

ISO 9001:2015

ISO 14001:2015

*Integrated Management Systems
Manual*

[Preview]

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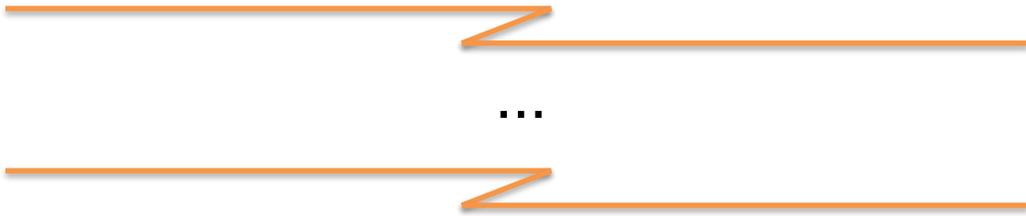
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Section 4: Context of the Organization

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. These issues include environmental conditions that are affected or may be affected by the organization.

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 IMS processes;
- communication of information about the context inside the organization;
- use of information about the context of the organization.



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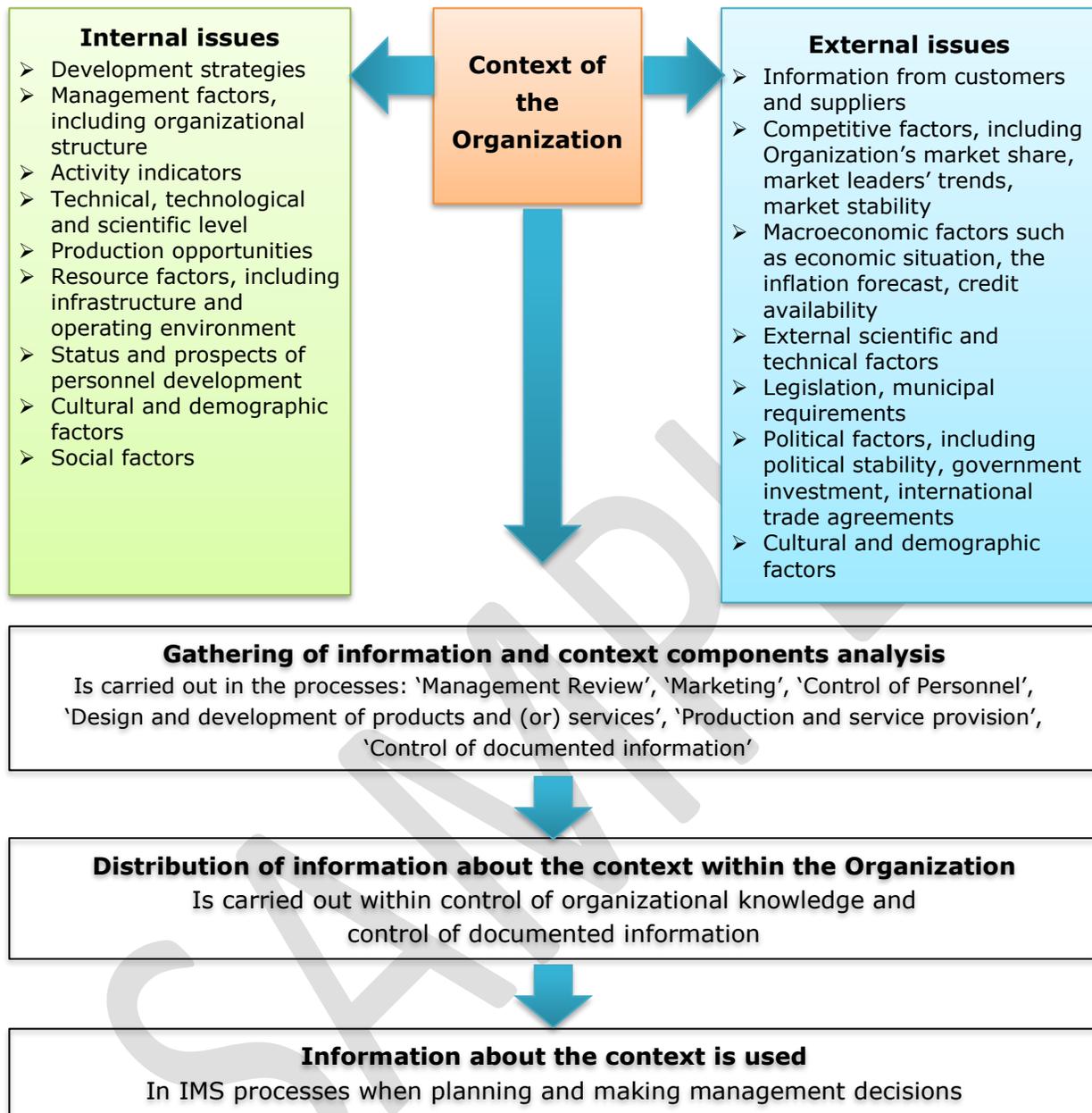
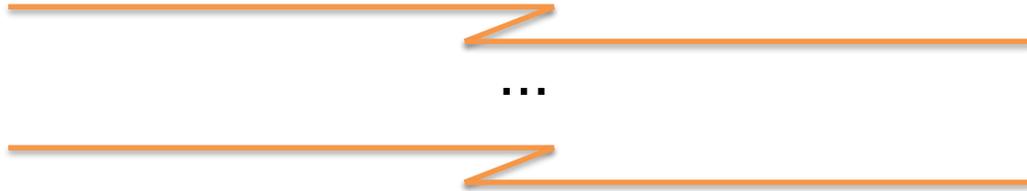


Fig.4.1.-01 The diagram of activities to monitor, analyze and communicate the information about the internal and external context within the Organization.

