



TAIEX Workshop, Albania, December 21th–22nd, 2016



ISO 9001:2008 to ISO 9001:2015 Summary of Changes



Source: ISO

ISO 9001:2015 - Key perspectives

ISO 9001 needs to change, to:

- adapt to a changing world
- reflect the increasingly complex environments in which organizations operate
- provide a consistent foundation for the future
- reflect the increasingly complex environments in which organizations operate
- ensure the new standard reflects the needs of all relevant interested parties
- ensure alignment with other management system standards

ISO 9001:2015 - Key feature changes

- 10-clause structure and core text for all Management System Standards (MSS)
- More compatible with services and non-manufacturing users
- Clearer understanding of the organization's context is required "one size doesn't fit all"
- Process approach strengthened/more explicit
- Concept of preventive action now addressed throughout the standard by risk identification and mitigation
- The term documented information replaces the terms document and record
- Control of externally provided products and services replaces purchasing/outsourcing
- Increased emphasis on seeking opportunities for improvement

Beneficial changes to ISO 9001

- Enhanced leadership involvement in the management system
- Risk-based thinking
- Simplified language, common structure and terms
- Aligning QMS policy and objectives with the strategy of the organization

Potential benefits to the user

- Focus on achieving planned results
- Flexibility for documented information
- Improved risk control
- Better process control leading to improved results
- Improved customer satisfaction
- Customer retention and loyalty
- Improved image and reputation
- Greater credibility

ISO 9001:2015 - Scope

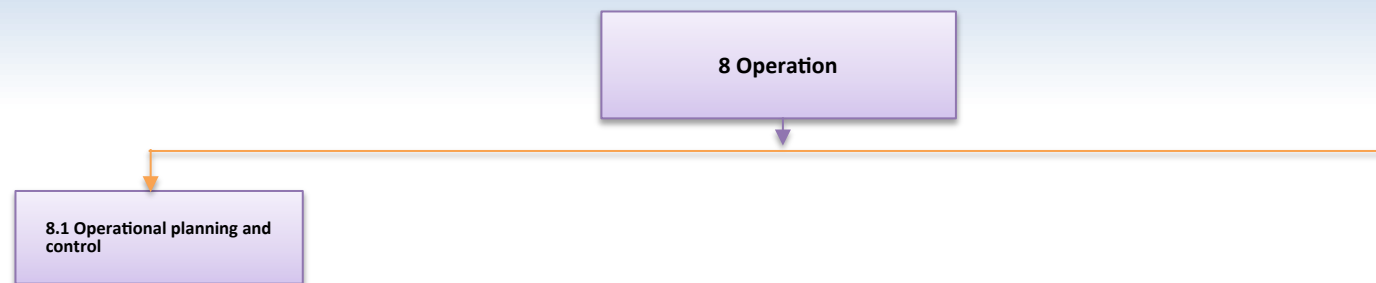
This International Standard specifies requirements for a quality management system where an organization:

- a) needs to demonstrate its ability to consistently provide product or service that meets customer and applicable statutory and regulatory requirements, and
- b) 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.

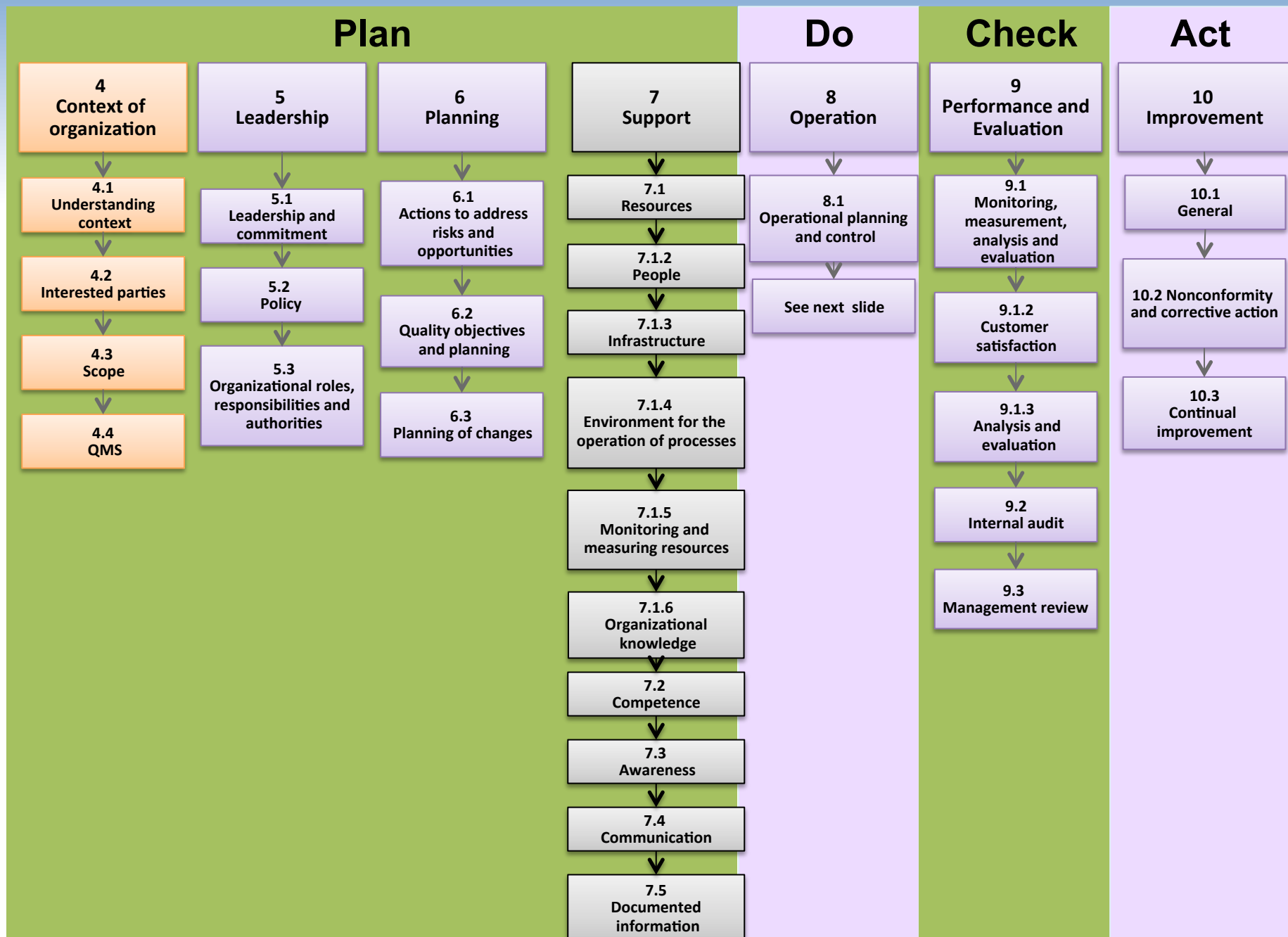
The common structure and ISO 9001:2015 additions

