



Vocational training center for undergraduate university students and teachers in Jordan (VTC)

(Project no.: 561708-EPP-1-2015-1-DE-EPPKA2-CBHE-JP)



Quality Management Systems



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Leipzig – Germany, 29th September 2018



Learning Objectives

- The history and development of ISO 9001
- What is a Quality Management System (QMS)
- The benefits of a QMS

KNOWLEDGE

- The terms and definitions used
- Key concepts, principles and structure
- The main requirements of ISO 9001:2015 and how to implement

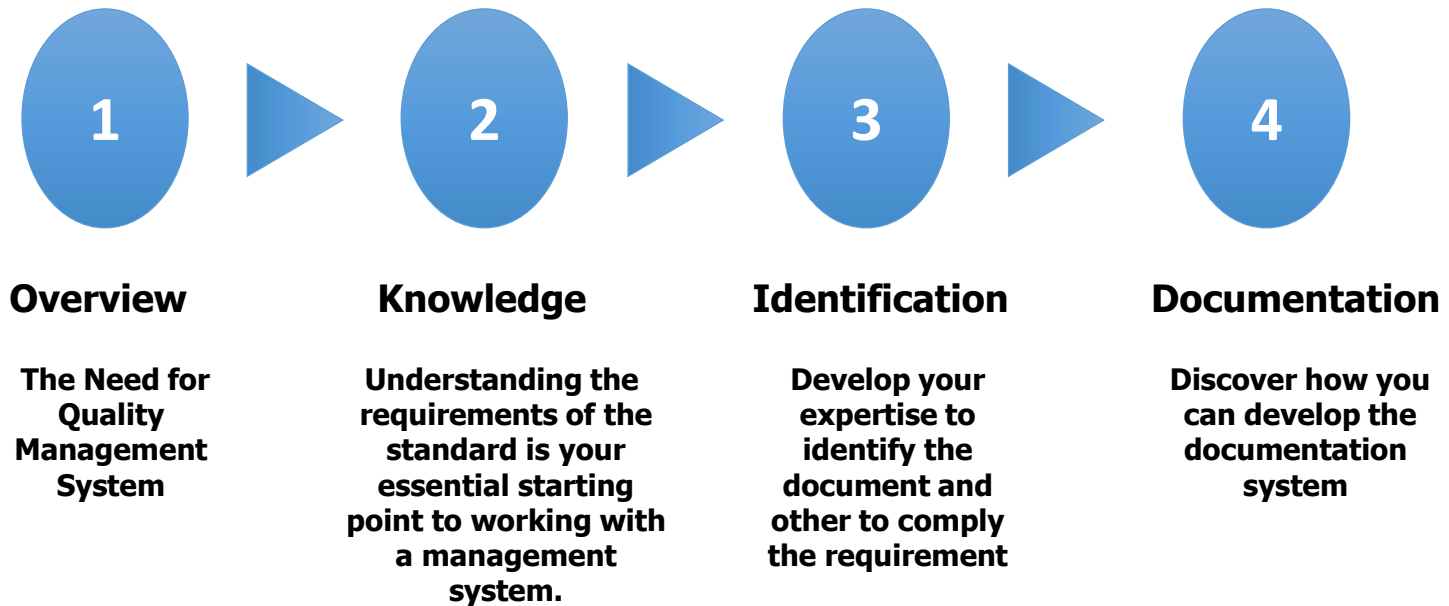
- Have the skills to develop documentation :
- process mapping
 - documented information such as procedure and supporting document

SKILLS

.....QMS shall establishing the documented information for the effectiveness (Clause 7.5 9001:2015)

Solution & Result...

training journey





Module 1

- Concept of Quality

Module 2 Overview

- Principle of QMS
- Terminology (Workshop 1)

Module 3 ISO 9001 - General

- Historical of ISO 9001
- ISO 9000, ISO 9001 & ISO 9004

Module 4 Interpretation & Documentation of Context Organisation

- Interested Party
- Scope
- Process Mapping (Workshop 2)

Module 5 Interpretation & Documentation of Leadership

- Commitment
- Quality Policy
- Role & Responsibility

Module 9 Interpretation & Documentation of Performance Evaluation

- Customer Satisfaction
- Internal Audit
- Management Review

Module 8 Interpretation & Documentation of Operation

- Planning and provision of services ((Workshop 5)
- Control of external providers
- Release & Control of Non Conforming

Module 6 Interpretation & Documentation of Planning

- Risk Management (Workshop 3)
- Quality Objective
- Management of Change

Module 10 Interpretation & Documentation of Improvement

- Improvement
- Nonconformity & Corrective action
- Continual Improvement)

Module 7 Interpretation & Documentation of Resources

- People
- Infrastructure
- Process Environment
- Monitoring & Measurement
- Knowledge Management)
- Competence
- Awareness
- Documented Information(Workshop 4



Closing



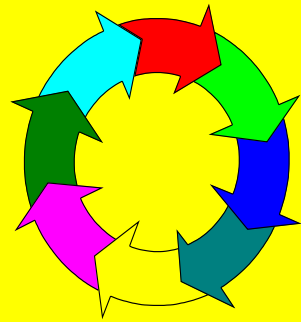
Erasmus+ Programme of the European Union



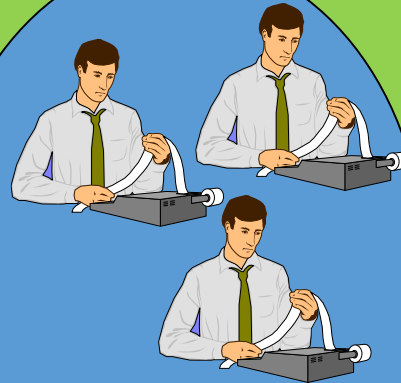
Concept of Quality



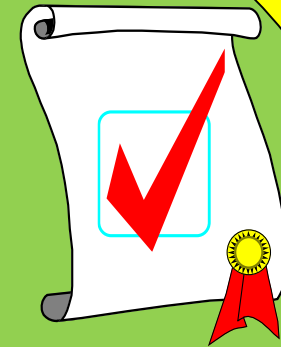
Quality ?



Quality Management



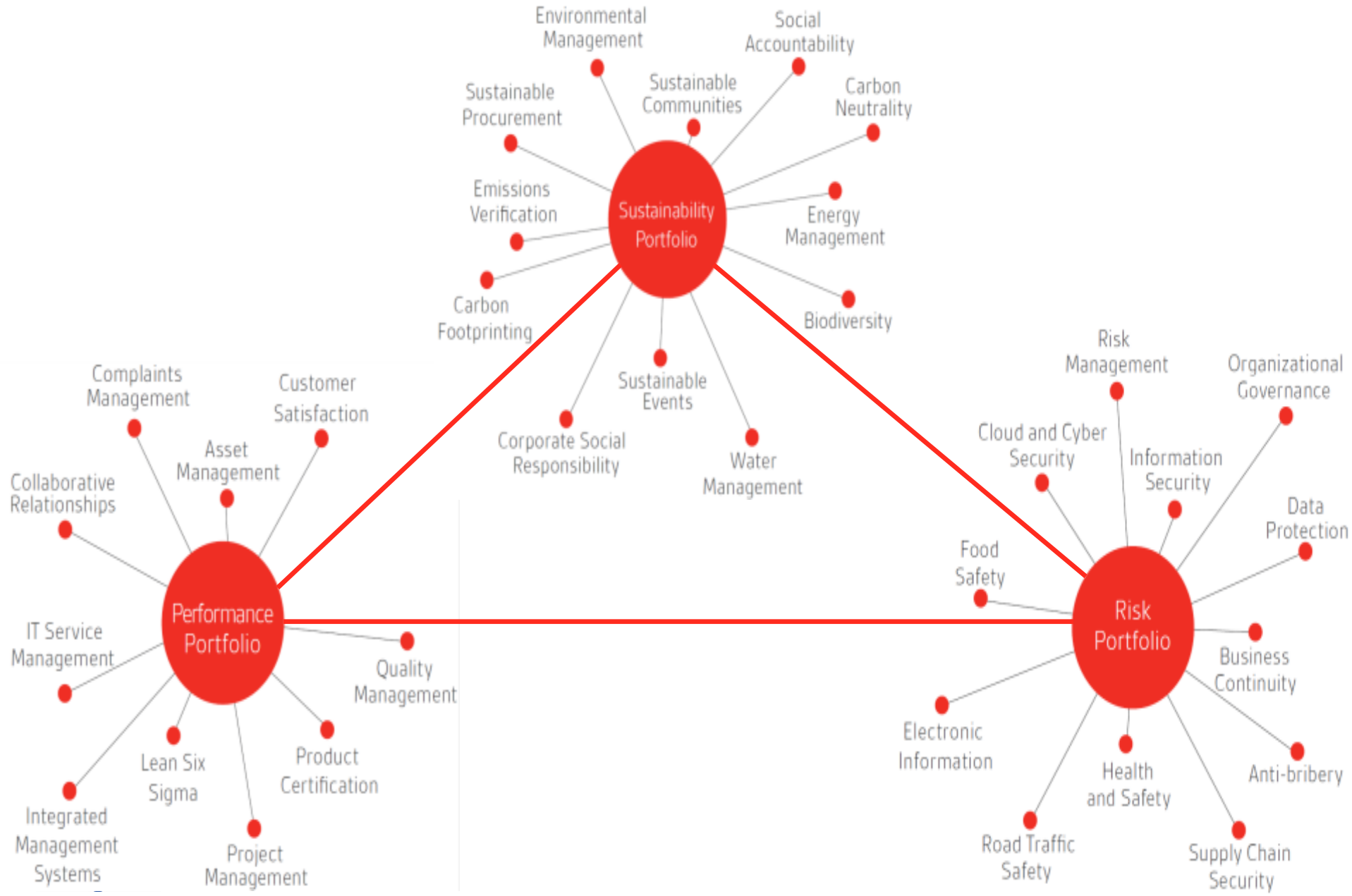
Quality Control



Quality Assurance



comprehensive portfolios ensure your corporate reputation remains secure



Key terms and definitions

Management ?

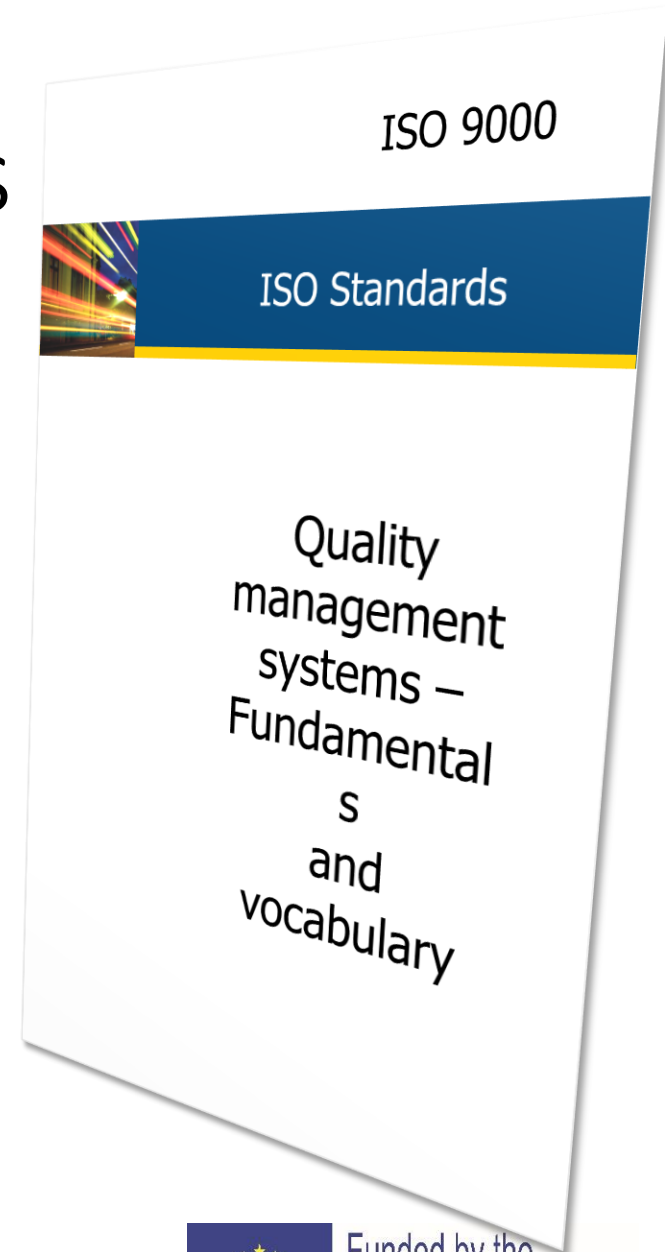
“Coordinated activities to direct and control an organization”

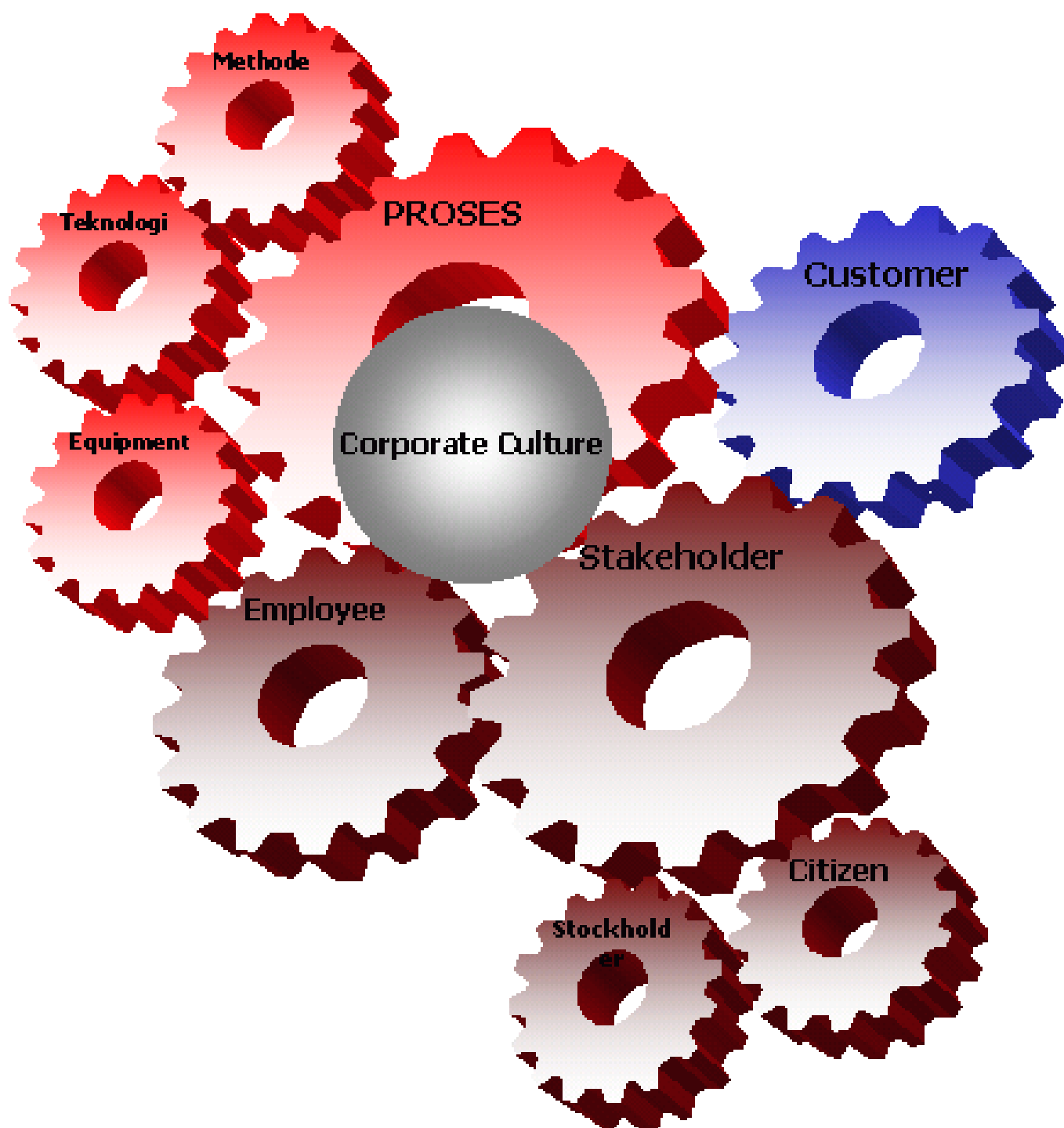
Quality Management ?

“Management with regard to quality”

Quality Management System ?

