ISO 9001 and the Supply Chain

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• Provide insight into understanding of Clause 4. Context of the Organization
• Discuss Clauses that will include issues concerning external resources (supply-chain) - 6 (Planning) – 8 (Operations) and 9 (Performance Evaluation)
• Review risk-based thinking and its application in the organization
• Outline the impact the revision may have on supply chains
Directive 1 – 10 Clauses

1. Scope
2. Normative references
3. Terms and definitions
4. Context of the organization
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance evaluation
10. Improvement
4. Context of the organization

4.1 Understanding the organization and its context

Determine relevant external and internal issues that affect the ability to achieve the intended outcome(s)
4.2 Understanding the needs and expectations of interested parties

<table>
<thead>
<tr>
<th>Interested party</th>
<th>Needs and expectations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customers</td>
<td>Quality, price and delivery performance of products</td>
</tr>
<tr>
<td>Owners/shareholders</td>
<td>Sustained profitability, Transparency</td>
</tr>
<tr>
<td>People in the organization</td>
<td>Good work environment, Job security, Recognition and reward</td>
</tr>
<tr>
<td>Suppliers and partners</td>
<td>Mutual benefits and continuity</td>
</tr>
<tr>
<td>Society</td>
<td>Environmental protection, Ethical behaviour, Compliance with statutory and regulatory requirements</td>
</tr>
</tbody>
</table>

Source ISO 9004

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4.3 Determining the scope of the management system

Source: ISO 9001:2015
4.4 Management system

Establish, implement, maintain, and continually improve a management system, including the processes needed and their interactions, in accordance with the requirements of the International Standard.

A “Process” can be defined as a “set of interrelated or interacting activities, which transforms inputs into outputs”

Source: ISO/TC 176/SC 2/N 544R3

*Interrelated or interacting elements of an organization Policies, Processes and Objectives*
6. Planning

6.1 Actions to address risks and opportunities
Let’s discuss objectives first!

6.2 Objectives and planning to achieve them
- Establish objectives at relevant functions and levels
- Consistent with policy
- Measureable
- Consider applicable requirements
- Monitored, communicated, updated
- Determine resources, responsibilities, targets and how to evaluate results

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POLL Question

Do you use a formal risk assessment process?

1. Yes
2. Ad Hoc
3. No
What is “risk-based thinking”?

- Risk-based thinking is something we all do automatically and often subconsciously.
- The concept of risk has always been understood in ISO 9001 and not new to ISO 14001 – this revision makes it more explicit and builds it into the whole of the management process.
- Risk-based thinking should already part of the process approach.
- Risk-based thinking makes preventive action routine.
Integration into organizational processes

- Risk management should be embedded in all the organization's practices and processes in a way that it is relevant, effective and efficient.

- The risk management process should become part of, and not separate from, those organizational processes.

- In particular, risk management should be embedded into the policy development, business and strategic planning and review, and change management processes.
6.1 Actions to address risks and opportunities

Consider the issues referred to in 4.1* and the requirements referred to in 4.2** and determine the risks and opportunities that need to be addressed to:

- give assurance that the management system can achieve its intended outcome(s);
  - prevent, or reduce, undesired effects; (mitigate)
  - achieve continual improvement

*4.1 Understanding the organization and its context
**4.2 Understanding the needs and expectations of interested parties
6.1 Actions to address risks and opportunities

The organization shall plan:

• actions to address these risks and opportunities

How to:

• integrate and implement the actions into its management system processes
• evaluate the effectiveness of these actions
Coverage of Risk in the ISO 9001:2015 Clauses

• In Clause 4 – the organization is required to determine the risks that can affect its ability to meet these objectives.

• In Clause 5 - Top Management is required to commit to ensuring that Clause 4 is followed. Section 5.1.2 indicates that: ‘Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that the risks which can affect conformity of goods and services and customer satisfaction are identified and addressed.’

• In Clause 6 - the organization is required to take action to address risks and opportunities.
Coverage of Risk in the ISO 9001:2015 Clauses

• Clause 8 - the organization is required to have processes which identify and address risk in its operations.