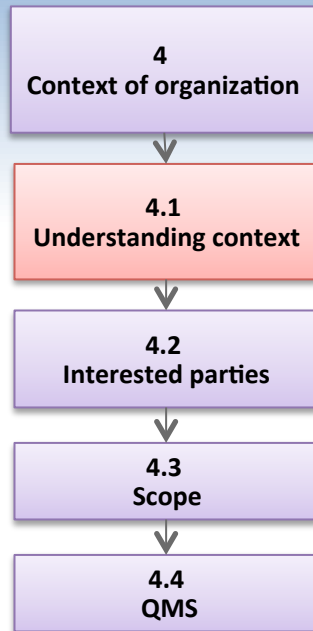


The common structure and ISO 9001:2015 additions



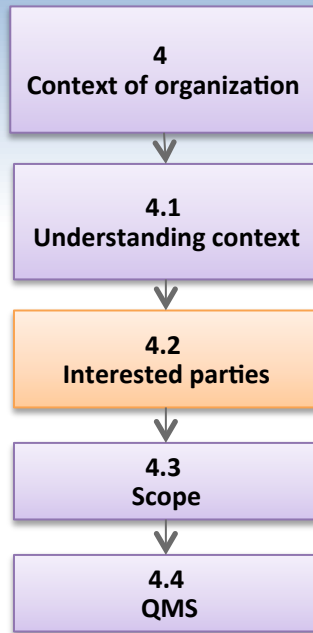
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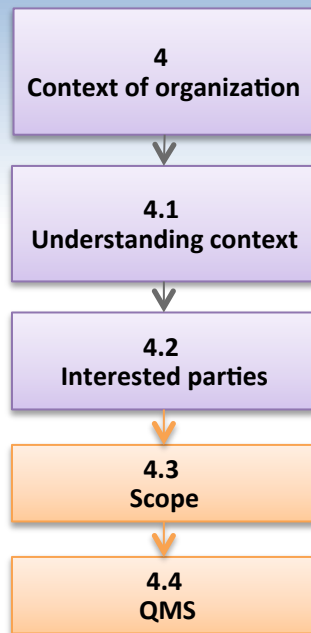
Clause 4.1

Determine what the relevant external and internal issues are for your organization, and that are relevant to its strategic direction



Clause 4.2

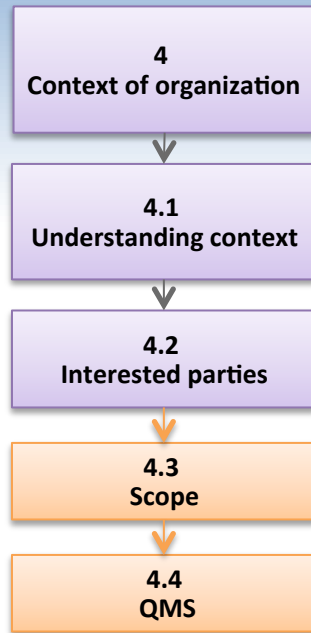
Identify the relevant interested parties and their relevant requirements



Clause 4.3 and 4.4

The requirement for the scope is now better defined, must be documented and consider:

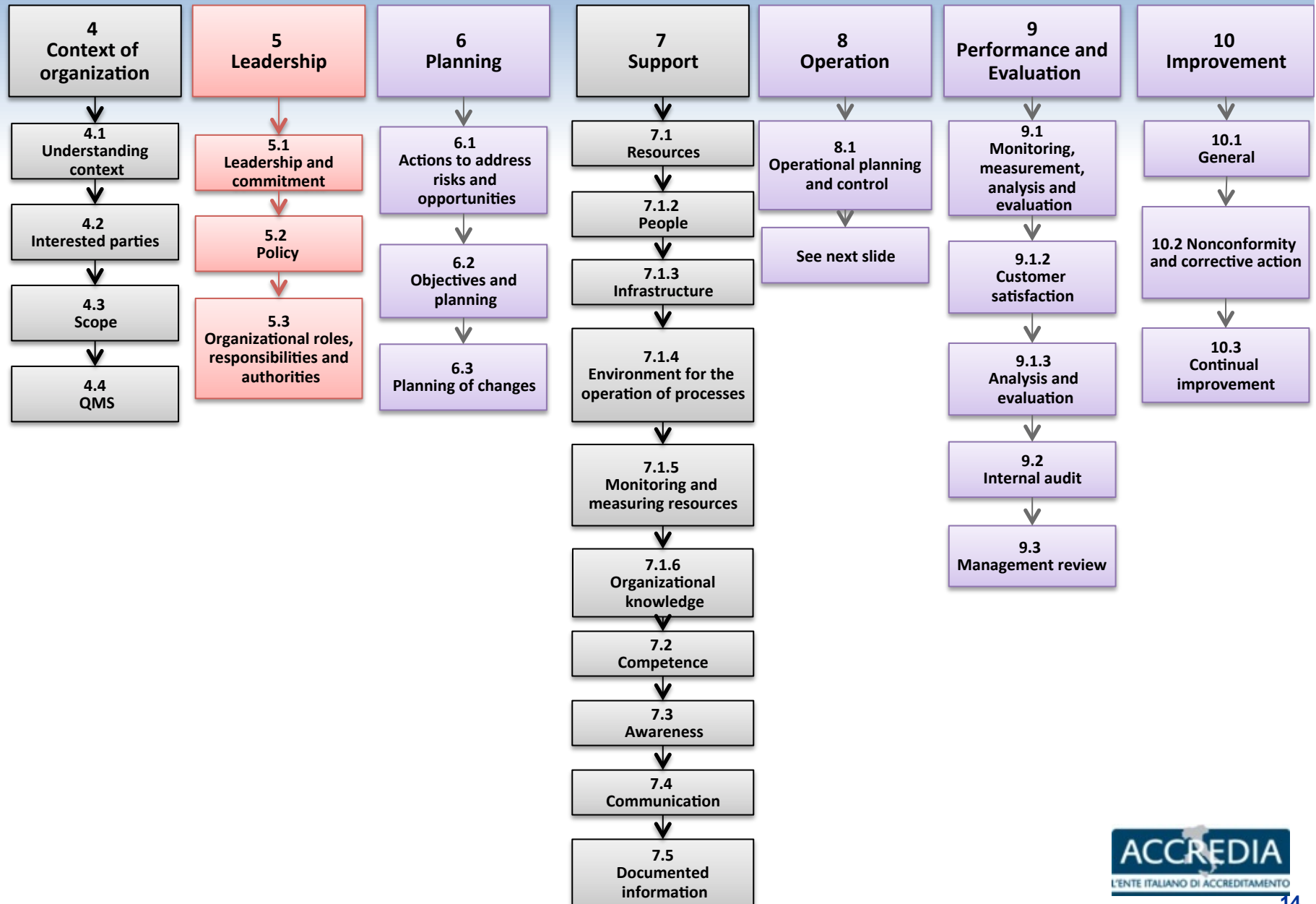
- external and internal issues
- requirements of relevant interested parties
- the products and services covered (must also be stated in scope)
- allowing applicability of specific requirements
- justification for any case where a requirement cannot be applied (exclusion)

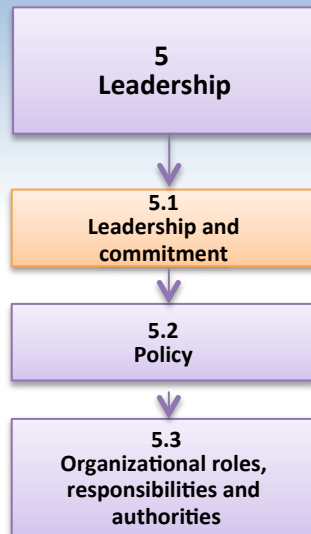


Example

Evaluate the analysis of the context

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Clause 5.1.1

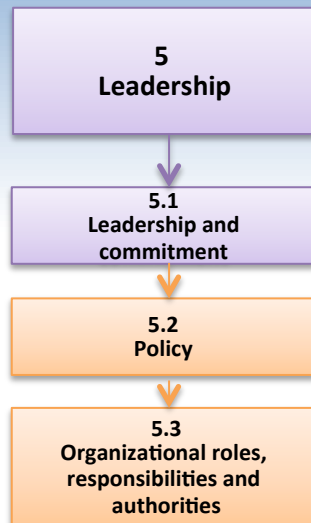
Leadership is required to ensure:

