

ISO 9001:2015

Quality Management Systems

Manual

[Preview]

[Company Name]

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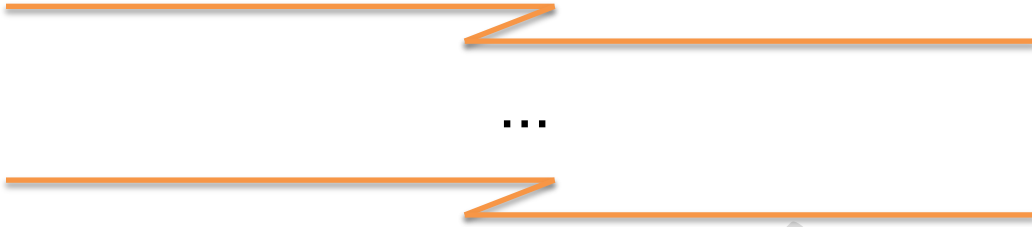


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Section 4: Context of the Organization

4.1 Understanding Organization and its Context

[Company Name]'s leadership defines the context of the organization – a set of internal issues (internal context) and external issues (external context), that are relevant to the Organization's objectives and strategic directions of development that affect the Organization's ability to achieve planned results.

Activities to monitor, analyze, and communicate the information about the internal and external context (Fig. 4.1-01) include three components:

- gathering of information and analysis of the components of internal and external context in QMS processes;
- communication of information about the context inside the organization;
- use of information about the context of the organization.

