

ISO 9001:2015

ISO 14001:2015

*Integrated Management Systems
Manual*

[Preview]

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Contents

Introduction	8
Section 1: Scope	10
Section 2: Reference documents	10
Section 3: Terms and definitions	11
3.1 Terms related to organization and leadership	11
3.2 Terms related to planning	11
3.3 Terms related to support and operation	12
3.4 Terms related to performance evaluation and improvement	14
Section 4: Context of the Organization	15
4.1 Understanding Organization and its context	15
4.2 Understanding requirements and expectations of interested parties	19
4.3 Determining the scope of the Integrated Management System	22
4.4 Integrated Management System and its processes	23
Section 5: Leadership	27
5.1 Leadership and commitment	27
5.1.1 General	27
5.1.2 Customer focus	28
5.2 Quality & Environmental Policy	29
5.2.1 Quality & Environmental Policy development	29
5.2.2 Quality & Environmental Policy communication	31
5.3 Roles, responsibilities, and authorities in the Organization	31
Section 6: Integrated Management System Planning	34
6.1 General	34
6.1.1 Actions to address risks and opportunities	34
6.1.1.1 Planning of actions to address risks and opportunities. Risk management framework design.	36



Integrated Management Systems Manual

- 6.1.1.2 Integration and implementation of actions to address risks and opportunities into the IMS processes..... 37
- 6.1.1.3 Evaluation of the effectiveness of actions to address risks and opportunities. Monitoring and analysis of risk management framework..... 40
- 6.1.1.4 Achieving improvement 41
- 6.1.2 Environmental aspects 41
- 6.1.3 Compliance obligations..... 44
- 6.1.4 Planning action 46
- 6.2 IMS objectives and planning to achieve them 48
- 6.3 Planning of changes 49
- Section 7: Maintenance 50
- 7.1 Resources 50
- 7.1.1 General..... 50
- 7.1.2 People 51
- 7.1.3 Infrastructure..... 55
- 7.1.4 Processes Operation Environment..... 58
- 7.1.5 Monitoring and Measuring Resources..... 59
- 7.1.6 Organizational knowledge 64
- 7.2 Competence 70
- 7.3 Awareness 71
- 7.4 Communication 71
- 7.5 Documented Information 78
- 7.5.1 General..... 78
- 7.5.2 Creating and updating..... 79
- 7.5.3 Control of Documented Information 80
- Section 8: Operation 81
- 8.1 Operational planning and control 81
- 8.2 Requirements for products and services..... 88
- 8.2.1 Customer communication 88



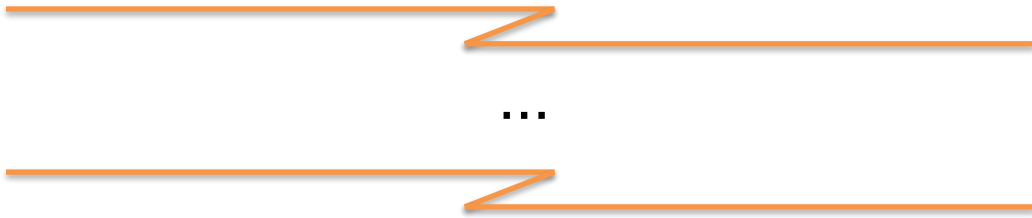
Integrated Management Systems Manual

8.2.2 Marketing	88
8.2.3 Review of requirements relevant to products and services.....	93
8.3 Design and development of products and services.....	98
8.3.1 General	98
8.3.2 Design and development inputs may include the following.....	98
8.3.3 Design and development planning and controls	99
8.3.4 Design and development outputs	101
8.3.5 Changes to the Design and Development	102
8.4 Control of externally provided products and services	102
8.4.1 General	102
8.4.2 Purchasing management	103
8.4.3 Outsourcing management.....	107
8.4.4 Management of Supply Chain on behalf of the Organization	108
8.4.5 2nd party audits	108
8.4.6 Drafting and control of Supplier contracts execution.....	109
8.5 Production and service provision.....	110
8.5.1 Control of production and service provision	110
8.5.2 Identification and traceability	111
8.5.3 Property belonging to customers or external providers	112
8.5.4 Preservation.....	112
8.5.5 Post-delivery activities	113
8.5.6 Control of changes	114
8.6 Release of products and services	114
8.7 Control of nonconforming process outputs, products and services	114
8.8 Emergency preparedness and response	116
Section 9: Performance evaluation.....	119
9.1 Monitoring, measurement, analysis and evaluation.....	119
9.1.1 General	119
9.1.2 Customer satisfaction.....	119



Integrated Management Systems Manual

9.1.3 Analysis and evaluation of quality indicators	120
9.1.4 Monitoring, measurement, analysis and evaluation of environmental indicators	121
9.1.5 Evaluation of compliance	126
9.2 Internal audit.....	127
9.2.1 Audit planning	127
9.2.2 Preparation and Conducting of the Audit.....	128
9.2.3. Results presentation and Audit report.....	130
9.2.4 'Internal Audit' Process Analysis and Improvement.....	131
9.3 Management review.....	131
Section 10: Improvement	133
10.1 General.....	133
10.2 Nonconformity and corrective action.....	134
10.3 Continual improvement	136
10.3.1. Breakthrough projects.....	138
10.3.2 Small steps improvements	138
Related Documents	139



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.



