

# ISO 9001:2015 Basic principles – Top management overview



- Understand the importance of leadership and involvement
- Understand the relationship of Annex SL
- Understand key requirements of ISO 9001 2015
- Establish a clear understanding of context of the organisation
- Learn the importance of risk based thinking
- Understand key requirements of stake holders
- Awareness of internal and external factors that could affect the organisation

## 0.2 Quality management principles

This International Standard is based on the quality management principles described in ISO 9000. The descriptions include a statement of each principle, a rationale of why the principle is important for the organization, some examples of benefits associated with the principle and examples of typical actions to improve the organization's performance when applying the principle.

### Assess your own organisation

The quality management principles are:

customer focus;

leadership;

engagement of people;

process approach;

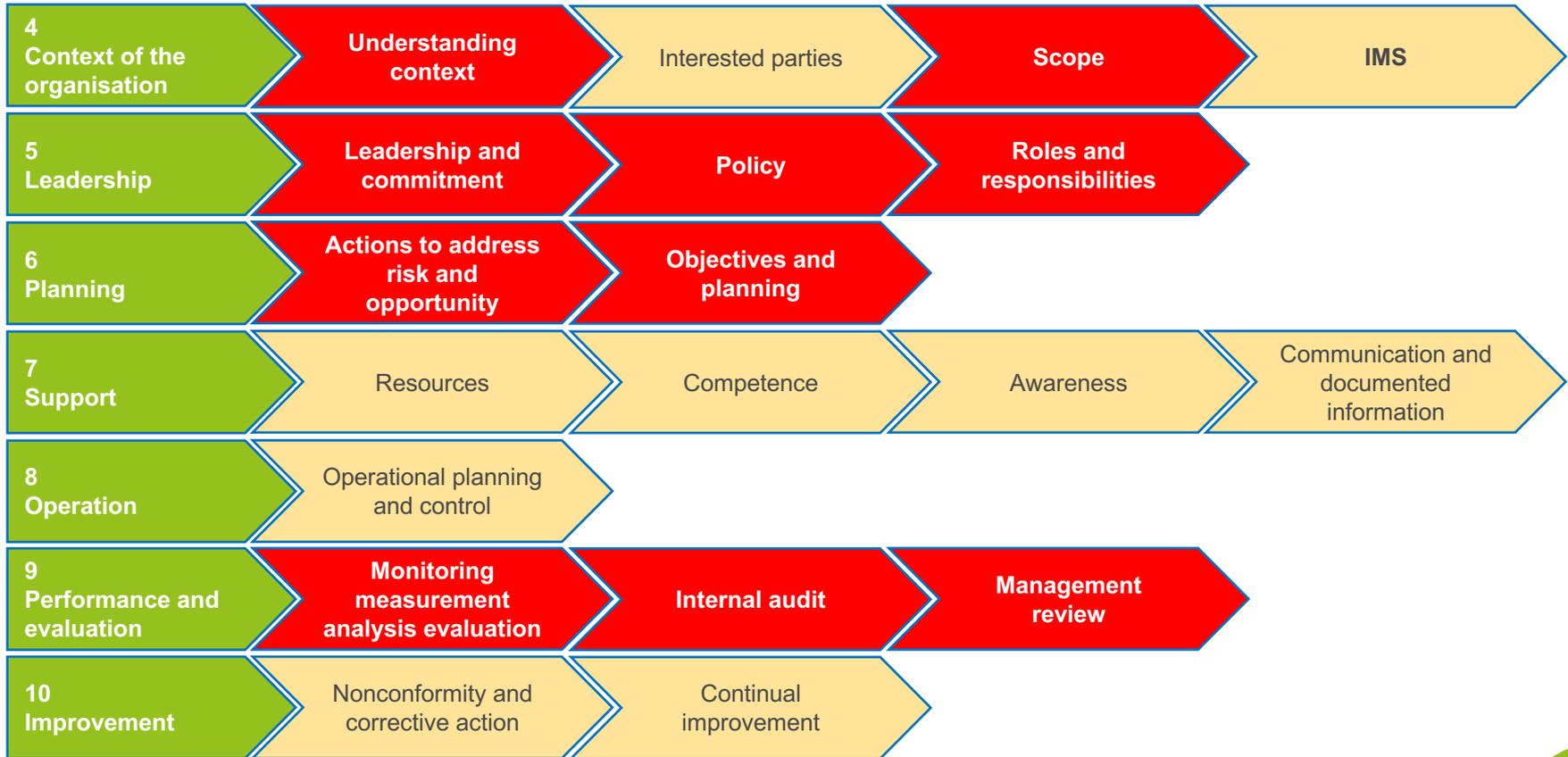
improvement;

