

ISO 9004

A Process Approach to Sustained Success

Participant Workbook

You can purchase ISO 9004:2018 at the ISO site, here: <https://www.iso.org/standard/70397.html>

1. Terms and definitions [Clause 3]
2. Quality of an organization and sustained success - Clause 4]
 1. Quality of an organization [4.1]
 2. Managing for the sustained success of an organization [4.2]
 3. Considering the needs and expectations of Interested Parties [4.2.2]
3. Context of an organization [Clause 5]
 1. Relevant interested parties [5.2]
 2. External and internal issues [5.3]
4. Identity of an organization [Clause 6]
 1. Mission, vision, values and culture [6.2]
5. Leadership [Clause 7]
 1. Top Management's Leadership role relevant to sustained success [7.1.1, 7.1.2]
 2. Policy and strategy [7.2]
 3. Objectives [7.3]
 4. Communication [7.4]
6. Process Management [Clause 8]
 1. Determination of processes [8.2]
 2. Responsibility and authority for processes [8.3]

3. Managing processes [8.4]
1. Resource Management [Clause 9]
 1. People [9.2]
 2. Organizational knowledge [9.3]
 3. Technology [9.4]
 4. Infrastructure and Work Environment [9.5]
 5. Externally Provided Resources [9.6]
 6. Natural Resources [9.7]
2. Analysis and Evaluation of Organizational Performance [Clause 10]
 1. Performance indicators [10.2]
 2. Performance analysis [10.3]
 3. Performance evaluation [10.4]
 4. Internal audit [10.5]
 5. Self assessment [10.6]
 6. Reviews [10.7]
3. Improvement, Learning and Innovation [Clause 11]
 1. Improvement [11.2]
 2. Learning [11.3]
 3. Innovation [11.4]

ISO 9004

A Process Approach to Sustained Success

Unit 1: Clauses 3, 4 & 5

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ISO 9004

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Unit 2: Clauses 6, 7 & 8

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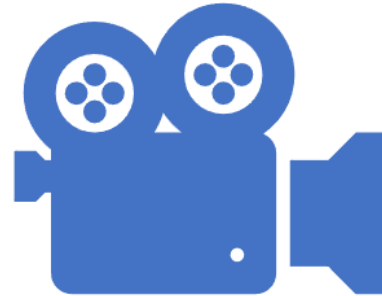
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Unit 3: Clauses 9, 10 & 11

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Each unit has a
video followed by
a quiz...





STOP THE VIDEO ANY TIME TO
MAKE NOTES!



STOP THE VIDEO ANY TIME
TO MAKE NOTES!



REFER BACK TO THE VIDEO
DURING THE QUIZ...

- This is the first course in the series of 6 courses
- Do the quizzes after each section
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2.1 Quiz #1 - Section 1: Principles 3 questions

UNIT #2 0/2

3.1 Unit #2 - ISO 31000 Part 2: Framework ✓

3.1 Quiz #2 - ISO 31000 - Section 2: Framework 3 questions

UNIT #3 0/2

4.1 Unit #3 - ISO 31000 Part 3: The Process ✓

4.1 Quiz #3 - ISO 31000 - Section 3: The Process 3 questions

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3.1 Unit #2 - ISO 31000 Part 2: Framework

3.1 Quiz #2 - ISO 31000 - Section 2: Framework 3 questions

UNIT #3 0/2

4.1 Unit #3 - ISO 31000 Part 3: The Process 20 min

4.1 Quiz #3 - ISO 31000 - Section 3: The Process 3 questions

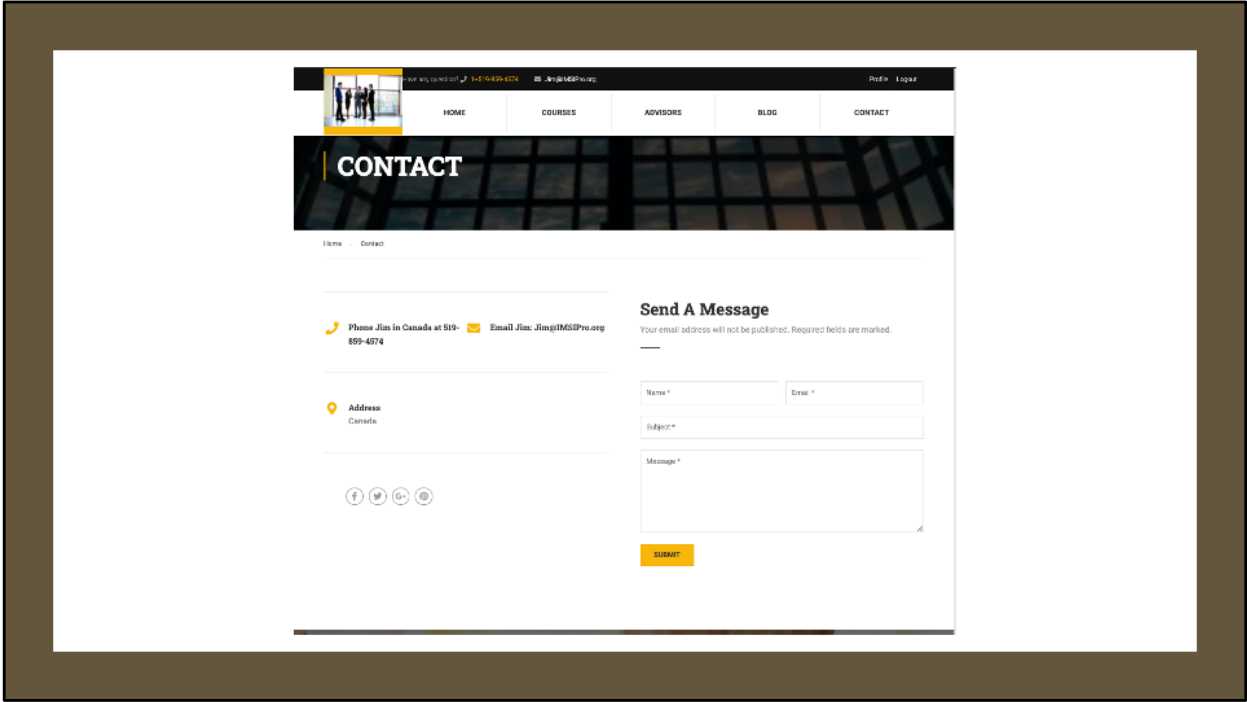
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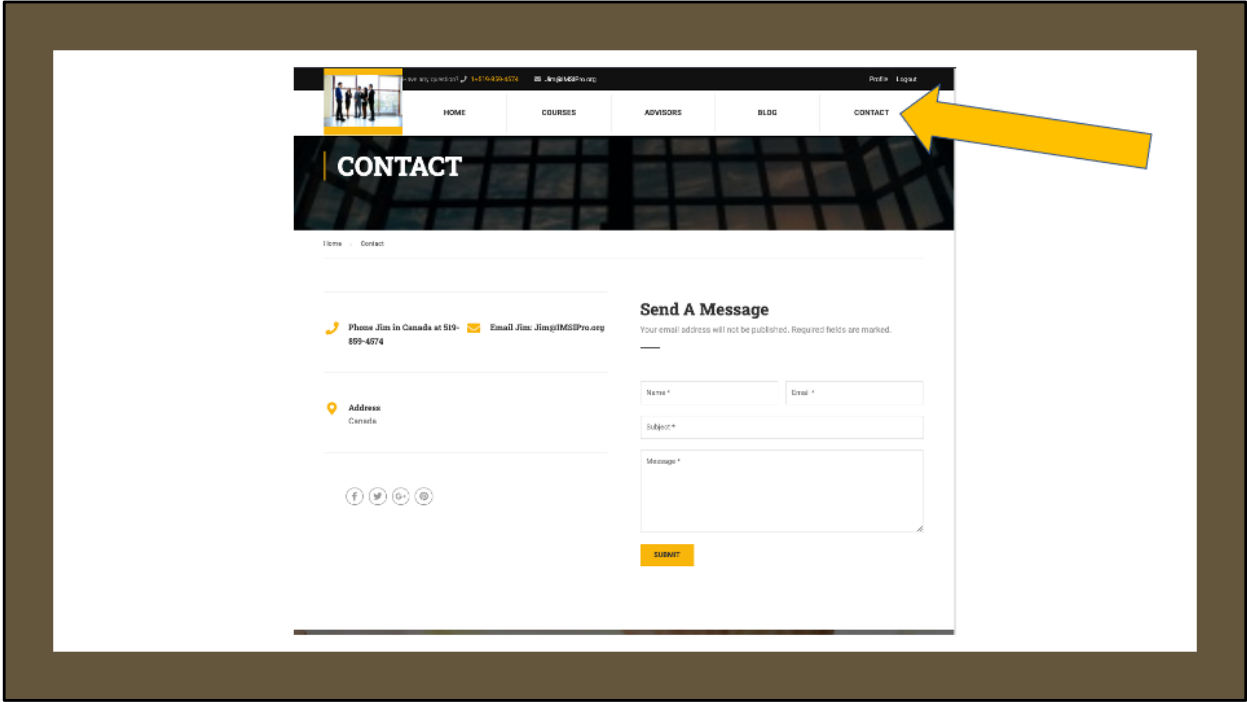
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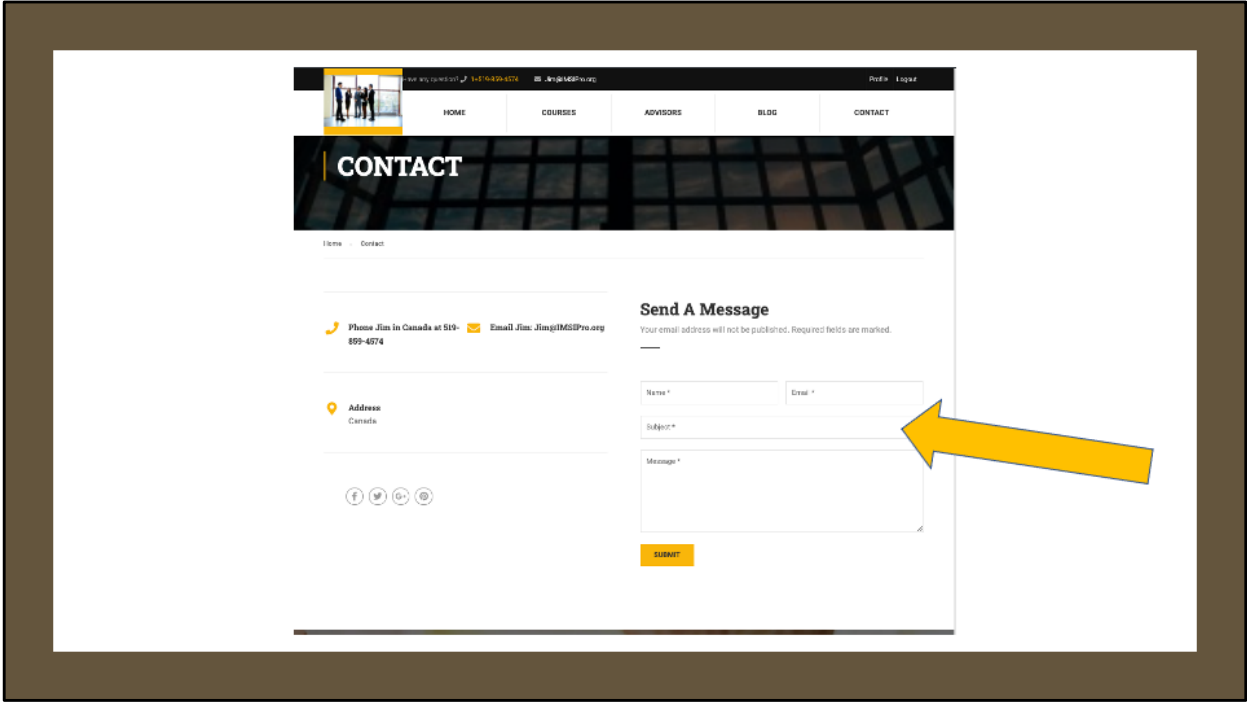
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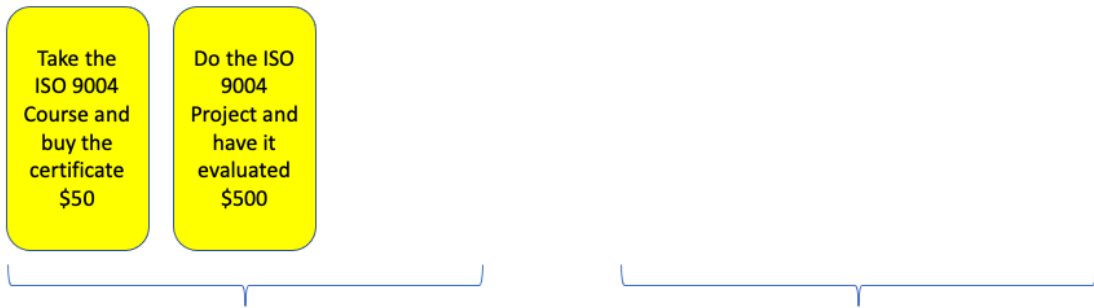