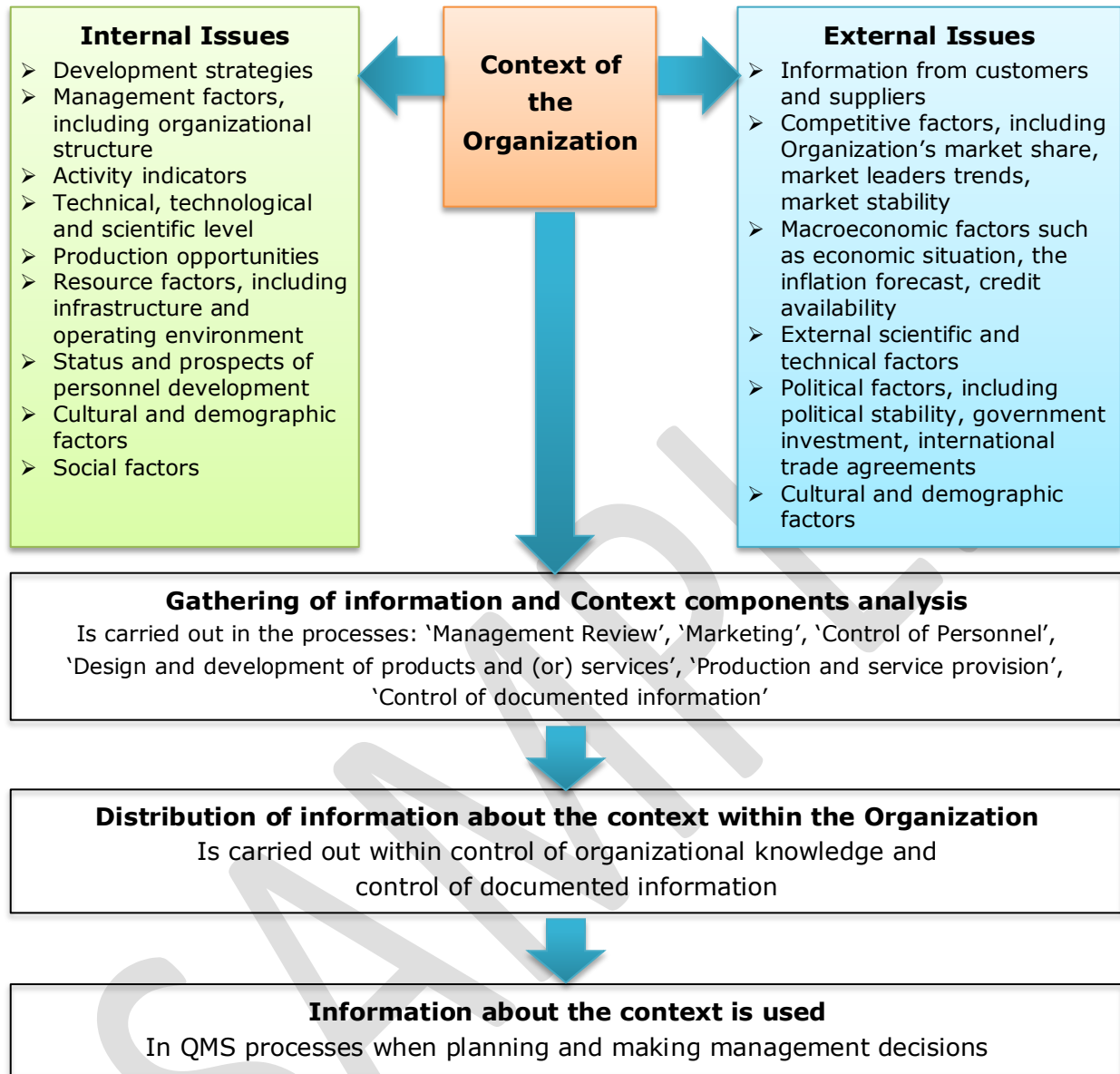


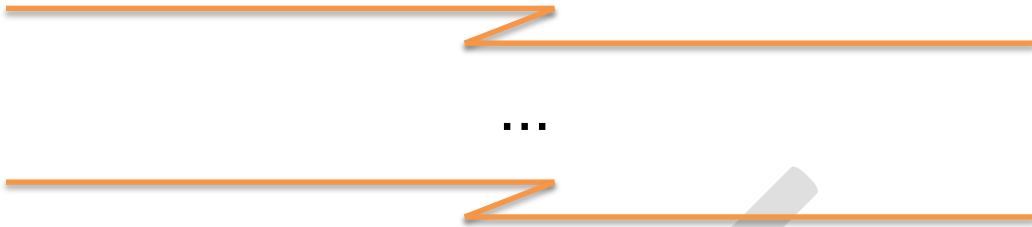
Fig.4.1.-01 The diagram of activities to monitor, analyze and communicate the information about the internal and external context within the Organization.

4.1.1 Gathering of information and analysis of the components of internal and external context are carried out in the following QMS processes.

- 1) Analysis of the context of the organization’s components is carried out in the ‘Management review’ process (sec. 9.3):



- Organization management factors such as organizational structure, the use of risk management in decision-making, etc.;



4.2 Understanding Requirements and Expectations of Interested Parties

Interaction of [Company Name] with the interested parties (fig. 4.2-01) includes:

- defining interested parties relevant to the QMS;
- monitoring and analysis of interested parties' needs and expectations.

Defining interested parties relevant to the QMS is carried out in management review (sec.9.3).

Monitoring and analysis of interested parties' needs and expectations is held on a regular basis in the processes of the QMS in accordance with the diagram shown in Fig. 4.2-01. Reports on the results of the analysis of the needs and expectations of interested parties are addressed in the management review (sec. 9.3).

Interested party	Form of Information about Interested Parties Needs and Expectations	Process, where monitoring and analysis of Interested Parties Needs and Expectations is carried out
<i>Owners Stakeholders</i>	Shareholders (owners) Meetings minutes	'Management Review'
<i>Customers</i>	Customer contracts that came into effect	'Contract analysis'
	Marketing research reports (parts relevant to the potential requirements)	'Marketing'
	Letters	'Service provision' (post-delivery activity),