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

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



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 IMS;
- monitoring and analysis of interested parties' needs and expectations.

Defining interested parties relevant to the IMS 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 IMS 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</i> <i>Stakeholders</i>	Shareholders (owners) Meetings minutes	'Management review' (sec. 9.3)
<i>Customers</i>	Customer contracts that came into effect	'Contract analysis' (sec. 8.2.3)
	-Marketing research reports (parts relevant to the potential requirements); - Information for customers regarding the absence of negative impact of products or services on the customers' health; - Information for customers regarding the fact that the	'Marketing' (sec. 8.2.2)

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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
	customer does not pollute the environment when using products or services.	
	-Letters; -Minutes of meetings with customers' participation; -Claims	'Service provision' (post-delivery activity) (sec. 8.5.5), 'Management review' (sec. 9.3), 'Control of nonconforming process outputs, products, and services' (sec. 8.7), 'Corrective actions' (sec. 10.2)
	Legal requirements relevant to the protection of consumers' rights.	'Control of documented information' (sec. 7.5), 'Design and development of products and services' (sec. 8.3)
<i>Suppliers</i>	-Supplier contracts; -Supplier meetings minutes.	'Control of externally provided processes, products, and services' (sec. 8.4), 'Management review' (sec. 9.3)
<i>Employees</i>	-Labor contract; -Personnel meeting minutes; -Union documents (protocols, contracts, decisions); - Information on the minimizing negative impact on health.	'Control of personnel' (sec. 7.1.2), 'Management review' (sec. 9.3), Internal communication (sec.7.4.2)
State via <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; - Compliance obligations are reviewed by the Department of Environmental Management.	'Control of documented information' (sec. 7.5), 'Management review' (sec. 9.3), 'Environmental management' (sec. 8.8)
<i>Society</i>	- Information acquired during PR actions; - Municipal programs; - Information on the absence of negative impact on human health and the environment.	'Marketing' (sec. 8.2.2), 'Management review' (sec. 9.3), External communication (sec.7.4.3)



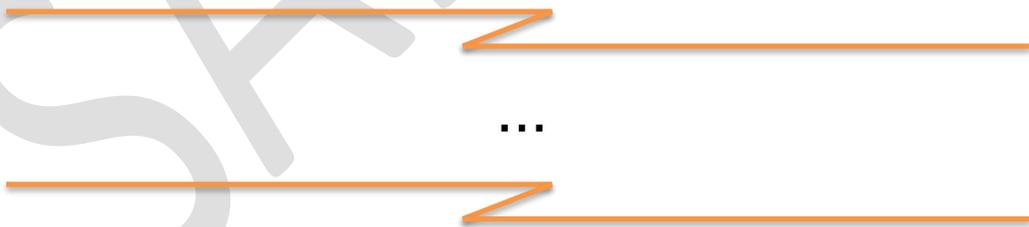
Interested party	Form of information about interested parties needs and expectations	Process, where monitoring and analysis of interested parties needs and expectations is carried out
<i>Competitors</i>	Marketing research reports	'Marketing' (sec. 8.2.2)

Fig.4.2-01. Monitoring and analysis of interested parties needs and expectations diagram

When operating the IMS 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 IMS.

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

- when defining the scope of the IMS (sec. 4.3.);
- in the IMS development, implementation, provision and continual improvement (sec. 4.4.);
- in the 'Management review' process when elaborating the mission, the strategic directions of development, Quality & Environmental Policy and Organization development programs (sec. 9.3, sec. 6.2),
- when carrying actions to address risks and opportunities, including the work with environmental aspects (sec.6.1);
- in IMS processes when planning and making management decisions.



4.4 Integrated Management System and its processes

[Company Name] developed, implemented, maintains, and continuously improves Integrated Management System (IMS) in compliance with the requirements of ISO 9001:2015 and ISO 14001:2015.

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

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

- Defines IMS processes, based on the requirements of ISO 9001:2015 and ISO 14001:2015, the strategic directions of development, internal and external context (sec.4.1), the needs and expectations of interested parties (sec.4.2), and IMS scope (sec.4.3);
- Provides IMS processes with the required resources (sec.7.1), including resources to address risks and opportunities (sec.6.1);
- Conducts the overall IMS processes implementation review based on the process owners' information;
- Ensures implementation of projects to improve processes and IMS.