“Management system with regard to quality”





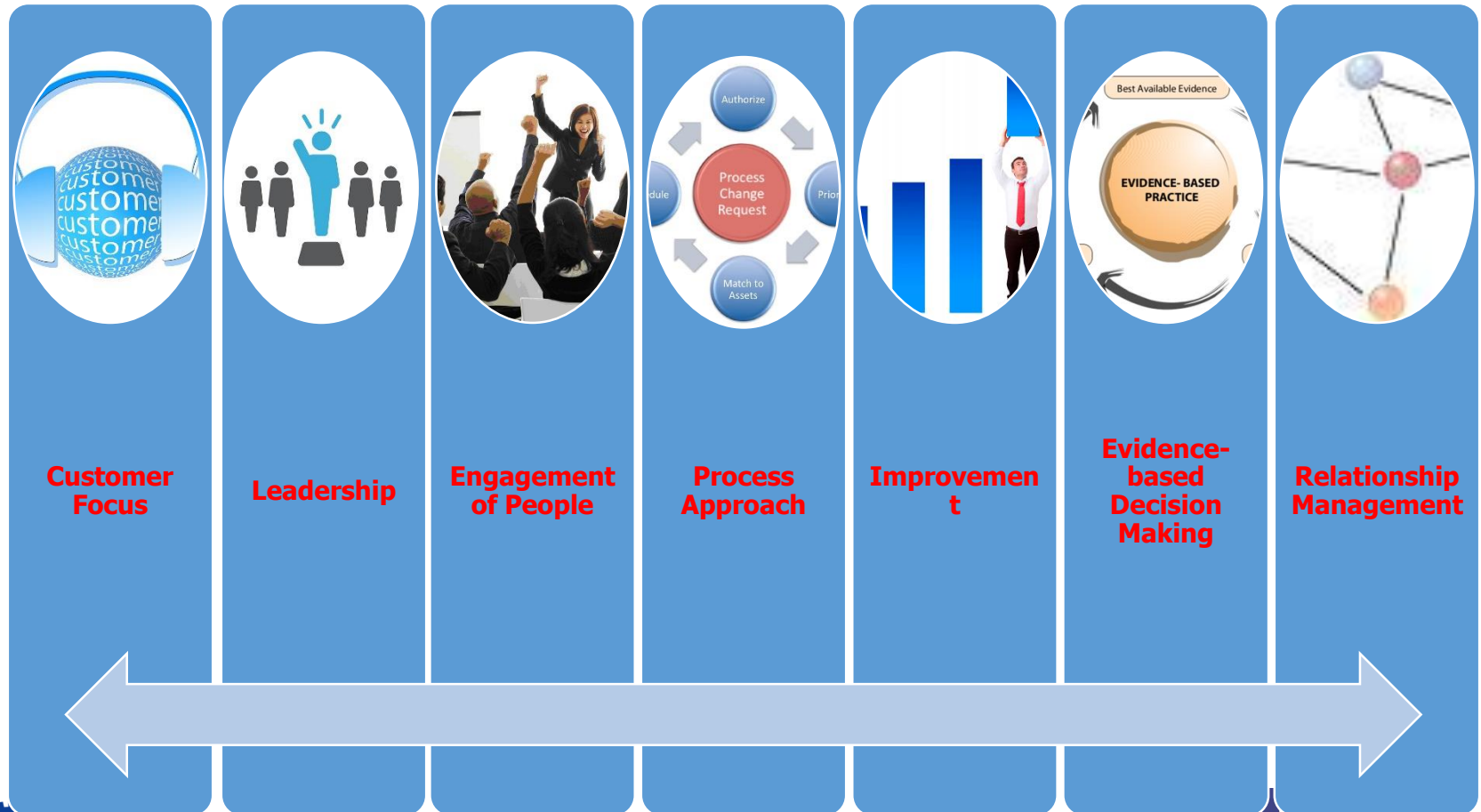
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Management Principle



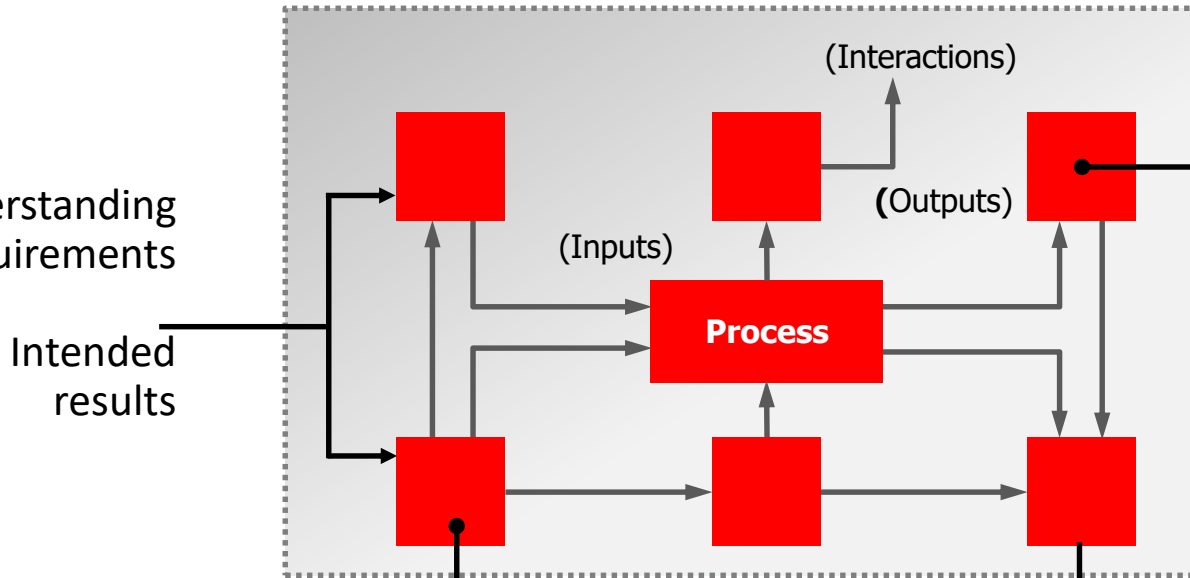
Key concepts : 7 Management Principles



Key concepts : Process Approach

- A Coherent System:

- Understanding requirements



- Activities understood and managed as interrelated processes

Consistent,
predictable results
Meeting requirements
Customer satisfaction

- Processes adding value
- Processes providing effective performance
- Improvements (through evaluation) of data/information
- PDCA (process) methodology





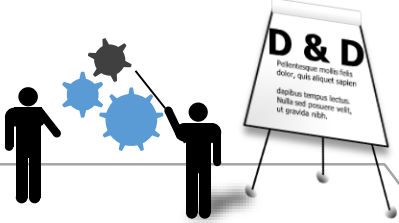
ISO Revisions
Latest update



ISO 9000 Family



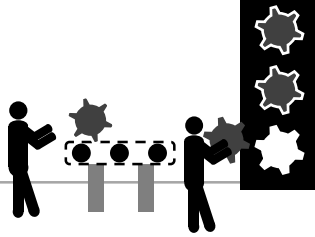
ISO 9001 – History



ISO 9001 – 1987
EN 29001 - 1987

Quality systems

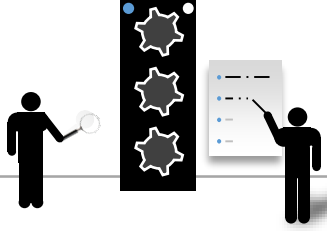
Part 1. Specification for design/development, production, installation and servicing



ISO 9002 – 1987
EN 29002 - 1987

Quality systems

Part 1. Specification for production and installation



ISO 9003 – 1987
EN 29003 - 1987

Quality systems

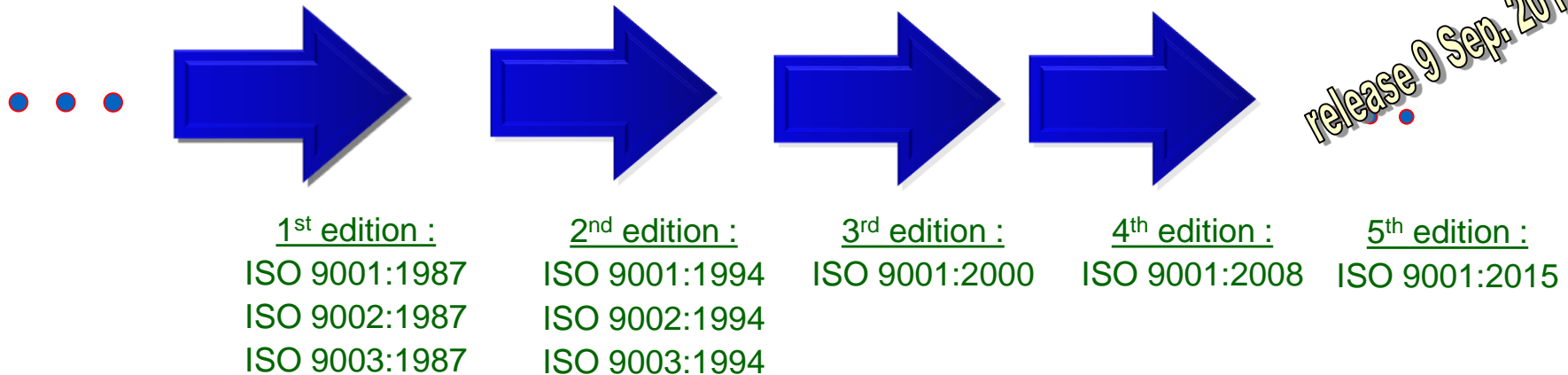
Part 1. Specification for final inspection and test

Evolution of ISO 9000

ISO Revisions
Latest update



ISO 9001



ISO 9001

Standards Publication

Quality Management systems – Requirements

ISO 9000

British Standards

Quality management systems – Fundamentals and vocabulary

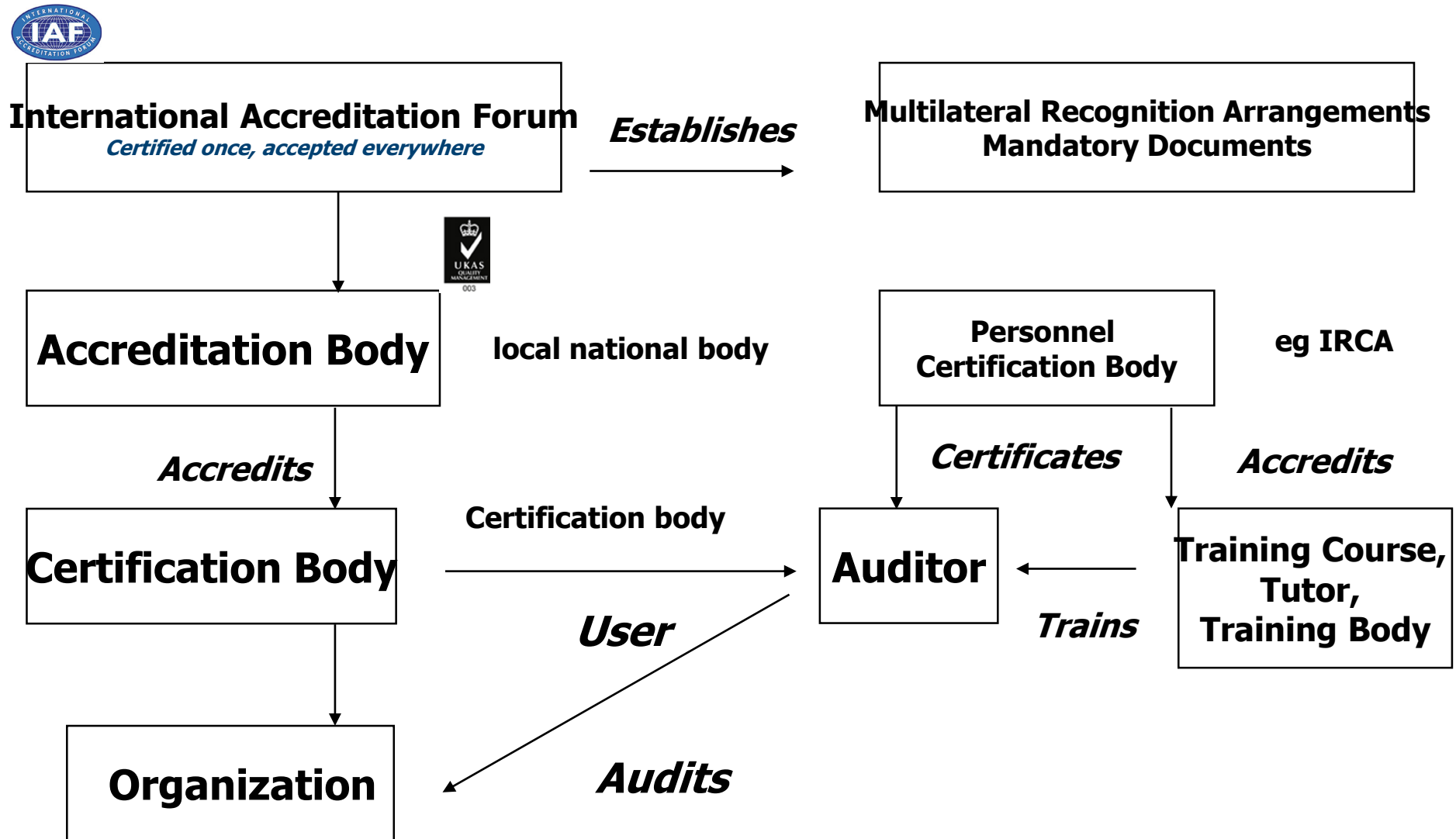
ISO 9004

British Standards

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



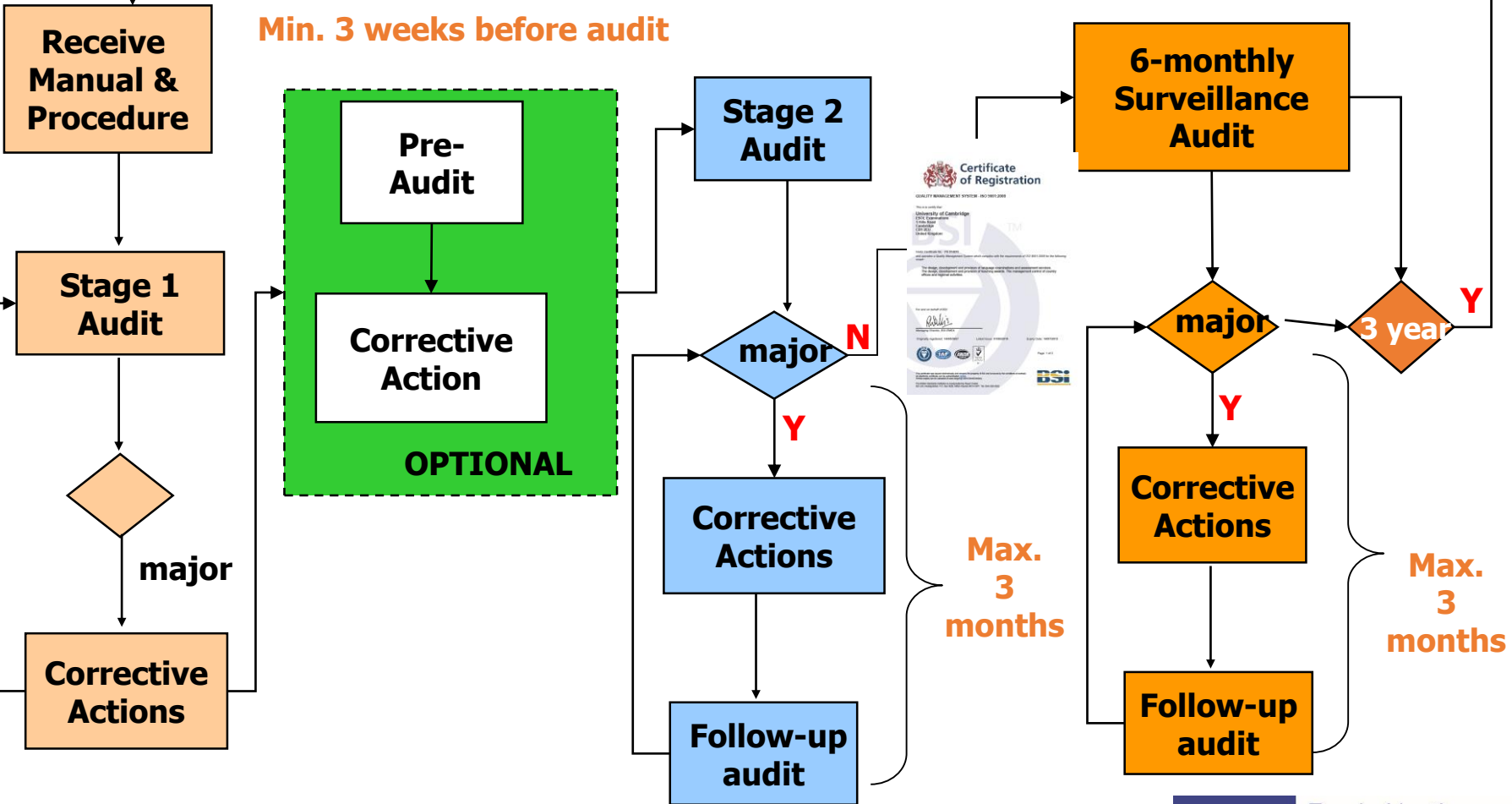
Accredited Certification



CERTIFICATION PROCESS – ISO 9001

Renewal Certification Process

Min. 3 weeks before audit





Clause of ISO 9001:2015

1 Scope

2 Normative references

3 Terms and definitions

4 Context of the organization

5 Leadership

6 Planning

7 Support

8 Operation

9 Performance evaluation

10 Improvement



1) Scope

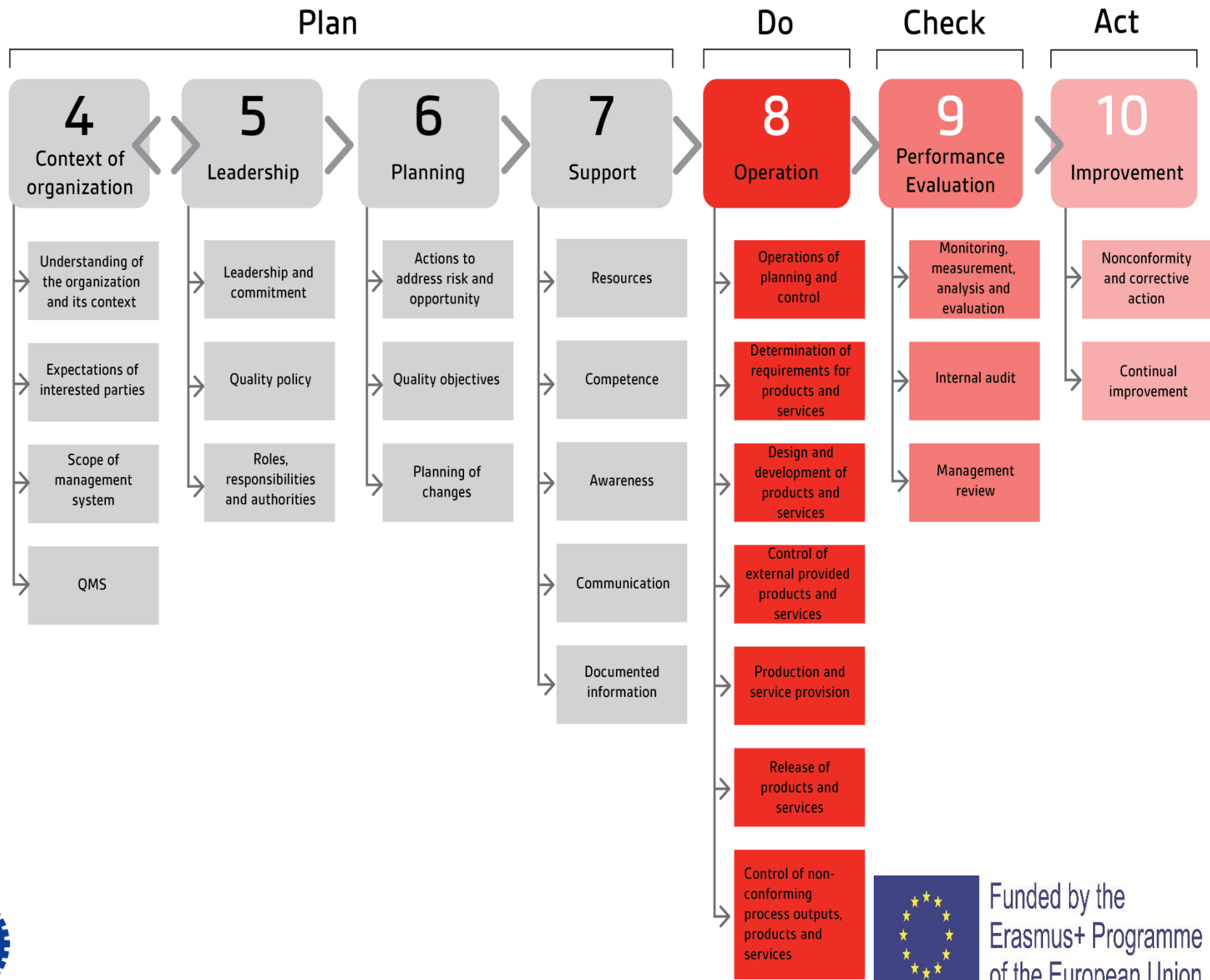
this particular Management System Standard (MSS) is addressed, and this includes the ‘intended result(s)’ of the application of this Standard. These have already in the main been addressed through the promotion of the process approach, namely:

- Consistent provision of products and services that meet customer and applicable statutory and regulatory requirements (legal requirements)
- ‘Intended outcome’ is that which is ‘intended’ as a result of the application of the standard, or process etc.
- ‘Expected outcome’ is that which is ‘expected’ by interested parties

2) Normative references

cites ISO 9000:2015 Quality Management Systems – Fundamentals and vocabulary as indispensable for its application

3) Terms and definitions





Context of Organisation

Clause 4 - ISO 9001:2015



4. Context of the organization

4.1. Understanding the organization and its context

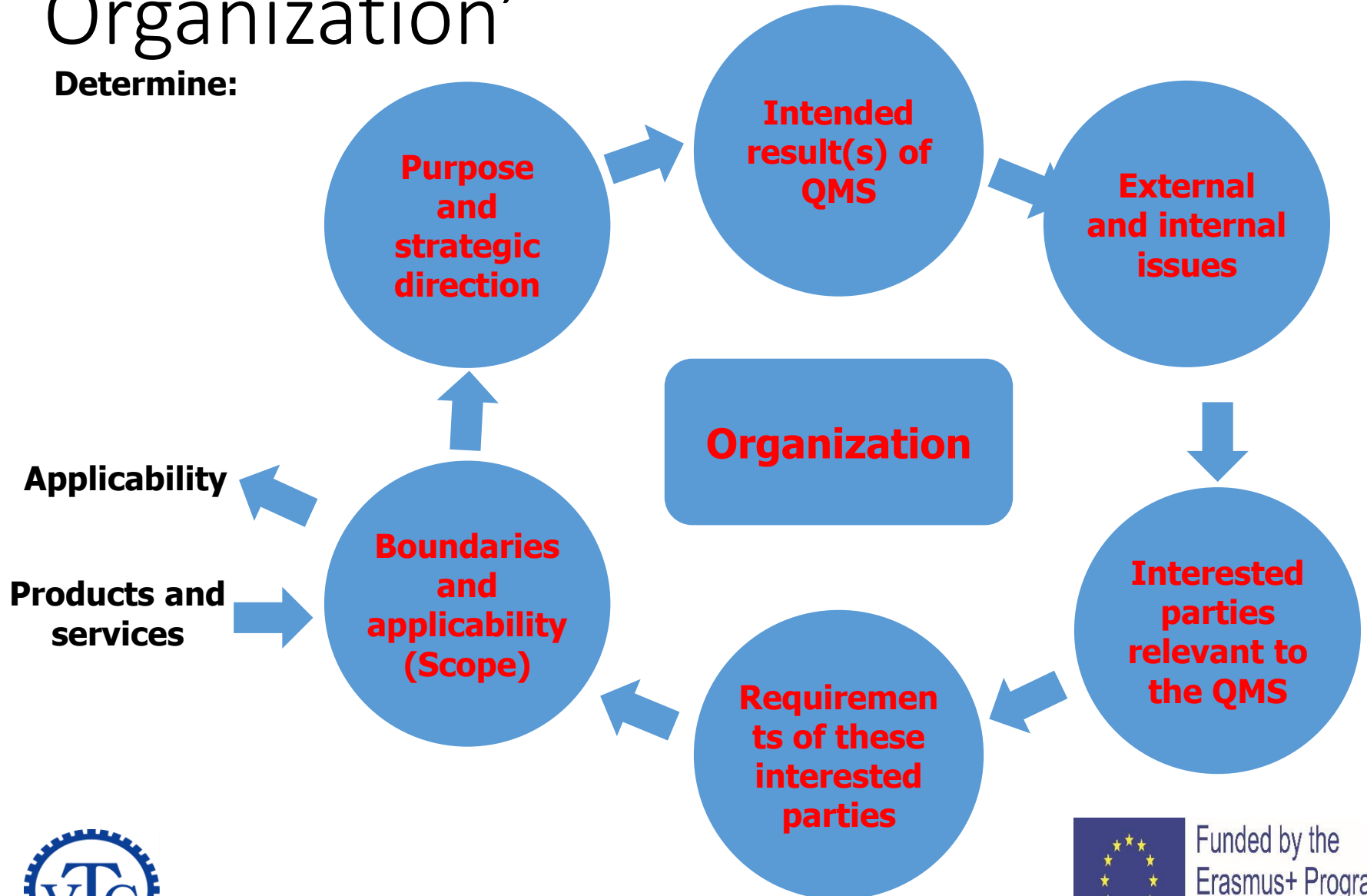
The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.

The organization shall monitor and review information about these external and internal issues.



Understand the 'Context of your Organization'

Determine:



4.2. Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:

- a) the interested parties that are relevant to the quality management system;
- b) the requirements of these interested parties that are relevant to the quality management system.

The organization shall monitor and review information about these interested parties and their relevant requirements.



Clause 4: Context of the Organization (2)

4.2. Understanding the needs and expectations of interested parties

Citizens
Customers
Distributors
Shareholders
Investors
Owners
Insurers
Government
Regulators
Recovery service suppliers

The Organization

Management

- Top Management
- Those accountable for Quality policy and implementation

Those who implement and maintain the QMS

- Those who maintain QMS and risk procedures

Other Staff

Contractors

Competitors

Media

Commentators

Trade groups

Neighbors

Pressure groups

Emergency services

Other response agencies

Transport services

Staff dependents

4.3. Determining the scope of the quality management system

The organization shall determine the boundaries and applicability of the quality management system to establish its scope.

When determining this scope, the organization shall consider:

- a) the external and internal issues referred to in 4.1;
- b) the requirements of relevant interested parties referred to in 4.2;
- c) the products and services of the organization.

The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.

The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.



Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.



Clause 4: Context of the

- 4.3. Determining the scope of the QMS
- 4.4. QMS and its Processes



4.4. Quality management system and its processes

4.4.1. The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall:

- a) determine the inputs required and the outputs expected from these processes;
- b) determine the sequence and interaction of these processes;
- c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;
- d) determine the resources needed for these processes and ensure their availability;

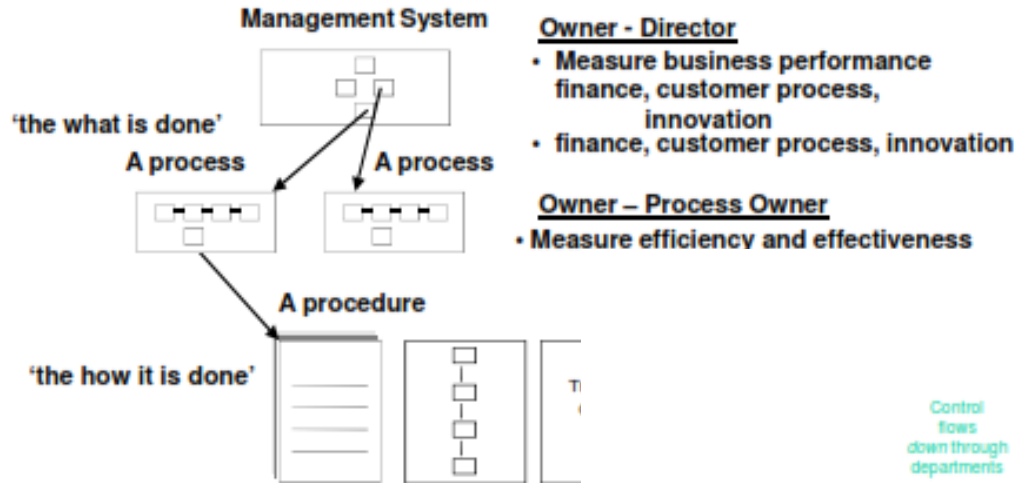
- e) assign the responsibilities and authorities for these processes;
- f) address the risks and opportunities as determined in accordance with the requirements of 6.1;
- g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;
- h) improve the processes and the quality management system.

4.4.2. To the extent necessary, the organization shall:

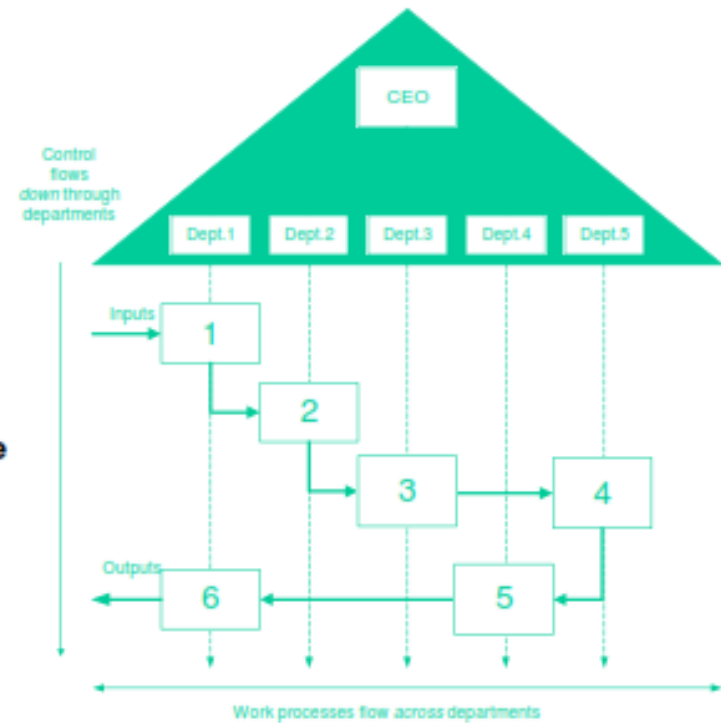
- a) maintain documented information to support the operation of its processes;
- b) retain documented information to have confidence that the processes are being carried out as planned.



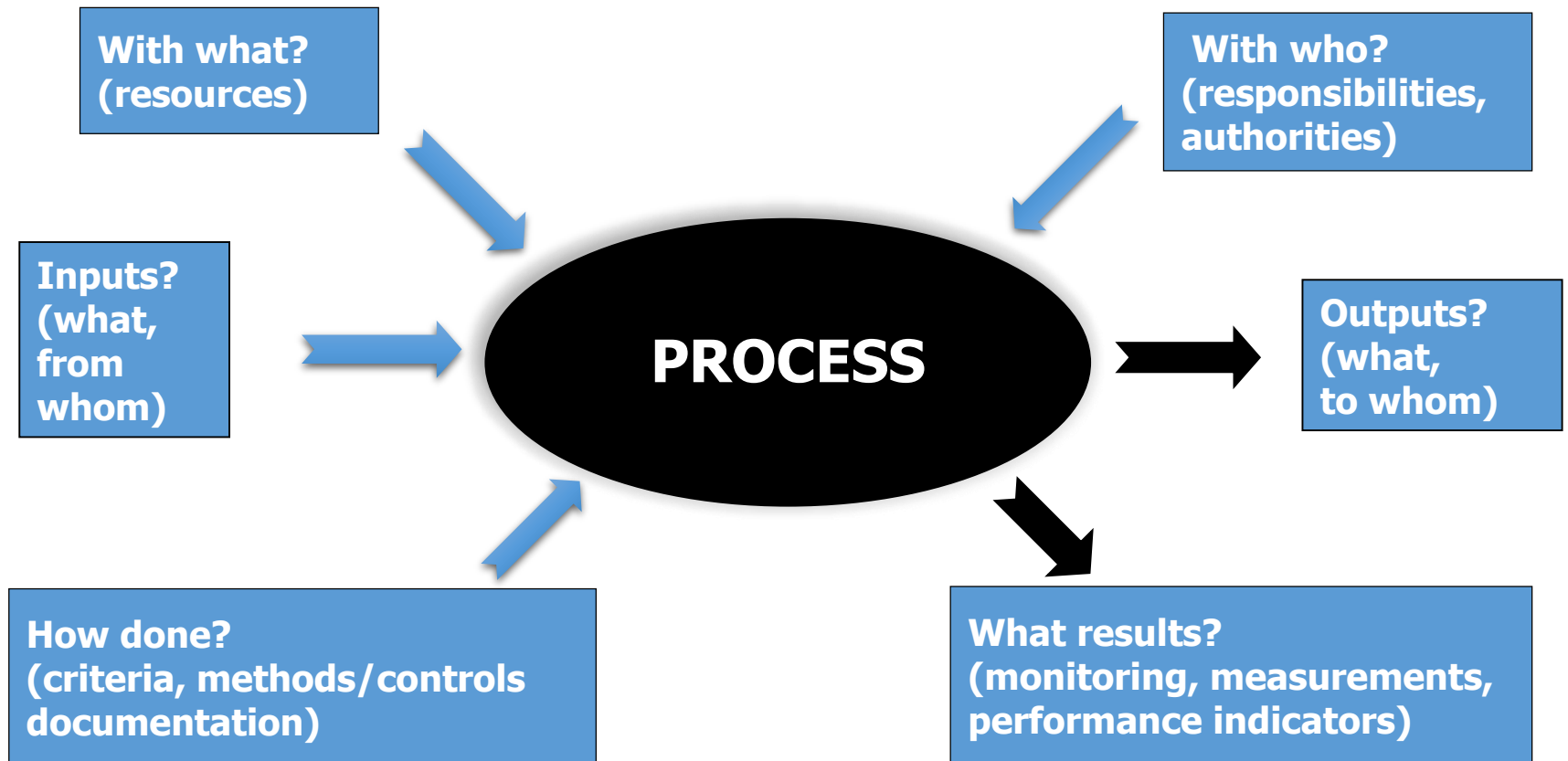
Management system structure multi-level mapping



Functional Hierarchy vs. Product/Service Flow



Key concepts : Process

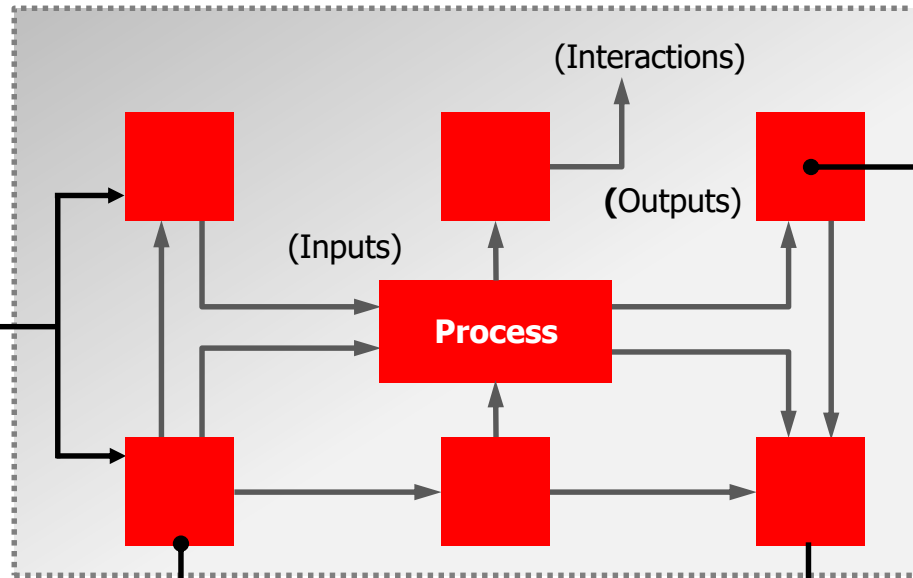


Key concepts Process Approach

- A Coherent System:

- Understanding requirements

Intended results



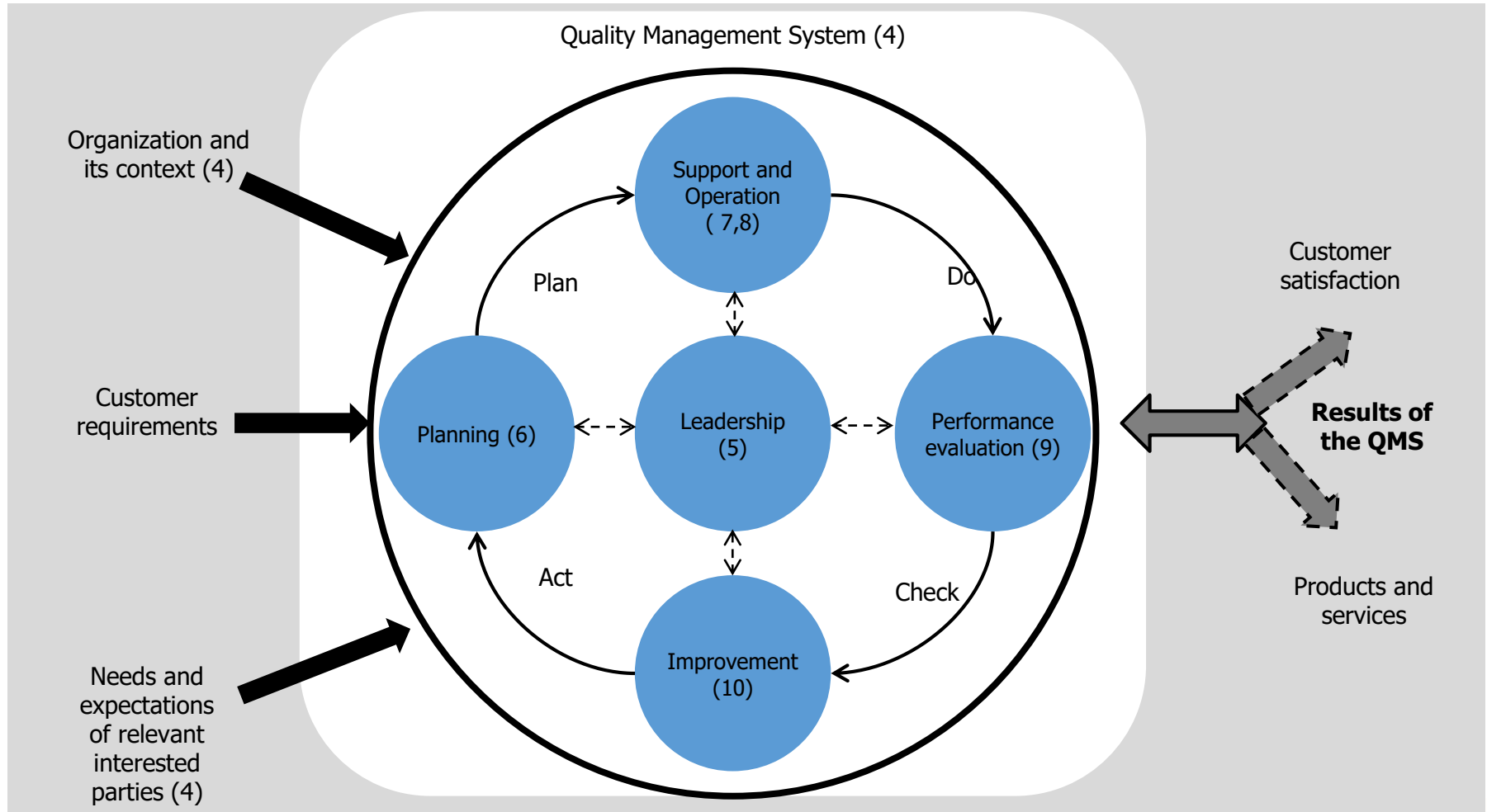
- Activities understood and managed as interrelated processes

Consistent, predictable results
Meeting requirements
Customer satisfaction

- Processes adding value
- Processes providing effective performance
- Improvements (through evaluation) of data/information
- PDCA (process) methodology



Representation of the structure of this International Standard in the PDCA cycle



Workflow/Dependency Diagram

Activity	Dept A	Dept B	Person C
1. Set New Account Criteria	█	█	
2. Accept New Account	█	█	
3. Determine Requirements	█		█
4. Allocate Manpower	█		█
5. Allocate Supplies	█		
6. Sell Lottery tickets		█	
7. Select Winning Ticket		█	█
8. Announce Winning Ticket	█		
9. Accept Credit Information			█
10. Accept Personal References			█
11. Approve/Reject Loan		█	█

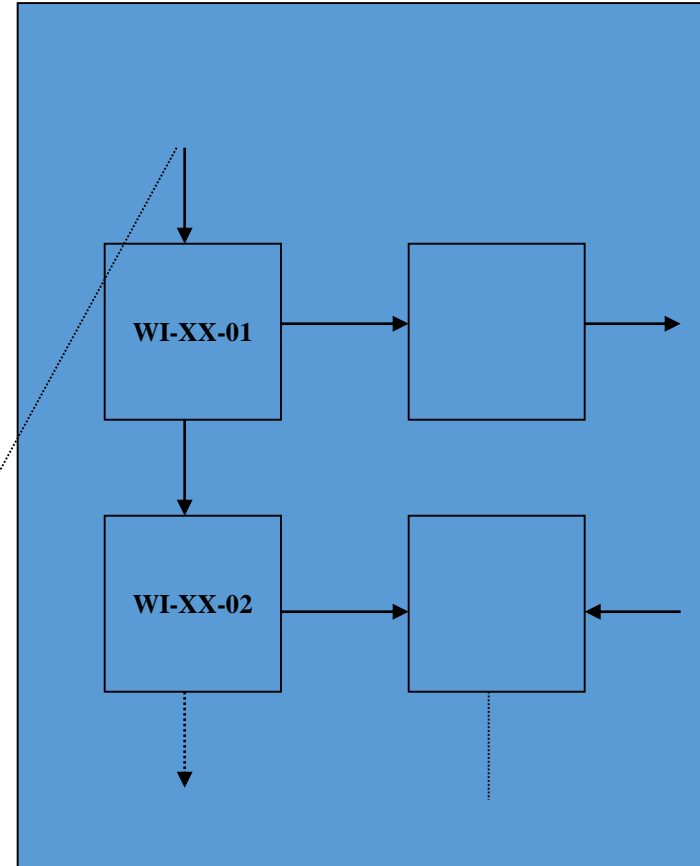
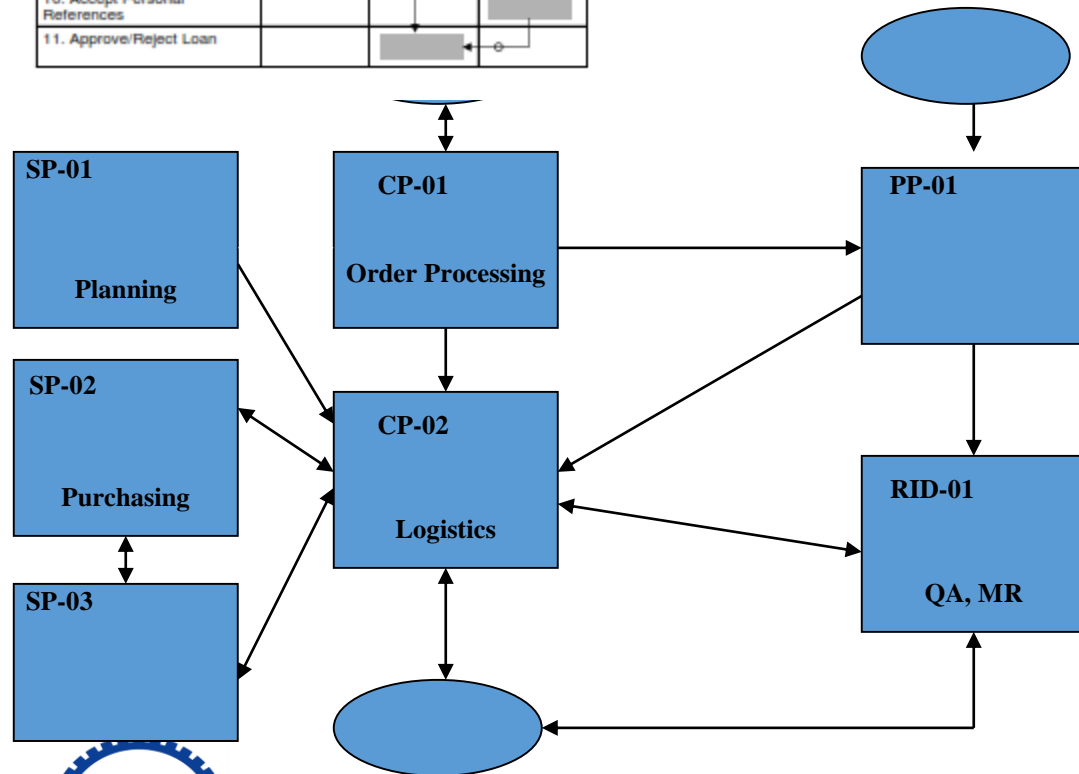
Sequential dependency

Parallel dependency

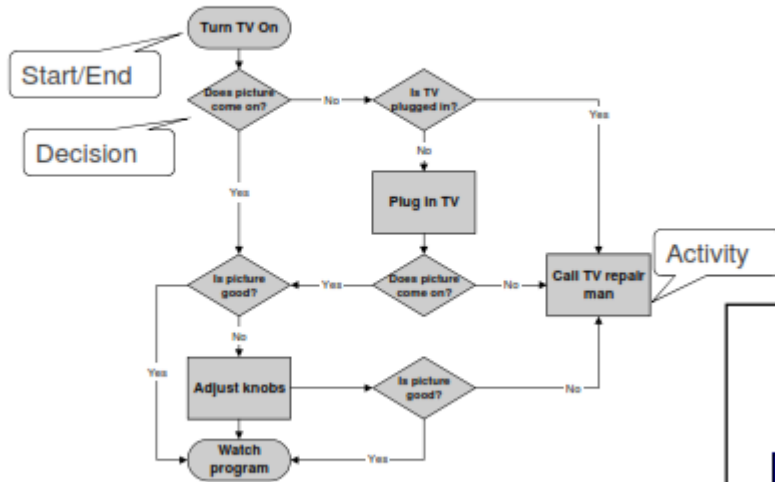
Repetitive dependency

Optional dependency

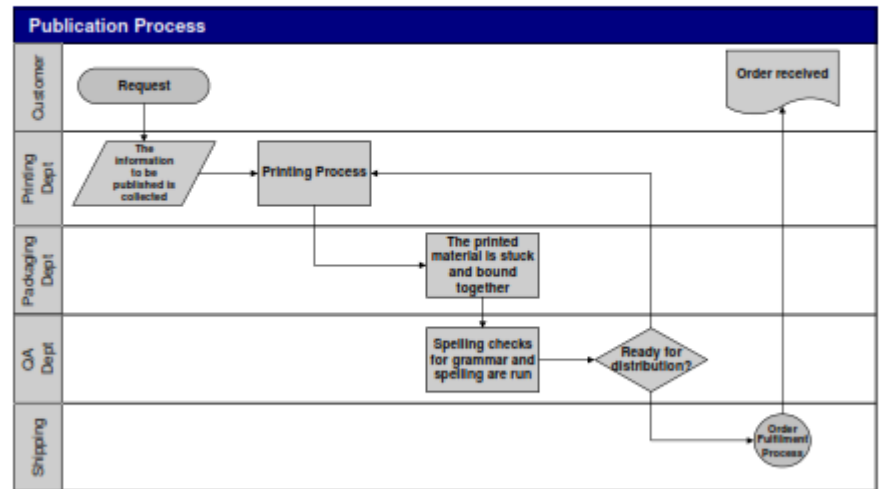
Business Process



Flowcharts

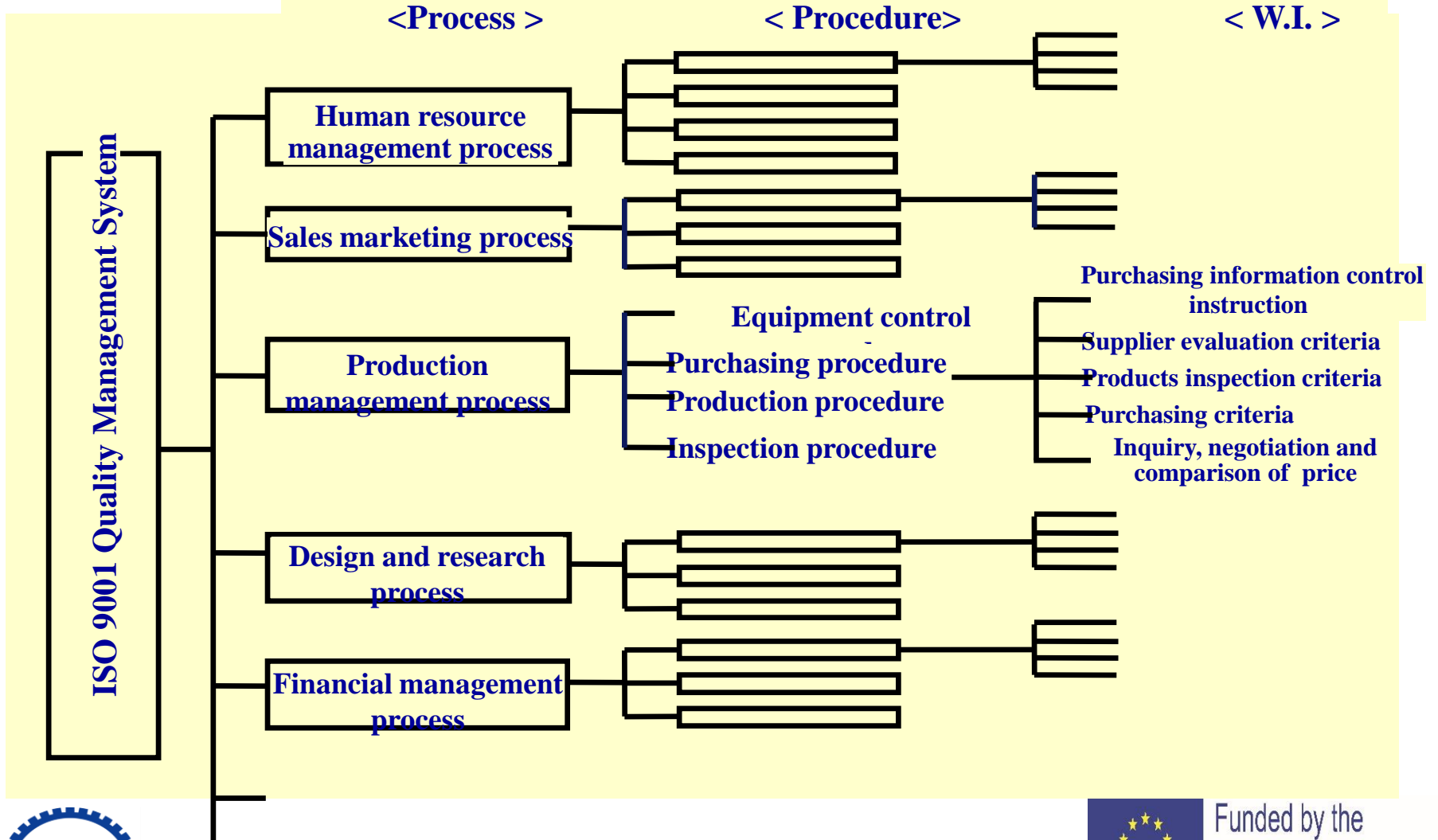


Cross-Functional Flowcharts - 'Swim Lanes'



Structure of quality management system and documentation

Sample 1



MATRIX OF DOCUMENTS - STANDARD

No	Departement/ Process	Name of document	No Doc-	Clause ISO 9001		
				Procedu re



Leadership

Clause 5 - ISO 9001:2015





5. Leadership

5.1. Leadership and commitment

5.2. Quality policy

5.3. Organizational roles, responsibilities and authorities

Leadership and commitment for the quality management system

Customer focus



5. Leadership

5.1. Leadership and commitment

5.5.1. General

Top management shall demonstrate leadership and commitment with respect to the quality management system by:

- a) taking accountability for the effectiveness of the quality management system;
- b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;

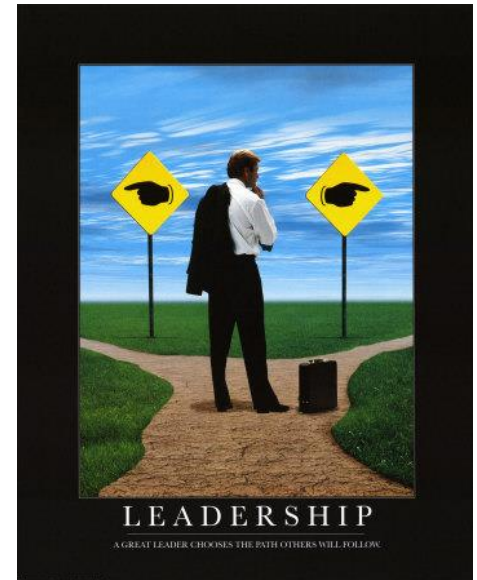
5. LEADERSHIP

- c) ensuring the integration of the quality management system requirements into the organization's business processes;
- d) promoting the use of the process approach and risk-based thinking;
- e) ensuring that the resources needed for the quality management system are available;
- f) communicating the importance of effective quality management and of conforming to the quality management system requirements;



5. LEADERSHIP

- g) ensuring that the quality management system achieves its intended results;
- h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
- i) promoting improvement;
- j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.



5. LEADERSHIP



5.1.2. Customer focus

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

- a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;
- b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
- c) the focus on enhancing customer satisfaction is maintained.

5. LEADERSHIP

5.2. Policy

5.2.1. Establishing the quality policy

Top management shall establish, implement and maintain a quality policy that:

- a) is appropriate to the purpose and context of the organization and supports its strategic direction;
- b) provides a framework for setting quality objectives;
- c) includes a commitment to satisfy applicable requirements;
- d) includes a commitment to continual improvement of the quality management system.