Interested party	Form of Information about Interested Parties Needs and Expectations	Process, where monitoring and analysis of Interested Parties Needs and Expectations is carried out
	Minutes of meetings with customers' participation Claims	'Management review', 'Control of nonconforming process outputs, products, and services', 'Corrective actions'
	Legal requirements relevant to the protection of consumers' rights	'Control of Documented Information', 'Design and development of products and services'
<i>Suppliers</i>	Supplier contracts Supplier meetings minutes	'Control of externally provided processes, products, and services', 'Management Review'
<i>Employees</i>	Labor contract; Personnel meeting minutes; Union documents (protocols, contracts, decisions)	'Control of Personnel', 'Management Review'
<i>Legislative and regulatory bodies (local, regional, state / provincial, national or international)</i>	- The laws and regulations. - International, national and industry codes and standards. - Permits, licenses and other forms of authorization; - Regulatory bodies orders	'Control of Documented Information', 'Management Review'
<i>Society</i>	- Information acquired during PR actions; - Municipal programs	'Marketing', 'Management Review'
<i>Competitors</i>	Marketing research reports	'Marketing'

Fig.4.2-01. Monitoring and Analysis of Interested Parties Needs and Expectations Diagram

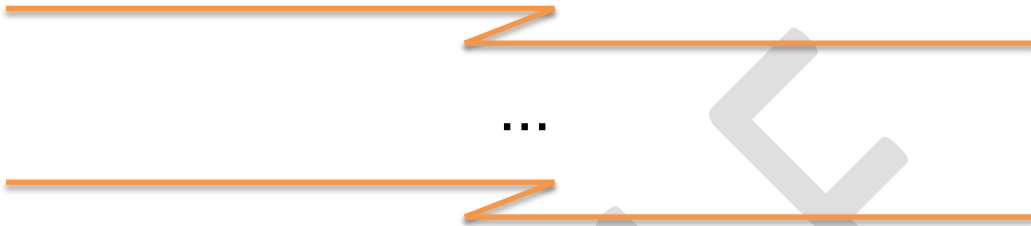
When operating the QMS processes listed in the Diagram (Fig. 4.2-01) the two-way communication is carried out between the organization and the interested parties, that includes the transfer of information about the organization's activities and the QMS.

The results of monitoring and analysis of the interested parties needs and expectations are taken into account:

- when defining the scope of the QMS (sec. 4.3.);



- when defining the QMS processes (sec. 4.4.);
- in the 'Management Review' process when elaborating the mission, the strategic directions of development, policy and Organization development programs (sec. 9.3, sec. 6.2);
- in QMS processes when planning and making management decisions.



4.4 Quality Management System and its Processes

[Company Name] developed, implemented, maintains, and continuously improves Quality Management System (QMS) in compliance with the requirements of ISO 9001:2015.

Process approach is the basis of the QMS. It was implemented as follows.

4.4.1 Organization Leadership as part of the management review (section 9.3):

- Defines QMS processes, based on the requirements of ISO 9001:2015, the strategic directions of the Organization's development, internal and external context (sec.4.1), the needs and expectations of interested parties (sec.4.2), and QMS scope (sec.4.3);
- Provides QMS processes with the required resources (sec.7.1), including resources to address risks and opportunities (sec.6.1);
- Conducts the overall QMS processes implementation review based on the process owners' information;
- Ensures implementation of projects to improve processes and QMS.

4.4.2 QMS processes implementation is regulated by documented procedures (QSP). QSP format, that describes the QMS processes, includes mandatory requirements:

- identify necessary inputs and expected outputs of the process by applying the process model;

- determine the sequence and interaction of QMS processes through the application of the process model;
- define process criteria, including effectiveness; the criteria are measured and analyzed at the established intervals;
- define resources, necessary to operate the process;
- define responsibility and authority of participants, including process owners;
- address risks and opportunities, including identification, analysis, and treatment (sec. 6.1).

The diagram illustrating the sequence and interaction of QMS processes is displayed in Fig. 4.4-01.

4.4.3 Process owners are responsible for process operation in conformance with the QSP, and, above other, ensure:

- The completeness of process description;
- The definition of Process criteria, trends analysis, and providing information for management review;
- Identification, analysis, and treatment of risks and opportunities;
- Activities to improve the process using process resources and (or) the initiation (and escalation to the leadership) of process improvement projects that require the budget of the organization (sec.6.2).