• Clause 9 - the organization is required to measure the effectiveness of actions taken to address risks and opportunities

• In Clause 10 - the organization is required to update risks and opportunities determined during planning, if necessary
• One of the key purposes of a formal management system is to act as a preventive tool.

• Consequently, the standard requires an assessment of the organization’s “external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended output(s)” in clause 4.1, and to “determine the risks and opportunities that need to be addressed to: assure the quality management system can achieve its intended outcome(s); prevent, or reduce, undesired effects; achieve improvement” in clause 6.1.
8. Operation

8.1 Operational planning and control

- Plan, implement and control the processes needed to meet requirements, and to implement the actions determined in 6.1*
9. Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation
• What needs to be measured, methods, when (what intervals) and when data should be analyzed and reported

9.2 Internal audit
• Conducted at planned intervals to ensure compliance with the standard and internal requirements

9.3 Management review
• Review the organization's management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness
Determine requirements and Control of externally provided products and services
POLL Question

Does your organization use a formal supply-chain management process?

1. Yes
2. Ad Hoc
3. No
A.8 Control of externally provided products and services

Clause 8.4 Control of externally provided products and services addresses all forms of external provision, whether it is by purchasing from a supplier, through an arrangement with an associate company, through the outsourcing of processes and functions of the organization or by any other means.

The organization is required to take a risk-based approach to determine the type and extent of controls appropriate to particular external providers and externally provided products and services.
Control of externally supplied products or services

- Determination of requirements for products and services
- Control of externally provided products and services
- Type and extent of control of external provision
- Information for external providers
What is a supplier?

• Supplier or provider
  • Person or organization that provides a product or a service

• A supplier can be internal or external to the organization

• In a contractual situation, a supplier is sometimes called “contractor”
  (Source: DIS ISO 9000:2014)

19/10/2015
What is the Supply-Chain?
• 8.2.2 Determination of requirements related to products and services

• 8.2.3 Review of requirements related to products and services
Control of externally provided products and services

8.4 Control of externally provided products and services

- ensure that externally provided processes, products, and services conform to specified requirements.

- apply the specified requirements for the control of externally provided products and services
Control of externally provided products and services

“The organization shall establish and apply criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers based on their ability to provide processes or products and services in accordance with specified requirements”
(Source: ISO 9001:2015)
8.4.2 Type and extent of control

• Ensure that externally provided processes, products and services do not adversely affect the organization’s ability to consistently deliver conforming products and services to its customers.

• The effectiveness of the controls applied by the external provider.
8.4.3 Information for external providers

• Communicate to external providers applicable requirements

• Ensure the adequacy of specified requirements prior to their communication to the external provider

• Control and monitoring of the external providers’ performance

• Verification or validation activities that the organization, or its customer, intends to perform at the external providers’ premises.
How do you manage all this?
Benefits

• Bringing management systems into the heart of our business
  • Management systems will be integrated and aligned with business strategies which will improve performance and drive value up while driving costs down

• Introduction of Risk & Opportunity Management
  • Will help identify and manage risk more effectively and opportunities that contribute to bottom line improvements

• An Integrated Approach
  • It will be easier to implement more than one management system providing a more holistic view leading to cost savings

• Leadership
  • Greater involvement by our leadership team will ensure that we’ll all be motivated towards the organizations goals and objectives
What you need to do

- Set up a project team to manage the changes
- Communicate the project across the whole organization
- Create an implementation plan and monitor progress
- Take a fresh look at your QMS
- Highlight the changes as opportunities for improvement
- Make changes to your documentation to reflect the new structure (as necessary)
- Implement the new requirements on leadership, risk and context of the organization
- Review the effectiveness of your current control set
- Carry out an impact assessment
Accredited Courses

ISO 9K LA
ISO 14K LA
OHSAS 18K LA

Non Accredited Courses

Transition Course
Implementing Changes
Risk Based Thinking
Annex SL
Auditing Leadership
Management Briefing