- take accountability for the effectiveness of the quality management system
- ensure the quality policy and quality objectives are compatible with the context and strategic direction of the organization
- ensure the integration of the QMS requirements into the organization's business processes
- promote the use of the process approach and risk-based thinking
- ensure that the QMS achieves its intended results
- engage, direct and support persons to contribute to the effectiveness of the QMS
- supporting relevant management roles
- promotion of improvement

Clause 5.1.2

Top management needs to ensure customer satisfaction through:

- customer and applicable statutory and regulatory requirements being determined and met
- risk and opportunities are being addressed
- the focus on products and services meeting customers and other requirements



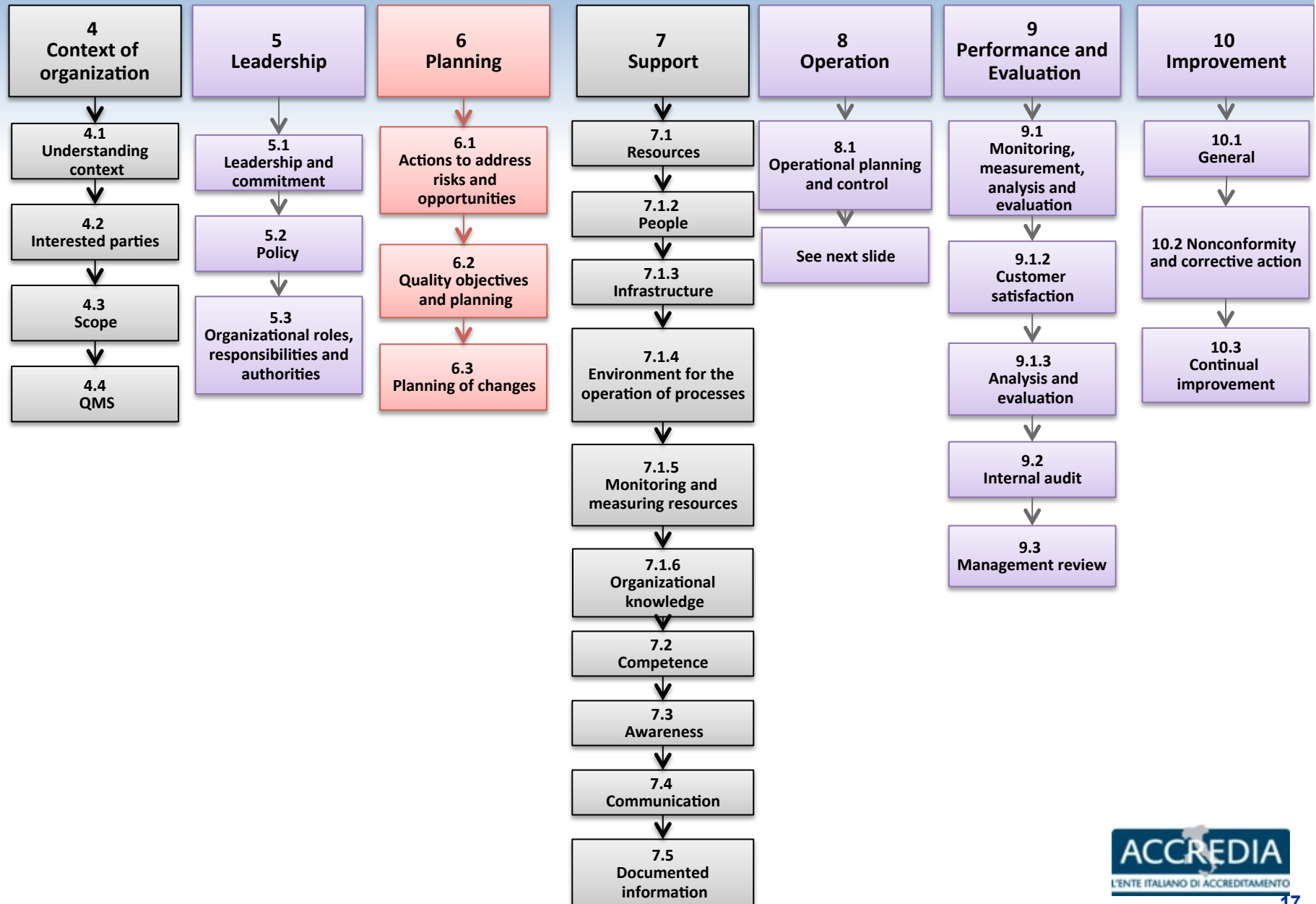
Clause 5.2

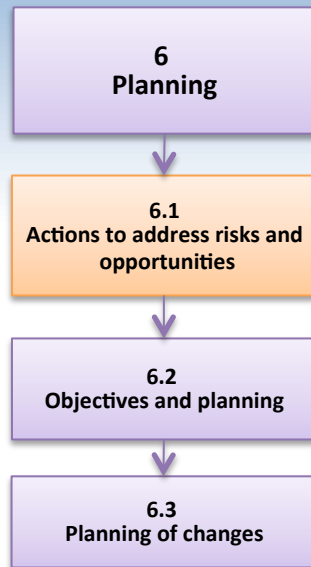
- Explicit requirement to apply the policy

Clause 5.3

- Explicit requirement for relevant roles to be assigned, communicated and understood
- No requirement for a specific management representative and the responsibility now resides with top management to assign and manage
- Requirement for defining responsibility and authority for ensuring processes are delivering their intended outputs

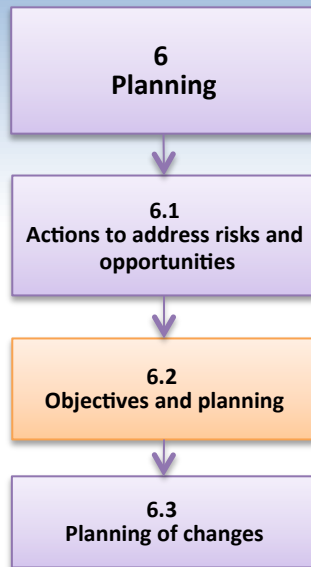
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Clause 6.1

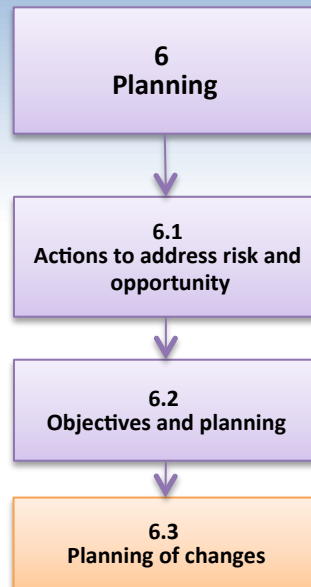
- Considering the issues raised and relevant interested parties' requirements identified (4.1 and 4.2), this clause requires the determination of risks and opportunities which need to be addressed, actions to be taken and evaluation of the effectiveness of these actions



Clause 6.2

Objectives should be:

- established for processes relevant to the QMS
- in line with customer requirements
- in line with products and services conformity
- monitored, communicated & updated



