

THE NEW ISO STANDARDS ON MANAGEMENT SYSTEMS & THE EFQM EXCELLENCE MODEL





1. Introduction

In the year 2015 two ISO standards were revised. ISO 9001:2015, released on October 1, and ISO 14001:2015, released on September 15. The changes of these standards effect organisations that use them for their quality management and environmental management respectively, but also the customers of these organisations and professionals, like auditors. These changes also effect the reference to other management approaches like the EFQM Excellence Model.

It is interesting to investigate how the revised standards relate to the EFQM Excellence Model. ISO 9001 and the EFQM Excellence Model are different approaches for different purposes. ISO contributes to consistent delivery of products and services that meet customer requirements and applicable statutory and regulatory requirements and aims to enhance customer satisfaction. The EFQM Excellence Model supports organisations on their journey to excellence, taking into account all their stakeholders.

In practice a lot of organisations combine the two approaches. The changes in the revised ISO 9001 make it even more attractive to do so. The combination of ISO 9001 and the EFQM Excellence Model will be able to reinforce a future oriented (quality)management approach, focused on continuous improvement, risk management and innovation.

This leaflet focuses on the question how ISO 9001:2015 and the EFQM Excellence Model relate, what purposes they serve, the main principles they are based upon, their contents, their differences and similarities and how the EFQM Excellence Model and ISO 9001:2015 can complement each other.

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2. ISO 9001:2015

Purpose

This international standard specifies requirements for a quality management system of an organization:

- that needs to demonstrate its ability to consistently deliver products and services that meet customer requirements and applicable statutory and regulatory requirements;
- that aims to enhance customer satisfaction through the system's effective application, including processes for improvement of the system and the assurance of conformity to customer requirements and requirements of applicable statutory and regulatory requirements.

Need for Change

Every five years a systematic review is conducted under the ISO member bodies to decide whether the standard is to be confirmed, revised, amended or withdrawn to keep them fit for their purpose.

Business needs and expectations have changed significantly since the last major revision of ISO 9001 in the year 2000. Examples of these changes are ever more demanding customers, the emergence of new technologies, increasingly more complex supply chains and a much greater awareness of the need for sustainable development initiatives.

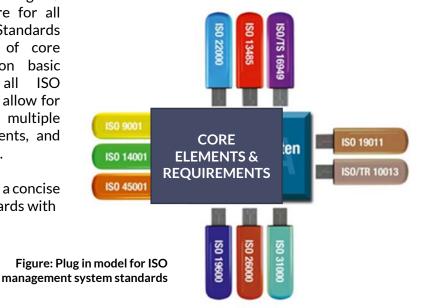
Major changes ISO 9001:2015 vs ISO 9001:2008

Introduction High Level structure (HLS)

Not only the standards ISO 9001 and ISO 14001 have been revised, also a High Level Structure

has been introduced, providing a standardised 10-clause structure for all ISO Management System Standards including a standardized set of core definitions. Using this common basic structure and terminology all ISO management systems standards, allow for more efficiently addressing multiple management systems requirements, and integrating management systems.

The HLS is used by ISO to develop a concise set of management system standards with core elements and requirements.





Introduction of a context analysis

The context analysis implies the determination of those internal and external factors that are relevant to the purpose and strategic direction of an organisation and that affect an organization's ability to deliver products and services to its customer.

External factors can include, for example, market, cultural, social, economic, political, legal, regulatory, financial, technological, economic, and competitive environment, at the international, national, regional or local level.

Internal factors typically include the organization's values, culture, knowledge and performance. Attention should be paid to:

- issues that affect the ability to achieve the intended results;
- needs and expectations of interested parties
- determination of the scope of the quality management system.

Risk-based thinking

One of the key changes in the 2015 revision of ISO 9001 is to establish a systematic approach to considering risk. There are risks in all systems, processes and functions. They can be positive (opportunities) or negative. Risk-based thinking ensures that these risks are identified, considered and integrated throughout the quality management system.