Integrated Management Systems Manual

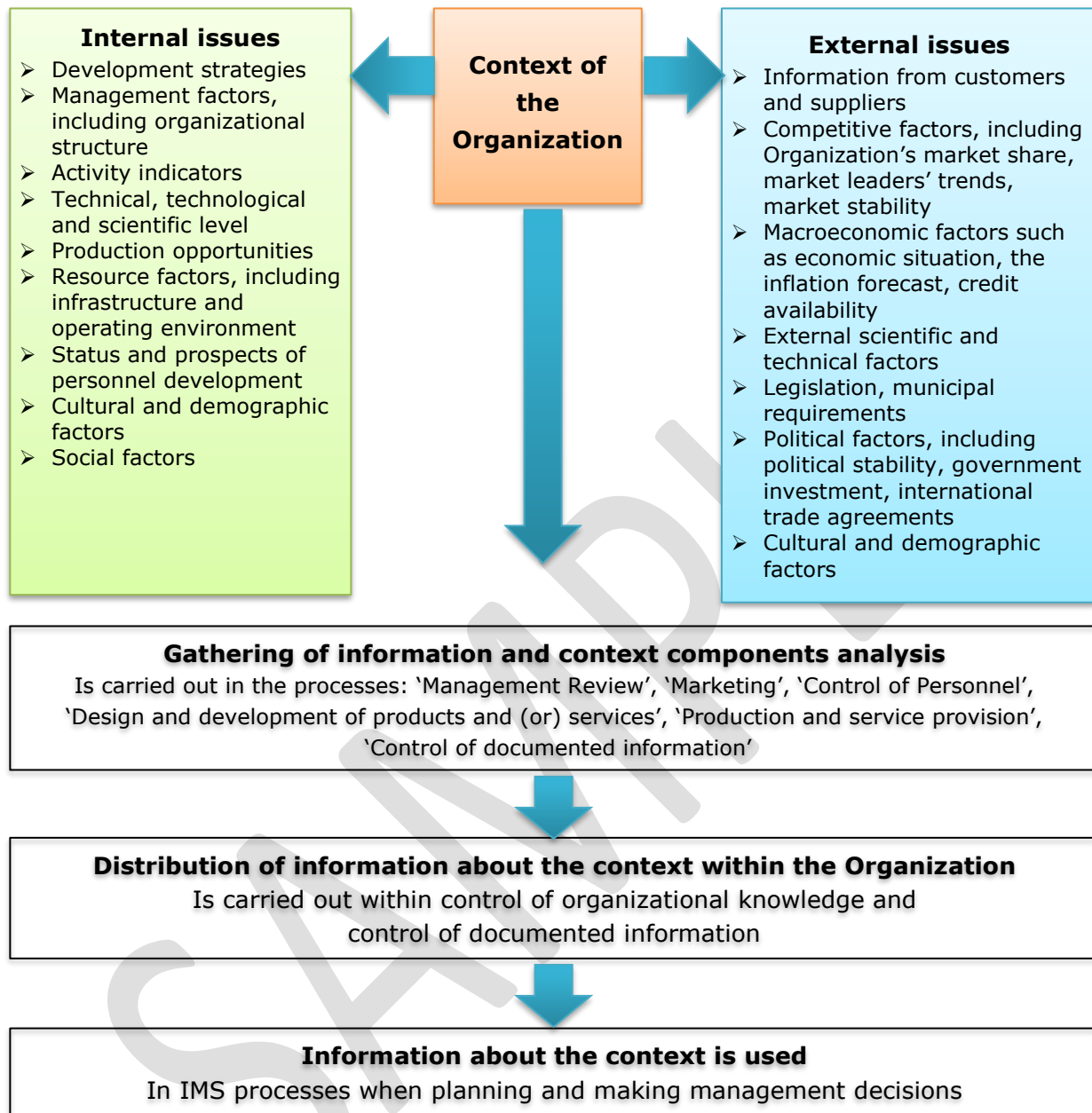
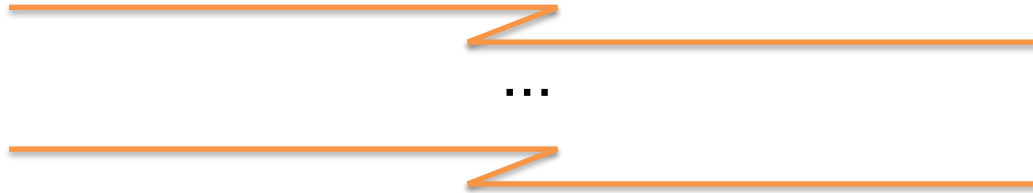


Fig.4.1.-01 The diagram of activities to monitor, analyze and communicate the information about the internal and external context within the Organization.