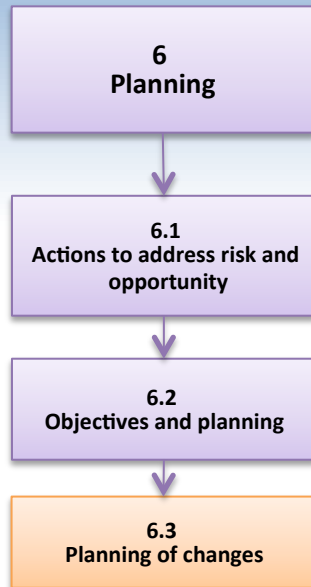
Clause 6.3

- Changes to the QMS should be carried out in a planned manner

- The standard has evolved to enable organizations to adapt to changing environments or circumstances

Note: It is important to know that change is addressed in the following clauses:

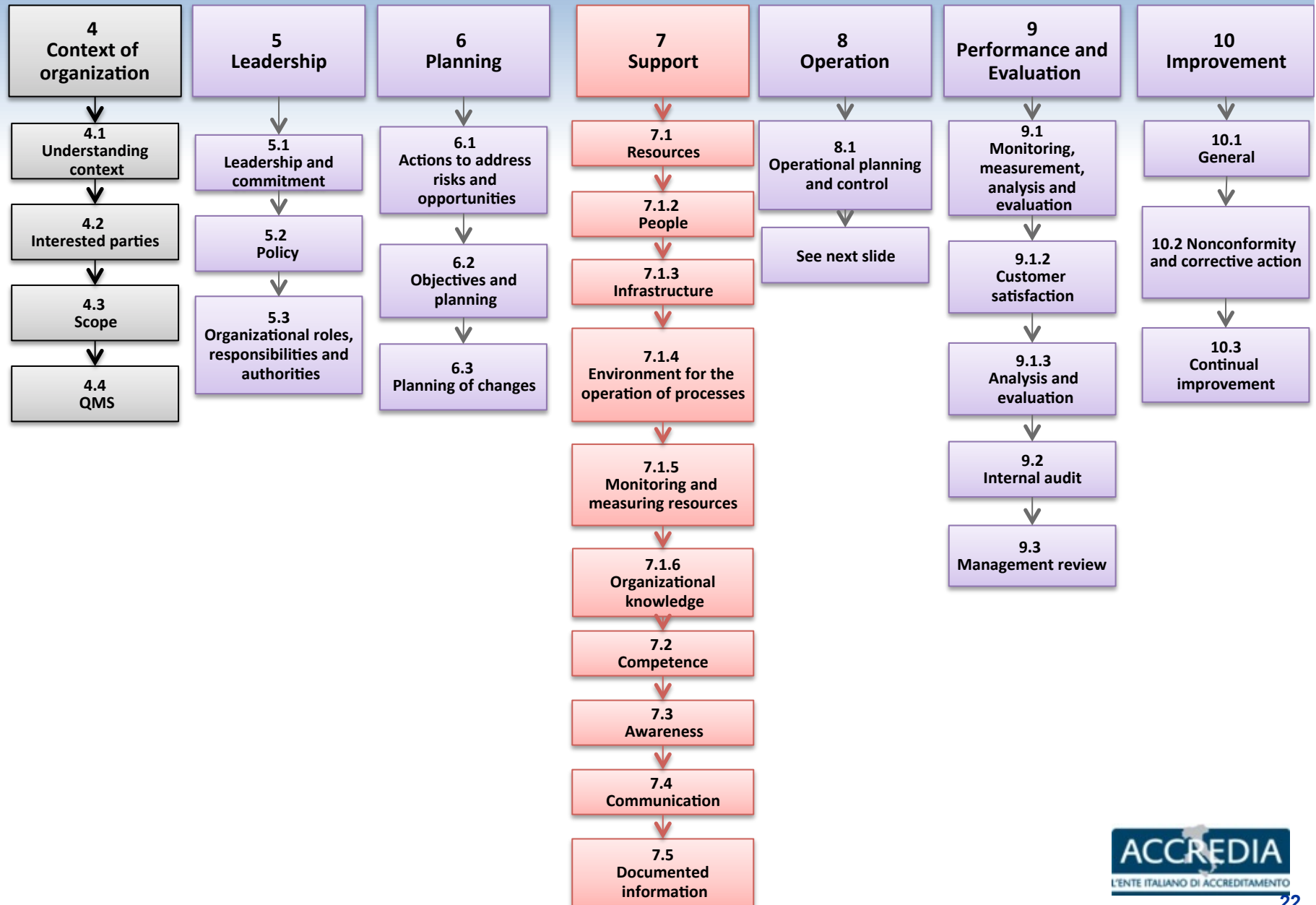
- Clause 6.3 - Planning/implementing changes to the QMS
- Clause 7.1.6 - Organizational knowledge - for addressing changing needs and trends, with respect to knowledge
- Clause 8.1 - Controlling operational changes, planned and unintentional
- Clause 8.5.6 - Addressing changes affecting products & services

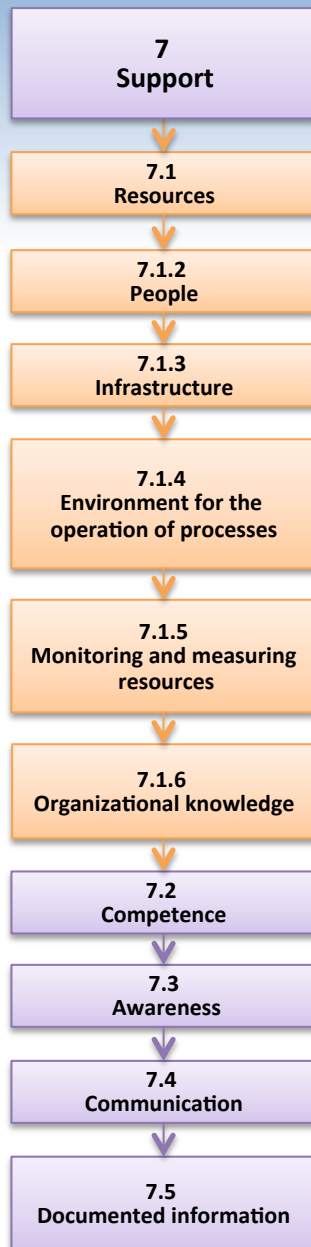


Example

Evaluate the change management procedure

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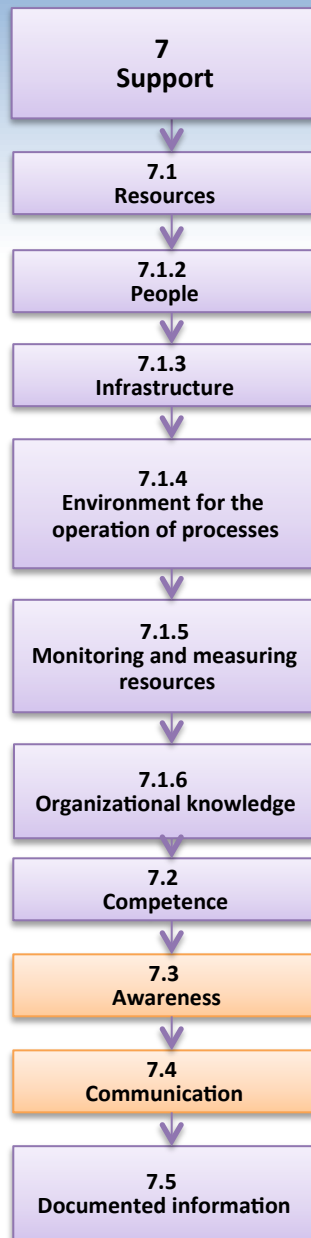