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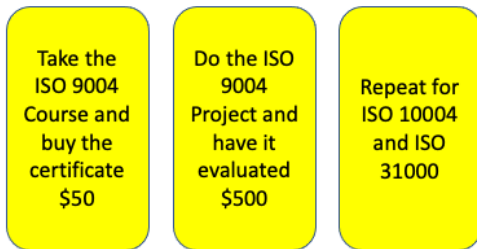
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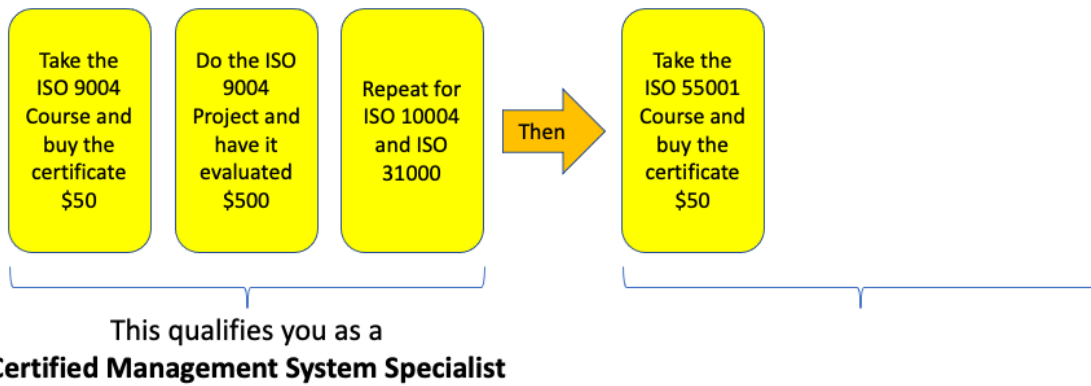


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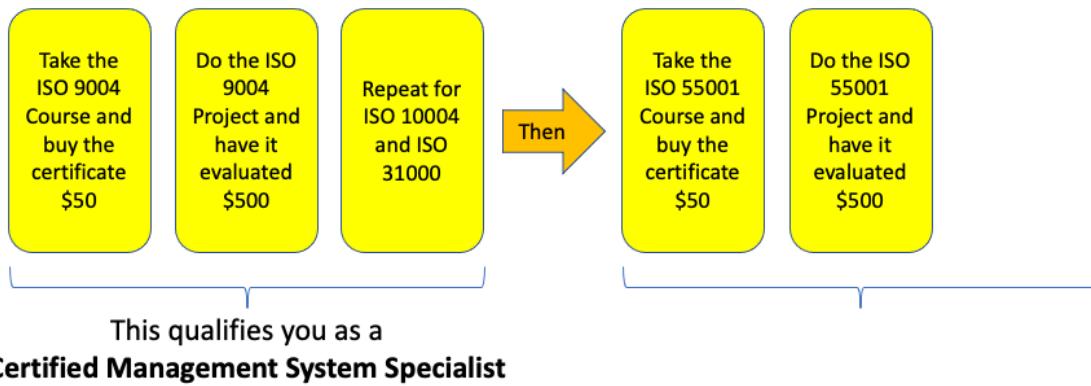