- Risk-based thinking is something we all do automatically and often sub-consciously to get the best result;
- The concept of risk has always been implicit in ISO 9001 this edition makes it more explicit and builds it into the whole management system;
- Risk-based thinking ensures risk is considered from the beginning and throughout;
- Risk-based thinking makes preventive action part of strategic and operational planning.

Leadership

Enhanced leadership involvement in the management system

- Connecting strategy and operational management;
- Engaging people.

Enhanced Process approach

More emphasis on processes being managed to achieve planned results.

Performance Evaluation

- More focus on business results;
- Evaluation of customer satisfaction;
- Increased emphasis on improvement.

Quality Manual

- Specific documented procedures are no longer required;
- It is the responsibility of the organization to maintain documented information to support the operation of its processes and retain the documented information necessary to have confidence that the processes are being carried out as planned;



The extent of the documentation that is needed will depend on the business context and the risk based approach.

Improvement

ISO 9001:2008 used the term continual improvement to emphasise the fact that this is an ongoing activity. However, it is important to recognise that there are a number of ways for an organisation to improve. Small step continual improvement is only one of these. Others may include breakthrough improvements, re-engineering initiatives or innovation. ISO 9001:2015 therefore uses the more general term improvement, of which continual improvement is one but not the only component.

Organisational knowledge management

The concept of organisational knowledge has been introduced to ensure the organization acquires and maintains the necessary knowledge.

- Communication now explicitly expanded to include external.
- More compatible with services and easier to use for non-manufacturing organisations

Principles

ISO

Customer focus

The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations.

Leadership

Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organisation's quality objectives.

Engagement of people

Competent, empowered and engaged people at all levels throughout the organisation are essential to enhance the organisation's capability to create and deliver value

Relationship management

For sustained success, organisations manage their relationships with relevant interested parties, such as providers

Process approach

Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system

Evidence-based decision making

Decisions based o the analysis and evaluation of data and information are more likely to produce desired results.

Improvement

Successful organisations have an ongoing focus on improvement.



Content of the Standard

- 1. Introduction
- 2. Scope
- 3. Normative Reference
- 4. Terms and Definitions
- 5. Context of the Organisation
 - Understanding the context of the organisation;
 - Understanding the needs and expectations of interested parties;
 - Determining the scope of the quality management system;
 - Quality management system and its processes.

6. Leadership

- Leadership and commitment;
- Policy;
- Organizational roles, responsibilities and authorities.

7. Planning

- Actions to address risks and opportunities;
- Quality objectives and planning to achieve them;
- Planning of changes.

8. Support

- Resources;
- Competence;
- Awareness;
- Communication.
- Documented information;

9. Operations

- Operational planning and control;
- Requirements for products and services;
- Design and development of products and services;
- Control of externally provided processes, products and services;
- Production and service provision;
- Release of products and services;
- Control of nonconforming outputs.

10. Performance Evaluation

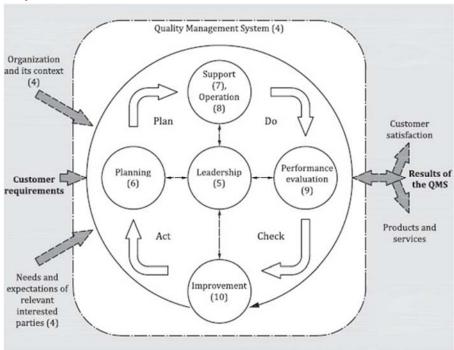
- Monitoring, measurement, analysis and evaluation;
- Internal audit;
- Management review.

11. Improvement

- General;
- Non conformity and corrective action;
- Continual improvement.



Dynamics (PDCA)





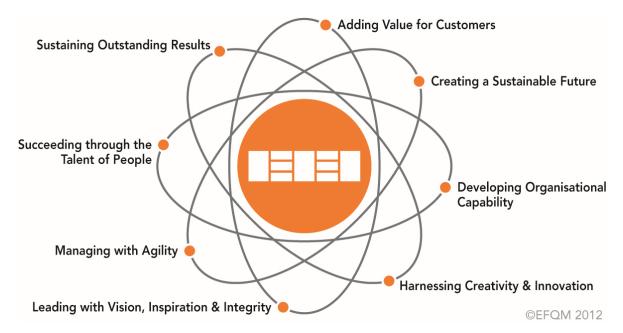
3. The EFQM Excellence Model

The EFQM Excellence Model is an integrated business management framework aimed at sustainable value creation for stakeholders. It is a framework capturing the organisation and its' stakeholders as an integrated system. It allows to identify and understand cause and effect relationships between what an organization does and the results it achieves.