Clause 7.1

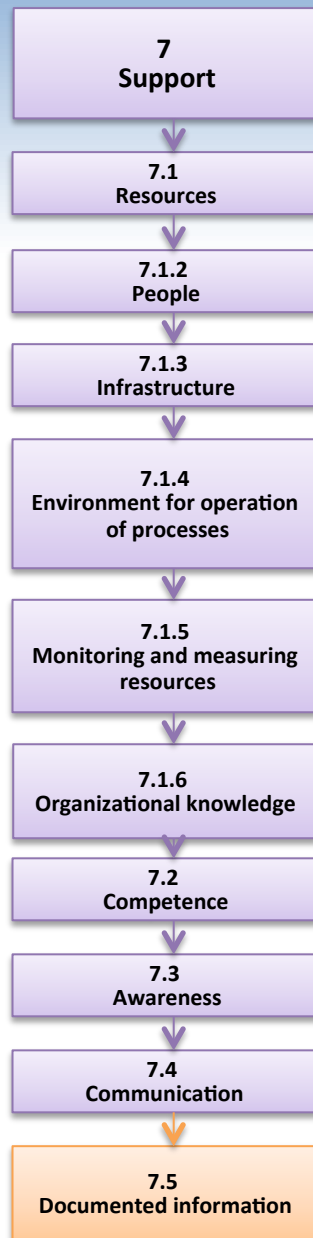
There should be adequate resources to ensure effectiveness of the QMS. Resource considerations now include:

- internal resources
- external providers
- people
- monitoring and measuring resources
- organizational knowledge required to ensure the processes provide conforming products and services
- external communication



Clause 7.3 and 7.4

Relevant persons doing work under the organization's control need to have awareness and communication (internal and external) of the QMS and benefits of improving performance



Clause 7.5.1

Requirements that used to be required for a quality manual have been enhanced and made more flexible to allow for the use of documented information needed for the quality management system

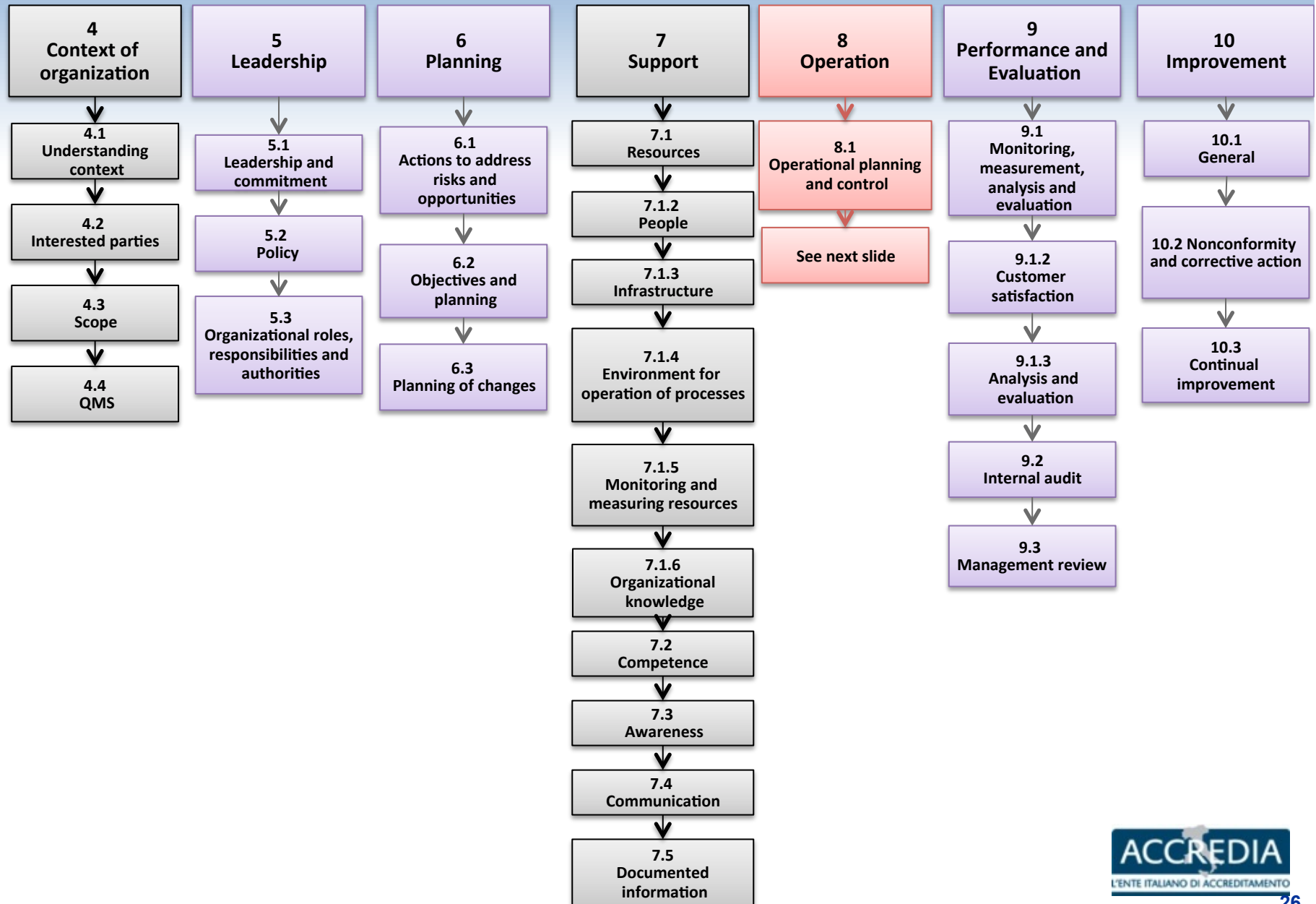
Clause 7.5.2

Enhanced requirement for the creation and updating of documented information, e.g. description, format & suitability

