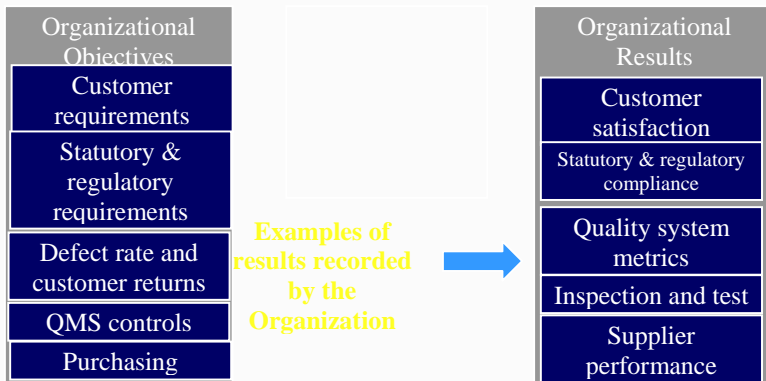
The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review (ISO 9001 clause 8.5).

The concept of the Sydney model

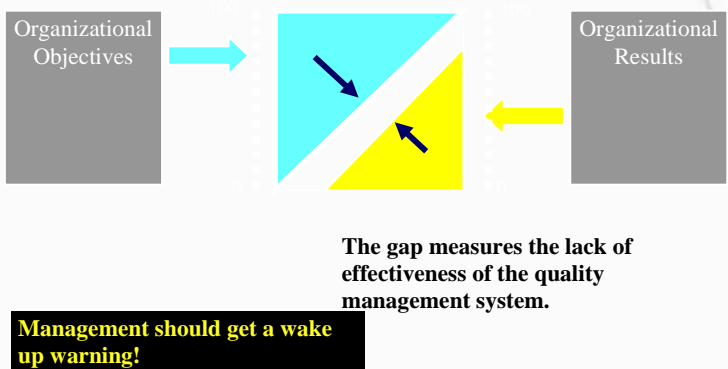
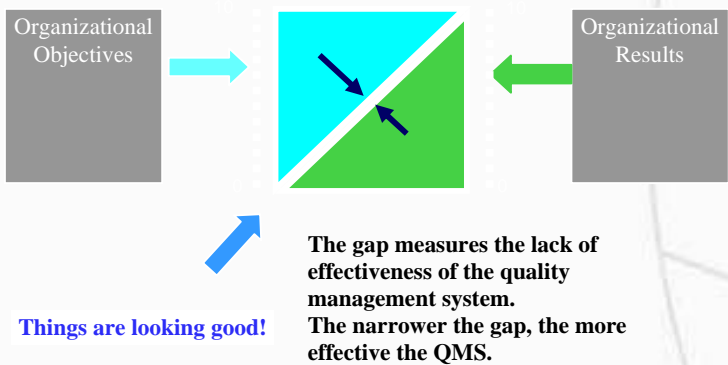
The organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made (ISO 9001 clause 8.4) and to ensure that the organization's quality and/or business objectives have been met.

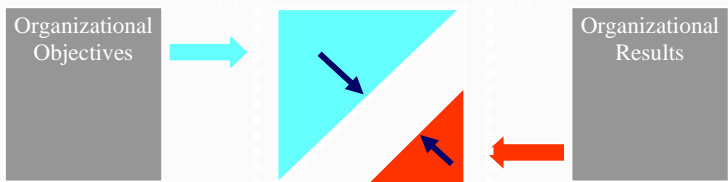
In the following example, an organization has identified several quality objectives and has collected data on the results of these objectives. Using a gap analysis technique, the results are compared to the objectives and the degree of effectiveness of the QMS is established for a given time period. The same data also allows the organization to measure improvement and to take any necessary action based on the information and results.





