

ISO 9001:2015 TRANSITIONS

4.0 – Context of the Organization

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- 4 Context of the organization
 - 4.1 Understanding the organization and its context
 - 4.2 Understanding the needs and expectations of interested parties
 - 4.3 Determining the scope of the quality management system
 - 4.4 Quality management system and its processes

Understanding the organization and its context (4.1)

- This is the combination of those internal and external factors that affect an organization's approach to the way in which it provides products and services that are delivered to its customer.
- External factors can include, for example, cultural, social, political, legal, regulatory, financial, technological, economic factors, and competitive environment, at the international, national, regional or local level.
- Internal factors typically include the organization's corporate culture, governance, organizational structure, technologies, information systems, and decision-making processes (both formal and informal).

Internal and External Factors (example)

Internal Factors

- Employee relations
- Organizational structure
- Company financial performance
- Organizational culture

External Factors

- Potential legislative or regulatory changes
- Inherent environmental risks (fire, flood, hurricane)
- Economic factors
- Changes in technology
- Competition

Understanding needs and expectations of interested parties (4.2)

- The organization will need to determine the interested parties that are relevant to the quality management system and the requirements of those interested parties, as outlined in clause 4.2. This does not extend past the quality management system requirements and the scope of this International Standard.
- As stated in the scope, this International Standard is applicable where an organization needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction.

Interested Parties (example)

- Customers
- Employees
- Suppliers
- Partners
- Owners
- Investors
- Insurance companies
- Regulatory bodies
- Creditors
- Trade Unions
- End-users
- Community

Determining the scope of the Quality Management System (4.3)

- The organization will need to determine the boundaries and applicability of the quality management system to establish its scope.
- When determining this scope, the organization shall consider:
 - The internal and external issues referred to in 4.1;
 - The requirements of relevant interested parties referred to in 4.2;
 - The products and services of the organization.

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