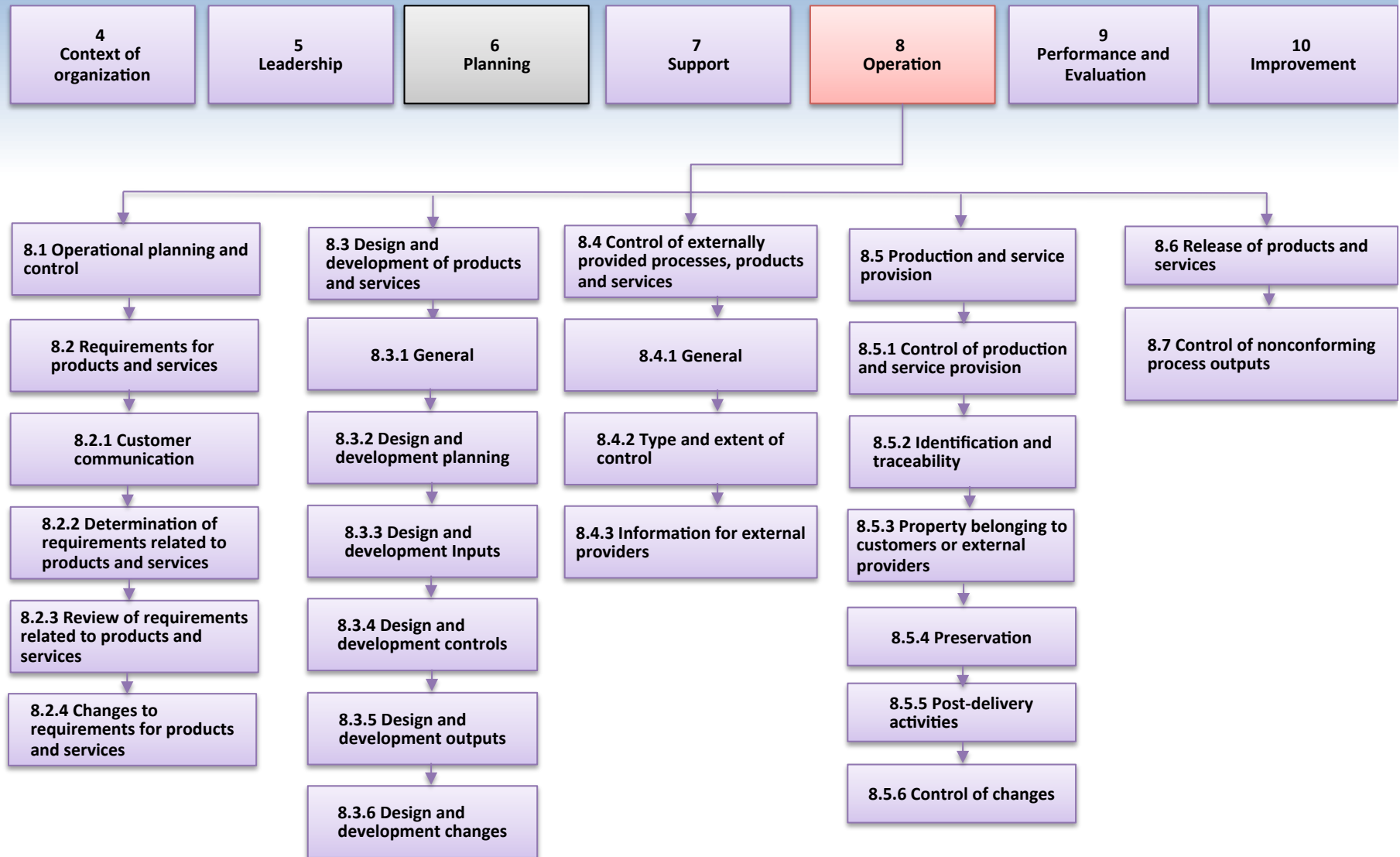
Clause 7.5.3

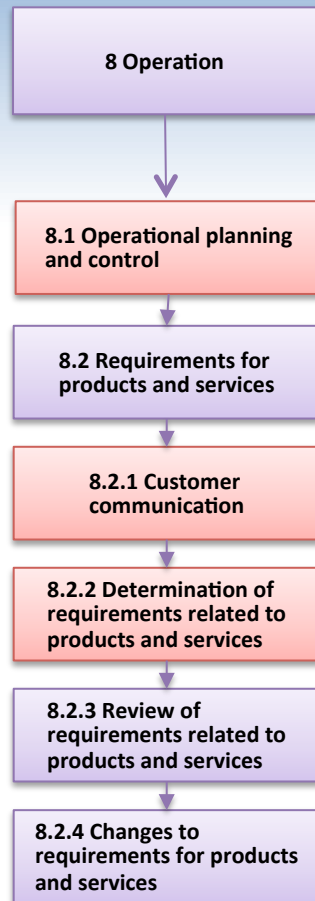
Control of documented information – now explicitly includes confidentiality, integrity and access

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Clause 8.1.b

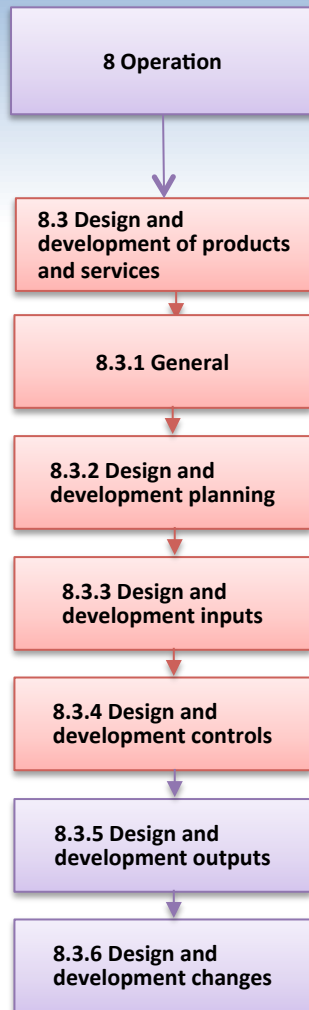
- explicit requirement for establishing criteria for processes

Clause 8.2.1

- explicit considerations are now linked to: customer communications; customer property, and contingency actions

Clause 8.2.2

- Determination of requirements; this requires a process and is explicit with regard to substantiating claims for products and services being offered



Clause 8.3

This section on design and development of products and services has substantively changed and simplified:

Clause 8.3.2

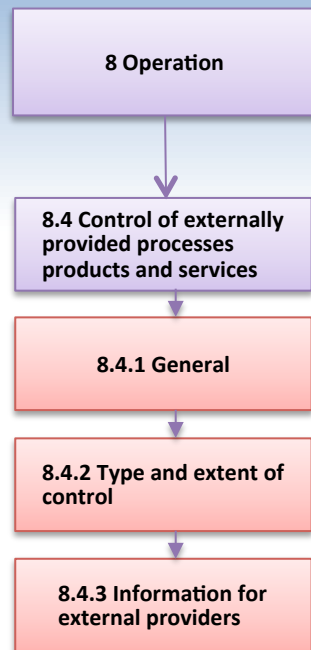
- Design and development has been restructured to allow for a more process orientated approach
- Involvement of customers and users as part of design planning to be considered

Clause 8.3.3

- Design and development inputs – explicit requirements for internal and external resource needs, potential consequences of failure, level of control expected by customers

Clause 8.3.4

- Design and development controls – new clause combining Reviews, Verification & Validation



Clause 8.4

- The terms which previously referred to purchasing and ‘outsourcing’ is now ‘Control of externally provided processes, products and services’

Clause 8.4.1

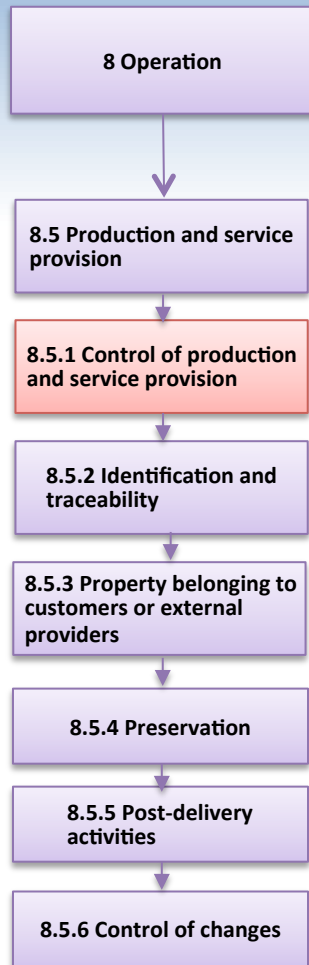
- Conditions are applied when controls are required for externally provided processes, products and service
- Terminology has changed from ‘supplier’ to ‘external provider’

Clause 8.4.2

- Type and extent of control of external provision previous notes in 4.1 (ISO 9001:2008) now turned into requirements