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
Owners Stakeholders	Shareholders (owners) Meetings minutes	'Management review' (sec. 9.3)
Customers	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)

Integrated Management Systems Manual

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.	
	<ul style="list-style-type: none"> -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>	<ul style="list-style-type: none"> -Supplier contracts; -Supplier meetings minutes. 	'Control of externally provided processes, products, and services' (sec. 8.4), 'Management review' (sec. 9.3)
<i>Employees</i>	<ul style="list-style-type: none"> -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>	<ul style="list-style-type: none"> - 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>	<ul style="list-style-type: none"> - 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)



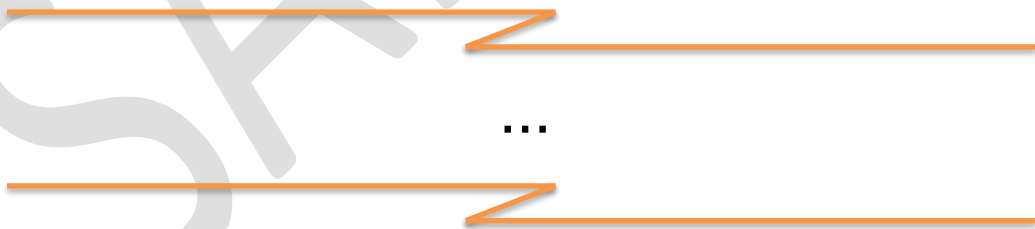
Interested party	Form of information about interested parties needs and expectations	Process, where monitoring and analysis of interested parties needs and expectations is carried out
Competitors	Marketing research reports	'Marketing' (sec. 8.2.2)

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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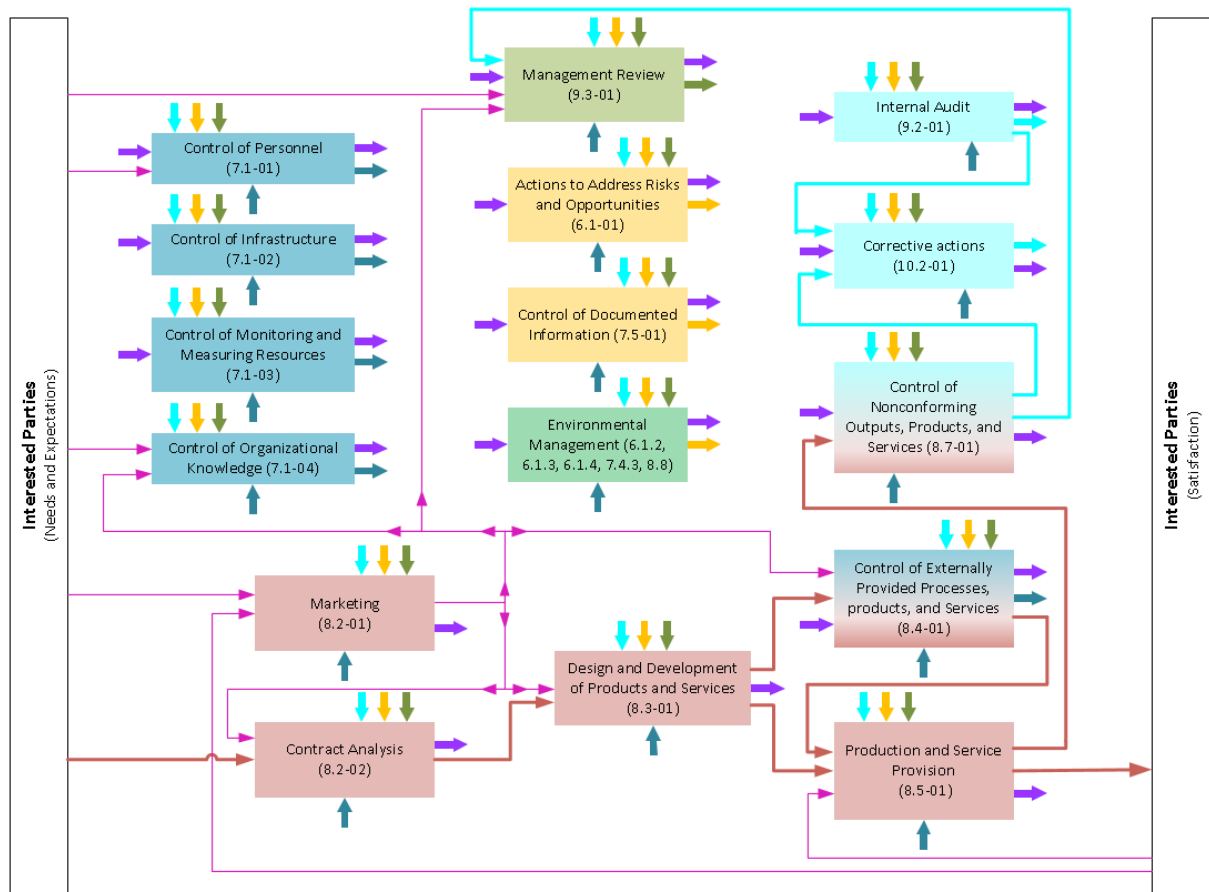


Fig. 4.4-01 [Company Name] sequence and interaction of IMS processes diagram

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