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

- identify necessary inputs and expected outputs of the process by applying the process model;
- determine the sequence and interaction of IMS 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 risks identification, risks analysis, and risks treatment (sec. 6.1.1);
- determine environmental aspects and associated environmental impacts and identifies significant environmental aspects (sec. 6.1.2);
- fulfill the compliance obligations (sec. 6.1.3) and planning action (sec.6.1.4).

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

4.4.3 Process owners are responsible for process operation in conformance with the MSP, 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, including environmental aspects, compliance obligations, planning action (sec.6.1);



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- 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 Environmental management activity is carried out:

- in all business processes of the Organization, that are in scope of the IMS;
- centrally in 'Environmental management' process.

In 'Environmental management' process:

- determination of environmental aspects and associated environmental impacts and identification of significant environmental aspects (sec. 6.1.2) are coordinated;
- fulfilling the compliance obligations (sec. 6.1.3) is coordinated;
- planning action activity (sec. 6.1.4) is coordinated;
- interested parties' external communication (sec. 7.4.3) is ensured;
- emergency response and preparation, actions to prevent or mitigate the effects of emergencies, periodic verification of planned response actions, periodic analysis and review of emergency preparedness and response (sec. 8.8) are ensured.

Environmental Management Department head is the owner of the 'Environmental management' process.

4.4.5 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 MSP, including the results of analysis and determination of process criteria; results of identification, analysis, and treatment of process risks and opportunities, etc.

4.4.6 Control of changes is an essential part of IMS operation. Analysis of changes in the IMS is done via Management review (sec.9.3). Monitoring of the results of changes in the IMS is carried out during internal audits (sec. 9.2).

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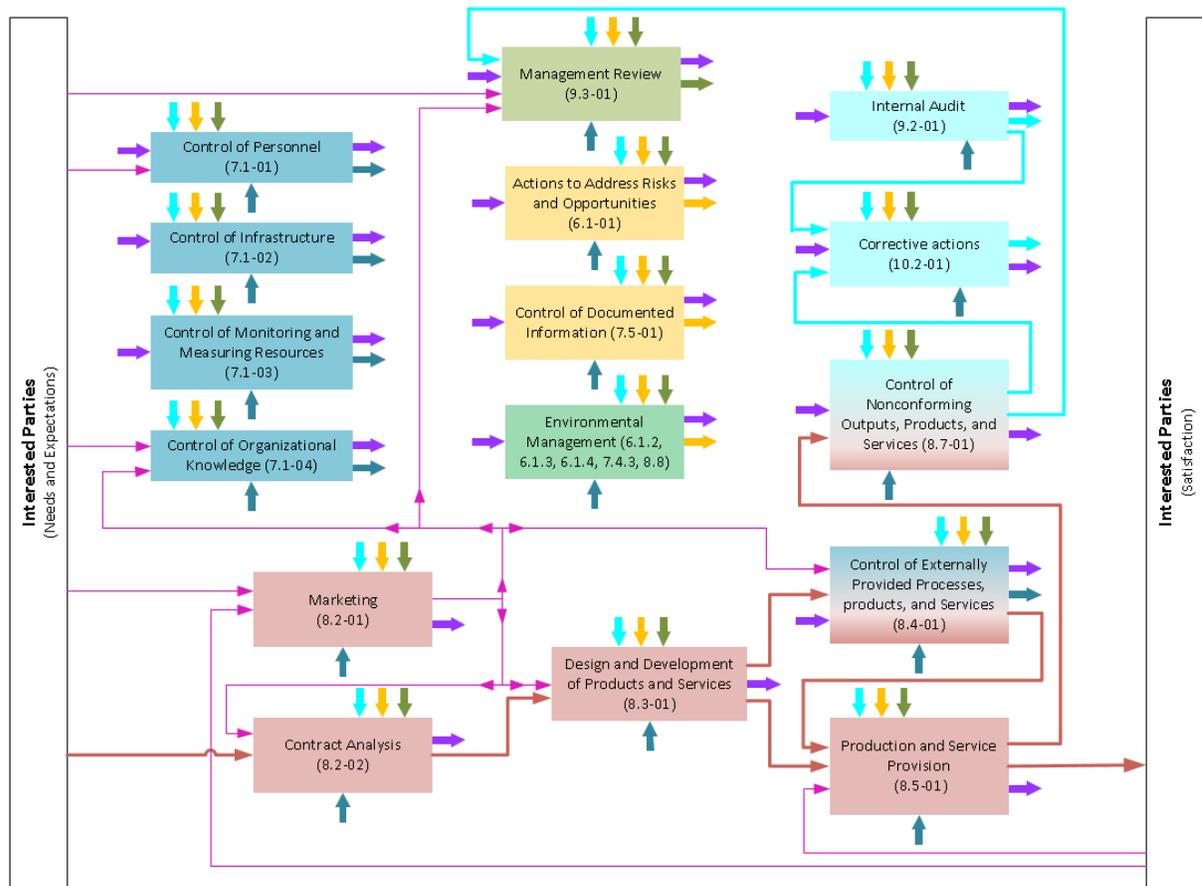


Fig. 4.4-01 [Company Name] sequence and interaction of IMS processes diagram

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