This qualifies you as a
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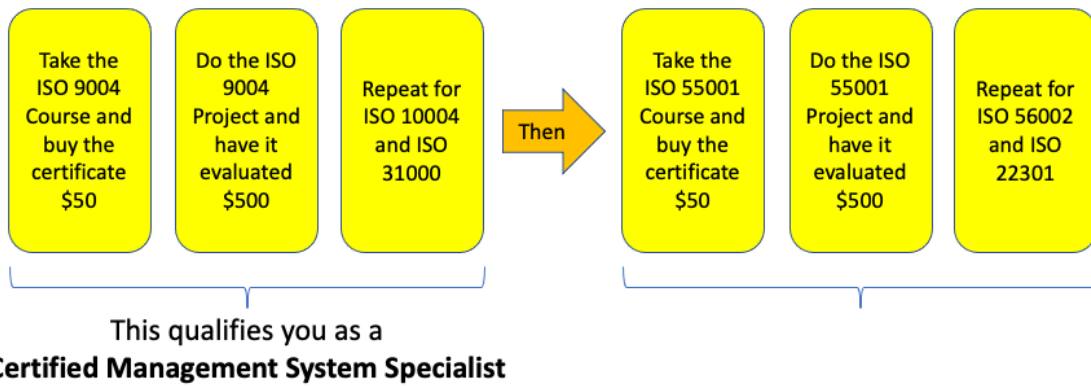
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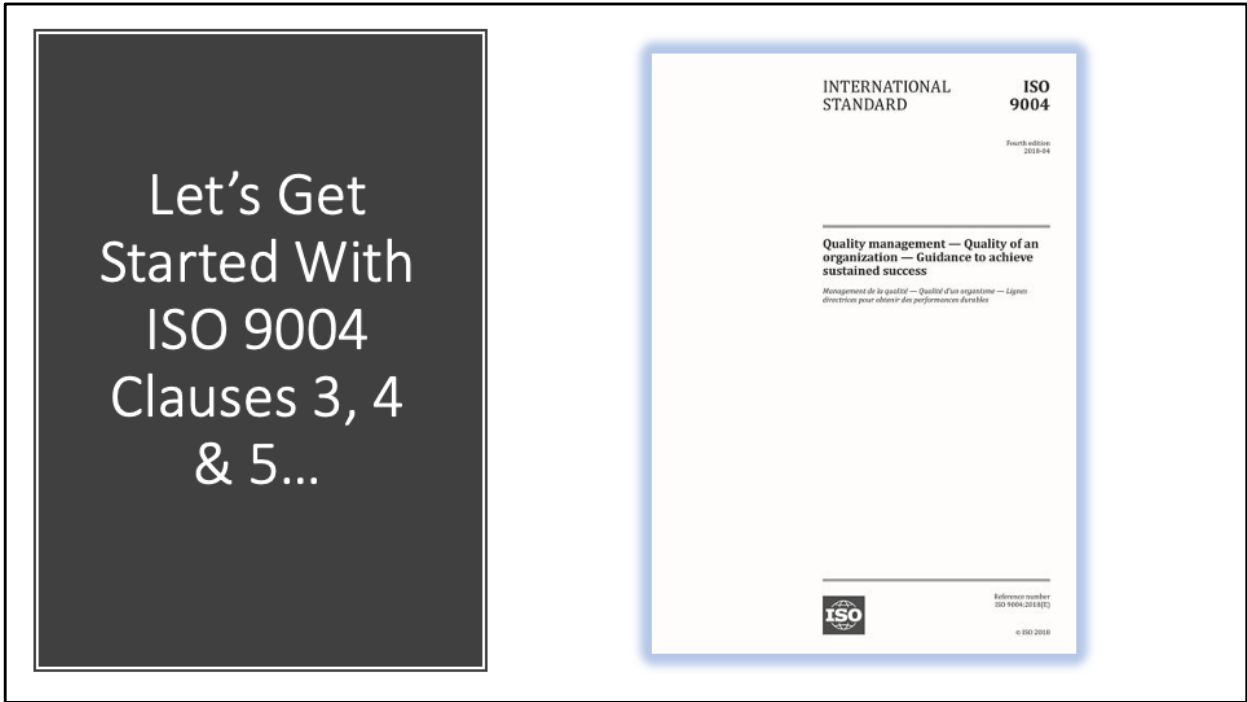


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From ISO 9004:2018 Clause 4.1...

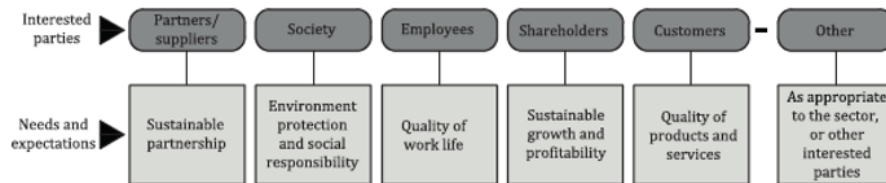


Figure 2 — Examples of interested parties and their needs and expectations



Consideration of the needs and expectations of interested parties can enable the organization:

- a) to achieve objectives effectively and efficiently;
- b) to eliminate conflicting responsibilities and relationships;
- c) to harmonize and optimize practices;
- d) to create consistency;
- e) to improve communication;
- f) to facilitate training, learning and personal development;
- g) to facilitate focus on the most important characteristics of the organization;
- h) to manage risks and opportunities to its brand or reputation;
- i) to acquire and share knowledge.



Communicate These Goals Continually Throughout
Your Organization

This will help your organization...

- ✓ Achieve targets and enhance profit
- ✓ Harmonize responsibilities and departmental interactions
- ✓ Improve work flow
- ✓ Improve consistent product and service delivery;
- ✓ Improve communication;
- ✓ Improve training, learning and employee development;
- ✓ Focus on the most important aspects of the organization relevant to customer satisfaction;
- ✓ Manage risks and opportunities to its brand or reputation;
- ✓ Acquire and share knowledge.

Context includes Internal and External Conditions and 'Relevant Interested Parties'

“Interested parties are those that can affect, be affected by, or perceive themselves to be affected by a decision or activity of the organization”

ISO 9000:2015 Clause 3.2.3

5.2 Relevant interested parties

Interested parties are those that can affect, be affected by, or perceive themselves to be affected by a decision or activity of the organization. The organization should determine which interested parties are relevant.

ISO 9000:2015 Clause 3.2.3

These relevant interested parties can be both external and internal, including customers,

and can impact the organization's ability to achieve sustained success.

The organization should determine which interested parties:

- a) are a risk to its sustained success if their relevant needs and expectations are not met;
- b) can provide opportunities to enhance its sustained success.

Once the relevant interested parties are determined, the organization should:

— identify their relevant needs and expectations, determining the ones that should

be addressed;

— establish the necessary processes to fulfil the needs and expectations of the interested parties.

The organization should consider how to establish ongoing relationships with interested parties for benefits such as improved performance, common understanding of objectives and values, and enhanced stability.

Context includes Internal and External Conditions and 'Relevant Interested Parties'

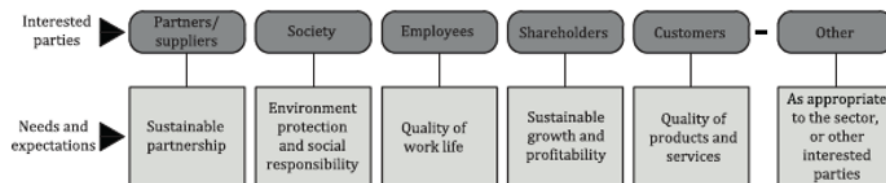


Figure 2 — Examples of interested parties and their needs and expectations

5.2 Relevant interested parties

Interested parties are those that can affect, be affected by, or perceive themselves to be affected by a

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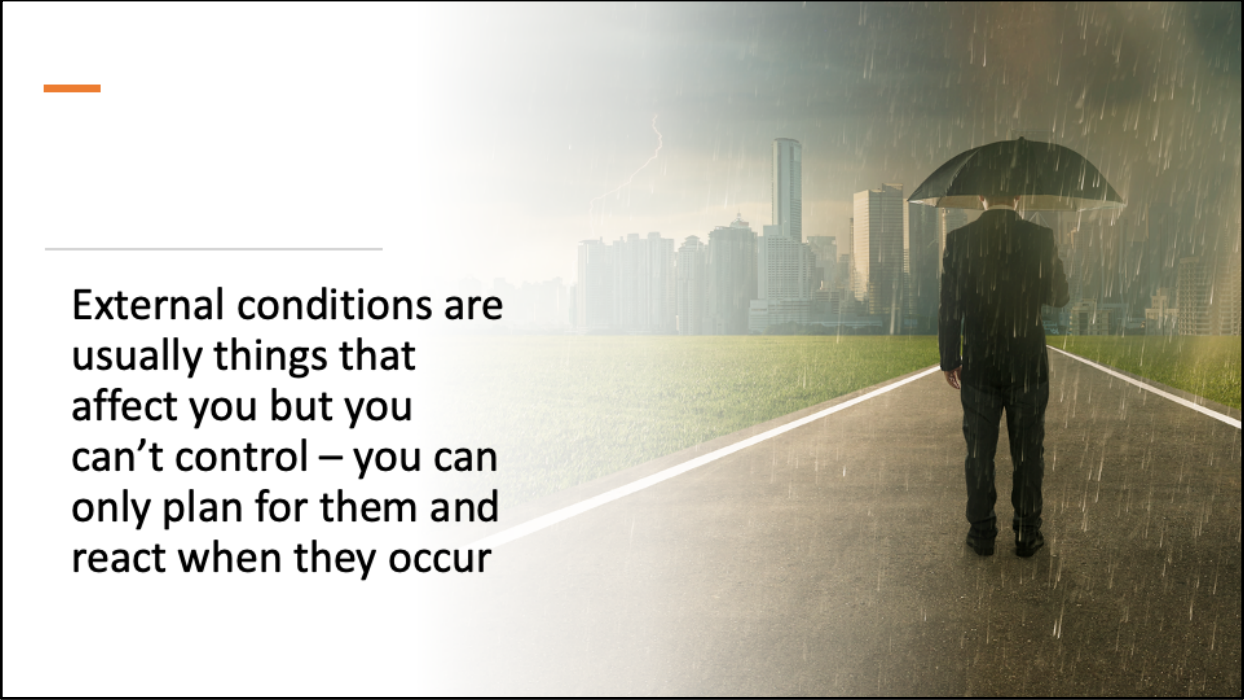
for benefits such as improved performance, common understanding of objectives and values, and enhanced stability.