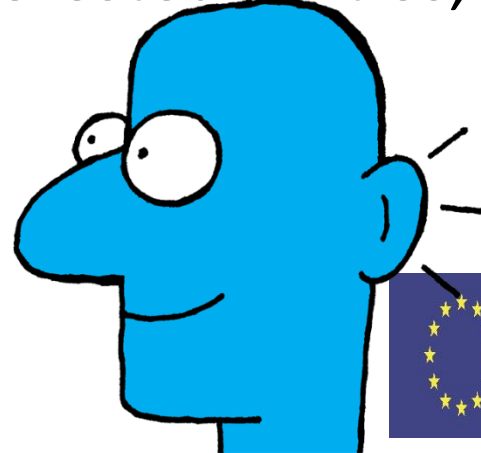
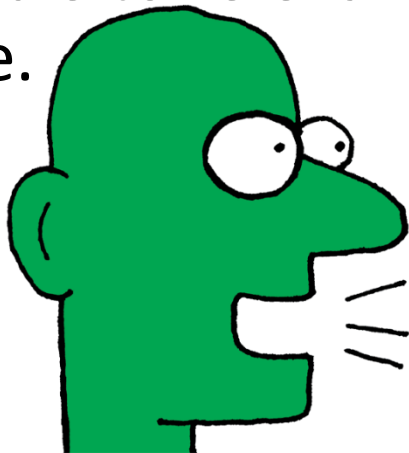


5. LEADERSHIP

5.2.2. Communicating the quality policy

The quality policy shall:

- a) be available and be maintained as documented information;
- b) be communicated, understood and applied within the organization;
- c) be available to relevant interested parties, as appropriate.



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5. LEADERSHIP

5.3. Organizational roles, responsibilities and authorities

Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

Top management shall assign the responsibility and authority for:

- a) ensuring that the quality management system conforms to the requirements of this International Standard;
- b) ensuring that the processes are delivering their intended outputs;

5. LEADERSHIP

- c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;
- d) ensuring the promotion of customer focus throughout the organization;
- e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.



Planning

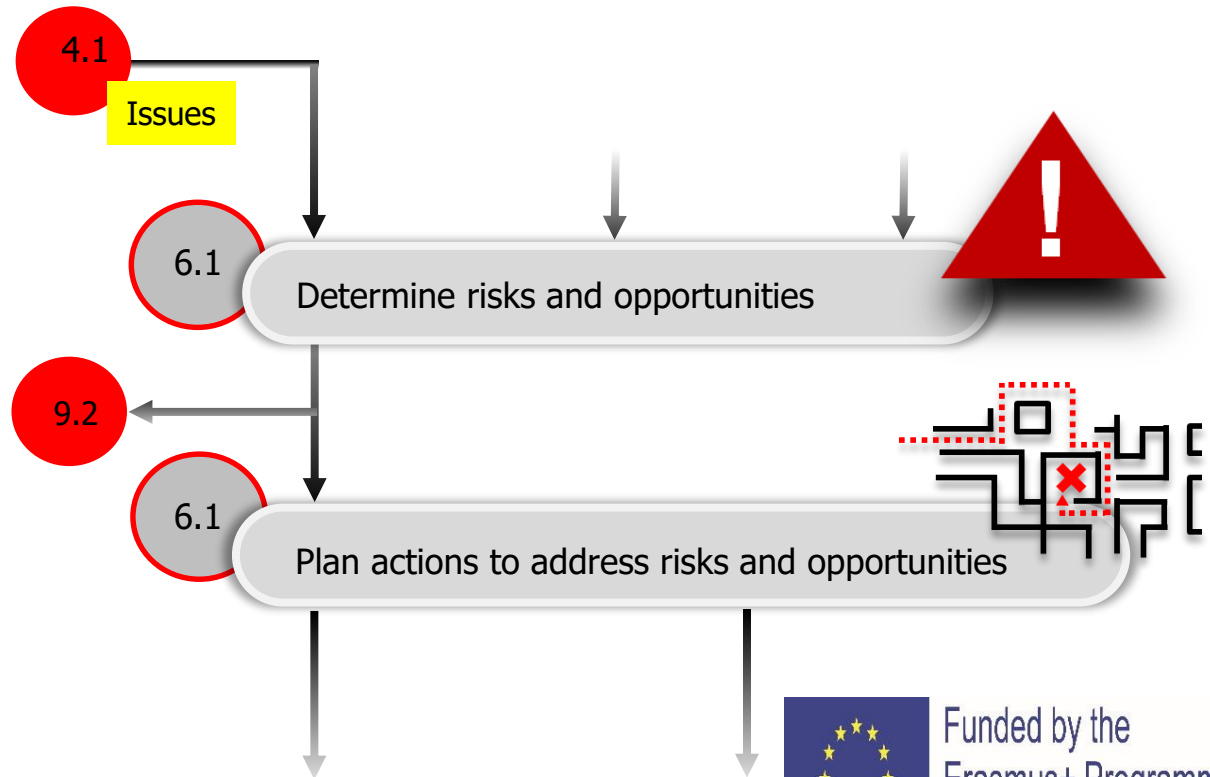
Clause 6 - ISO 9001:2015



Clause 6: Planning for the QM



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



6. PLANNING

6.1. Actions to address risks and opportunities

6.1.1. When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

- a) give assurance that the quality management system can achieve its intended result(s);
- b) enhance desirable effects;
- c) prevent, or reduce, undesired effects;
- d) achieve improvement.

6. PLANNING

6.1.2. The organization shall plan:

a) actions to address these risks and opportunities;

b) how to:

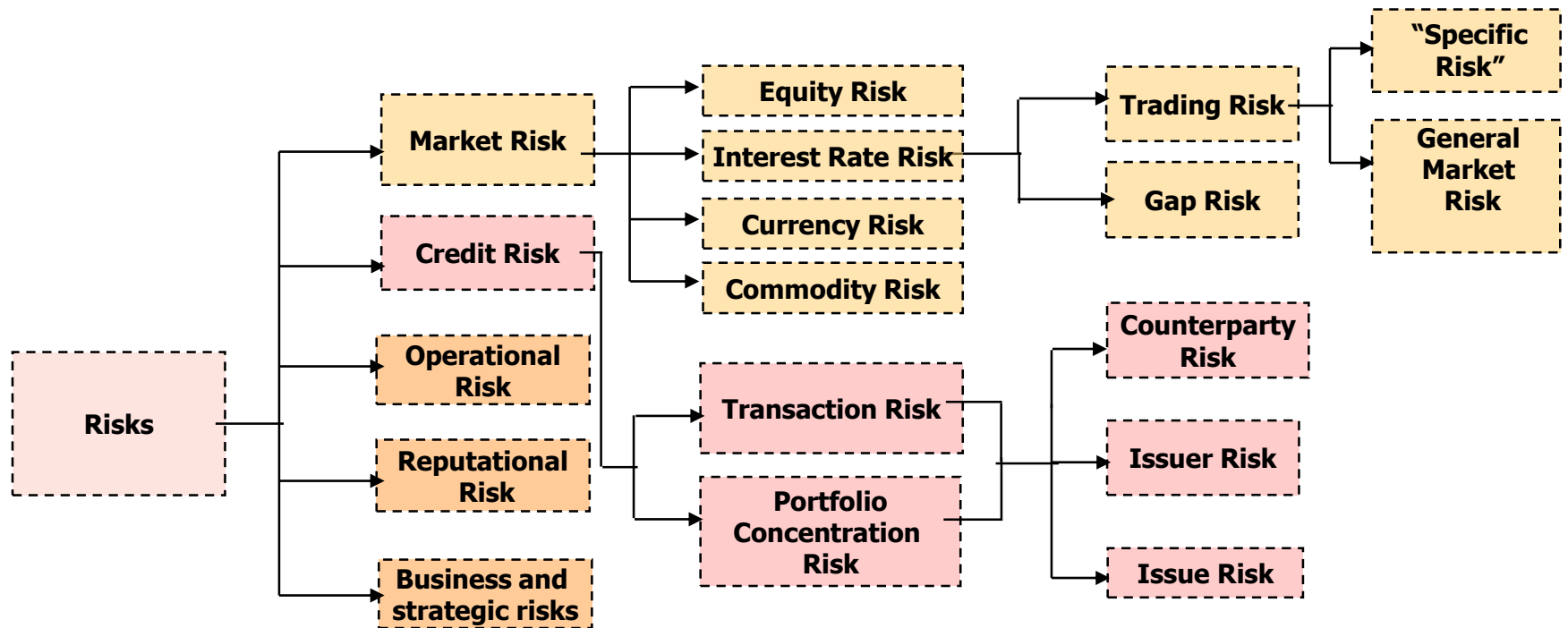
1) integrate and implement the actions into its quality management system processes (see [4.4](#));

2) evaluate the effectiveness of these actions.

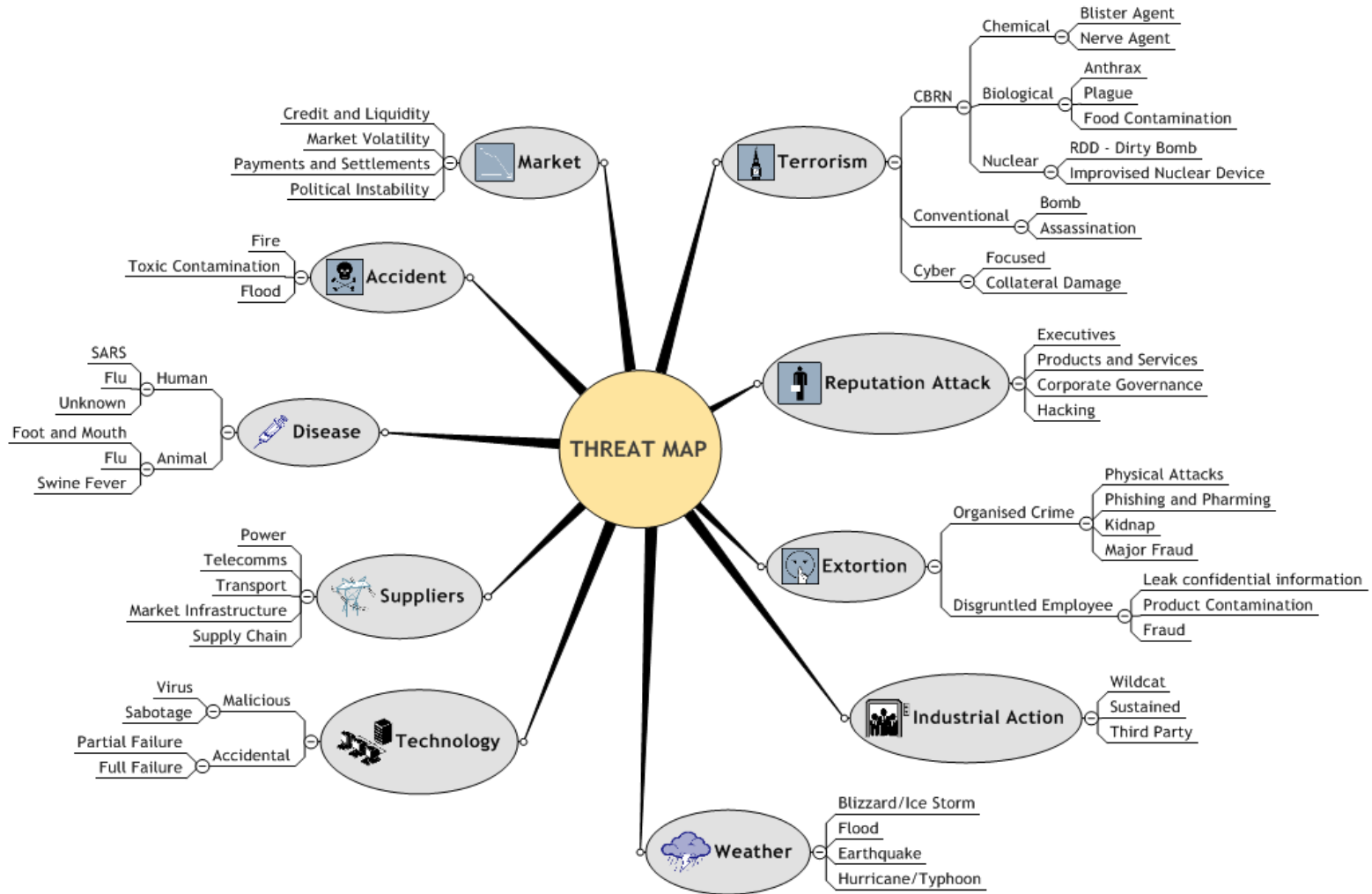
Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.



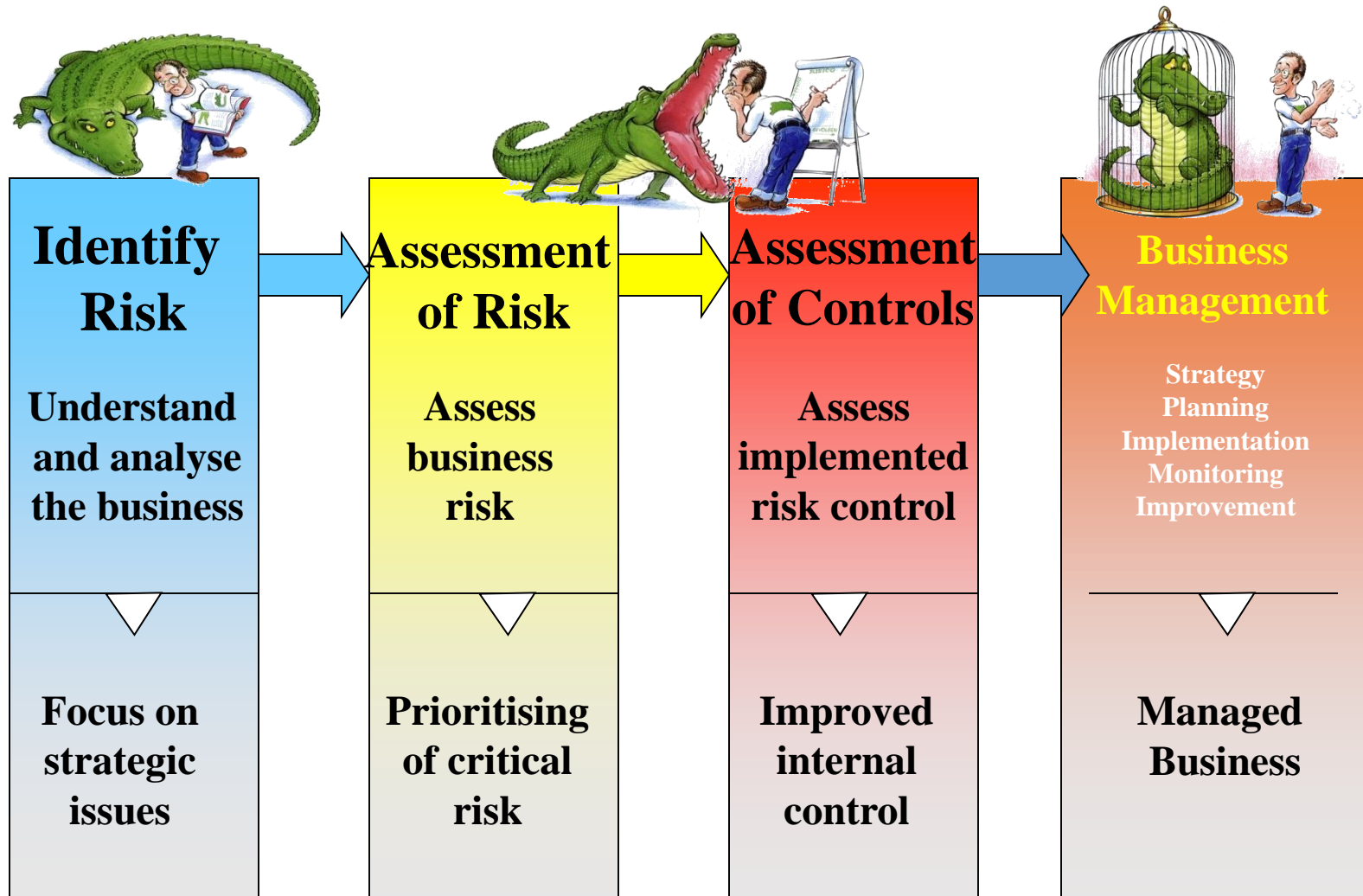
One can “slice and dice” these multiple dimensions of risk



Threat map



Business Risk Assessment Process



Risk context, assessment and treatment

Relevant Issues (from context) red = -ve green = +ve	Risk Identification	Risk Analysis	Risk Evaluation	Risk Treatment	Residual risk
Neighbourhood disruption in street cabling					
New fibre technology available					
Workforce retention					
Share holders: Stock market crash	Economic – Significant effect on profit objectives and liquidity if share price collapses	Impact significant but likelihood unknown (high uncertainty)	Unable to qualify as likelihood unknown	Subscribe to Economic indicators service for horizon scanning economic conditions and global trends	Unknown pending horizon scan. Re-evaluate on report receipt. Tolerate risk. Transfer emergency funds to holding company

SAMPLE - LIST OF RISK ITEMS

Design Engineering Risks	Procurement Risks	HSE Risks	Project Management Risks	Organizational Risks	Terms & Conditions Contract Risks
FEED Docs in ITB Docs are not detail and incomplete additional some percentage for Bill of Quantity calculation may required.	RFQ & RFP documents are not clear such as : Scope of Supply, Data Sheet, Bill of Quantity, Specification, Test Witness, Chemical /Oil/Grease Supply, Spare Part For Commissioning & 2 Years Operations, engineering document should be supply, Fabrication Schedule, Packaging Specification, General Condition, etc are not clear.	HSE Project Plan Implementation. High standard will impact to project cost and schedule	Project purpose and need is not well-defined	Inexperienced staff assigned	Refer To Legal Analysis on Draft of Contract from Legal Department or Refer to Analysis from Contract Engineer
Plot Plan, P&ID, One Line Diagram & Hazardous Area Change	Critical Items and Very tight Schedule that need special attentions	Risk Register and Risk Management Execution are not well done since Engineering Design Stage.	Project scope, schedule, objectives, cost, and deliverables are not clearly defined or understood	Losing critical staff at crucial time of the project	
Inaccurate assumptions on technical issues in planning stage	Increase in material cost due to market forces	Environmental analysis (AMDAL) incomplete	Unreasonably high expectations from stakeholders	Insufficient time to plan	
Surveys incomplete	Political Situation is unstable, War, Riot, Embargo	Environmental regulation or local regulation is not Clear or Changed	Vendor or contractor delays	Unanticipated project manager workload	
Changes to Capacity, Materials or Specification	Economic is Unstable, Depression, Inflation, Currency Rate is unstable, Oil Price is unstable or increase.	Construction Waste Treatment Availability	Estimating and/or scheduling errors	Internal "red tape" causes delay getting approvals, decisions	
SIL, HAZID & HAZOP Study have potential to add more materials, instrument & equipments.	Disaster, Climate, High/Low Tide and Other Nature Conditions.	Availability of project data and mapping at the beginning of the environmental study is insufficient	Unplanned work that must be accommodated	Functional units not available, overloaded	
Basic Engineering Design Data & Detail Engineering Design Data are wrong.	Massive Development or Massive Construction in some country or Province that requires a lot of Cosntruction materials	New information after Environmental Document is completed may require re-evaluation or a new document (i.e. utility relocation beyond document coverage)	Lack of coordination/communication	Lack of specialized staff or Skilled MP resources are limited.	
P&ID and Plot Plan Review Meeting are not so carefully done so it does not find a crucial problem	Loading & Unloading and Transportation Plan which need special attentions	New alternatives required to avoid, mitigate or minimize impact	Underestimated support resources or overly optimistic delivery schedule	Overlapping of one or more projects	
Don't Consider Operability, Maintainability & Constructability	Import & Export Regulations are changed	Design changes require additional Environmental analysis	Inaccurate contract time estimates		
Approval Procedure for Engineering Products is very long	Procurement Planning & Control are wrong	Unanticipated Noise, Air Quality and Waste impacts	Unresolved project conflicts not escalated in a timely manner		
		Project causes an unanticipated barrier to wildlife	Unanticipated escalation in right of way values or construction cost		

Broadleaf

Bow-Tie Risk Treatment Tool

2. Causes

1.
2.
3.
4.
5.
6.
7.
8.
9.
10.