Effectiveness of the QMS





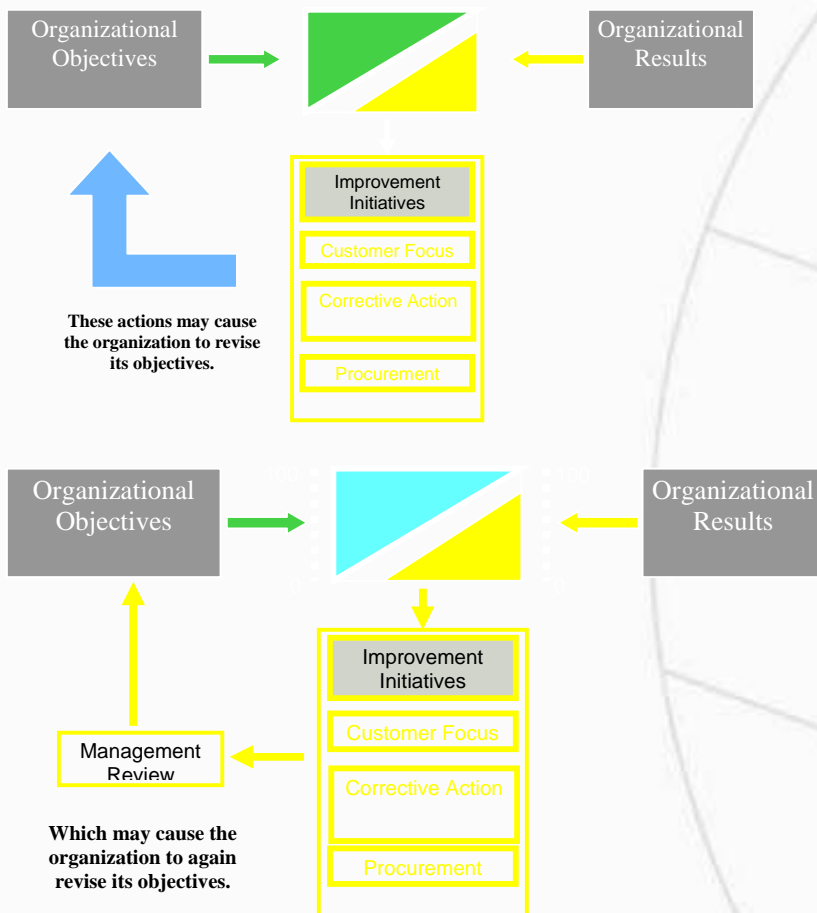
The gap measures the lack of effectiveness of the quality management system.

The Organization is in trouble!



Improvement can also be measured

What actions are taken when gaps are identified?



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

ISO 9001 and ISO 9004 form a consistent pair of standards on quality management. ISO 9001 aims to give quality assurance of product and to enhance customer satisfaction, while ISO 9004 uses a broader perspective of quality management to give guidance for performance improvement.

Top management should therefore define methods for measurement of the organization's performance in order to determine whether planned objectives have been achieved.

Methods include:

- financial measurement
- measurement of process performance throughout the organization
- external measurement, such as benchmarking and third-party evaluation
- assessment of the perceptions of customers and other interested parties of performance of products provided
- measurement of other success factors identified by management
- assessment of the satisfaction of customers, people in the organization and other interested parties

(ISO 9004 clause 5.1.1)

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.



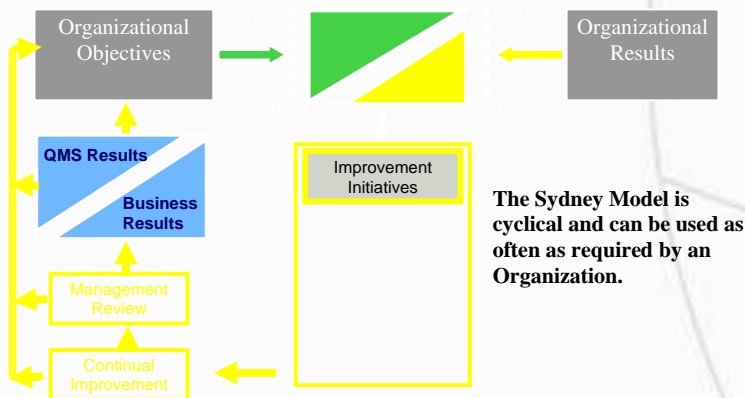
The gap now measures the lack of business effectiveness of the organization. The narrower the gap, the more effective the organization.

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 QMS 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 QMS within the corporate environment.

This article is an edited version of 'Measuring QMS effectiveness & improvements' from the website of the ISO 9001 Auditing Practices Group, and is reproduced courtesy of ISO and the IAF. These papers were developed on current best practice and therefore have not been formally endorsed as International Accreditation Forum (IAF) guidance or ISO TC176 interpretations. For further information about the Auditing Practices Group

<http://isotc.iso.org/livelink/livelink/fetch/2000/2122/138402/138403/%203541460/customview.html?func=ll&objId=3541460&objAction=browse&sort=name>.

The ISO 9001 Auditing Practices Group is an informal group of QMS experts, auditors and practitioners drawn from the ISO Technical Committee 176 Quality Management and Quality Assurance (ISO/TC 176) and the IAF. It has developed a number of guidance papers and presentations that contain explanations about the auditing of QMSs. These reflect the process-based approach that is essential for auditing the requirements of ISO 9001.

JANUARY 2005