Interested parties are a risk to your organization's sustained success if their needs and expectations are not met

**External and internal conditions (ISO 9004, Clause 5.3)
need to be optimized to ensure 'Sustained Success'**

See your copy of ISO 9000 for details You can purchase it here:
<https://www.iso.org/standard/70397.html>



External conditions are usually things that affect you but you can't control – you can only plan for them and react when they occur

See your copy of ISO 9004 for details You can purchase it here:
<https://www.iso.org/standard/70397.html>

External:

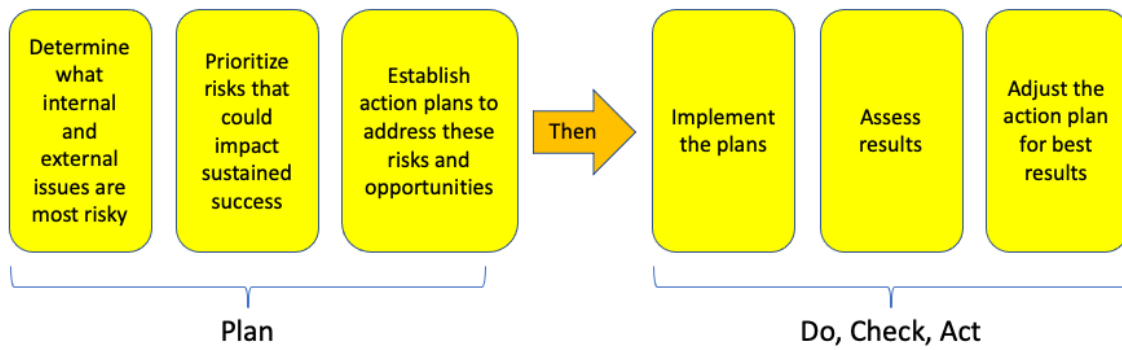
- a) statutory and regulatory requirements;
- b) sector-specific requirements and agreements;
- c) competition;
- d) globalization;
- e) social, economic, political and cultural factors;
- f) innovations and advances in technology;
- g) natural environment.



**Internal Conditions
are under your
control and can be
impacted by your
organization**

Examples of Internal issues or conditions:
size and complexity;
activities and associated processes;
strategy;
type of products and services;
performance;
resources;
levels of competence and organizational knowledge;
maturity;
innovation.

To manage Internal and External Issues...

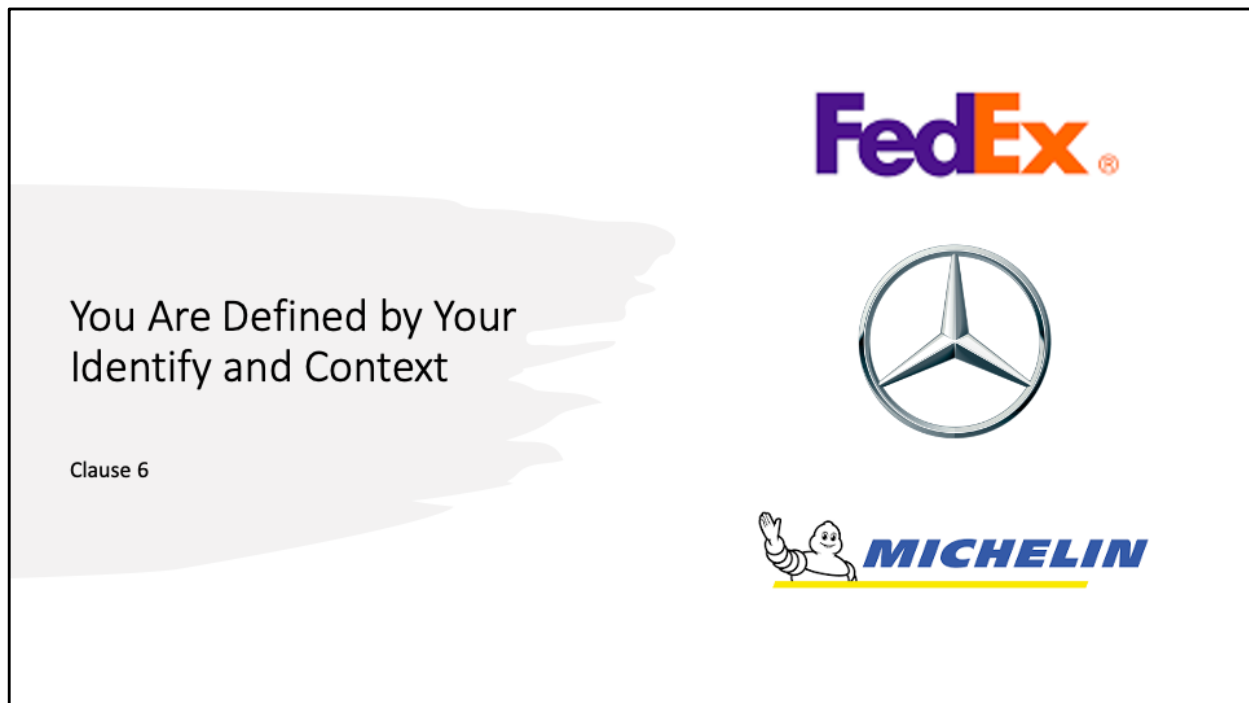


Quiz!

Now We'll Look at Clauses 6, 7 & 8

6	Identity of an organization	4
6.1	General	4
6.2	Mission, vision, values and culture	5
7	Leadership	5
7.1	General	5
7.2	Policy and strategy	6
7.3	Objectives	8
7.4	Communication	8
8	Process management	8
8.1	General	8
8.2	Determination of processes	9
8.3	Responsibility and authority for processes	10
8.4	Managing processes	10

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Clause 6:

6.1 General

An organization is defined by its identity and context. The identity of an organization is determined by its characteristics, based on its mission, vision, values and culture. Mission, vision, values and culture are interdependent and the relationship between them should be recognized as dynamic.

6.2 Mission, vision, values and culture

The identity of an organization includes its:

- a) mission: the organization's purpose for existing;
- b) vision: aspiration of what an organization would like to become;
- c) values: principles and/or thinking patterns intended to play a role in shaping the organization's culture and to determine what is important to the organization, in support of the mission and vision;
- d) culture: beliefs, history, ethics, observed behaviour and attitudes that are interrelated with the

identity of the organization.

It is essential that the organization's culture aligns with its mission, vision, and values.

Top management

should ensure that the context of the organization is considered when determining its mission, vision

and values. This should include an understanding of its existing culture and assessing the need to

change the culture. The strategic direction of the organization and its policy should be aligned with

these identity elements.

Top management should review the mission, vision, values and culture at planned intervals and

whenever the context of the organization changes. This review should consider external and internal

issues that can have an effect on the organization's ability to achieve sustained success. When changes

are made to any of the identity elements, they should be communicated within the organization and to

interested parties, as appropriate.

'Identity' is made up of...

Mission



Vision



Values



6.2 Mission, vision, values and culture

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Management
(Clause 7) Leads
By Example
Whether They
Want To Or Not

7 Leadership

7.1 General

7.1.1 Top management, through its leadership, should:

- a) promote the adoption of the mission, vision, values and culture in a way that is concise and easy to understand, to achieve unity of purpose;
- b) create an internal environment in which people are engaged and committed to the achievement of the organization's objectives;
- c) encourage and support managers at appropriate levels to promote and maintain the unity of purpose and direction as established by the top management.

7.1.2 To achieve sustained success, top management should demonstrate leadership and commitment within the organization, by:

- a) establishing the organization's identity (see Clause 6);
- b) promoting a culture of trust and integrity;
- c) establishing and maintaining teamwork;
- d) providing people with the necessary resources, training and authority to act with

accountability;

- e) promoting shared values, fairness and ethical behaviour so that these are sustained at all levels of the organization;
- f) establishing and maintaining an organizational structure to enhance competitiveness, where applicable;
- g) individually and collectively reinforcing the organization's values;
- h) communicating achieved successes externally and internally, as appropriate;
- i) establishing a basis for effective communication with people in the organization, discussing issues that have general impact, including financial impact, where applicable;
- j) supporting leadership development at all levels of the organization.

7.2 Policy and strategy

Top management should set out the organization's intentions and direction in the form of the organization's policy, to address aspects such as compliance, quality, environment, energy, employment, occupational health and safety, quality of work life, innovation, security, privacy, data protection and customer experience. Policy statements should include commitments to satisfy the needs and expectations of interested parties and to promote improvement.

When establishing the strategy, top management should either apply a recognized and appropriate model available in the market, or design or implement an organization-specific customized model.

Once chosen, it is crucial to maintain the stability of the model as the solid foundation and reference for managing the organization.

Strategy should reflect the identity of the organization, its context and long-term perspective. All short and medium-term objectives should be aligned accordingly (see 7.3).

Top management should make strategic decisions regarding competitive factors (see Table 1).

These policy and strategy decisions should be reviewed for continued suitability. Any changes to the external and internal issues, as well as any new risks and opportunities, should be addressed.

