ISO 9001:2015

ISO 14001:2015

ISO 45001:2018

Integrated Management Systems

Manual

[Preview]

[Company Name]

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| Revision | Issue Date | Revision Description | |
|----------|------------|--|--|
| А | | Initial Issue | |
| В | | Change of structure and modifications relevant to the transition to the new version of ISO 9001:2015 | |
| С | | Integration of Quality Management System in accordance with ISO 9001:2015 and Environmental Management System in accordance with ISO 14001:2015 | |
| D | | Integration of Management System in accordance with ISO 9001:2015, ISO 14001:2015 and Occupational Health and Safety Management System in accordance with ISO 45001:2018 | |
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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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Internal issues

- Development strategies
- Management factors, including organizational structure
- Activity indicators
- Technical, technological and scientific level
- Production opportunities
- Resource factors, including infrastructure and operating environment
- Status and prospects of personnel development
- Cultural and demographic factors
- Social factors

Context of the Organization

External issues

- Information from customers and suppliers
- Competitive factors, including Organization's market share, market leaders' trends, market stability
- Macroeconomic factors such as economic situation, the inflation forecast, credit availability
- External scientific and technical factors
- Legislation, municipal requirements
- Political factors, including political stability, government investment, international trade agreements
- Cultural and demographic factors

Gathering of information and context components analysis

Is carried out in the processes: 'Management Review', 'Marketing', 'Control of Personnel', 'Design and development of products and (or) services', 'Production and service provision', 'Control of documented information'



Distribution of information about the context within the Organization

Is carried out within control of organizational knowledge and control of documented information



Information about the context is used

In IMS processes when planning and making management decisions

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

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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 |
|------------------------|---|--|
| Workers | -Labor contract; -Expressing one's opinion at the organization's meetings, including OH&S meetings; -Discussing drafts of the normative documents on the intranet before their approval; -Submitting proposals related to their needs and expectations, as well as deficiencies or improvements in the IMS. | 'Control of personnel' (sec. 7.1.2), 'Consultation and participation of workers' (sec. 5.4), 'Internal communication' (sec. 7.4.2), 'Control of documented information' (sec. 7.5), 'Management review' (sec. 9.3) |
| Owners Stakeholders | Shareholders (owners) Meetings minutes | 'Management review' (sec. 9.3) |

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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 | |
|---|--|--|--|
| 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 customer does not pollute the environment when using products or services. | | 'Marketing' (sec. 8.2.2) | |
| | -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) | |
| Suppliers | -Supplier contracts; -Supplier meetings minutes. | 'Control of externally provided processes, products, and services' (sec. 8.4), 'Management review' (sec. 9.3) | |
| State via Legislative and regulatory bodies (local, regional, state / provincial, national or international) | 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) | |
| Society | Information acquired during PR actions;Municipal programs; | 'Marketing' (sec. 8.2.2), 'Management review' (sec. 9.3), External communication (sec.7.4.3) | |

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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 | |
|--|--|--|--|
| | - Information on the absence of negative impact on human health and the environment. | | |
| 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 twoway 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, IMS 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, ISO 14001:2015, and ISO 45001:2018.

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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):
 - <u>Defines IMS processes</u>, based on the requirements of ISO 9001:2015, ISO 14001:2015, and ISO 45001:2018, 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);
 - <u>Provides</u> IMS processes with the required <u>resources</u> (sec.7.1), including resources to address risks and opportunities (sec.6.1);
 - Conducts the overall IMS <u>processes implementation review</u> 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:
 - <u>identify</u> necessary <u>inputs</u> and expected <u>outputs</u> of the process by applying the process model;
 - <u>determine the sequence and interaction</u> of IMS processes through the application of the process model;
 - <u>define process criteria</u>, including effectiveness; the criteria are measured and analyzed at the established intervals;
 - <u>define resources</u>, necessary to operate the process;
 - <u>define responsibility and authority</u> of participants, including process owners;
 - <u>address risks and opportunities</u>, including risks identification, risks analysis, and risks treatment (sec. 6.1.1);
 - <u>determine environmental aspects</u> and associated environmental impacts and identifies significant environmental aspects (sec. 6.1.2);
 - identify hazard (sec. 6.1.2);
 - <u>fulfill the compliance obligations</u> (sec. 6.1.3) and <u>planning action</u> (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:

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- The completeness of process description;
- The definition of <u>Process criteria</u>, trends analysis, and providing information for management review;
- <u>Identification, analysis, and treatment of risks and opportunities</u>, including environmental aspects, hazard identification, compliance obligations, planning action (sec.6.1);
- Activities to <u>improve the process</u> 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 coordination;
- 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 OH&S activity is carried out:

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

In 'OH&S management' process:

- consultation and participation of workers (sec. 5.4) is ensured;
- hazard identification and assessment of OH&S risks and opportunities (sec. 6.1.2) are coordinated;

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- 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.

Occupational Safety Department head is the owner of the 'OH&S management' process.

- 4.4.6 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.
- 4.4.7 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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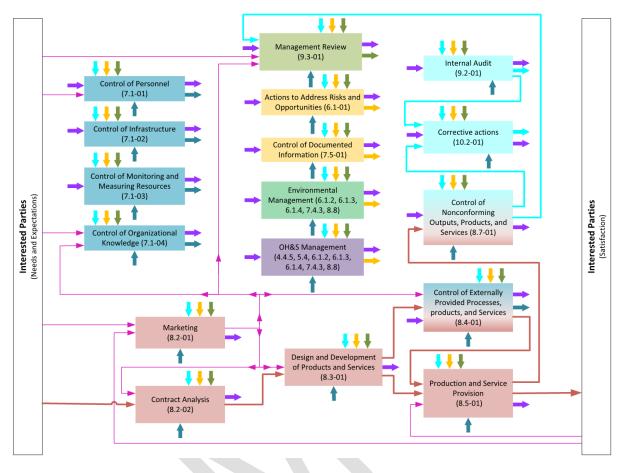


Fig. 4.4-01 [Company Name] sequence and interaction of IMS processes diagram

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