Quality is a moving target, the permanent quest for the optimal alignment of the ambitions and competences of the organisation on one hand, and the needs and requirements of the stakeholders on the other.

The Fundamental Concepts of Excellence

The fundamental concepts define the underlying principles that form the foundation for achieving sustainable excellence in any organisation.



EFQM

Adding value for customers

Excellent organisations consistently add value for customers by understanding, anticipating, and fulfilling needs, expectations and opportunities

Leading with vision, inspiration & integrity

Excellent organisations have leaders who shape the future and make it happen, acting as role models for its values and ethics.

Succeeding through the talent of people

Excellent organisations value their people and create a culture of empowerment for the achievement of both organisational and personal goals.

Developing organisational capability

Excellent organisations enhance their capabilities by effectively managing change within and beyond the organisational boundaries.

Managing with agility

Excellent organisations are widely recognised for their ability to identify and respond effectively and efficiently to opportunities and threats.



Harnessing creativity & innovation

Excellent organisations generate increased value and levels of performance through continual improvement and systematic innovation by harnessing the creativity of their stakeholders

Sustaining outstanding results

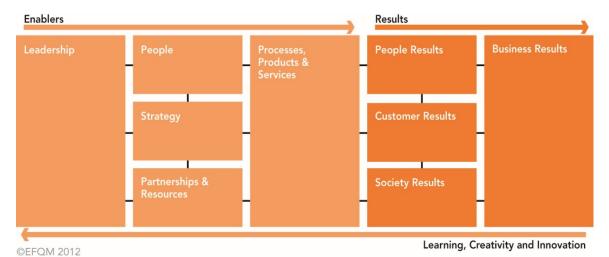
Excellent organisations achieve sustained outstanding results that meet both the short and the long term needs of all their stakeholders, within the context of their operating environment.

Creating a sustainable future

Excellent organisations have a positive impact on the world around them by enhancing their performance whilst simultaneously advancing the economic, environmental and social conditions within the communities they touch.

The Criteria

The criteria of the model provide the framework to help organisations to convert the fundamental concepts into practice.

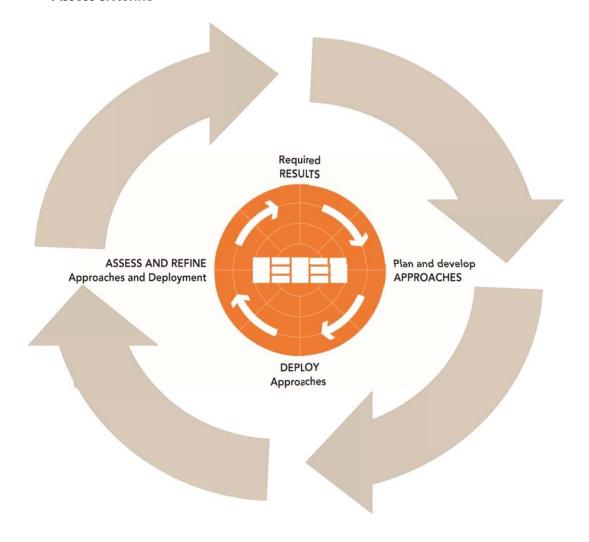




Dynamics: RADAR

RADAR is a powerful tool for driving systematic improvement in all areas of the organisation. RADAR is the acronym for:

- Results
- Approaches
- Deploy
- Assess & Refine





4. Differences & Similarities

Principles/Fundamental Concepts

Remarkable differences

ISO	EFQM
Customer focus The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations. Leadership	Adding value for customers Excellent organisations consistently add value for customers by understanding, anticipating, and fulfilling needs, expectations and opportunities Leading with vision, inspiration & integrity
Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organisation's quality objectives.	Excellent organisations have leaders who shape the future and make it happen, acting as role models for its values and ethics.
Engagement of people Competent, empowered and engaged people at all levels throughout the organisation are essential to enhance the organisation's capability to create and deliver value	Succeeding through the talent of people Excellent organisations value their people and create a culture of empowerment for the achievement of both organisational and personal goals.
Relationship management For sustained success, organisations manage their relationships with relevant interested parties, such as providers	Developing organisational capability Excellent organisations enhance their capabilities by effectively managing change within and beyond the organisational boundaries.
Process approach Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system	Sustaining outstanding results Excellent organisations achieve sustained outstanding results that meet both the short and the long term needs of all their stakeholders, within the context of their operating environment.
Evidence-based decision making Decisions based o the analysis and evaluation of data and information are more likely to produce desired results.	Managing with agility Excellent organisations are widely recognised for their ability to identify and respond effectively and efficiently to opportunities and threats.
Improvement Successful organisations have an ongoing focus on improvement.	Harnessing creativity & innovation Excellent organisations generate increased value and levels of performance through continual improvement and systematic innovation by harnessing the creativity of their stakeholders
	Creating a sustainable future Excellent organisations have a positive impact on the world around them by enhancing their performance whilst simultaneously advancing the economic, environmental and social conditions within the communities they touch.



5. Certification, Recognition & Award

Certification on an ISO standard means that the organisation shows conformity to the standards requirements. A third party certification audit is focused on conformity assessment to the standard. Either an organisation complies and gets certified, or the organisation doesn't (yet) and gets no certificate.

Certifications to ISO 9001:2008 will no longer be valid after September 2018. An assessment on the EFQM Excellent Model is focused on determining strengths and areas for improvement on each of the criteria of the EFQM Excellence Model. The assessment also provides a score, expressing the level of excellence an organisation has realised. To support organisations on their Journey to Excellence and to stimulate them to continue the pursuit of excellence EFQM introduced different levels of recognition, and finally a European Excellence Award.

6. Choose or Combine?

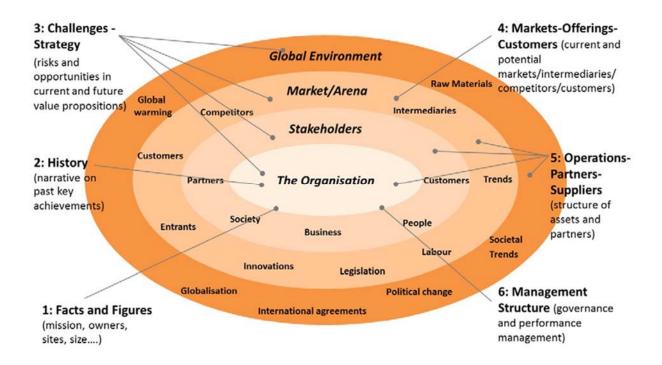
A lot of organisations that implemented the EFQM Excellence Model in the past, also are ISO 9001certified (or have got other certificates on ISO management system standards). These organisations decided to focus on certification of (a number of) their processes first, in order to deliver consistent products and services to their customers. In these cases, the EFQM Excellence Model is often used for its wider stakeholder perspective and its focus on business results for these stakeholders.

The changes in the ISO 9001:2015 offer opportunities to combine ISO 9001 and the EFQM Excellence Model in various ways.

Creating awareness by a wider context analysis

Since ISO 9001 uses now a wider stakeholder perspective in the standard and introduced the requirement of context analysis, the latter can be done with the EFQM Context analysis. The picture below shows the main characteristics of EFQM's context analysis. This analysis might be used at the start of (quality) management to create awareness of all internal and external factors that an organisation has to take into account. This analysis might also (?) help with the identification of key processes, for example related to the extent of external communication needed, or related to procurement of resources. Therefore, the context analysis is preferably carried out at the beginning of establishing the quality management process.