Clause 8.4.3

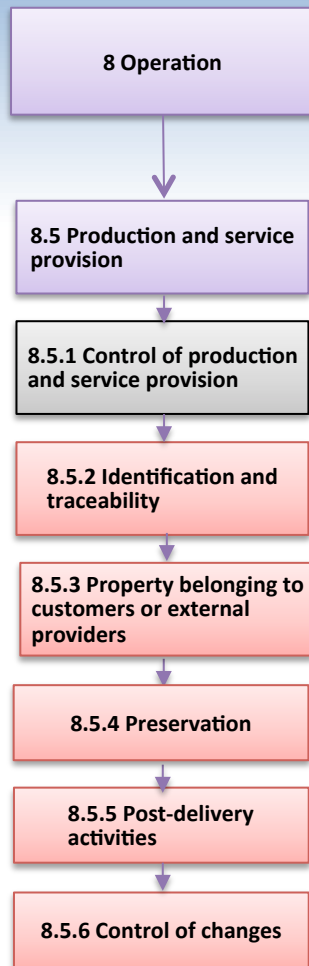
- Information for external providers are now more detailed and explicit



Clause 8.5.1

This clause specifically considers:

- monitoring and measurement activities will ensure the control of processes and output (clauses 8.2.3 and 8.2.4 of ISO 9001:2008 have been moved to 8.5.1)
- acceptance criteria for products and services are met
- the use, and control of suitable infrastructure and process environment
- suitable monitoring and measuring resources
- Requires competent persons



Clause 8.5.2

- The identification and traceability now focus on ‘outputs’ rather than on ‘product’ (includes intermediate products and services) rather than on ‘product’

Clause 8.5.3

- Customer property has been expanded to include external providers’ property

Clause 8.5.4

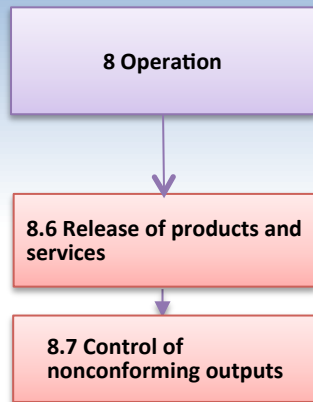
- Preservation of product has been changed to preservation of the output

Clause 8.5.5

- Post-delivery activities is a new clause

Clause 8.5.6

- A new requirement for the control of changes is addressed in the slide introducing the concept of change



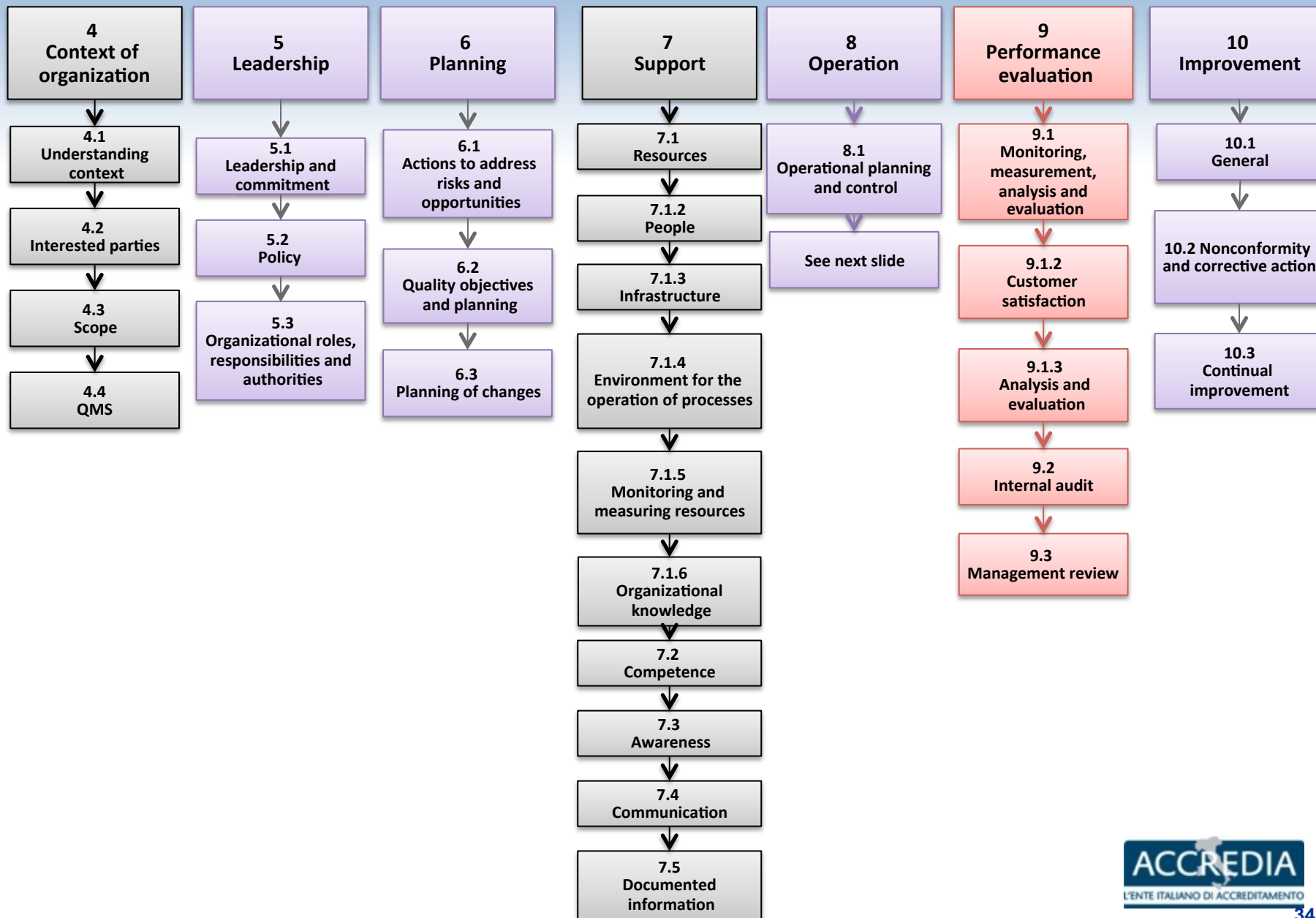
Clause 8.6

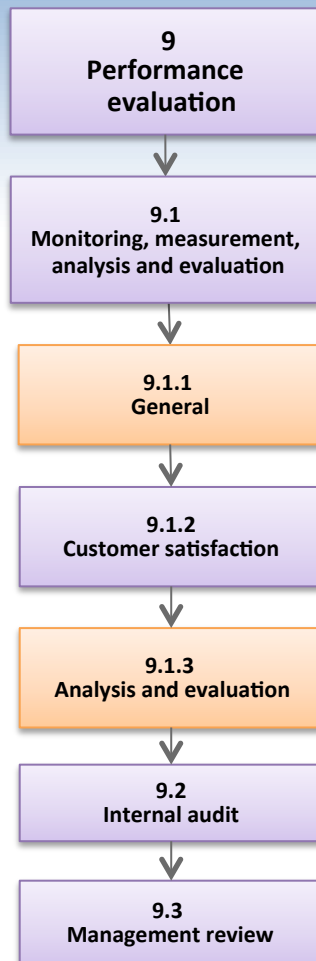
- The release of products and services is now part of the operational requirements

Clause 8.7

- The control of nonconforming output is more explicit; it now considers the options to apply correction and corrective action
- Nonconforming product changed to nonconforming output