4.4.4 Processes operation in accordance with the planned indicators is ensured by two categories of documented information:

- Documented procedures (sec. 4.4.2);
- Records, specified in the QSP, including the results of analysis and determination of process criteria; results of identification, analysis, and treatment of process risks and opportunities, etc.

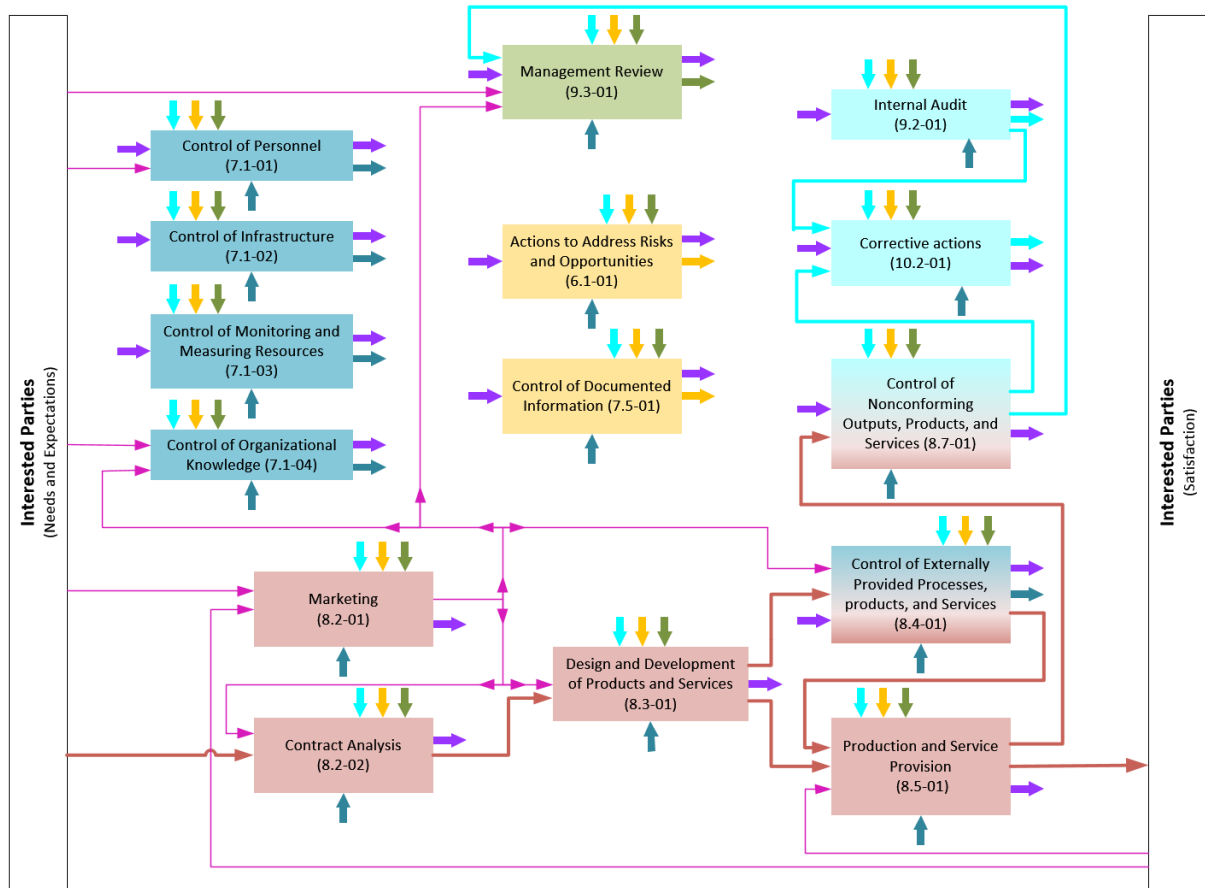


Fig. 4.4-01 [Company Name] sequence and interaction of QMS processes diagram

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All **diagrams and models** included in the package **in original format (MS Visio, MS Power Point)**.

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