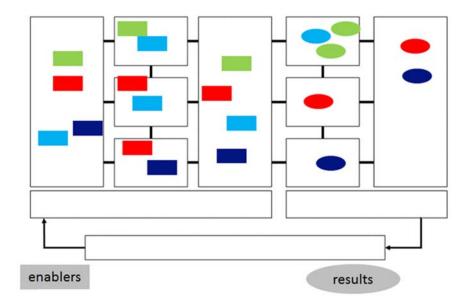




Mapping the current state

Another way to combine the EFQM Excellence Model with ISO 9001:2015 is to map key enablers (policies and approaches) of the EFQM Excellence Model and key results into the criteria of the model. This exercise will show what the organisation already has in place. By using Post-its of different colours during the mapping the connection can be shown between policies, approaches and the resulting outcomes. No procedures or rules are necessary in using the model this way. There can be a free flow of thought of the participants in this mapping process.

Engagement of managers and employees can be stimulated this way.





Business Excellence: the next level

Organizations can consider the EFQM Excellence Model to be the next level of quality, in the same way as before the revision of ISO 9001:2015. After having implemented an ISO 9001 quality management system, the organisation can proceed by using the EFQM Excellence Model for further development.

Taking risk into account

ISO 9001:2015 explicitly takes risk into account as a basis for determining the extent of control that is necessary in the process. This subject is rather implicit in the EFQM Excellence Model.

Being a Quality Manager

Quality Managers should be focused on Quality and not on the Quality Management System. If we define quality as 'fitness for use', like Juran does, a quality manager should have:

- external orientation
 - being able to facilitate a context analysis;
 - having a good understanding of requirements and needs of stakeholders (since quality is -like beauty- in the eye of the beholder) and their impact on the organisation;
- awareness of the life cycle of products and services and determining when the organisation should focus on feedback or on feedforward to reach excellence;
- connection to the strategic issues and focusing on constant evaluation of value for customers and other stakeholders;
- the ability to facilitate (stakeholder) dialogue and change.

8. Audits and Assessments

It will be a challenge for third party auditors to assess the fulfilment of new requirements (for example the context analysis and risk based approach). The EFQM Excellence Model can be used to assess organisation's current capabilities. The output of an EFQM assessment is a number of strengths and opportunities to improve future performance. Identifying an organisation's strengths is important, not only so because you do not stop doing the things you are good at, but also because strengths may help in addressing the issues identified.

Excellence is about going beyond what is expected. Unlike third party auditing against a standard, an EFQM assessment gives the management team a number of opportunities: options. Which aspects the organisation chooses to address and how the organisation choose to address them, will depend on the strategic priorities of the organization.



9. Recommended readings

- ISO 9001:2015
- ISO 9000:2015
- EFQM Excellence Model, EFQM Brussels, 2012

10. ISO & EFQM

ISO

The International Organization for Standardization (ISO) was established in 1947 and is (currently) an association of over 160 National Standards Bodies, which each represent their own country. ISO employs a system of Technical Committees, Sub-committees and Working Groups to develop International Standards. Besides the National Standards Bodies, ISO permits other international organizations that develop standards to participate in its work, by accepting them as Liaison members. ISO works in accordance with an agreed set of rules of procedure, the ISO/IEC Directives, which also include requirements on the presentation of standards. For further details please refer to ISO's own web site at http://www.iso.org.

EFQM

The European Foundation for Quality Management was founded in October 1989 when the CEO/Presidents of 67 European companies subscribed to the EFQM Policy Document and declared their commitment to achieving EFQM mission and vision. The Foundation set up a team of experts, from industry and academia, to develop the EFQM Excellence Model, a holistic framework that can be applied to any organisation, regardless of size or sector. This was first used to support the assessment of organizations in the European Quality Award in 1992.

Over the last 25 years, we have seen many changes. The EFQM Excellence Model has adapted and evolved over time to reflect changes in the global market place. Hundreds of organisations, from both public and private sector, small and big, have participated in the EFQM Excellence Awards and have contributed to the knowledge and experience on Excellence.

One thing that has not changed is the objective: to increase the competitiveness of European organisations and support the sustainable development of the European economies. EFQM is an independent, not-for-profit foundation; committed to supporting her members in their journey towards excellence. EFQM focusses on Europe, but has a global reach and welcomes the opportunity to support all organisations. For further details please refer to http://www.efqm.org.

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