1. Risk

3. Impacts

1.
2.
3.
4.
5.
6.
7.
8.
9.
10.

Existing Likelihood affecting controls	Control Owner
1.	
2.	
3.	
4.	
5.	
6.	

Tasks (future controls)	Task Owner	Due Date
1.		
2.		
3.		

Existing Consequence affecting Controls	Control Owner
1.	
2.	
3.	
4.	
5.	
6.	

Tasks (future controls)	Task Owner	Due Date
1.		
2.		
3.		

6. Risk Control Effectiveness

--

7. Consequence factor

--

8. Likelihood factor

--

9. RISK RATING

--

10. Potential exposure

--

11. Risk Owner

--

Attachment 1 :Impact Assessment

Consequence	Cost (AUD)	Operations	Incident or Accident	Environmental	Political	Commercial
1 Insignificant	<\$10,000	Minimal impact to progress.	First aid treatment.	Minimal impact or disruption.	Minimal interest.	Minimal impact.
2 Minor	\$10-100,000	Limited disruption. Progress is slowed or temporarily stopped.	Medical treatment required. Lost time injury.	Some disruption or minor impact to community infrastructure.	Minor interest. Questions raised in local forums.	Client inconvenienced. Claims from businesses for damages.
3 Severe	\$100-500,000	Significant impact. Progress is reduced or stopped for up to two weeks.	Serious injury. Extensive medical treatment required.	Impact on public and disruptions to community infrastructure for up to two weeks.	Community concern. Media attention.	Significant claims. Client forced to impose penalties.
4 Major	>\$500,000 – 2,000,000	Disruption or impact that threatens to undermine the success of project or venture.	Serious injury or loss of life.	Extensive disruption to community infrastructure. Potential for further follow-on risks to community.	Extensive media coverage. Lack of confidence in project management and Company credibility threatened.	Loss of substantial profit and business opportunity. Threats of legal action.
5 Catastrophic	Very High. Extensive losses to project and Company 2M and over	Extensive disruption and damage that impacts on Company business remote from project or venture.	Loss of more than one life and extensive injuries.	Broad impact on community health and environment.	Public Outrage. Extensive investigation and management changes demanded.	Loss of substantial part of business. Definite legal action to defend Company.



Attachment 2: Risk Likelihood (Probability)

Likelihood	Description	Probability of Occurrence during Project Life
Almost certain	The event is expected to occur in most circumstances	>90%
Likely	The event will probably occur in most circumstances	50% - 90%
Moderate	The event should occur at some time	15% - 49%
Unlikely	The event could occur at some time	5% - 14%
Rare	The event may occur but only in exceptional circumstances	<5%

Attachment 3: Risk Level Matrix (Assessed Risk)

RISK LEVEL MATRIX					
Likelihood	Consequences				
	5 Catastrophic	4 Major	3 Severe	2 Minor	1 Insignificant
A: Almost Certain	1 - Extreme	2 - Extreme	3 - Extreme	High	High
B: Likely	2 - Extreme	3 - Extreme	High	High	Moderate
C: Moderate	3 - Extreme	3 - Extreme	High	Moderate	Low
D: Unlikely	3 - Extreme	High	Moderate	Low	Low
E: Rare	High	High	Moderate	Low	Low



The FMEA Form

**Process/Product
Failure Modes and Effects Analysis Form
(FMEA)**

Prepared by: _____	Page ____ of ____
FMEA Date (Orig) _____ (Rev) _____	

Prepared by: _____	Page ____ of ____
FMEA Date (Orig) _____ (Rev) _____	

Process Step / Input	Potential Failure Mode	Potential Failure Effects	S E V E R I T Y	Potential Causes	O C C U R R E N C E	Current Controls	D E T E C T I O N	R P N	Actions Recommended	R e s p.	Actions Taken	S E V E R I T Y	O C C U R R E N C E	D E T E C T I O N	R P N
What is the process step and input under investigation?	In what ways does the Key Input go wrong?	What is the impact on the Key Output Variables (Customer Requirements)?		What causes the Key Input to go wrong?		What are the existing controls and procedures (inspection and test) that prevent either the cause or the Failure Mode?			What are the actions for reducing the occurrence of the cause, or improving detection?		What are the completed actions taken with the recalculated RPN?				
								0							0
								0							0
								0							0
								0							0
								0							0
								0							0

Identify failure modes and their effects

Identify causes of the failure modes and controls

Prioritize

Determine and assess actions



6. PLANNING

6.2. Quality objectives and planning to achieve them

6.2.1. The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system.

The quality objectives shall:

- a) be consistent with the quality policy;
- b) be measurable;
- c) take into account applicable requirements;



6. PLANNING

- d) be relevant to conformity of products and services and to enhancement of customer satisfaction;
- e) be monitored;
- f) be communicated;
- g) be updated as appropriate.

The organization shall maintain documented information on the quality objectives.



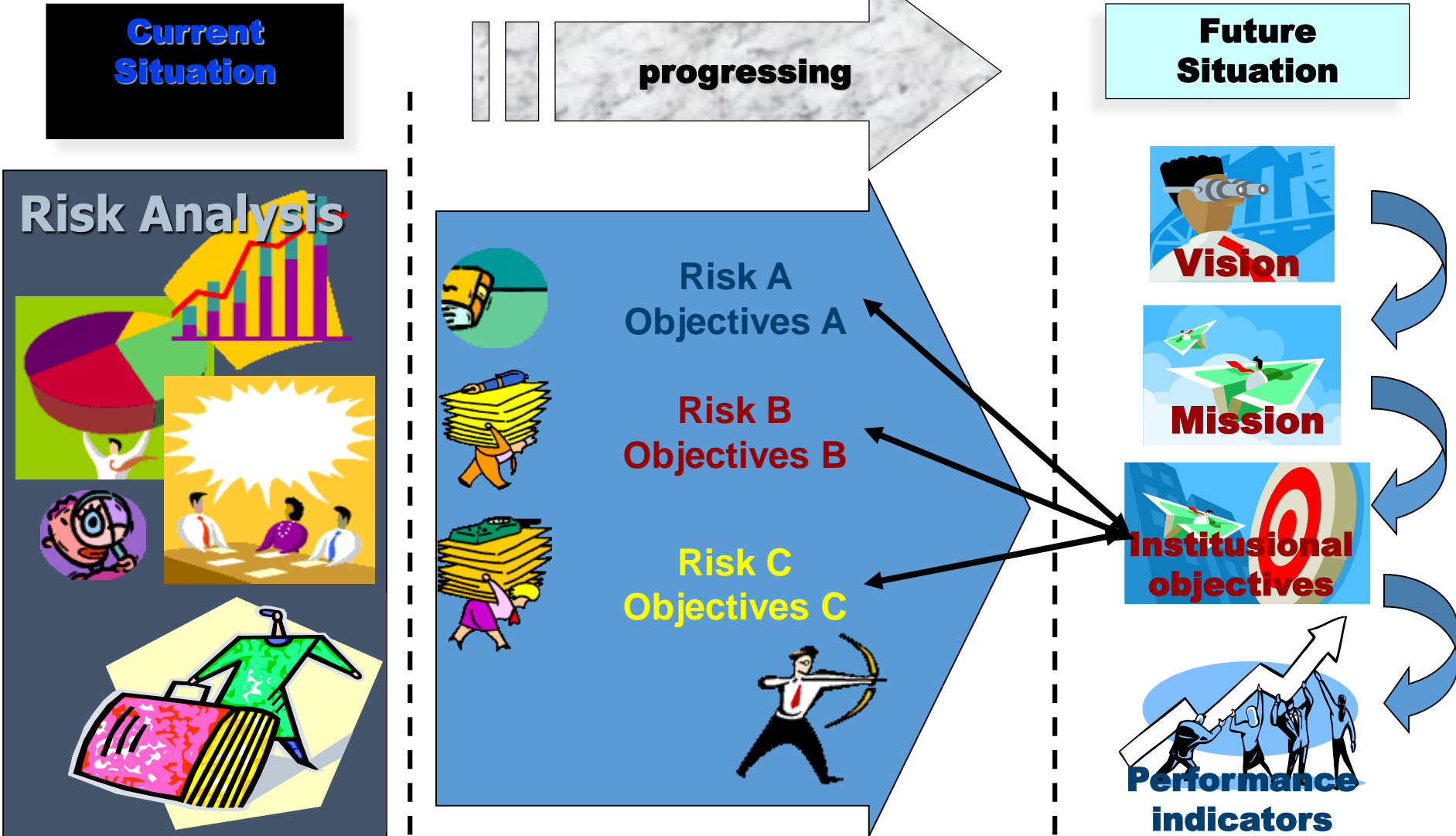
6. PLANNING

6.2.2. When planning how to achieve its quality objectives, the organization shall determine:

- what will be done;
- what resources will be required;
- who will be responsible;
- when it will be completed;
- how the results will be evaluated.



Objective and Effort of the whole institution



6. PLANNING

6.3. Planning of changes

When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4).

The organization shall consider:

- a) the purpose of the changes and their potential consequences;
- b) the integrity of the quality management system;
- c) the availability of resources;
- d) the allocation or reallocation of responsibilities and authorities.





6.3. 'Planning of Changes'

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





Resources

Clause 7 - ISO 9001:2015



Clause 7: Support



- **7.1 – Resources**
 - Determine and provide the necessary resources including people, infrastructure, operational processes, and knowledge
- **7.2 – Competence**
 - Identify and maintain competence
- **7.3 – Awareness**
 - Make objectives known, and ensure awareness of QMS
- **7.4 – Communication**
 - What, when, how, who, and to whom
- **7.5 – Documented information**
 - Reflects variety of sources and need to back up information

7. Support

7.1. Resources

7.1.1. General

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

The organization shall consider:

- a) the capabilities of, and constraints on, existing internal resources;
- b) what needs to be obtained from external providers.



7. SUPPORT

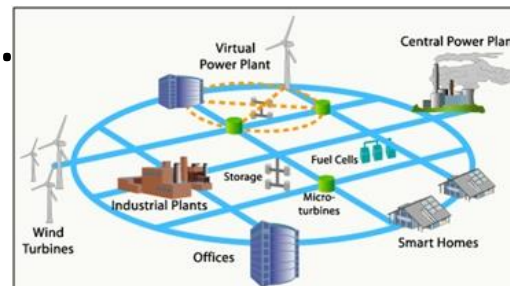
7.1.2. People

The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.



7.1.3. Infrastructure

The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.



Funded by the
Erasmus+ Programme
of the European Union

7. SUPPORT

7.1.4. Environment for the operation of processes

The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.



7. SUPPORT

7.1.5. Monitoring and measuring resources

7.1.5.1. General

The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

The organization shall ensure that the resources provided:

a) are suitable for the specific type of monitoring and measurement activities being undertaken;



7. SUPPORT

b) are maintained to ensure their continuing fitness for their purpose.

The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.



7. SUPPORT

7.1.5.2. Measurement traceability

When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;



7. SUPPORT

b) identified in order to determine their status;

c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.

-



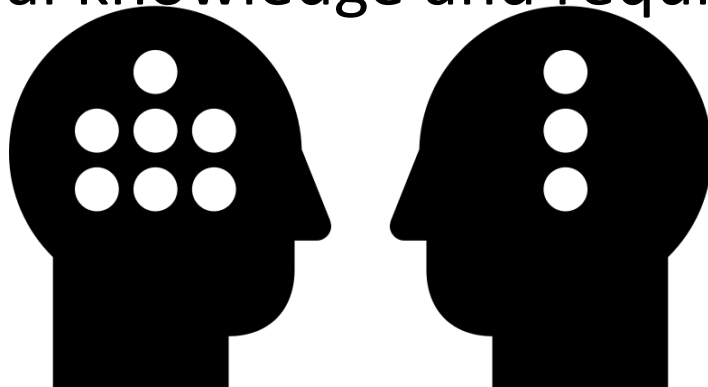
7. SUPPORT

7.1.6. Organizational knowledge

The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge shall be maintained and be made available to the extent necessary.

When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.



7.1.6. Organisational Knowledge

- Defined as ‘available collection of information (meaningful data – facts about an object) being a justified belief and having a high certainty to be true’.
- This can include information such as intellectual property and lessons learned.
- The requirement here is to determine, maintain and make available (extent necessary) the knowledge necessary for the operation of its processes, AND to achieve conformity of products and services.
- Knowledge necessary to address changing needs and trends will also need considering, and how to acquire or access any additional knowledge necessary.
- Sources: (Internal) learning from failure/success, capturing knowledge of experts, etc. (External) academia, standards, conferences, customers, external providers etc.



7. SUPPORT

7.2. Competence

The organization shall:

- a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;
- b) ensure that these persons are competent on the basis of appropriate education, training, or experience;
- c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
- d) retain appropriate documented information as evidence of competence.



7. SUPPORT

7.3. Awareness

The organization shall ensure that persons doing work under the organization's control are aware of:

- a) the quality policy;
- b) relevant quality objectives;
- c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
- d) the implications of not conforming with the quality management system requirements.



7. SUPPORT

7.4. Communication

The organization shall determine the internal and external communications relevant to the quality management system, including:

- a) on what it will communicate;
- b) when to communicate;
- c) with whom to communicate;
- d) how to communicate;
- e) who communicates.



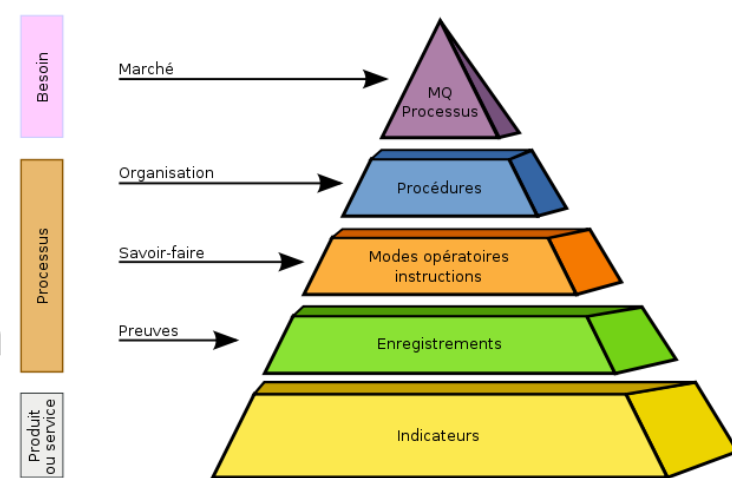
7. SUPPORT

7.5. Documented information

7.5.1. General

The organization's quality management system shall include:

- a) documented information required by this International Standard;
- b) documented information determined by the organization as being necessary for the effectiveness of the quality management system.



7. SUPPORT

7.5.2. Creating and updating

When creating and updating documented information, the organization shall ensure appropriate:

- a) identification and description (e.g. a title, date, author, or reference number);
- b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);
- c) review and approval for suitability and adequacy.

7. SUPPORT

7.5.3. Control of documented information

7.5.3.1. Documented information required by the quality management system and by this International Standard shall be controlled to ensure:

- a) it is available and suitable for use, where and when it is needed;
- b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

7. SUPPORT

7.5.3.2. For the control of documented information, the organization shall address the following activities, as applicable:

- a) distribution, access, retrieval and use;
- b) storage and preservation, including preservation of legibility;
- c) control of changes (e.g. version control);
- d) retention and disposition.

7. SUPPORT

Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled.

Documented information retained as evidence of conformity shall be protected from unintended alterations.