The organization's policies and strategy constitute the basis to establish process management

(see Clause 8).

Table 1 — Examples of actions to consider when addressing competitive factors



7.1.1 Top management, through its leadership, should:

- a) promote the adoption of the mission, vision, values and culture in a way that is concise and easy to understand, to achieve unity of purpose;
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The 'How' of getting to your objectives needs to match your culture and context...

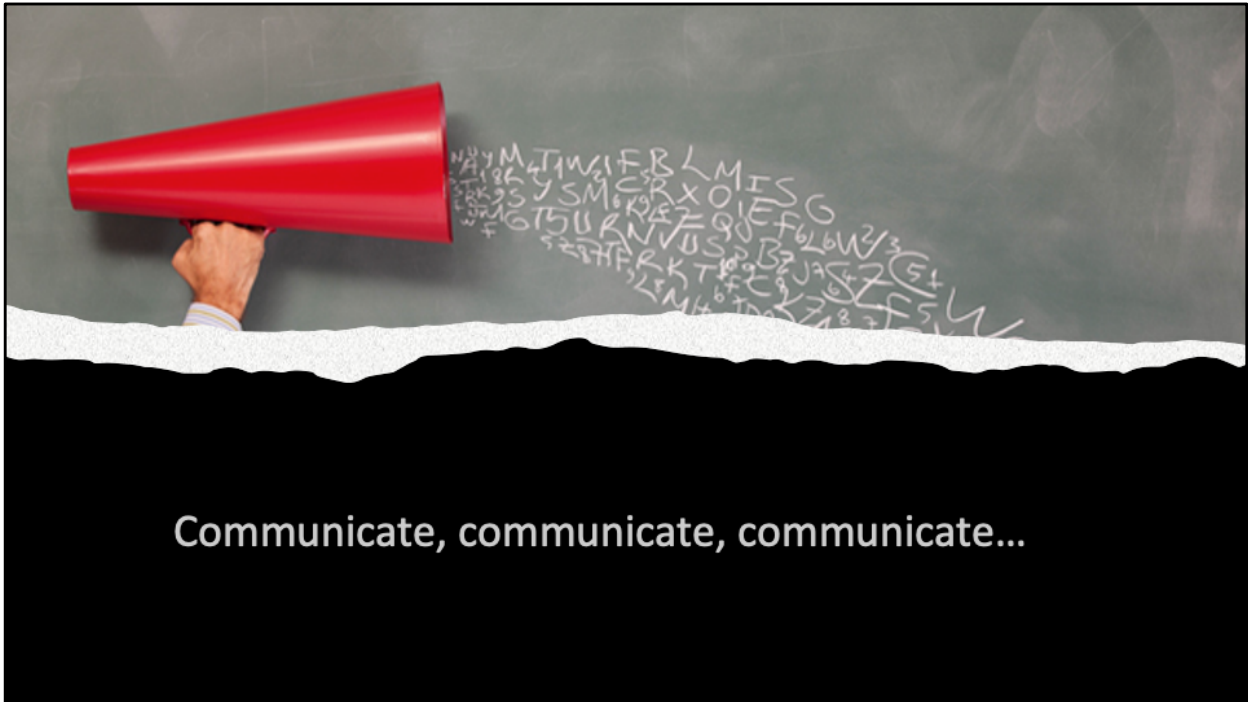
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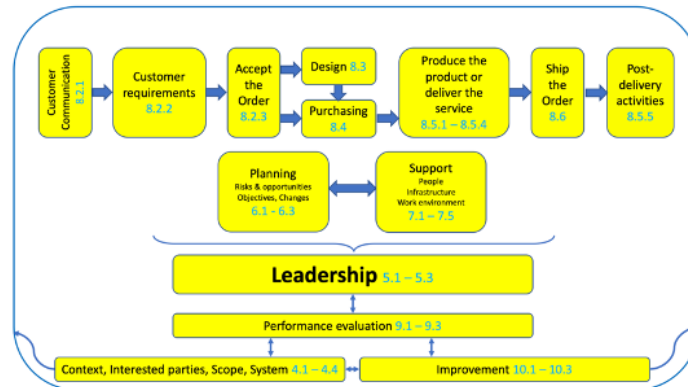
The organization's policies and strategy constitute the basis to establish process management (see Clause 8).

Table 1 — Examples of actions to consider when addressing competitive factors



Then communicate some more!

Clause 8 Is All About Process...



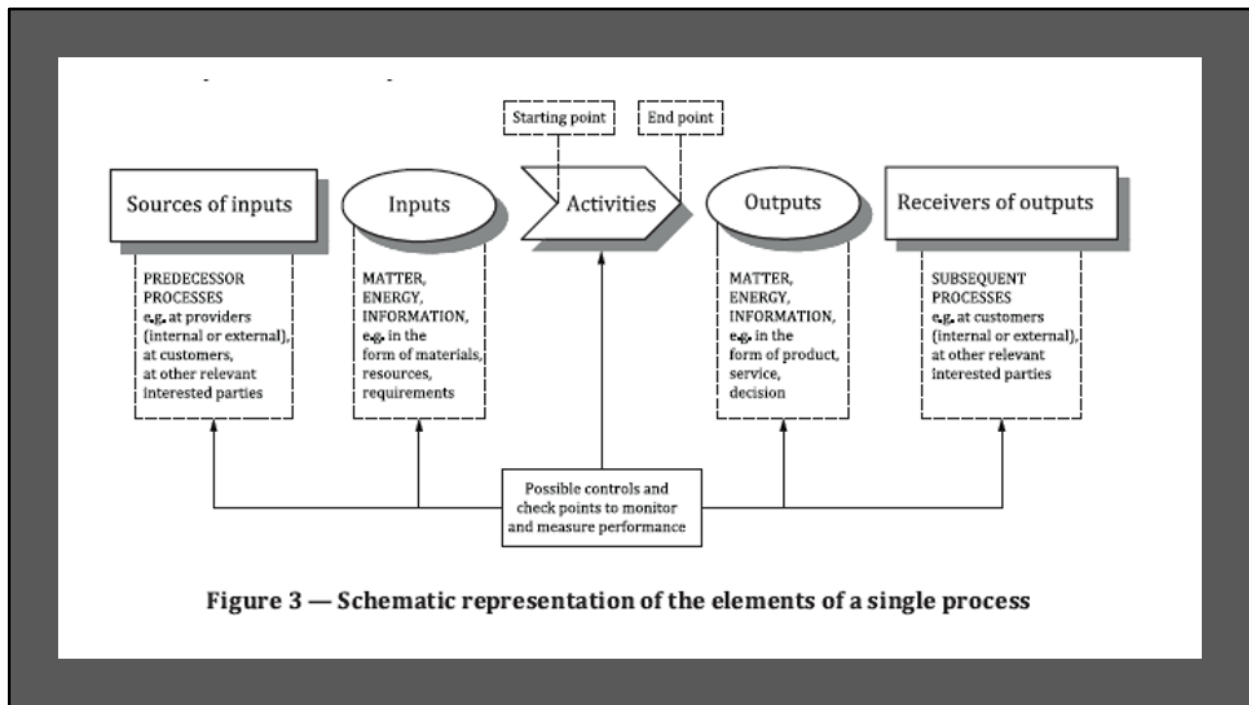


Figure 3 — Schematic representation of the elements of a single process

8.2.2 In determining its processes and their interactions, the organization should give consideration,

as appropriate, to:

- a) the purpose of the process;
- b) the objectives to be achieved and related performance indicators;
- c) the outputs to be provided;
- d) the needs and expectations of interested parties, and their changes;
- e) changes in operations, markets and technologies;
- f) the impacts of the processes;
- g) the inputs, resources and information needed, and their availability;
- h) the activities that need to be implemented and methods that can be used;
- i) constraints for the process;
- j) risks and opportunities.

Identify your process owners and communication channels...