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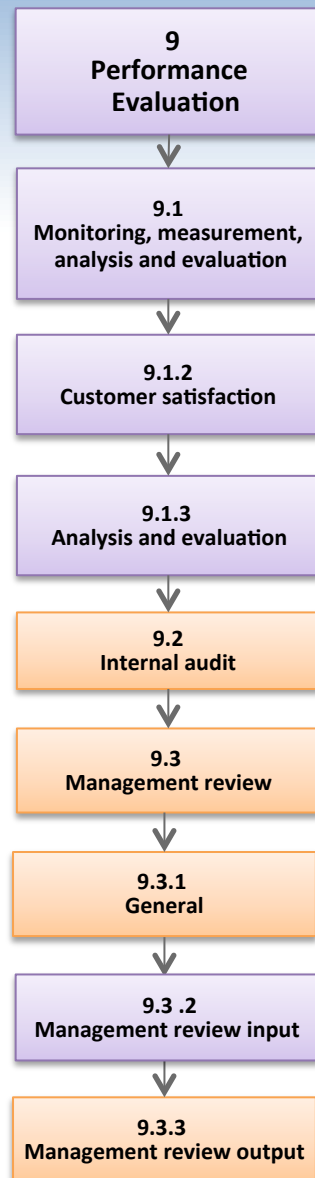


Clause 9.1.1

- In 8.1 ISO 9001:2008 (clause 8.1) there was a requirement for planning. This is replaced with identifying what needs monitoring and measuring, and the methods to be used

Clause 9.1.3

- There are specific requirements for analysis and evaluation when using results as inputs to management review
- Effective implementation of planning and actions to address risks and opportunities are new requirements in this clause



Clause 9.2

- Internal audit program now has explicit considerations for: quality objectives, customer feedback and changes impacting the organization; management responsibility for action is now implicit whereas previously this was explicit
- An auditor is now required to be impartial versus in the previous version they could not audit their own work

Clause 9.3

- There are now additional requirements for management review. These include:
 - changes in external and internal issues (such as strategic direction)
 - performance concerning external providers
 - adequacy of resources for effective QMS and effectiveness of actions taken addressing risks & opportunities

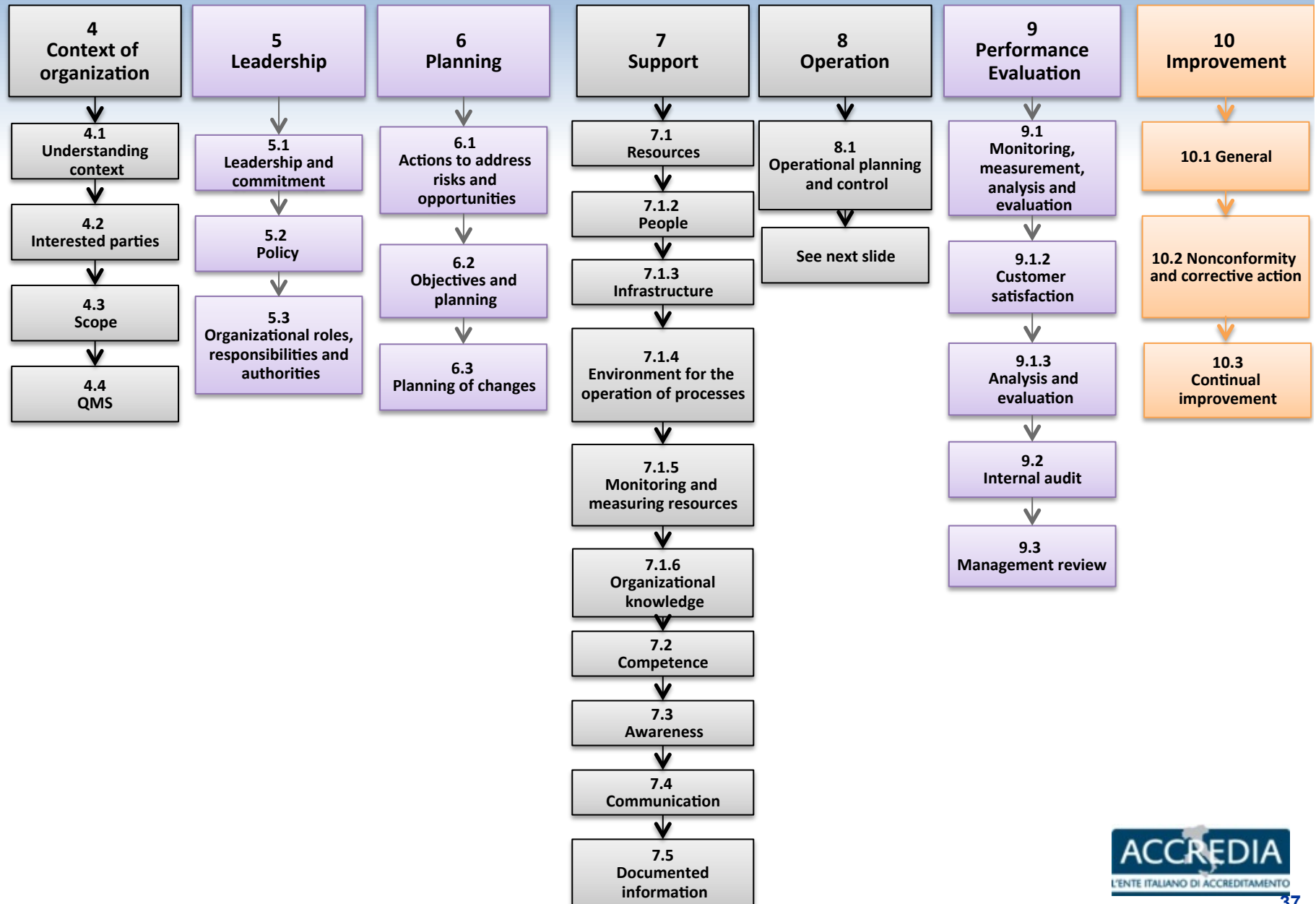
Clause 9.3.1

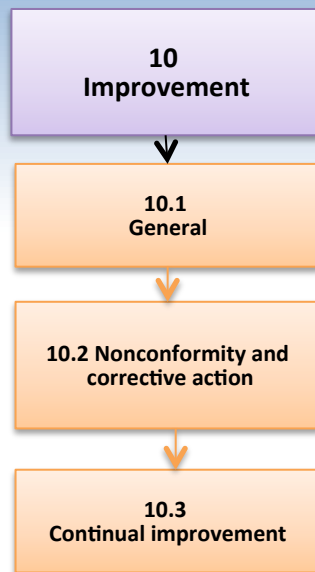
- Management reviews should be aligned to the strategic direction of the organization

Clause 9.3.3

- Management review outputs have been enhanced to include many of the new areas of focus

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Clause 10.1

- This clause is new, it addresses more comprehensive opportunities for improvement; not only continual improvement
- Addresses improvement of products and services and future needs and expectations
- Emphasis is now on improving processes to prevent nonconformities and improving products and services

Clause 10.2

- The nonconformity referred to in this clause concerns the entire QMS and not specifically the products or services which are addressed under clause 8.7

Clause 10.2.1

- New emphasis is placed on nonconformity and corrective action
- Consequences are now included thus actions taken now recognize the potential occurrence of a similar nonconformity elsewhere
- Risks and opportunities now need to be updated when required following a nonconformity

Clause 10.2.2

- Documented information is now required on the nature of the nonconformity and subsequent actions taken

Clause 10.3

- Opportunities shall be addressed as part of continual improvement

Summary

- Determining the organizational context enables a more effective implementation of the quality management system
- Greater emphasis on processes being managed to achieve planned results
- Alignment with strategic direction
- Integration of the QMS into organization's business processes
- Determining risks and opportunities increase the effectiveness of the organization's QMS
- Change management has been expanded to add emphasis that the QMS should be carried out in a planned manner
- The concept of organizational knowledge introduced to ensure the organization acquires and maintains the necessary knowledge
- Communication expanded to include external

ISO 9001:2015 Certification Transition Timeline