Operational

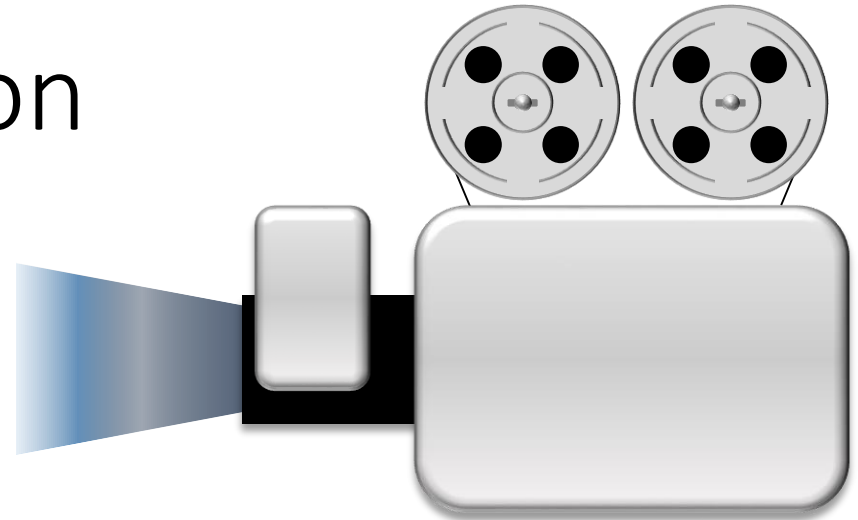
Clause 8 - ISO 9001:2015

Clause 8: Operation

Operational planning and control

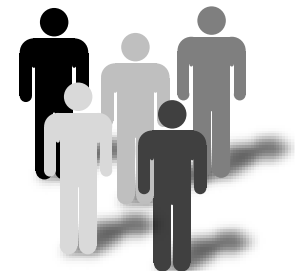
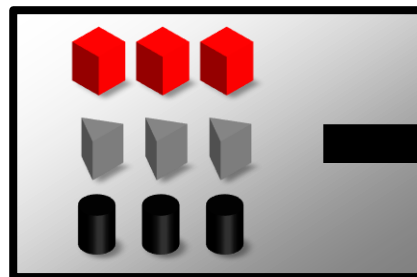
Requirements for products and services

Design and development of products' and services

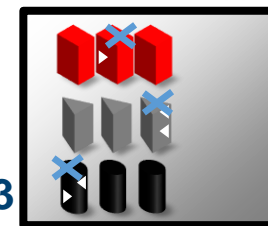


Control of externally provided products and services

Production and service provision, including release



Control of nonconforming process...



8. Operation

8.1. Operational planning and control

The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:

- a) determining the requirements for the products and services;
- b) establishing criteria for:
 - 1) the processes;
 - 2) the acceptance of products and services;

8. OPERATION

c) determining the resources needed to achieve conformity to the product and service requirements;

d) implementing control of the processes in accordance with the criteria;

e) determining, maintaining and retaining documented information to the extent necessary:

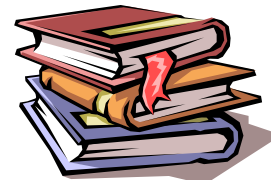
- 1) to have confidence that the processes have been carried out as planned;
- 2) to demonstrate the conformity of products and services to their requirements. The output of this planning shall be suitable for the organization's operations.

8. OPERATION

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The organization shall ensure that outsourced processes are controlled (see 8.4).





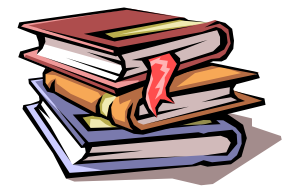
8. OPERATION

8.2. Requirements for products and services

8.2.1. Customer communication

Communication with customers shall include:

- a) providing information relating to products and services;
- b) handling enquiries, contracts or orders, including changes;
- c) obtaining customer feedback relating to products and services, including customer complaints;
- d) handling or controlling customer property;
- e) establishing specific requirements for contingency actions, when relevant.



8. OPERATION

8.2.2. Determining the requirements for products and services

When determining the requirements for the products and services to be offered to customers, the organization shall ensure that:

- a) the requirements for the products and services are defined, including:
 - 1) any applicable statutory and regulatory requirements;
 - 2) those considered necessary by the organization;
- b) the organization can meet the claims for the products and services it offers.



8. OPERATION

8.2.3. Review of the requirements for products and services

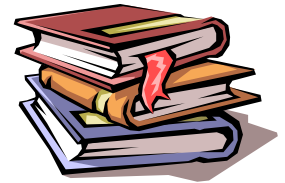
8.2.3.1. The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer, to include:

a) requirements specified by the customer, including the requirements for delivery and post- delivery activities;



8. OPERATION

- b) requirements not stated by the customer, but necessary for the specified or intended use, when known;
- c) requirements specified by the organization;
- d) statutory and regulatory requirements applicable to the products and services;
- e) contract or order requirements differing from those previously expressed.



8. OPERATION

The organization shall ensure that contract or order requirements differing from those previously defined are resolved.

The customer's requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.



8. OPERATION

8.2.3.2. The organization shall retain documented information, as applicable:

- a) on the results of the review;
- b) on any new requirements for the products and services.



8. OPERATION

8.2.4. Changes to requirements for products and services

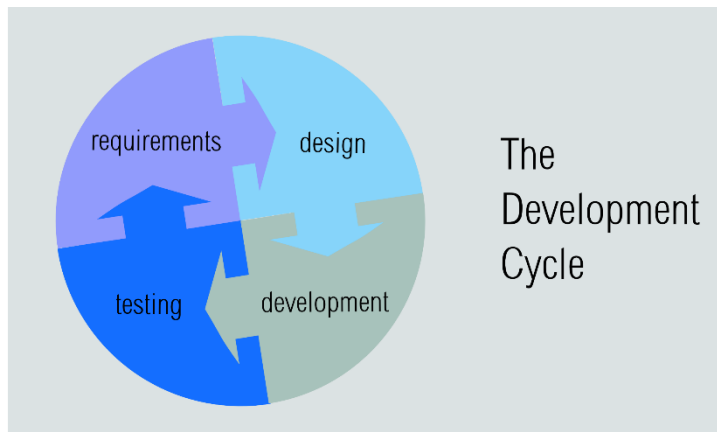
The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

8. OPERATION

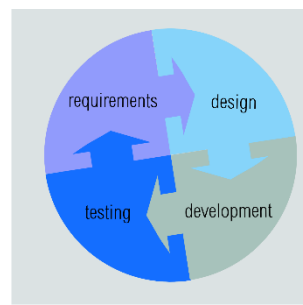
8.3. Design and development of products and services

8.3.1. General

The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.



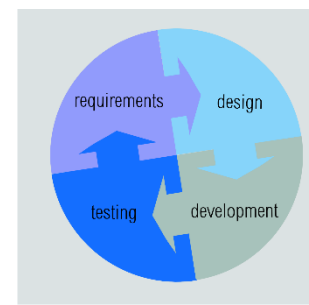
8. OPERATION



8.3.2. Design and development planning

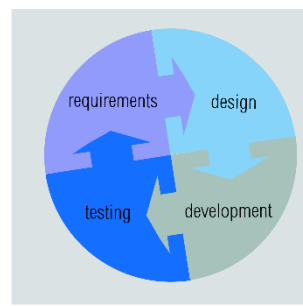
In determining the stages and controls for design and development, the organization shall consider:

- a) the nature, duration and complexity of the design and development activities;
- b) the required process stages, including applicable design and development reviews;
- c) the required design and development verification and validation activities;
- d) the responsibilities and authorities involved in the design and development process;



8. OPERATION

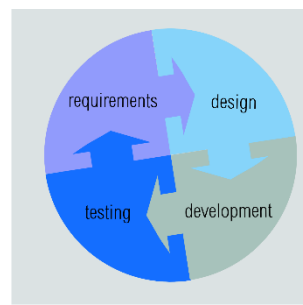
- e) the internal and external resource needs for the design and development of products and services;
- f) the need to control interfaces between persons involved in the design and development process;
- g) the need for involvement of customers and users in the design and development process;
- h) the requirements for subsequent provision of products and services;



8. OPERATION

- i) the level of control expected for the design and development process by customers and other relevant interested parties;
- j) the documented information needed to demonstrate that design and development requirements have been met.

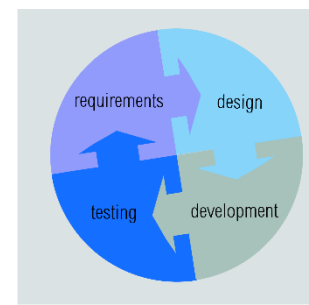
8. OPERATION



8.3.3. Design and development inputs

The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider:

- a) functional and performance requirements;
- b) information derived from previous similar design and development activities;
- c) statutory and regulatory requirements;
- d) standards or codes of practice that the organization has committed to implement;
- e) potential consequences of failure due to the nature of the products and services.

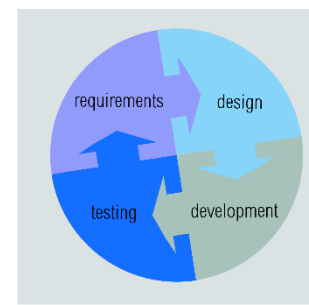


8. OPERATION

Inputs shall be adequate for design and development purposes, complete and unambiguous.

Conflicting design and development inputs shall be resolved.

The organization shall retain documented information on design and development inputs.

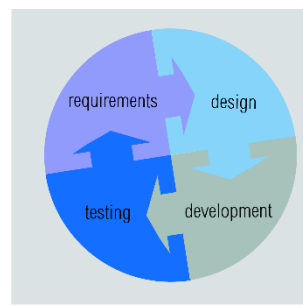


8. OPERATION

8.3.4. Design and development controls

The organization shall apply controls to the design and development process to ensure that:

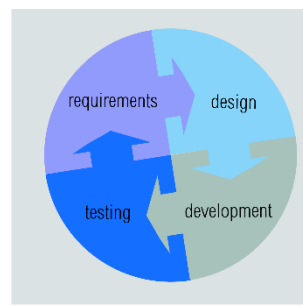
- a) the results to be achieved are defined;
- b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements;
- c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;



8. OPERATION

- d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;
- e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities;
- f) documented information of these activities is retained.

8. OPERATION



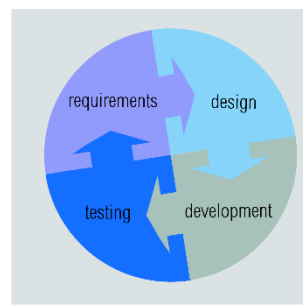
8.3.5. Design and development outputs

The organization shall ensure that design and development outputs:

- a) meet the input requirements;
- b) are adequate for the subsequent processes for the provision of products and services;
- c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;
- d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

The organization shall retain documented information on design and development outputs.

8. OPERATION

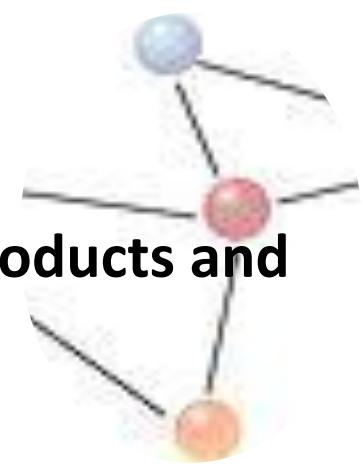


8.3.6. Design and development changes

The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

The organization shall retain documented information on:

- a) design and development changes;
- b) the results of reviews;
- c) the authorization of the changes;
- d) the actions taken to prevent adverse impacts.



8. OPERATION

8.4. Control of externally provided processes, products and services

- **8.4.1. General**

The organization shall ensure that externally provided processes, products and services conform to requirements.

The organization shall determine the controls to be applied to externally provided processes, products and services when:

a) products and services from external providers are intended for incorporation into the organization's own products and services;

8. OPERATION

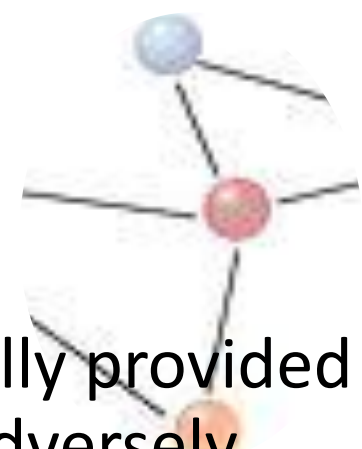
- b) products and services are provided directly to the customer(s) by external providers on behalf of the organization;
- c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization.



8. OPERATION

The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.





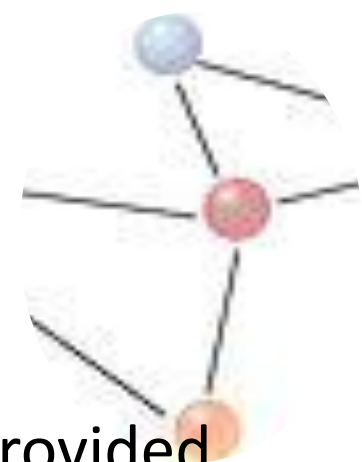
8. OPERATION

8.4.2. Type and extent of control

The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers.

The organization shall:

- a) ensure that externally provided processes remain within the control of its quality management system;
- b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;

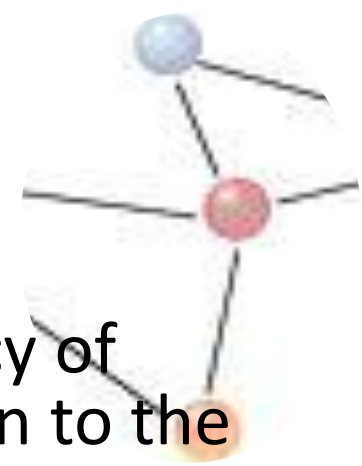


8. OPERATION

c) take into consideration:

- 1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;
- 2) the effectiveness of the controls applied by the external provider;

d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.



8. OPERATION

8.4.3. Information for external providers

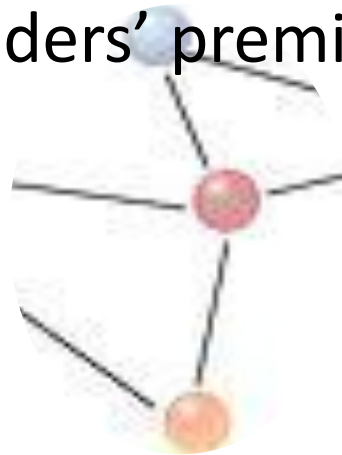
The organization shall ensure the adequacy of requirements prior to their communication to the external provider.

The organization shall communicate to external providers its requirements for:

- a) the processes, products and services to be provided;
- b) the approval of:
 - 1) products and services;
 - 2) methods, processes and equipment;
 - 3) the release of products and services;

8. OPERATION

- c) competence, including any required qualification of persons;
- d) the external providers' interactions with the organization;
- e) control and monitoring of the external providers' performance to be applied by the organization;
- f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.



8. OPERATION

8.5. Production and service provision

8.5.1. Control of production and service provision

The organization shall implement production and service provision under controlled conditions.

Controlled conditions shall include, as applicable:

a) the availability of documented information that defines:

- 1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;
- 2) the results to be achieved;



8. OPERATION

- b) the availability and use of suitable monitoring and measuring resources;
- c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;
- d) the use of suitable infrastructure and environment for the operation of processes;
- e) the appointment of competent persons, including any required qualification;



8. OPERATION



- f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
- g) the implementation of actions to prevent human error;
- h) the implementation of release, delivery and post-delivery activities.

8. OPERATION



8.5.2. Identification and traceability

The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.

8. OPERATION



8.5.3. Property belonging to customers or external providers

The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.

The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred.

8. OPERATION



8.5.4. Preservation

The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

8. OPERATION



8.5.5. Post-delivery activities

The organization shall meet requirements for post-delivery activities associated with the products and services.



8. OPERATION

In determining the extent of post-delivery activities that are required, the organization shall consider:

- a) statutory and regulatory requirements;
- b) the potential undesired consequences associated with its products and services;
- c) the nature, use and intended lifetime of its products and services;
- d) customer requirements;
- e) customer feedback.

8. OPERATION

8.5.6. Control of changes

The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.



8. OPERATION



8.6. Release of products and services

The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.



8. OPERATION

The organization shall retain documented information on the release of products and services. The documented information shall include:

- a) evidence of conformity with the acceptance criteria;
- b) traceability to the person(s) authorizing the release.

8. OPERATION



8.7. Control of nonconforming outputs

8.7.1. The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.



8. OPERATION

The organization shall deal with nonconforming outputs in one or more of the following ways:

- a) correction;
- b) segregation, containment, return or suspension of provision of products and services;
- c) informing the customer;
- d) obtaining authorization for acceptance under concession.

Conformity to the requirements shall be verified when nonconforming outputs are corrected.



8. OPERATION

8.7.2. The organization shall retain documented information that:

- a) describes the nonconformity;
- b) describes the actions taken;
- c) describes any concessions obtained;
- d) identifies the authority deciding the action in respect of the nonconformity.