8.3 Responsibility and authority for processes

For each process, the organization should appoint a person or a team (often referred to as the

"process owner"), depending on the nature of the process and the organization's culture, with defined

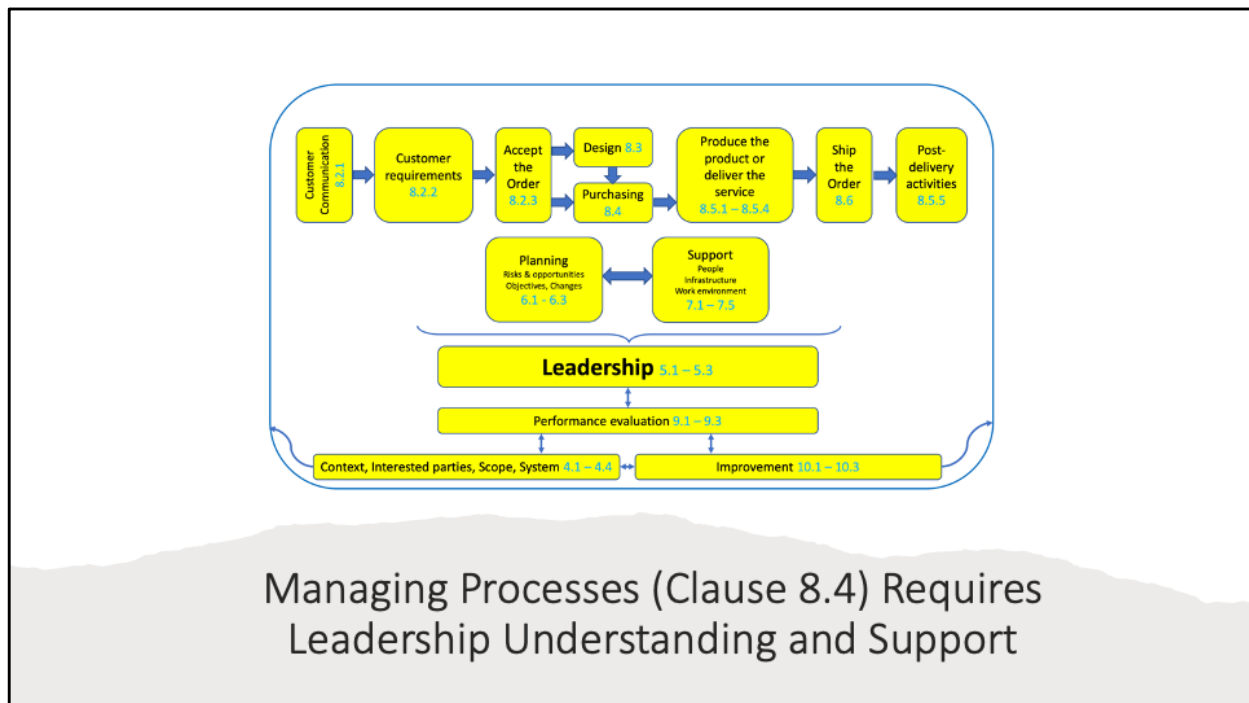
responsibilities and authorities to determine, maintain, control and improve the process and its

interaction with other processes it impacts and those that have impact on it. The organization should

ensure that the responsibilities, authorities and roles of process owners are recognized throughout

the organization and that the people associated with the individual processes have the competences

needed for the tasks and activities involved.



8.4 Managing processes

8.4.1 To manage its processes effectively and efficiently, the organization should:

- a) manage the processes and their interactions, including externally provided processes, as a system to enhance alignment/linkage between the processes;
- b) visualize the network of processes, their sequence and interactions in a graphic (e.g. process map, diagrams) in order to understand the roles of each process in the system and its effects on the performance of the system;
- c) determine criteria for the outputs of processes, evaluate the capability and performance of processes by comparing the outputs with the criteria, and plan actions to improve the processes when they are not effectively achieving the performance expected by the system;
- d) assess the risks and opportunities associated with the processes and implement any actions that are necessary in order to prevent, detect and mitigate undesired events, including risks such as:

- 1) human factors (e.g. shortage of knowledge and skills, rule violations, human errors);
 - 2) inadequate capability, deteriorations and breakdowns of equipment;
 - 3) design and development failure;
 - 4) unplanned changes in incoming materials and services;
 - 5) uncontrolled variation in the environment for the operation of processes;
 - 6) unexpected changes in the needs and expectations of interested parties, including market demand;
- e) review the processes and their interrelationships on a regular basis and take suitable actions for control and improvement, to ensure they continue to be effective and support the sustained success of the organization.

8.4.2 Processes should operate together within a coherent management system.

Some processes will relate to the overall management system and some will additionally relate to a specific managerial aspect, such as:

- a) the quality of products and services, including cost, quantity and delivery (e.g. ISO 9001);
- b) health, safety, security (e.g. ISO 45001, ISO/IEC 27001);
- c) environment, energy (e.g. ISO 14001, ISO 50001);
- d) social responsibility, anti-bribery, compliance (e.g. ISO 26000, ISO 37001, ISO 19600);
- e) business continuity, resilience (e.g. ISO 22301, ISO 22316).

8.4.3 To attain a higher level of performance, the processes and their interactions should be continually

improved according to the organization's policies, strategy and objectives (see 7.2 and 7.3), including

consideration of the need to develop or acquire new technologies, or to develop new products and services or their features, for added value.

The organization should motivate people to engage in improvement activities and propose opportunities

for improvement in the processes in which they are involved.

The organization should regularly review the achievement of objectives for the improvement of

processes and their interactions, the progress of action plans, and the effects on the organization's

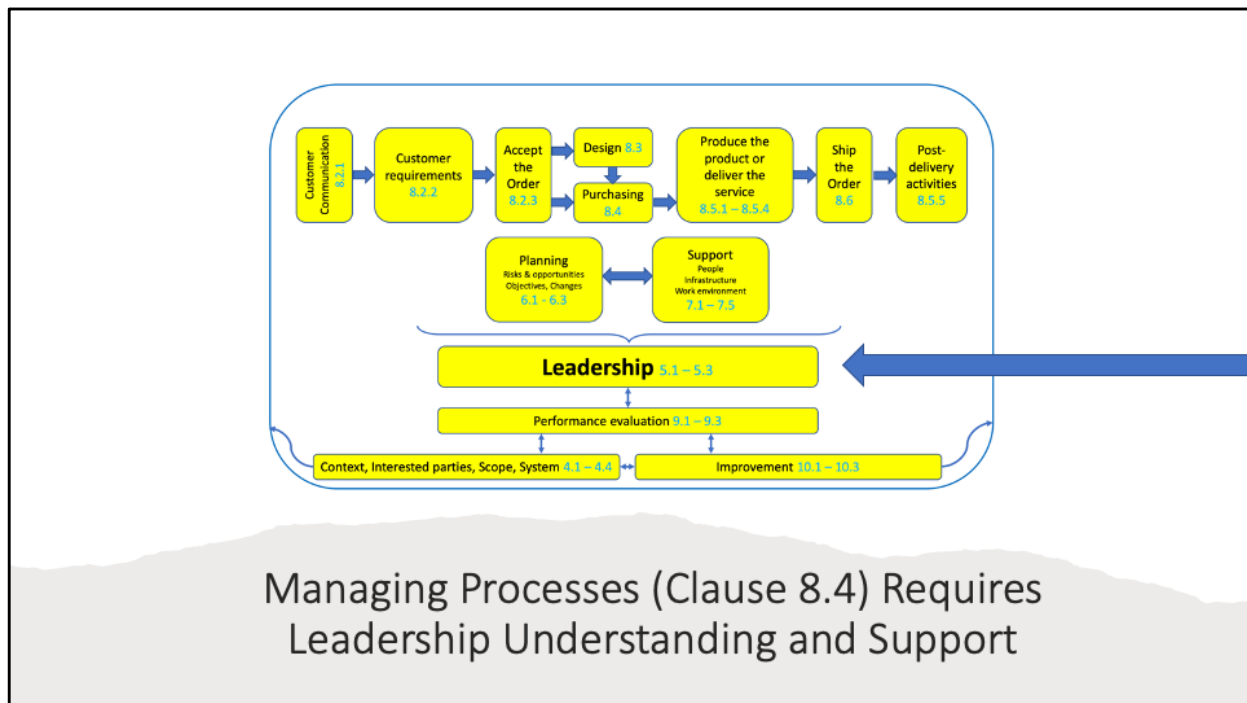
policies, objectives and strategies. It should take any necessary corrective actions, or other appropriate

actions, when gaps are identified between the planned and actual activities.

8.4.4 To maintain the level of performance attained, processes should be operated under controlled conditions, regardless of any planned and unplanned changes. The organization should determine what procedures (if any) are needed to manage a process, including the criteria for process outputs and operational conditions, to ensure conformity with the criteria. When procedures are applied, in order to ensure that they are followed by people involved in the operation of the process, the organization should ensure that:

- a) a system is established to define the knowledge and skills needed for processes and evaluate the knowledge and skills of the process operators;
- b) risks in the procedures are identified, assessed and reduced by improving the procedures (e.g. making it difficult to make errors or not allowing progression to the next process if an error occurs);
- c) resources necessary for people to follow the procedures are made available;
- d) people have the knowledge and skills needed for following the procedures;
- e) people understand the impacts of not following the procedures (e.g. by using examples of experienced undesired events) and managers at appropriate levels take the actions that are necessary whenever a procedure is not followed;
- f) consideration is given to learning, training, motivation and prevention of human error.

8.4.5 The organization should monitor its processes on a regular basis to detect deviations, and should identify and take appropriate actions when necessary without delay. Deviations are mainly caused by changes in equipment, method, material, measurement, environment and people for the operation of processes. The organization should determine check points and related performance indicators that will be effective and efficient in detecting deviations.