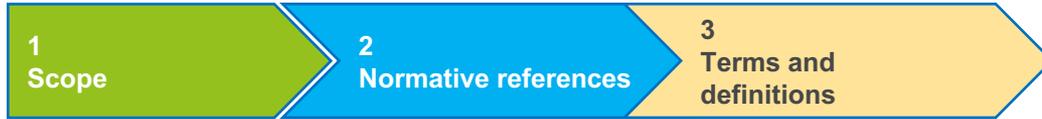
evidence-based decision making;

relationship management.

	Poor	Fair	Good	Very Good	Excellent

# Annex SL — A standard ISO format established in 2014 and used in ISO 9001:2015





This International Standard specifies requirements for a quality management system when an organization:

- a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
- b) 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.

All Statutory and regulatory requirements can be expressed as legal requirements.

# Understanding context and Scope



## Company profile

The context of the organisation is a summary of the activities that appear on the organisations website

In addition it will contain the inputs / materials used, together with outputs to customer

The Interested Parties and Issues, both Internal and External must be assessed, together with their respective needs and control. Review of control and associated Risk should be constantly reviewed.

## 1.0 Scope

Company activities to be included in the Scope. This description will appear on the ISO Certificate

# Understanding Leadership, Policy and Roles and responsibilities



Top management shall demonstrate leadership and commitment with respect to the quality management system ( **IMS** ) by:

- Taking accountability for the effectiveness of the IMS;
- Ensuring that the quality policy and **quality objectives are established for the IMS** and are compatible with the context and strategic direction of the organisation;
- **Ensuring the integration** of the IMS requirements into the organisations business processes;
- Promoting the use of the process approach and risk based thinking;
- Ensuring that the resources needed for the IMS are available;
- **Communicating** the importance of effective quality management and of conforming to the IMS requirements
- Ensuring that the IMS achieves its intended results;
- Engaging directing and supporting persons to contribute to the effectiveness of the IMS;
- Promoting improvement;
- Supporting other relevant management roles to demonstrate their leadership as it applies to their area of responsibility
- The importance of **communicating relevant policies**

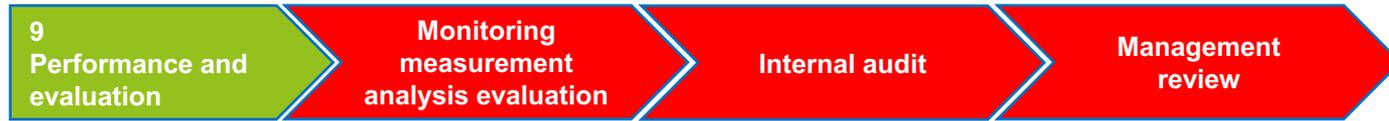
# Actions to reduce risk and opportunity – objectives and planning



Top management shall demonstrate Risk based assessments are being used with respect to the quality management system ( **IMS** ) by:

- Formalised risk analysis based processes used – e.g. SWOT, Failure Mode and Effect Analysis (FMEA)
- Formalised processes to identify continuous improvements and opportunities for growth
- These control measures will be monitored in an Objectives and Targets summary

# Monitoring measurement analysis evaluation Internal audit and MRM.



The organisation shall determine performance evaluation:

- what needs to be monitored and measured;
- the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
- when monitoring and measuring shall be performed;
- when the results from monitoring and measurement shall be analysed and evaluated;
- determine the extent to which customers perceptions, needs and expectations have been fulfilled;

The organisation shall conduct internal audits:

- plan, establish and maintain an audit program;
- define the audit criteria and scope;
- select trained impartial auditors;
- Objective evidence obtained to validate process flows and stated intentions.
- take appropriate correction and corrective action without delay;
- Modify IMS where necessary and document within an action plan, detailing timeline and responsibilities

The organisation shall conduct Management review meetings:

- inputs conducted to a set agenda;
- outputs related to opportunities for improvement, changes to the system or context, and ongoing resource needs;