Performance Evaluation

Clause 9 - ISO 9001:2015





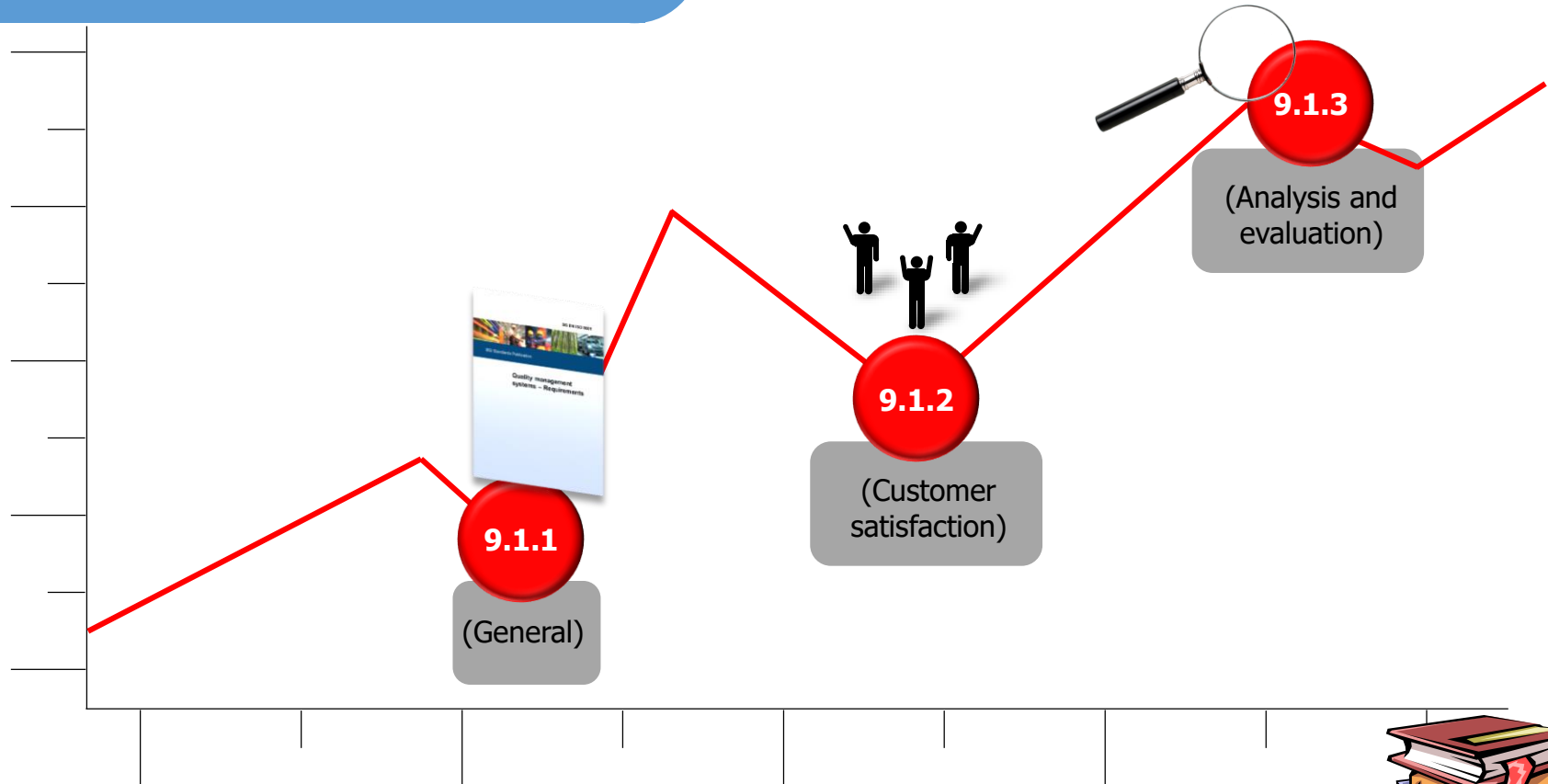
Clause 9 – Performance evaluation

- **9.1** – Monitoring, measurement, analysis and evaluation
 - What needs to be monitored and measured, how and when
- **9.2** – Internal audit
 - To establish whether the QMS conforms to requirements and is effectively implemented and maintained
- **9.3** – Management review
 - Top management must regularly review the QMS

Clause 9 – Performance

9.1. Monitoring, measurement, analysis and evaluation

- What needs to be monitored and measured, how and when





9. PERFORMANCE EVALUATION

9. Performance evaluation

9.1. Monitoring, measurement, analysis and evaluation

9.1.1. General

The organization shall determine:

- a) what needs to be monitored and measured;
- b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
- c) when the monitoring and measuring shall be performed;



9. PERFORMANCE EVALUATION

d) when the results from monitoring and measurement shall be analysed and evaluated.

The organization shall evaluate the performance and the effectiveness of the quality management system.

The organization shall retain appropriate documented information as evidence of the results.



9. PERFORMANCE EVALUATION

9.1.2. Customer satisfaction

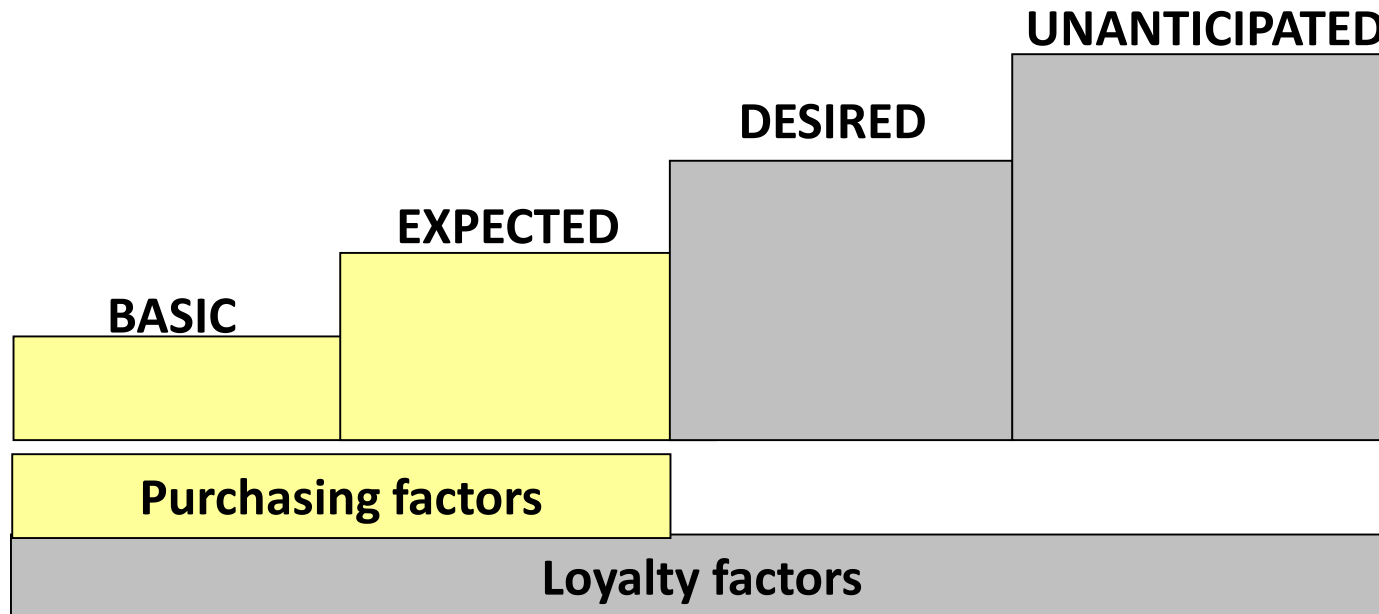
The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring and reviewing this information.

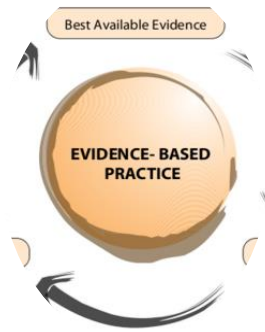
9.1.2. Customer Satisfaction



The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring and reviewing this information.

NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.





9. PERFORMANCE EVALUATION

9.1.3. Analysis and evaluation

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

The results of analysis shall be used to evaluate:

- a) conformity of products and services;
- b) the degree of customer satisfaction;
- c) the performance and effectiveness of the quality management system;
- d) if planning has been implemented effectively;



9. PERFORMANCE EVALUATION

- e) the effectiveness of actions taken to address risks and opportunities;
- f) the performance of external providers;
- g) the need for improvements to the quality management system.

Clause 9 – Performance

9.2. Internal Audit

To establish whether the QMS conforms to requirements and is effectively implemented and maintained

At planned intervals (status and importance)	Ensure system conforms to planned arrangements	Ensure system conforms to ISO 9001	Effectively implemented and maintained	Follow-up actions
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Audit criteria, scope, frequency, methods defined in documented information



9. PERFORMANCE EVALUATION

9.2. Internal audit

9.2.1. The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:

a) conforms to:

- 1) the organization's own requirements for its quality management system;
- 2) the requirements of this International Standard;

b) is effectively implemented and maintained.



9. PERFORMANCE EVALUATION

9.2.2. The organization shall:

- a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;
- b) define the audit criteria and scope for each audit;

9. PERFORMANCE EVALUATION

- c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- d) ensure that the results of the audits are reported to relevant management;
- e) take appropriate correction and corrective actions without undue delay;
- f) retain documented information as evidence of the implementation of the audit programme and the audit results.



9. PERFORMANCE EVALUATION

9.3. Management review

9.3.1. General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.



9. PERFORMANCE EVALUATION

9.3.2. Management review inputs

The management review shall be planned and carried out taking into consideration:

- a) the status of actions from previous management reviews;
- b) changes in external and internal issues that are relevant to the quality management system;
- c) information on the performance and effectiveness of the quality management system, including trends in:
 - 1) customer satisfaction and feedback from relevant interested parties;



9. PERFORMANCE EVALUATION

- 2) the extent to which quality objectives have been met;
 - 3) process performance and conformity of products and services;
 - 4) nonconformities and corrective actions;
 - 5) monitoring and measurement results;
 - 6) audit results;
 - 7) the performance of external providers;
- d) the adequacy of resources;
- e) the effectiveness of actions taken to address risks and opportunities (see 6.1);
- f) opportunities for improvement.



9. PERFORMANCE EVALUATION

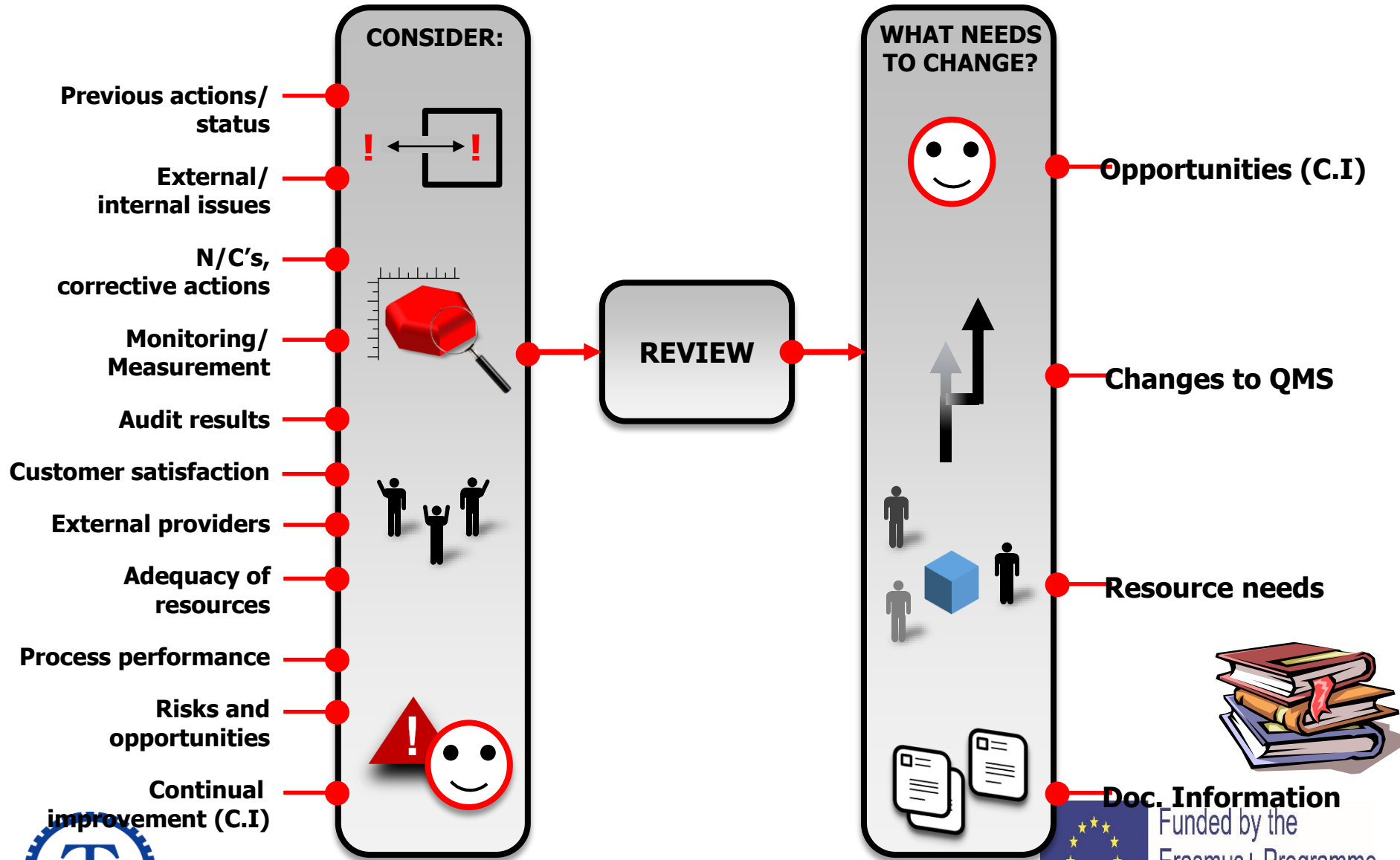
9.3.3. Management review outputs

The outputs of the management review shall include decisions and actions related to:

- a) opportunities for improvement;
- b) any need for changes to the quality management system;
- c) resource needs.

The organization shall retain documented information as evidence of the results of management reviews.

9.3. Management Review





Improvement

Clause 10- ISO 9001:2015



Clause 10: Improvement

Improvement

Nonconformity and corrective action

Continual improvement



10. IMPROVEMENT

10. Improvement

10.1. General

The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

These shall include:

- a) improving products and services to meet requirements as well as to address future needs and expectations;
- b) correcting, preventing or reducing undesired effects;
- c) improving the performance and effectiveness of the quality management system.

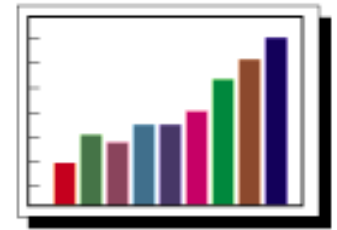


What to evaluate ?

- Policy
- Critical Success Factor
- Measurement
- Program

How to evaluate ?

- Data collected
- Responsibility
- Frequency
- Method



Analyze

Action

- Corrective
- Correction
- Improvement

10. IMPROVEMENT

10.2. Nonconformity and corrective action

When a nonconformity occurs, including any arising from complaints, the organization shall:

a) react to the nonconformity and, as applicable:

- 1) take action to control and correct it;
- 2) deal with the consequences;

b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

- 1) reviewing and analysing the nonconformity;
- 2) determining the causes of the nonconformity;
- 3) determining if similar nonconformities exist, or could potentially occur;



10. IMPROVEMENT

- c) implement any action needed;
- d) review the effectiveness of any corrective action taken;
- e) update risks and opportunities determined during planning, if necessary;
- f) make changes to the quality management system, if necessary.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.



10. IMPROVEMENT

10.2.2. The organization shall retain documented information as evidence of:

- a) the nature of the nonconformities and any subsequent actions taken;
- b) the results of any corrective action.

10. IMPROVEMENT

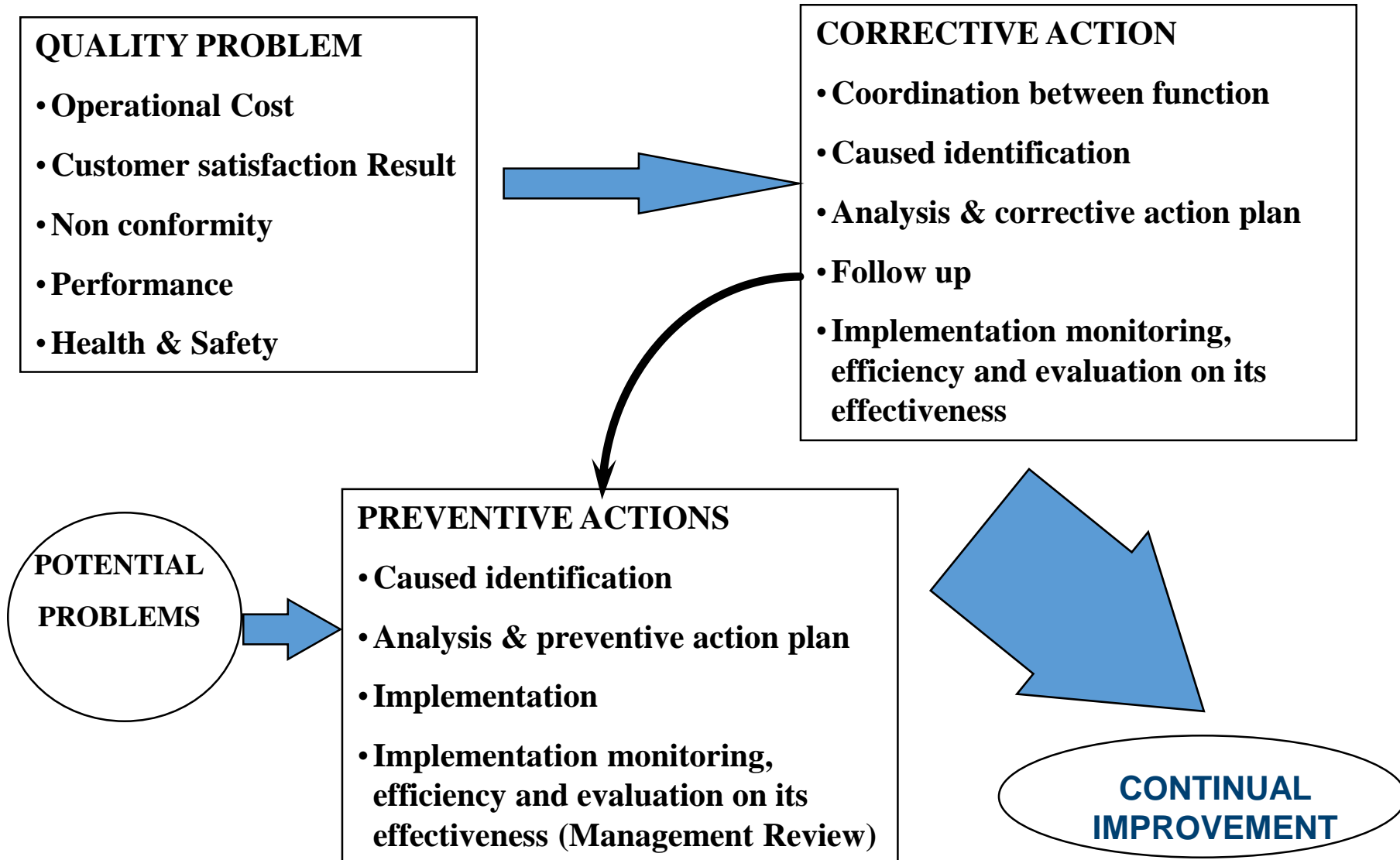
10.3. Continual improvement

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

The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.



Continual improvement



Review and Final Questions