8.4 Managing processes

8.4.1 To manage its processes effectively and efficiently, the organization should:

- a) manage the processes and their interactions, including externally provided processes, as a system to enhance alignment/linkage between the processes;
- b) visualize the network of processes, their sequence and interactions in a graphic (e.g. process map, diagrams) in order to understand the roles of each process in the system and its effects on the performance of the system;
- c) determine criteria for the outputs of processes, evaluate the capability and performance of processes by comparing the outputs with the criteria, and plan actions to improve the processes when they are not effectively achieving the performance expected by the system;
- d) assess the risks and opportunities associated with the processes and implement any actions that are necessary in order to prevent, detect and mitigate undesired events, including risks such as:

- 1) human factors (e.g. shortage of knowledge and skills, rule violations, human errors);
 - 2) inadequate capability, deteriorations and breakdowns of equipment;
 - 3) design and development failure;
 - 4) unplanned changes in incoming materials and services;
 - 5) uncontrolled variation in the environment for the operation of processes;
 - 6) unexpected changes in the needs and expectations of interested parties, including market demand;
- e) review the processes and their interrelationships on a regular basis and take suitable actions for control and improvement, to ensure they continue to be effective and support the sustained success of the organization.

8.4.2 Processes should operate together within a coherent management system.

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Quiz!

Now We'll Look at Clauses 9, 10 & 11

	9	Resource management	11
	9.1	General.....	11
	9.2	People.....	12
	9.2.1	General.....	12
	9.2.2	Engagement of people.....	12
	9.2.3	Empowerment and motivation of people.....	12
	9.2.4	Competence of people.....	13
	9.3	Organizational knowledge.....	13
	9.4	Technology.....	14
	9.5	Infrastructure and work environment.....	14
	9.5.1	General.....	14
	9.5.2	Infrastructure.....	14
	9.5.3	Work environment.....	14
	9.6	Externally provided resources.....	15
	9.7	Natural resources.....	15
	10	Analysis and evaluation of an organization's performance	16
	10.1	General.....	16
	10.2	Performance indicators.....	16
	10.3	Performance analysis.....	18
	10.4	Performance evaluation.....	18
	10.5	Internal audit.....	19
	10.6	Self-assessment.....	20
	10.7	Reviews.....	20
	11	Improvement, learning and innovation	21
	11.1	General.....	21


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<https://www.iso.org/standard/70397.html>

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	11.1	General	21

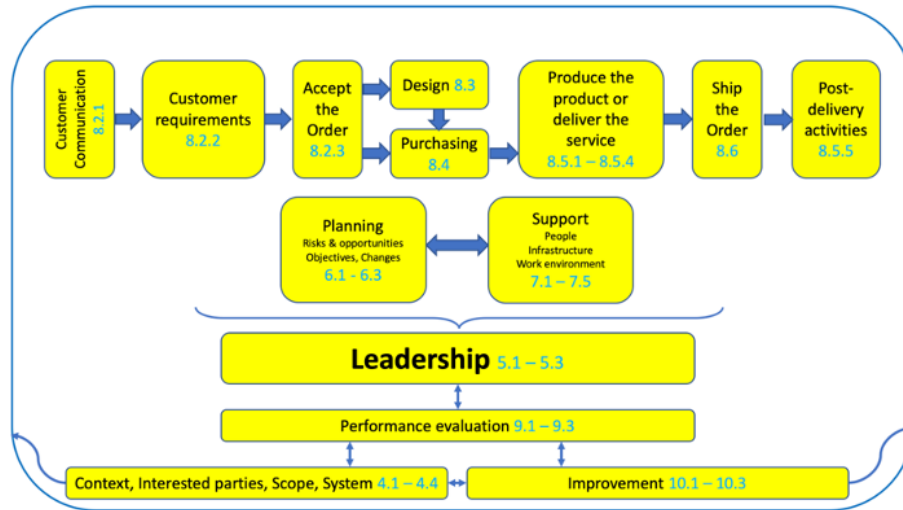
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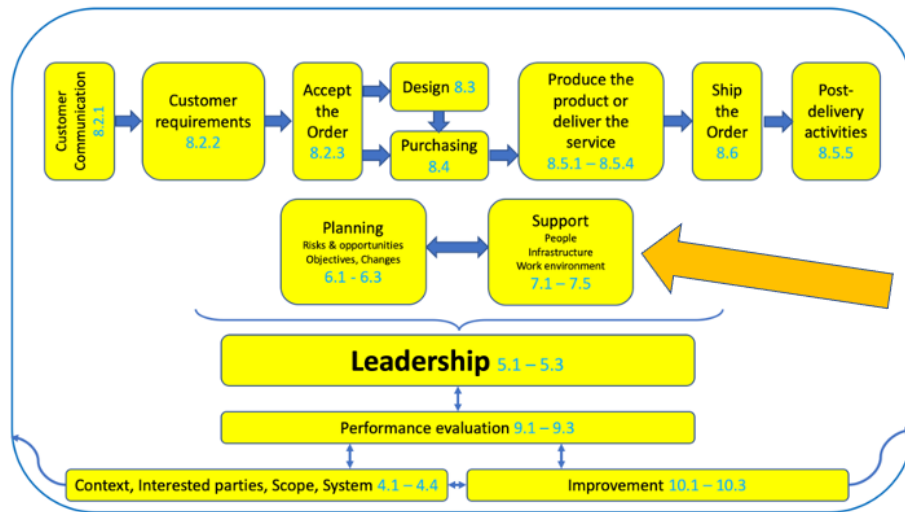
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Clause 9 in ISO 9004 Lines Up With Clause 7 (Support) of the HLS Standards...



ISO 9001
 ISO 14001
 ISO 22000
 ISO 27001
 ISO 45001
 ISO 55001
 Others...

Clause 9 in ISO 9004 Lines Up With Clause 7 (Support) of the HLS Standards...



ISO 9001
 ISO 14001
 ISO 22000
 ISO 27001
 ISO 45001
 ISO 55001
 Others...



We Always Need People!





The Infrastructure Needs to be Adequate...

For services, too



And a supportive Work Environment

Clause 10 in ISO 9004 Matches Clause 9 (Performance Evaluation) in
the HLS Standards



1. Performance indicators [10.2]
2. Performance analysis [10.3]
3. Performance evaluation [10.4]
4. Internal audit [10.5]
5. Self assessment [10.6]
6. Reviews [10.7]

Clause 10 in ISO 9004 Matches Clause 9 (Performance Evaluation) in the HLS Standards



Performance
Indicators (10.2)



Performance
Analysis (10.3)



Performance
Evaluation (10.4)



Internal
Audit (10.5)

Self assessment (10.6) Management Reviews (10.7)

1. Performance indicators [10.2]
2. Performance analysis [10.3]
3. Performance evaluation [10.4]
4. Internal audit [10.5]
5. Self assessment [10.6]
6. Reviews [10.7]



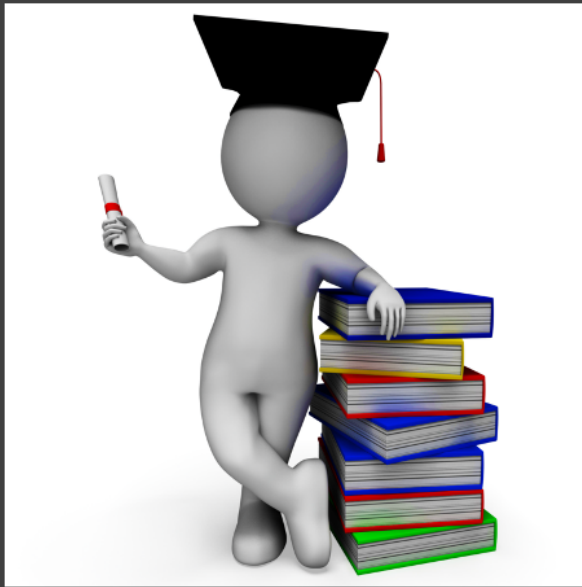
Clause 11 has Guidance for Improvement, Learning and Innovation to Improve Your Organizational Resilience



Improvement
(11.2) is the
Best Insurance
For Sustained
Success

$$\text{\$50,000} \times .02 = \text{\$1,000}$$

This means that if you have a \$1,000 mistake and if you operate at a 2% net profit, you'll need **\$50,000** in new business to make up for the error

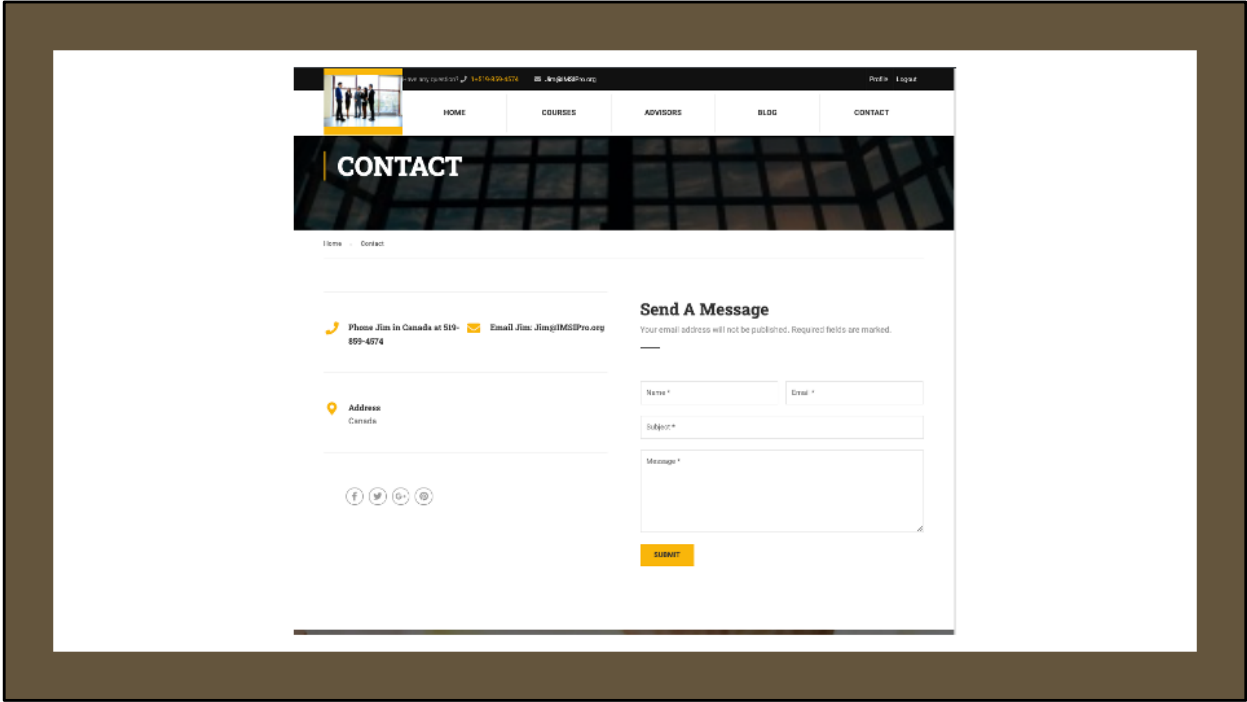


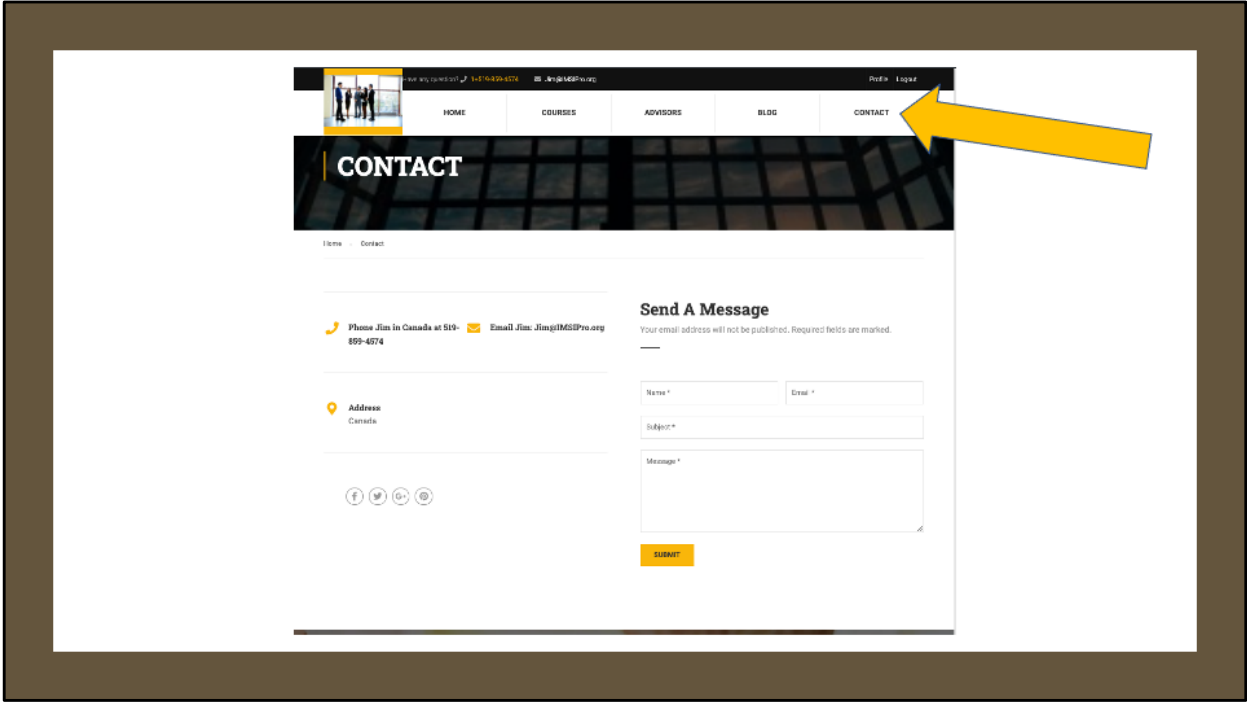
Learning
(11.3) Makes
Your People
More Valuable
and Can Really
Help Morale

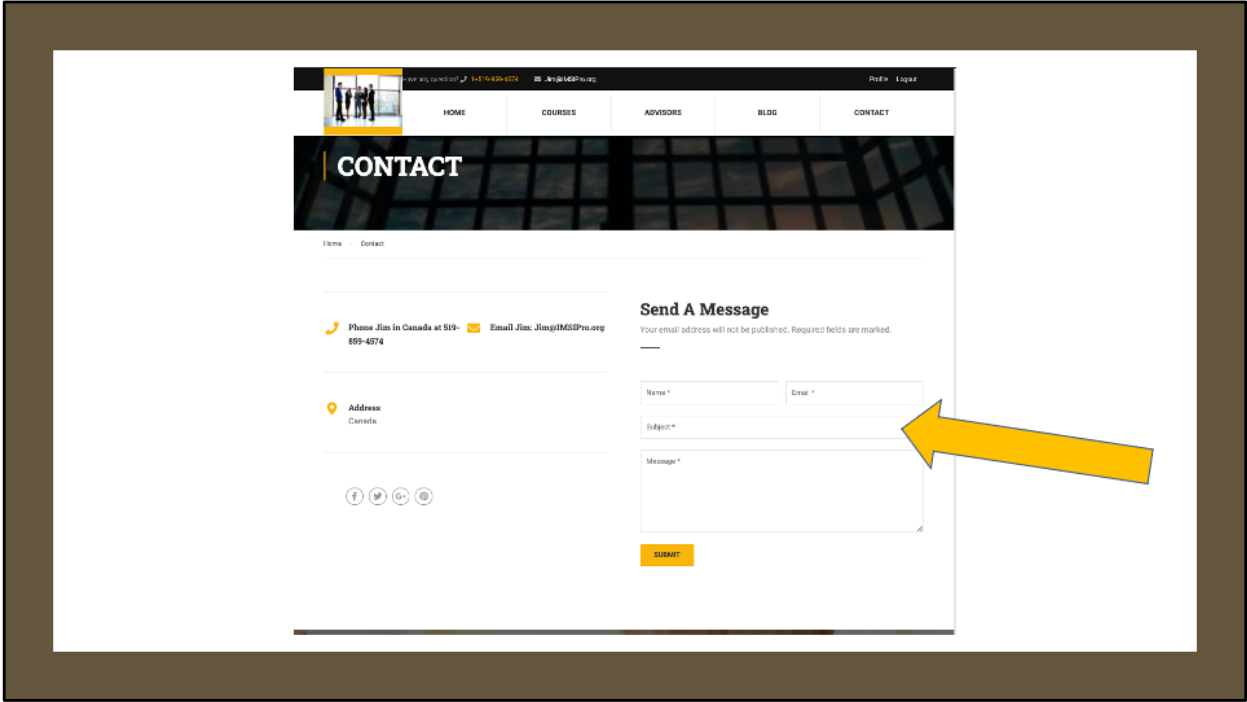


Innovation (11.4) Will Keep You Ahead of Your Competition

Quiz!







← → ↻ 🏠 imsipro.org/courses/course-3-iso-55001-asset-management/lessons/iso-31000-part-2/

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- 1.2 Quiz #2 – ISO 31000 – Section 2: Framework
3 questions
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Unit #3 – ISO 31000 Part 3: The Process

Here's a quick overview of ISO 31000 'Process':



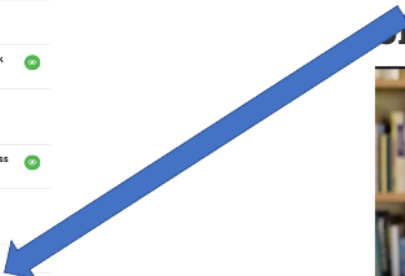
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- 1.2 Quiz #2 – ISO 31000 – Section 2:
Framework
3 questions
- 1.4 Unit #3 – ISO 31000 Part 3: The Process ✔
- 1.3 Quiz #3 – ISO 31000 – Section 3: The
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Unit #3 – ISO 31000 Part 3: The Process

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**Next up: MSP Course #2: ISO ISO 10004 –
Customer satisfaction — Guidelines for
monitoring and measuring**

We hope you found ISO 9004 helpful!